

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 20-F**

- Registration Statement Pursuant to Section 12(b) or 12(g) of The Securities Exchange Act of 1934**  
**OR**
- Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the fiscal year ended December 31, 2012**  
**OR**
- Transition Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934**  
**OR**
- Shell Company Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934**

**Commission file number 0-30752**

**AETERNA ZENTARIS INC.**  
(Exact Name of Registrant as Specified in its Charter)

**Not Applicable**  
(Translation of Registrant's Name into English)

**Canada**  
(Jurisdiction of Incorporation)  
**1405 du Parc-Technologique Blvd.**

**Quebec City, Quebec**  
**Canada, G1P 4P5**  
(Address of Principal Executive Offices)

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**Canada, G1P 4P5**

(Name, Telephone, E-mail and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
Common Shares	NASDAQ Global Market Toronto Stock Exchange

Securities registered or to be registered pursuant to Section 12(g) of the Act: **NONE**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **NONE**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as at the close of the period covered by the annual report: 25,329,288 common shares as at December 31, 2012.

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or, or a non-accelerated filer. See definitions of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

US GAAP  International Financial Reporting Standards as issued by the Other   
International Accounting Standards Board

If "other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

## **Basis of Presentation**

### General

Except where the context otherwise requires, all references in this annual report on Form 20-F to the "Company", "Aeterna Zentaris Inc.", "we", "us", "our" or similar words or phrases are to Aeterna Zentaris Inc. and its subsidiaries, taken together. In this annual report on Form 20-F, references to "\$" and "US\$" are to United States dollars, references to "CAN\$" are to Canadian dollars and references to "EUR" are to euros. Unless otherwise indicated, the statistical and financial data contained in this annual report on Form 20-F are presented as at December 31, 2012.

On October 2, 2012, Aeterna Zentaris completed a consolidation of its issued and outstanding common shares on a 6-to-1 basis ("Share Consolidation"). All references in this annual report on Form 20-F to common shares and options for periods prior to the effective date of the Share Consolidation have been retroactively adjusted to reflect the Share Consolidation.

This annual report on Form 20-F also contains certain information regarding products or product candidates that may potentially compete with our products and product candidates, and such information has been primarily derived from information made publicly available by the companies developing such potentially competing products and product candidates and has not been independently verified by Aeterna Zentaris Inc.

### **Forward-Looking Statements**

This annual report on Form 20-F contains forward-looking statements made pursuant to the safe harbor provisions of the U.S. Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "intend," "believe," "designed to," "vision," "aimed at," "expect," "may," "should," "would," "will" and similar references. Such statements include, but are not limited to, statements about the progress of our research, development and clinical trials and the timing of, and prospects for, regulatory approval and commercialization of our product candidates, the timing of expected results of our studies and anticipated results of these studies, and estimates regarding our capital requirements and our needs for, and our ability to obtain, additional financing. 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 our research and development ("R&D") projects, the successful and timely completion of clinical studies, the degree of market acceptance once our products are approved for commercialization, the ability of the Company to take advantage of business opportunities in the pharmaceutical industry, the ability of the Company to protect its intellectual property, 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 and disclaims 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 required to do so by a governmental authority or applicable law.

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**PART I**

**Item 1. Identity of Directors, Senior Management and Advisers**

**A. Directors and senior management**

Not applicable.

**B. Advisors**

Not applicable.

**C. Auditors**

Not applicable.

**Item 2. Offer Statistics and Expected Timetable**

**A. Offer statistics**

Not applicable.

**B. Method and expected timetable**

Not applicable.

**Item 3. Key Information**

**A. Selected financial data**

The consolidated statement of comprehensive loss data set forth in this Item 3.A with respect to the years ended December 31, 2012, 2011 and 2010 and the consolidated statement of financial position data as at December 31, 2012 and 2011 have been derived from the audited consolidated financial statements listed in Item 18, which have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The consolidated statement of financial position as at December 31, 2010 set forth in this Item 3.A have been derived from our previous consolidated financial statements not included herein, and have been prepared in accordance with IFRS. The selected financial data should be read in conjunction with our audited consolidated financial statements and the related notes included elsewhere in this annual report on Form 20-F, as well as "Item 5. – Operating and Financial Review and Prospects" of this annual report on Form 20-F.

**Consolidated Statements of Comprehensive Loss Data**  
*(in thousands of US dollars, except share and per share data)*

Derived from financial statements prepared in accordance with IFRS

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
<b>Revenues</b>			
Sales and royalties	31,538	31,306	24,857
License fees and other	2,127	4,747	2,846
	<u>33,665</u>	<u>36,053</u>	<u>27,703</u>
<b>Operating expenses</b>			
Cost of sales	26,820	27,560	18,700
Research and development costs, net of refundable tax credits and grants	20,604	24,517	21,257
Selling, general and administrative expenses	13,245	16,170	12,552
	<u>60,669</u>	<u>68,247</u>	<u>52,509</u>
<b>Loss from operations</b>	<u>(27,004)</u>	<u>(32,194)</u>	<u>(24,806)</u>
Finance income	6,974	6,231	1,792
Finance costs	(382)	—	(5,437)
<b>Net finance (costs) income</b>	<u>6,592</u>	<u>6,231</u>	<u>(3,645)</u>
Loss before income taxes	<u>(20,412)</u>	<u>(25,963)</u>	<u>(28,451)</u>
Income tax expense	—	(1,104)	—
Net loss	<u>(20,412)</u>	<u>(27,067)</u>	<u>(28,451)</u>
<b>Other comprehensive loss:</b>			
Items that may be reclassified subsequently to profit or loss			
Foreign currency translation adjustments	(504)	(789)	1,001
Items that will not be reclassified to profit or loss			
Actuarial loss on defined benefit plans	(3,705)	(1,335)	191
<b>Comprehensive loss</b>	<u>(24,621)</u>	<u>(29,191)</u>	<u>(27,259)</u>
<b>Net loss per share</b>			
Basic	<u>(1.03)</u>	<u>(1.72)</u>	<u>(2.26)</u>
Diluted	<u>(1.03)</u>	<u>(1.72)</u>	<u>(2.26)</u>
<b>Weighted average number of shares outstanding</b>			
Basic	<u>19,775,073</u>	<u>15,751,331</u>	<u>12,609,902</u>
Diluted	<u>19,775,073</u>	<u>15,751,331</u>	<u>12,609,902</u>

**Consolidated Statement of Financial Position Data**  
(in thousands of US dollars)

Derived from financial statements prepared in accordance with IFRS.

	As at December 31,		
	2012	2011	2010
	\$	\$	\$
Cash and cash equivalents	39,521	46,881	31,998
Short-term investments	—	—	1,934
Working capital	42,925	47,695	34,497
Restricted cash	826	806	827
<b>Total assets</b>	<b>67,665</b>	<b>75,369</b>	<b>61,448</b>
Warrant liability short-term	—	42	955
Warrant liability long-term	6,176	9,162	13,412
Long-term payable	—	29	90
Share capital	122,791	101,884	60,900
Shareholders' (deficiency) equity	(6,695)	(4,546)	(17,575)

**B. Capitalization and indebtedness**

Not applicable.

**C. Reasons for the offer and use of proceeds**

Not applicable.

**D. Risk factors**

**Risks Relating to Us and Our Business**

*Investments in biopharmaceutical companies are generally considered to be speculative.*

The prospects for companies operating in the biopharmaceutical industry may generally be considered to be uncertain, given the very nature of the industry and, accordingly, investments in biopharmaceutical companies should be considered to be speculative.

*We have a history of operating losses and we may never achieve or maintain operating profitability.*

Our product candidates remain at the development stage, and we have incurred substantial expenses in our efforts to develop products. Consequently, we have incurred recurrent operating losses and, as disclosed in our audited consolidated financial statements as at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010, we had an accumulated deficit of \$213.1 million as at December 31, 2012. Our operating losses have adversely impacted, and will continue to adversely impact, our working capital, total assets and shareholders' deficiency. We do not expect to reach operating profitability in the immediate future, and our expenses are likely to increase as we continue to expand our R&D and clinical study programs and our sales and marketing activities and seek regulatory approval for our product candidates. Even if we succeed in developing new commercial products, we expect to incur additional operating losses for at least the next several years. If we do not ultimately generate sufficient revenue from commercialized products and achieve or maintain operating profitability, an investment in our common shares could result in a significant or total loss.

***Our clinical trials may not yield results which will enable us to obtain regulatory approval for our products, and a setback in any of our clinical trials would likely cause a drop in the price of our common shares.***

We will only receive regulatory approval for a product candidate if we can demonstrate in carefully designed and conducted clinical trials that the product candidate is both safe and effective. We do not know whether our pending or any future clinical trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products. Unfavorable data from those studies could result in the withdrawal of marketing approval for approved products or an extension of the review period for developmental products. Clinical trials are inherently lengthy, complex, expensive and uncertain processes and have a high risk of failure. It typically takes many years to complete testing, and failure can occur at any stage of testing. Results attained in preclinical testing and early clinical studies, or trials, may not be indicative of results that are obtained in later studies.

None of our product candidates has to date received regulatory approval for its intended commercial sale. We cannot market a pharmaceutical product in any jurisdiction until it has completed rigorous preclinical testing and clinical trials and passed such jurisdiction's extensive regulatory approval process. In general, significant research and development and clinical studies are required to demonstrate the safety and efficacy of our product candidates before we can submit regulatory applications. Preclinical testing and clinical development are long, expensive and uncertain processes. Preparing, submitting and advancing applications for regulatory approval is complex, expensive and time-consuming and entails significant uncertainty. Data obtained from preclinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. It may take us many years to complete the testing of our product candidates and failure can occur at any stage of this process. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval in the United States, in Canada and abroad and, accordingly, may encounter unforeseen problems and delays in the approval process. Though we may engage a contract research organization (a "CRO") with experience in conducting regulatory trials, errors in the conduct, monitoring and/or auditing could invalidate the results from a regulatory perspective. Even if a product candidate is approved by the United States Food and Drug Administration (the "FDA"), the Canadian Therapeutic Products Directorate or any other regulatory authority, we may not obtain approval for an indication whose market is large enough to recoup our investment in that product candidate. In addition, there can be no assurance that we will ever obtain all or any required regulatory approvals for any of our product candidates.

We are currently developing our product candidates based on R&D activities, preclinical testing and clinical trials conducted to date, and we may not be successful in developing or introducing to the market these or any other new products or technology. If we fail to develop and deploy new products successfully and on a timely basis, we may become non-competitive and unable to recoup the R&D and other expenses we incur to develop and test new products.

Interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies. Safety signals detected during clinical studies and preclinical animal studies may require us to do additional studies, which could delay the development of the drug or lead to a decision to discontinue development of the drug. Product candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite positive results in initial clinical testing. Results from earlier studies may not be indicative of results from future clinical trials and the risk remains that a pivotal program may generate efficacy data that will be insufficient for the approval of the drug, or may raise safety concerns that may prevent approval of the drug. Interpretation of the prior preclinical and clinical safety and efficacy data of our product candidates may be flawed and there can be no assurance that safety and/or efficacy concerns from the prior data were overlooked or misinterpreted, which in subsequent, larger studies appear and prevent approval of such product candidates.

Furthermore, we may suffer significant setbacks in advanced clinical trials, even after promising results in earlier studies. Based on results at any stage of clinical trials, we may decide to repeat or redesign a trial or discontinue development of one or more of our product candidates. Further, actual results may vary once the final and quality-controlled verification of data and analyses has been completed. If we fail to adequately demonstrate the safety and efficacy of our products under development, we will not be able to obtain the required regulatory approvals to commercialize our product candidates.

Clinical trials are subject to continuing oversight by governmental regulatory authorities and institutional review boards and:

- must meet the requirements of these authorities;
- must meet requirements for informed consent; and
- must meet requirements for good clinical practices.

We may not be able to comply with these requirements in respect of one or more of our product candidates.



In addition, we rely on third parties, including CROs and outside consultants, to assist us in managing and monitoring clinical trials. Our reliance on these third parties may result in delays in completing, or in failing to complete, these trials if one or more third parties fails to perform with the speed and level of competence we expect.

A failure in the development of any one of our programs or product candidates could have a negative impact on the development of the others. Setbacks in any phase of the clinical development of our product candidates would have an adverse financial impact (including with respect to any agreements and partnerships that may exist between us and other entities), could jeopardize regulatory approval and would likely cause a drop in the price of our common shares.

***If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.***

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the design of the protocol, the size of the patient population, the proximity of patients to and availability of clinical sites, the eligibility criteria for the study, the perceived risks and benefits of the drug under study and of the control drug, if any, the efforts to facilitate timely enrollment in clinical trials, the patient referral practices of physicians, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. Certain clinical trials are designed to continue until a pre-determined number of events have occurred to the patients enrolled. Such trials are subject to delays stemming from patient withdrawal and from lower than expected event rates and may also incur increased costs if enrollment is increased in order to achieve the desired number of events. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective or timely basis. In addition, conducting multi-national studies adds another level of complexity and risk as we are subject to events affecting countries outside Canada. Moreover, negative or inconclusive results from the clinical trials we conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all. If we or any third party have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing clinical trials.

Additionally, we have never filed a New Drug Application ("NDA"), or similar application for approval in the United States or in any country for our current product candidates, which may result in a delay in, or the rejection of, our filing of an NDA or similar application. During the drug development process, regulatory agencies will typically ask questions of drug sponsors. While we endeavor to answer all such questions in a timely fashion, or in the NDA filing, some questions may not be answered by the time we file our NDA. Unless the FDA waives the requirement to answer any such unanswered questions, submission of an NDA may be delayed or rejected.

***We are and will be subject to stringent ongoing government regulation for our products and our product candidates, even if we obtain regulatory approvals for the latter.***

The manufacture, marketing and sale of our products and product candidates are and will be subject to strict and ongoing regulation, even if regulatory authorities approve any of the latter. Compliance with such regulation will be expensive and consume substantial financial and management resources. For example, an approval for a product may be conditioned on our agreement to conduct costly post-marketing follow-up studies to monitor the safety or efficacy of the products. In addition, as a clinical experience with a drug expands after approval because the drug is used by a greater number and more diverse group of patients than during clinical trials, side effects or other problems may be observed after approval that were not observed or anticipated during pre-approval clinical trials. In such a case, a regulatory authority could restrict the indications for which the product may be sold or revoke the product's regulatory approval.

We and our contract manufacturers will be required to comply with applicable current Good Manufacturing Practice ("cGMP") regulations for the manufacture of our products. These regulations include requirements relating to quality assurance, as well as the corresponding maintenance of rigorous records and documentation. Manufacturing facilities must be approved before we can use them in the commercial manufacturing of our products and are subject to subsequent periodic inspection by regulatory authorities. In addition, material changes in the methods of manufacturing or changes in the suppliers of raw materials are subject to further regulatory review and approval.

If we, or any future marketing collaborators or contract manufacturers, fail to comply with applicable regulatory requirements, we may be subject to sanctions including fines, product recalls or seizures and related publicity requirements, injunctions, total or partial suspension of production, civil penalties, suspension or withdrawals of previously granted regulatory approvals, warning or untitled letters, refusal to approve pending applications for marketing approval of new products or of supplements

to approved applications, import or export bans or restrictions, and criminal prosecution and penalties. Any of these penalties could delay or prevent the promotion, marketing or sale of our products and product candidates.

***If our products do not gain market acceptance, we may be unable to generate significant revenues.***

Even if our products are approved for commercialization, they may not be successful in the marketplace. Market acceptance of any of our products will depend on a number of factors including, but not limited to:

- demonstration of clinical efficacy and safety;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in the product's approved labeling;
- availability of alternative treatments for the indications we target;
- the advantages and disadvantages of our products relative to current or alternative treatments;
- the availability of acceptable pricing and adequate third-party reimbursement; and
- the effectiveness of marketing and distribution methods for the products.

If our products do not gain market acceptance among physicians, patients, healthcare payers and others in the medical community, which may not accept or utilize our products, our ability to generate significant revenues from our products would be limited and our financial conditions will be materially adversely affected. In addition, if we fail to further penetrate our core markets and existing geographic markets or successfully expand our business into new markets, the growth in sales of our products, along with our operating results, could be negatively impacted.

Our ability to further penetrate our core markets and existing geographic markets in which we compete or to successfully expand our business into additional countries in Europe, Asia or elsewhere is subject to numerous factors, many of which are beyond our control. Our products, if successfully developed, may compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products may also compete with new products currently under development by others or with products which may be less expensive than our products. There can be no assurance that our efforts to increase market penetration in our core markets and existing geographic markets will be successful. Our failure to do so could have an adverse effect on our operating results and would likely cause a drop in the price of our common shares.

***We may require significant additional financing, and we may not have access to sufficient capital.***

We may require additional capital to pursue planned clinical trials, regulatory approvals, as well as further R&D and marketing efforts for our product candidates and potential products. Except as expressly described in this annual report on Form 20-F, we do not anticipate generating significant revenues from operations in the near future and we currently have no committed sources of capital.

We may attempt to raise additional funds through public or private financings, collaborations with other pharmaceutical companies or financing from other sources. Additional funding may not be available on terms which are acceptable to us. If adequate funding is not available to us on reasonable terms, we may need to delay, reduce or eliminate one or more of our product development programs or obtain funds on terms less favorable than we would otherwise accept. To the extent that additional capital is raised through the sale of equity securities or securities convertible into or exchangeable for equity securities, the issuance of those securities could result in dilution to our shareholders. Moreover, the incurrence of debt financing could result in a substantial portion of our future operating cash flow, if any, being dedicated to the payment of principal and interest on such indebtedness and could impose restrictions on our operations. This could render us more vulnerable to competitive pressures and economic downturns.

We anticipate that our existing working capital, including the proceeds from any sale of common shares and anticipated revenues, will be sufficient to fund our development programs, clinical trials and other operating expenses for the near future. However, our future capital requirements are substantial and may increase beyond our current expectations depending on many factors including:

- the duration and results of our clinical trials for our various product candidates going forward;
- unexpected delays or developments in seeking regulatory approvals;
- the time and cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- other unexpected developments encountered in implementing our business development and commercialization strategies;
- the outcome of litigation, if any; and
- further arrangements, if any, with collaborators.

In addition, global economic and market conditions as well as future developments in the credit and capital markets may make it even more difficult for us to raise additional financing in the future.

***If we are unsuccessful in increasing our revenues and/or raising additional funding, we may possibly cease to continue operating as we currently do.***

We have had sustained losses, accumulated deficits and negative cash flows from operations since our inception and we expect that this will continue throughout 2013.

Although our audited consolidated financial statements as at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010 have been prepared on a going concern basis, which contemplates the realization of assets and liquidation of liabilities during the normal course of operations, our ability to continue as a going concern is dependent on the successful execution of our business plan, which will require an increase in revenue and/or additional funding to be provided by potential investors as well as non-traditional sources of financing. Although we stated in our audited consolidated financial statements as at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010 that management believed that the Company had, as at December 31, 2012, sufficient financial resources to fund planned expenditures and other working capital needs for at least, but not limited to, the 12-month period following such date, there can be no assurance that management will be able to reiterate such belief in the future, particularly in the event that we do not or are unable to raise additional capital, as we do not expect our operations to generate sufficient cash flow to fund our obligations.

Additional funding may be in the form of debt or equity or a hybrid instrument depending on the needs of the investor. In light of present and future global economic and credit market conditions, we may not be able to raise additional cash resources through these traditional sources of financing. Although we are also pursuing non-traditional sources of financing with third parties, the global credit markets may adversely affect the ability of potential third parties to pursue such transactions with us. Accordingly, as a result of the foregoing, we continue to review traditional sources of financing, such as private and public debt or various equity financing alternatives, as well as other alternatives to enhance shareholder value including, but not limited to, non-traditional sources of financing, such as alliances with strategic partners, the sale of assets or licensing of our technology or intellectual property, a combination of operating and related initiatives or a substantial reorganization of our business.

There can be no assurance that we will achieve profitability or positive cash flows or be able to obtain additional funding or that, if obtained, they will be sufficient, or whether any other initiatives will be successful, such that we may continue as a going concern. There could also be material uncertainties related to certain adverse conditions and events that could impact our ability to remain a going concern.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications for which there may be a greater likelihood of success.***

Because we have limited financial and managerial resources, we are currently focusing our efforts on our later-stage clinical research programs and product candidates, AEZS-108 and AEZS-130, for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for which there may be a greater likelihood of success or may prove to have greater commercial potential. Notwithstanding our investment to date and anticipated future expenditures on AEZS-108, AEZS-130 and our earlier-stage programs, we have not yet developed, and may never successfully develop, any marketed treatments using these products. Research programs to identify new product candidates or pursue alternative indications for current product candidates require substantial technical, financial and human resources. These activities may initially show promise in identifying potential product candidates or indications, yet fail to yield product candidates or indications for further clinical development.

***We may not achieve our projected development goals in the time-frames we announce and expect.***

We set goals and make public statements regarding the timing of the accomplishment of objectives material to our success, such as the commencement, enrollment and anticipated completion of clinical trials, anticipated regulatory submission and approval dates and time of product launch. The actual timing of these events can vary dramatically due to factors such as delays or failures in our clinical trials, the uncertainties inherent in the regulatory approval process and delays in achieving manufacturing or marketing arrangements sufficient to commercialize our products. There can be no assurance that our clinical trials will be completed, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the launch of any of our products. If we fail to achieve one or more of these milestones as planned, the price of our common shares would likely decline.

***If we fail to obtain acceptable prices or adequate reimbursement for our products, our ability to generate revenues will be diminished.***

The ability for us and/or our partners to successfully commercialize our products will depend significantly on our ability to obtain acceptable prices and the availability of reimbursement to the patient from third-party payers, such as governmental and private insurance plans. These third-party payers frequently require companies to provide predetermined discounts from list prices, and they are increasingly challenging the prices charged for pharmaceuticals and other medical products. Our products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us or our partners to sell our products on a competitive basis. It may not be possible to negotiate favorable reimbursement rates for our products.

In addition, the continuing efforts of third-party payers to contain or reduce the costs of healthcare through various means may limit our commercial opportunity and reduce any associated revenue and profits. We expect proposals to implement similar government control to continue. In addition, increasing emphasis on managed care will continue to put pressure on the pricing of pharmaceutical and biopharmaceutical products. Cost control initiatives could decrease the price that we or any current or potential collaborators could receive for any of our products and could adversely affect our profitability. In addition, in the United States, in Canada and in many other countries, pricing and/or profitability of some or all prescription pharmaceuticals and biopharmaceuticals are subject to government control.

If we fail to obtain acceptable prices or an adequate level of reimbursement for our products, the sales of our products would be adversely affected or there may be no commercially viable market for our products.

***Competition in our targeted markets is intense, and development by other companies could render our products or technologies non-competitive.***

The biomedical field is highly competitive. New products developed by other companies in the industry could render our products or technologies non-competitive. Competitors are developing and testing products and technologies that would compete with the products that we are developing. Some of these products may be more effective or have an entirely different approach or means of accomplishing the desired effect than our products. We expect competition from biopharmaceutical and pharmaceutical companies and academic research institutions to increase over time. Many of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Our competitors may succeed in developing products earlier and in obtaining regulatory approvals and patent protection for such products more rapidly than we can or at a lower price.

***We may not obtain adequate protection for our products through our intellectual property.***

We rely heavily on our proprietary information in developing and manufacturing our product candidates. Our success depends, in large part, on our ability to protect our competitive position through patents, trade secrets, trademarks and other intellectual property rights. The patent positions of pharmaceutical and biopharmaceutical firms, including us, are uncertain and involve complex questions of law and fact for which important legal issues remain unresolved. Applications for patents and trademarks in Canada, the United States and in other foreign territories have been filed and are being actively pursued by us. Pending patent applications may not result in the issuance of patents and we may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents to us or our licensing partners may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. The patents issued or to be issued to us may not provide us with any competitive advantage or protect us against competitors with similar technology. In addition, it is possible that third parties with products that are very similar to ours will circumvent our patents by means of alternate designs or processes. We may have to rely on method of use and new formulation protection for our compounds in development, and any resulting products, which may not confer the same protection as claims to compounds *per se*.

In addition, our patents may be challenged by third parties in patent litigation, which is becoming widespread in the biopharmaceutical industry. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There may also be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that our patents would, if challenged, be held by a court to be valid or enforceable or that a competitor's technology or product would be found by a court to infringe our patents. Our granted patents could also be challenged and revoked in opposition or nullity proceedings in certain countries outside the United States. In addition, we may be required to disclaim part of the term of certain patents.

Patent applications relating to or affecting our business have been filed by a number of pharmaceutical and biopharmaceutical companies and academic institutions. A number of the technologies in these applications or patents may conflict with our technologies, patents or patent applications, and any such conflict could reduce the scope of patent protection which we could otherwise obtain. Because patent applications in the United States and many other jurisdictions are typically not published until eighteen months after their first effective filing date, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensing partners can be certain that we or they were the first to make the inventions claimed in our or their issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. If a third party has also filed a patent application in the United States covering our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the United States Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful, resulting in a loss of our U.S. patent position.

In addition to patent protection, we may utilize orphan drug regulations, pediatric exclusivity or other provisions of the United States *Food, Drug and Cosmetic Act of 1938*, as amended, such as new chemical entity exclusivity or new formulation exclusivity, to provide market exclusivity for a drug candidate. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity provides an additional six months which are added to the term of data protection as well as to the term of any relevant patents, to the extent these protections have not already expired. We may also seek to utilize market exclusivities in other territories, such as in the EU. We cannot assure that any of our drug candidates will obtain such orphan drug designation, pediatric exclusivity, new chemical entity exclusivity or any other market exclusivity in the U.S., EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection.

We also rely on trade secrets and proprietary know-how to protect our intellectual property. If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected. We seek to protect our unpatented proprietary information in part by requiring our employees, consultants, outside scientific collaborators and sponsored researchers and other advisors to enter into confidentiality agreements. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of our employees, the agreements provide that all of the technology which is conceived by the individual during the course of employment is our exclusive property. These agreements may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of our proprietary information. In addition, it is possible that third parties could independently develop proprietary information and techniques substantially similar to ours or otherwise gain access to our trade secrets. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products and technologies, which could adversely impact our business.

We currently have the right to use certain patents and technologies under license agreements with third parties. Our failure to comply with the requirements of material license agreements could result in the termination of such agreements, which could cause us to terminate the related development program and cause a complete loss of our investment in that program.

As a result of the foregoing factors, we may not be able to rely on our intellectual property to protect our products in the marketplace.

***We may infringe the intellectual property rights of others.***

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. There could be issued patents of which we are not aware that our products or methods may be found to infringe, or patents of which we are aware and believe we do not infringe but which we may ultimately be found to infringe. Moreover, patent applications and their underlying discoveries are in some cases maintained in secrecy until patents are issued. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products or technologies are found to infringe. Moreover, there may be published pending applications that do not currently include a claim covering our products or technologies but which nonetheless provide support for a later drafted claim that, if issued, our products or technologies could be found to infringe.

If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business. Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be accused of infringing one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may subsequently be issued and to which we do not hold a license or other rights. Third parties may own or control these patents or patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

The biopharmaceutical industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. In the event of infringement or violation of another party's patent or other intellectual property rights, we may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us or our partners and collaborators.

***Patent litigation is costly and time consuming and may subject us to liabilities.***

Our involvement in any patent litigation, interference, opposition or other administrative proceedings will likely cause us to incur substantial expenses, and the efforts of our technical and management personnel will be significantly diverted. In addition, an adverse determination in litigation could subject us to significant liabilities.

***We may not obtain trademark registrations.***

We have filed applications for trademark registrations in connection with our product candidates in various jurisdictions, including the United States. We intend to file further applications for other possible trademarks for our product candidates. No assurance can be given that any of our trademark applications will be registered in the United States or elsewhere, or that the use of any registered or unregistered trademarks will confer a competitive advantage in the marketplace. Furthermore, even if we are successful in our trademark registrations, the FDA and regulatory authorities in other countries have their own process for drug nomenclature and their own views concerning appropriate proprietary names. The FDA and other regulatory authorities also have the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. No assurance can be given that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future. The loss, abandonment, or cancellation of any of our trademarks or trademark applications could negatively affect the success of the product candidates to which they relate.

***Our revenues and expenses may fluctuate significantly, and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in the price of our common shares.***

We have a history of operating losses. Our revenues and expenses have fluctuated in the past and are likely to do so in the future. These fluctuations could cause our share price to decline. Some of the factors that could cause our revenues and expenses to fluctuate include but are not limited to:

- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals to commercialize our product candidates;
- the timing of regulatory submissions and approvals;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize our product candidates;
- the revenue available from royalties derived from our strategic partners;
- licensing fees revenues;
- tax credits and grants (R&D);
- the outcome of litigation, if any;
- changes in foreign currency fluctuations;
- the timing of achievement and the receipt of milestone payments from current or future collaborators; and
- failure to enter into new or the expiration or termination of current agreements with collaborators.

Due to fluctuations in our revenues and expenses, we believe that period-to-period comparisons of our results of operations are not necessarily indicative of our future performance. It is possible that in some future quarter or quarters, our revenues and expenses will be above or below the expectations of securities analysts or investors. In this case, the price of our common shares could fluctuate significantly or decline.

***We will not be able to successfully commercialize our product candidates if we are unable to make adequate arrangements with third parties for such purposes.***

We currently have a lean sales and marketing staff. In order to commercialize our product candidates successfully, we need to make arrangements with third parties to perform some or all of these services in certain territories.

We contract with third parties for the sales and marketing of our products. Our revenues will depend upon the efforts of these third parties, whose efforts may not be successful. If we fail to establish successful marketing and sales capabilities or to make arrangements with third parties for such purposes, our business, financial condition and results of operations will be materially adversely affected.

If we had to resort to developing a sales force internally, the cost of establishing and maintaining a sales force would be substantial and may exceed its cost effectiveness. In addition, in marketing our products, we would likely compete with many companies that currently have extensive and well-funded marketing and sales operations. Despite our marketing and sales efforts, we may be unable to compete successfully against these companies.

We are currently dependent on strategic partners and may enter into future collaborations for the research, development and commercialization of our product candidates. Our arrangements with these strategic partners may not provide us with the benefits we expect and may expose us to a number of risks.

We are dependent on, and rely upon, strategic partners to perform various functions related to our business, including, but not limited to, the research, development and commercialization of some of our product candidates. Our reliance on these relationships poses a number of risks.

We may not realize the contemplated benefits of such agreements nor can we be certain that any of these parties will fulfill their obligations in a manner which maximizes our revenue. These arrangements may also require us to transfer certain material rights or issue our equity, voting or other securities to corporate partners, licensees and others. Any license or sublicense of our commercial rights may reduce our product revenue.

These agreements also create certain risks. The occurrence of any of the following or other events may delay product development or impair commercialization of our products:

- not all of our strategic partners are contractually prohibited from developing or commercializing, either alone or with others, products and services that are similar to or competitive with our product candidates and, with respect to our strategic partnership agreements that do contain such contractual prohibitions or restrictions, prohibitions or restrictions do not always apply to our partners' affiliates and they may elect to pursue the development of any additional product candidates and pursue technologies or products either on their own or in collaboration with other parties, including our competitors, whose technologies or products may be competitive with ours;
- our strategic partners may under-fund or fail to commit sufficient resources to marketing, distribution or other development of our products;
- we may not be able to renew such agreements;
- our strategic partners may not properly maintain or defend certain intellectual property rights that may be important to the commercialization of our products;
- our strategic partners may encounter conflicts of interest, changes in business strategy or other issues which could adversely affect their willingness or ability to fulfill their obligations to us (for example, pharmaceutical companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in this industry);
- delays in, or failures to achieve, scale-up to commercial quantities, or changes to current raw material suppliers or product manufacturers (whether the change is attributable to us or the supplier or manufacturer) could delay clinical studies, regulatory submissions and commercialization of our product candidates; and
- disputes may arise between us and our strategic partners that could result in the delay or termination of the development or commercialization of our product candidates, resulting in litigation or arbitration that could be time-consuming and expensive, or causing our strategic partners to act in their own self-interest and not in our interest or those of our shareholders or other stakeholders.

In addition, our strategic partners can terminate our agreements with them for a number of reasons based on the terms of the individual agreements that we have entered into with them. If one or more of these agreements were to be terminated, we would be required to devote additional resources to developing and commercializing our product candidates, seek a new partner or abandon this product candidate which would likely cause a drop in the price of our common shares.

We have entered into important strategic partnership agreements relating to certain of our product candidates for various indications. Detailed information on our research and collaboration agreements is available in our various reports and disclosure documents filed with the Canadian securities regulatory authorities and filed with or furnished to the United States Securities and Exchange Commission ("SEC"), including the documents incorporated by reference into this annual report on Form 20-F. See, for example, Note 5 to our audited consolidated financial statements as at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010 included in this annual report on Form 20-F.

We have also entered into a variety of collaboration agreements with various universities and institutes under which we are obligated to support some of the research expenses incurred by the university laboratories and pay royalties on future sales of the products. In turn, we have retained exclusive rights for the worldwide exploitation of results generated during the collaborations.

In particular, we have entered into an agreement with the Tulane Educational Fund ("Tulane"), which provides for the payment by us of single-digit royalties on future worldwide net sales of cetorelix and including Cetrotide<sup>®</sup>. Tulane is also entitled to receive a low double-digit participation payment on any lump-sum, periodic or other cash payments received by us from sub-licensees.

***We rely on third parties to conduct, supervise and monitor our clinical trials, and those third parties may not perform satisfactorily.***

We rely on third parties such as CROs, medical institutions and clinical investigators to enroll qualified patients and conduct, supervise and monitor our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. Our reliance on these third parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with Good Clinical Practice guidelines and the investigational plan and protocols contained in an Investigational New Drug ("IND") application, or comparable foreign regulatory submission. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. In addition, they may not complete activities on schedule, or may not conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and commercialize, our product candidates may be delayed or prevented.

***In carrying out our operations, we are dependent on a stable and consistent supply of ingredients and raw materials.***

There can be no assurance that we, our contract manufacturers or our partners, will be able, in the future, to continue to purchase products from our current suppliers or any other supplier on terms similar to current terms or at all. An interruption in the availability of certain raw materials or ingredients, or significant increases in the prices paid by us for them, could have a material adverse effect on our business, financial condition, liquidity and operating results.

***The failure to perform satisfactorily by third parties upon which we rely to manufacture and supply products may lead to supply shortfalls.***

We rely on third parties to manufacture and supply marketed products. We also have certain supply obligations *vis à vis* our licensing partners who are responsible for the marketing of the products. To be successful, our products have to be manufactured in commercial quantities in compliance with quality controls and regulatory requirements. Even though it is our objective to minimize such risk by introducing alternative suppliers to ensure a constant supply at all times, we cannot guarantee that we will not experience supply shortfalls and, in such event, we may not be able to perform our obligations under contracts with our partners.

***We are subject to intense competition for our skilled personnel, and the loss of key personnel or the inability to attract additional personnel could impair our ability to conduct our operations.***

We are highly dependent on our management and our clinical, regulatory and scientific staff, the loss of whose services might adversely impact our ability to achieve our objectives. Recruiting and retaining qualified management and clinical, scientific and regulatory personnel is critical to our success. Competition for skilled personnel is intense, and our ability to attract and retain qualified personnel may be affected by such competition.

***Our strategic partners' manufacturing capabilities may not be adequate to effectively commercialize our product candidates.***

Our manufacturing experience to date with respect to our product candidates consists of producing drug substance for clinical studies. To be successful, these product candidates have to be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. Our strategic partners' current manufacturing facilities have the capacity to produce projected product requirements for the foreseeable future, but we will need to increase capacity if sales continue to



grow. Our strategic partners may not be able to expand capacity or to produce additional product requirements on favorable terms. Moreover, delays associated with securing additional manufacturing capacity may reduce our revenues and adversely affect our business and financial position. There can be no assurance that we will be able to meet increased demand over time.

***We are subject to the risk of product liability claims, for which we may not have or be able to obtain adequate insurance coverage.***

The sale and use of our products, in particular our biopharmaceutical products, involve the risk of product liability claims and associated adverse publicity. Our risks relate to human participants in our clinical trials, who may suffer unintended consequences, as well as products on the market whereby claims might be made directly by patients, healthcare providers or pharmaceutical companies or others selling, buying or using our products. We manage our liability risks by means of insurance. We maintain liability insurance covering our liability for our preclinical and clinical studies and for our pharmaceutical products already marketed. However, we may not have or be able to obtain or maintain sufficient and affordable insurance coverage, including coverage for potentially very significant legal expenses, and without sufficient coverage any claim brought against us could have a materially adverse effect on our business, financial condition or results of operations.

***Our business involves the use of hazardous materials which requires us to comply with environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could be subject to significant fines, liabilities or other adverse consequences.***

Our discovery and development processes involve the controlled use of hazardous and radioactive materials. We are subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident or a failure to comply with environmental or occupational safety laws, we could be held liable for any damages that result, and any such liability could exceed our resources. We may not be adequately insured against this type of liability. We may be required to incur significant costs to comply with environmental laws and regulations in the future, and our operations, business or assets may be materially adversely affected by current or future environmental laws or regulations.

***We are a holding company, and claims of creditors of our subsidiaries will generally have priority as to the assets of such subsidiaries over our claims and those of our creditors and shareholders.***

Aeterna Zentaris Inc. is a holding company and a substantial portion of our assets is the share capital of our subsidiaries. AEZS GmbH, our principal operating subsidiary, based in Frankfurt, Germany, holds most of our intellectual property rights, which represent the principal assets of our business.

Because Aeterna Zentaris Inc. is a holding company, our obligations to our creditors are structurally subordinated to all existing and future liabilities of our subsidiaries. Therefore, our rights and the rights of our creditors to participate in any distribution of the assets of any subsidiary in the event that such subsidiary were to be liquidated or reorganized or in the event of any bankruptcy or insolvency proceeding relating to or involving such subsidiary, and therefore the rights of the holders of our common shares to participate in those assets, are subject to the prior claims of such subsidiary's creditors. To the extent that we may be a creditor with recognized claims against any such subsidiary, our claims would still be subject to the prior claims of our subsidiary's creditors to the extent that they are secured or senior to those held by us.

Holders of our common shares are not creditors of our subsidiaries. Claims to the assets of our subsidiaries will derive from our own ownership interest in those operating subsidiaries. Claims of our subsidiaries' creditors will generally have priority as to the assets of such subsidiaries over our own ownership interest claims and will therefore have priority over the holders of our common shares. Our subsidiaries' creditors may from time to time include general creditors, trade creditors, employees, secured creditors, taxing authorities, and creditors holding guarantees.

Accordingly, in the event of any foreclosure, dissolution, winding-up, liquidation or reorganization, or a bankruptcy or insolvency proceeding relating to us or our property, or any subsidiary, there can be no assurance as to the value, if any, that would be available to holders of our common shares.

In addition, any distributions to us by our subsidiaries could be subject to monetary transfer restrictions in the jurisdictions in which our subsidiaries operate.

Our subsidiaries may incur additional indebtedness and other liabilities.

***All existing and futures shares of our subsidiary holding rights to Cetrotide® have been pledged to an affiliate of HRP (as defined below). If we were to default on certain payments or other material obligations owed to HRP, or upon the commencement of insolvency proceedings by or against us, HRP could realize its interest and we would lose our ability to derive revenues from royalties derived indirectly from net sales of Cetrotide®.***

The Company's revenues are derived primarily from sales and royalties as well as from license fees. Sales are derived from Cetrotide® (cetorelix acetate solution for injection), marketed globally (ex-Japan) by ARES Trading S.A. ("Merck Serono") for reproductive health assistance for *in vitro* fertilization, as well as from active pharmaceutical ingredients. Royalties are derived indirectly from Merck Serono's net sales of Cetrotide® and represent the periodic amortization, under the units-of-revenue method, of the proceeds received in connection with the 2008 sale (or monetization) by IVF of the underlying future royalty stream to Healthcare Royalty Partners L.P. (formerly Cowen Healthcare Royalty Partners L.P.) ("HRP").

On November 11, 2008, IVF, AEZS GmbH and the Company signed a purchase agreement (the "Purchase Agreement") with HRP for the sale to HRP of IVF's rights to royalties on future net sales of Cetrotide®, covered by a license agreement with Merck Serono.

Pursuant to the Purchase Agreement, AEZS GmbH entered into a pledge agreement with an affiliate of HRP granting a pledge to such affiliate (the "Pledge") over all existing and future shares of the capital of IVF and all ancillary rights pertaining thereto (other than voting rights), including monetary claims (the "Pledged Shares"). The Pledge will expire when all obligations which are or become due, owing or payable to HRP or its assignee under or in connection with the Purchase Agreement have been fully and finally satisfied and discharged.

In the event we were to default on certain of our payment or other material obligations owed to HRP under the Purchase Agreement, or in the event any bankruptcy, insolvency, reorganization, liquidation, dissolution, or similar proceeding, domestic or foreign, is instituted by or against Aeterna Zentaris Inc., or if any of Aeterna Zentaris Inc., AEZS GmbH or IVF becomes insolvent as described in the Purchase Agreement, or if any corporate action, legal proceeding or other proceeding is taken in relation to the suspension of payments, winding-up, dissolution, administration or reorganization of Aeterna Zentaris Inc. or any subsidiary, HRP's affiliate could realize its interest in the Pledged Shares, subject to prior compliance with the German Civil Code with regard to the enforcement of pledges, and it may sell the Pledged Shares or otherwise dispose of such shares. If such affiliate were to realize its interest in the Pledged Shares, it would have a material adverse impact on our business, as we would lose our ability to derive revenues from royalties derived from Merck Serono's net sales of Cetrotide®. In addition, in the event of any bankruptcy or insolvency event relating to or involving any of Aeterna Zentaris Inc., AEZS GmbH or IVF, the rights related to Cetrotide® would not be available to either Aeterna Zentaris Inc. or our common shareholders as IVF would no longer be a subsidiary of Aeterna Zentaris Inc.

***It may be difficult for U.S. investors to obtain and enforce judgments against us because of our Canadian incorporation and German presence.***

We are a Company existing under the laws of Canada. Most of our directors and officers are residents of Canada or otherwise reside outside the U.S., and all or a substantial portion of their assets, and a substantial portion of our assets, are located outside the U.S. Consequently, although we have appointed an agent for service of process in the U.S., it may be difficult for investors in the United States to bring an action against such directors or officers or to enforce against those persons or us a judgment obtained in a United States court predicated upon the civil liability provisions of federal securities laws or other laws of the United States. Investors should not assume that foreign courts (1) would enforce judgments of U.S. courts obtained in actions against us or such directors, officers or experts predicated upon the civil liability provisions of the U.S. federal securities laws or the securities or "blue sky" laws of any state within the U.S. or (2) would enforce, in original actions, liabilities against us or such directors, officers or experts predicated upon the U.S. federal securities laws or any such state securities or "blue sky" laws. In addition, we have been advised by our Canadian counsel that in normal circumstances, only civil judgments and not other rights arising from U.S. securities legislation (for example, penal or similar awards made by a court in a regulatory prosecution or proceeding) are enforceable in Canada and that the protections afforded by Canadian securities laws may not be available to investors in the U.S.

***Health care reform measures could adversely affect our business***

The business prospects and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the U.S. and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as proposals relating to the pricing of healthcare products and services in the U.S. or internationally, the reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price), and the amount of reimbursement available from governmental agencies or other third party payers. For example, drug manufacturers are required to have a national rebate agreement with the Department of Health and Human Services in order to obtain state Medicaid

coverage, which requires manufacturers to pay a rebate on drugs dispensed to Medicaid patients. On January 27, 2012, the Centers for Medicare and Medicaid Services ("CMS") issued a proposed regulation covering the calculation of Average Manufacturer Price ("AMP") which is the key variable in the calculation of these rebates.

Furthermore, in the U.S., health care reform legislation titled the *Patient Protection and Affordable Care Act* ("PPACA") was signed into law in March 2010. The impact of this legislation on our business is inherently difficult to predict as many of the details regarding the implementation of this legislation have not been determined. In a decision issued on June 29, 2012, the United States Supreme Court upheld the majority of PPACA. The Court's decision allows implementation of key provisions impacting the pharmaceutical industry, including drug and device manufacturers. This includes PPACA changes to the Medicare Part D Program (including closing the "donut hole"), Medicaid Drug Rebate Program (including the definition of AMP), and expansion of the 340B Drug Discount Program. The decision also allows the FDA and CMS to continue with implementation efforts, including related to the *Biologics Price Competition and Innovation Act* and the *Physician Payments Sunshine Act*, both of which were enacted as part of the PPACA. Regulations to implement PPACA could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses. Government-financed comparative efficacy research could also result in new practice guidelines, labeling or reimbursement policies that discourages use of our products.

In addition, on September 27, 2007, the *Food and Drug Administration Amendments Act of 2007* was enacted, giving the FDA enhanced post-market authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority may result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, which may also increase costs related to complying with new post-approval regulatory requirements, and increase potential FDA restrictions on the sale or distribution of approved products.

***We are subject to additional reporting requirements under applicable Canadian securities laws and the Sarbanes-Oxley Act in the United States. We can provide no assurance that we will at all times in the future be able to report that our internal controls over financial reporting are effective.***

As a public company, we are required to comply with Section 404 of the Sarbanes-Oxley Act ("Section 404") and National Instrument 52-109 - *Certification of Disclosure in Issuers' Annual and Interim Filings*, and we are required to obtain an annual attestation from our independent auditors regarding our internal control over financial reporting. In any given year, we cannot be certain as to the time of completion of our internal control evaluation, testing and remediation actions or of their impact on our operations. Upon completion of this process, we may identify control deficiencies of varying degrees of severity under applicable SEC and Public Company Accounting Oversight Board rules and regulations. As a public company, we are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal controls that, or that are reasonably likely to, materially affect internal controls over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual consolidated financial statements will not be prevented or detected on a timely basis. If we fail to comply with the requirements of Section 404, Canadian requirements or report a material weakness, we might be subject to regulatory sanction and investors may lose confidence in our consolidated financial statements, which may be inaccurate if we fail to remedy such material weakness.

***It is possible that we may be a passive foreign investment company, which could result in adverse tax consequences to U.S. investors.***

Adverse U.S. federal income tax rules apply to "U.S. Holders" (as defined in "Item 10.E – Taxation – Certain Material U.S. Federal Income Tax Considerations" in this annual report on Form 20-F) that directly or indirectly hold common shares of a passive foreign investment company ("PFIC"). We will be classified as a PFIC for U.S. federal income tax purposes for a taxable year if (i) at least 75% of our gross income is "passive income" or (ii) at least 50% of the average value of our assets, including goodwill (based on annual quarterly average), is attributable to assets which produce passive income or are held for the production of passive income.

We believe that we were not a PFIC for the 2012 taxable year. However, the PFIC determination depends on the application of complex U.S. federal income tax rules concerning the classification of our assets and income for this purpose, and these rules are uncertain in some respects. In addition, the fair market value of our assets may be determined in large part by the market price of our common shares, which is likely to fluctuate, and the composition of our income and assets will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction. No assurance can be provided that we will not be classified as a PFIC for the 2013 taxable year and for any future taxable year.

PFIC characterization could result in adverse U.S. federal income tax consequences to U.S. Holders. In particular, absent certain elections, a U.S. Holder would generally be subject to U.S. federal income tax at ordinary income tax rates, plus a

possible interest charge, in respect of a gain derived from a disposition of our common shares, as well as certain distributions by us. If we are treated as a PFIC for any taxable year, a U.S. Holder may be able to make an election to "mark to market" common shares each taxable year and recognize ordinary income pursuant to such election based upon increases in the value of the common shares. In addition, U.S. Holders may mitigate the adverse tax consequences of the PFIC rules by making a "qualified electing fund" ("QEF") election; however, the Company does not expect to provide the information regarding its income that would be necessary for a U.S. Holder to make a QEF election.

Under U.S. tax legislation and subject to future guidance, if the Company is a PFIC, U.S. Holders will be required to file an annual information return with the Internal Revenue Service (the "IRS") (on IRS Form 8621, which PFIC shareholders will be required to file with their U.S. federal income tax or information returns) relating to their ownership of common shares. Pursuant to IRS Notice 2011-55, the IRS has suspended this new filing requirement for U.S. Holders that are not otherwise required to file the current version of the IRS Form 8621 until the IRS releases a subsequent revision of IRS Form 8621, modified to reflect the recently enacted U.S. tax legislation. Guidance has not yet been issued regarding the information required to be included on such form. This new filing requirement is in addition to any preexisting reporting requirements that apply to a U.S. Holder's interest in a PFIC (which the recently enacted tax legislation and IRS Notice 2011-55 do not affect).

For a more detailed discussion of the potential tax impact of us being a PFIC, see "Item 10.E – Taxation – Certain Material U.S. Federal Income Tax Considerations" in this annual report on Form 20-F. The PFIC rules are complex. U.S. Holders should consult their tax advisors regarding the potential application of the PFIC regime and any reporting obligations to which they may be subject under that regime.

***We may incur losses associated with foreign currency fluctuations.***

Our operations are in many instances conducted in currencies other than the euro, our functional currency. Fluctuations in the value of currencies could cause us to incur currency exchange losses. We do not currently employ a hedging strategy against exchange rate risk. We cannot assert with any assurance that we will not suffer losses as a result of unfavorable fluctuations in the exchange rates between the United States dollar, the euro, the Canadian dollar and other currencies. For more information, see "Item 11. – Quantitative and Qualitative Disclosures About Market Risk" in this annual report on Form 20-F.

***We may not be able to successfully integrate acquired businesses.***

Future acquisitions may not be successfully integrated. The failure to successfully integrate the personnel and operations of businesses which we may acquire in the future with ours could have a material adverse effect on our operations and results.

***Legislative actions, new accounting pronouncements and higher insurance costs are likely to impact our future financial position or results of operations.***

Changes in financial accounting standards or implementation of accounting standards may cause adverse, unexpected revenue or expense fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with greater frequency and are expected to occur in the future, and we may make or be required to make changes in our accounting policies in the future. Compliance with changing regulations of corporate governance and public disclosure, notably with respect to internal controls over financial reporting, may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for companies such as ours, and insurance costs are increasing as a result of this uncertainty.

**Risks Relating to our Common Shares**

***Our share price is volatile, which may result from factors outside of our control. If our common shares were to be delisted from NASDAQ Global Market ("NASDAQ") or Toronto Stock Exchange (the "TSX"), investors may have difficulty in disposing of our common shares held by them.***

Our common shares are currently listed and traded only on NASDAQ and TSX. Our valuation and share price since the beginning of trading after our initial listings, first in Canada and then in the United States, have had no meaningful relationship to current or historical financial results, asset values, book value or many other criteria based on conventional measures of the value of shares.

As adjusted for and giving effect to our 6-to-1 Share Consolidation on October 2, 2012, the closing price of our common shares ranged from \$1.87 to \$12.90 on NASDAQ and from C\$1.87 to C\$12.84 per share on TSX between January 1 and December 31, 2012. Our share price may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. The stock market generally, and the biopharmaceutical sector in particular, are vulnerable to abrupt changes in investor sentiment. Prices of shares and trading volume of companies in the biopharmaceutical industry can swing

dramatically in ways unrelated to, or that bear a disproportionate relationship to, operating performance. Our share price and trading volume may fluctuate based on a number of factors including, but not limited to:

- clinical and regulatory developments regarding our product candidates;
- delays in our anticipated development or commercialization timelines;
- developments regarding current or future third-party collaborators;
- other announcements by us regarding technological, product development or other matters;
- arrivals or departures of key personnel;
- governmental or regulatory action affecting our product candidates and our competitors' products in the United States, Canada and other countries;
- developments or disputes concerning patent or proprietary rights;
- actual or anticipated fluctuations in our revenues or expenses;
- general market conditions and fluctuations for the emerging growth and biopharmaceutical market sectors; and
- economic conditions in the United States, Canada or abroad.

Our listing on both NASDAQ and TSX may increase price volatility due to various factors, including different ability to buy or sell our common shares, different market conditions in different capital markets and different trading volumes. In addition, low trading volume may increase the price volatility of our common shares. A thin trading market could cause the price of our common shares to fluctuate significantly more than the stock market as a whole.

A period of large price decline in our common shares could increase the risk that securities class action litigation could be initiated against us. Litigation of this type and other litigation could result in substantial costs and diversion of management's attention and resources, which would adversely affect our business. Any adverse determination in litigation could also subject us to significant liabilities.

We must meet continuing listing requirements to maintain the listing of our common shares on NASDAQ and TSX. For continued listing, NASDAQ requires, among other things, that listed securities maintain a minimum closing bid price of not less than \$1.00 per share.

If our common shares trade for 30 consecutive business days below the required \$1.00 minimum closing bid price, we expect that NASDAQ would then send us a deficiency notice and provide us with a period of 180 calendar days to regain compliance with the minimum bid price requirement. In order to regain compliance, the closing bid price of our common shares would have to be at least US\$1.00 for a minimum of 10 consecutive business days. If we did not regain compliance within the initial 180-day period, but otherwise met the continued listing requirement for market value of publicly held shares and all other initial listing standards for the NASDAQ Capital Market, except for the bid price requirement, and we provided NASDAQ with notice of our intention to cure the bid price deficiency, the NASDAQ rules may then permit us to transfer to the NASDAQ Capital Market, which would give us an additional 180 calendar days to regain compliance. If we were not eligible for an additional compliance period, NASDAQ will notify us that our securities are subject to delisting. At that time, we could appeal the determination to delist our securities to a Listing Qualifications Panel.

In addition to the minimum bid price requirement, NASDAQ's continued listing rules require us to meet at least one of the following listing standards: (i) stockholders' equity of at least \$10 million (the "Equity Standard"), (ii) market value of listed securities (calculated by multiplying the daily closing bid price of our common shares by our total outstanding common shares) of at least \$50 million (the "Market Value Standard") or (iii) total assets and total revenue of at least \$50 million each (the "Total Assets/Total Revenue Standard"). If our total market capitalization decreases to an amount less than \$50 million we may no longer meet any of these three listing standards. Similar to the process described above in the minimum bid price context, if we fail to meet the Market Value Standard for 30 consecutive trading days and do not otherwise meet the Equity Standard or the Total Assets/Total Revenue Standard, we expect that we would then receive a notification letter from NASDAQ advising us that we fail to comply with the Market Value Standard and providing us a period of 180 calendar days to regain compliance with the Market Value Standard. In order to regain compliance with the Market Value Standard, the market value of our listed securities would have to be at least \$50 million for a period of 10 consecutive business days. Otherwise, our securities may then be subject to delisting.

There can be no assurance that our common shares will remain listed on NASDAQ. If we fail to meet any of NASDAQ's continued listing requirements, our common shares may be delisted. Any delisting of our common shares may adversely affect a shareholder's ability to dispose, or obtain quotations as to the market value, of such shares.

***We do not intend to pay dividends in the near future.***

To date, we have not declared or paid any dividends on our common shares. We currently intend to retain our future earnings, if any, to finance further research and the expansion of our business. As a result, the return on an investment in our common

shares will, for the foreseeable future, depend upon any future appreciation in value. There is no guarantee that our common shares will appreciate in value or even maintain the price at which shareholders have purchased them.

***Future issuances of securities and hedging activities may depress the trading price of our common shares.***

Any additional or future issuance of equity securities or securities convertible into or exchangeable for equity securities, including the issuance of common shares upon the exercise of stock options and upon the exercise of outstanding warrants, could dilute the interests of our existing shareholders, and could substantially decrease the trading price of our common shares. We may issue equity securities in the future for a number of reasons, including to finance our operations and business strategy, to satisfy our obligations upon the exercise of options or warrants or for other reasons. Our Stock Option Plan generally permits us to have outstanding, at any given time, stock options that are exercisable for a maximum number of common shares equal to 11.4% of all then issued and outstanding common shares. As at December 31, 2012, there were:

- 25,329,288 common shares issued and outstanding;
- no issued and outstanding preferred shares;
- 4,407,410 common shares issuable upon exercise of outstanding warrants; and
- 2,056,367 stock options outstanding.

In addition, the price of common shares could also be affected by possible sales of common shares by investors who view other investment vehicles as more attractive means of equity participation in us and by hedging or arbitrage trading activity that may develop involving our common shares. This hedging or arbitrage could, in turn, affect the trading price of our common shares.

***Our articles of incorporation contain "blank check" preferred share provisions, which could delay or impede an acquisition of our company.***

Our articles of incorporation, as amended, authorize the issuance of an unlimited number of "blank check" preferred shares, which could be issued by our board of directors without shareholder approval and may contain voting, liquidation, dividend and other rights equivalent or superior to our common shares. In addition, we could implement in our constating documents an advance notice procedure for shareholder approvals to be brought before an annual meeting of our shareholders, including proposed nominations of persons for election to our board of directors. These provisions, among others, whether alone or together, could delay or impede hostile takeovers and changes in control or changes in our management. Any provision of our constating documents that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their common shares and could also affect the price that some investors are willing to pay for our common shares.

***The outcome of pending and future claims and litigation could have a material adverse impact on the Company's business, financial condition and results of operation.***

The Company and its subsidiaries may, from time to time, be parties to litigation in the normal course of business. Due to the inherent uncertainties of litigation, it is not possible to predict the final outcome of these lawsuits or determine the amount of any potential losses, if any, and we may, in the future, be subject litigation proceedings, including class action lawsuits. In the event the Company is required or determines to pay amounts in connection with any such lawsuits, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operation.

On December 21, 2012, a second amended securities class action (the "U.S. Class Action") was filed against the Company and certain of its senior officers in the purported class action lawsuit initially filed in June 2012 in the United States District Court, Southern District of New York. On February 1, 2013, we filed a motion to dismiss the U.S. Class Action. This lawsuit, alleging failures to disclose certain information under U.S. federal securities laws, is being prosecuted by a lead plaintiff on behalf of shareholders who acquired the Company's common shares between June 1, 2009 and April 1, 2012 and does not claim a specified amount of damages. We have not recorded any liability related to the U.S. Class Action. The Company's directors' and officers' insurance policy provides for reimbursement of costs and expenses incurred in connection with this lawsuit, including legal and professional fees, as well as potential damages awarded, if any, subject to certain policy restrictions, limits and deductibles. While we continue to believe that there is no basis for the lawsuit and we intend to defend ourselves vigorously, no assurance can be given with respect to the ultimate outcome of such proceedings, and the amount of any damages awarded in such lawsuit could be substantial.

**Item 4. Information on the Company**

**A. History and development of the Company**

We are an oncology and endocrinology drug development company currently investigating treatments for various unmet medical needs.

We were incorporated on September 12, 1990 under the *Canada Business Corporations Act* (the "CBCA") and continue to be governed by the CBCA. Our registered office is located at 1405 du Parc-Technologique Blvd., Quebec City, Quebec, Canada G1P 4P5, our telephone number is (418) 652-8525 and our website is [www.aezsinc.com](http://www.aezsinc.com). None of the documents or information found on our website shall be deemed to be included in or incorporated by reference into this annual report on Form 20-F.

On December 30, 2002, we 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. With this acquisition, the Company changed its risk profile and inherited a product pipeline with capabilities from drug discovery to commercialization with a particular focus on endocrine therapy and oncology.

In May 2004, we changed our name to Aeterna Zentaris Inc. and on May 11, 2007, Zentaris GmbH was renamed Aeterna Zentaris GmbH ("AEZS GmbH"). AEZS GmbH is our principal operating subsidiary.

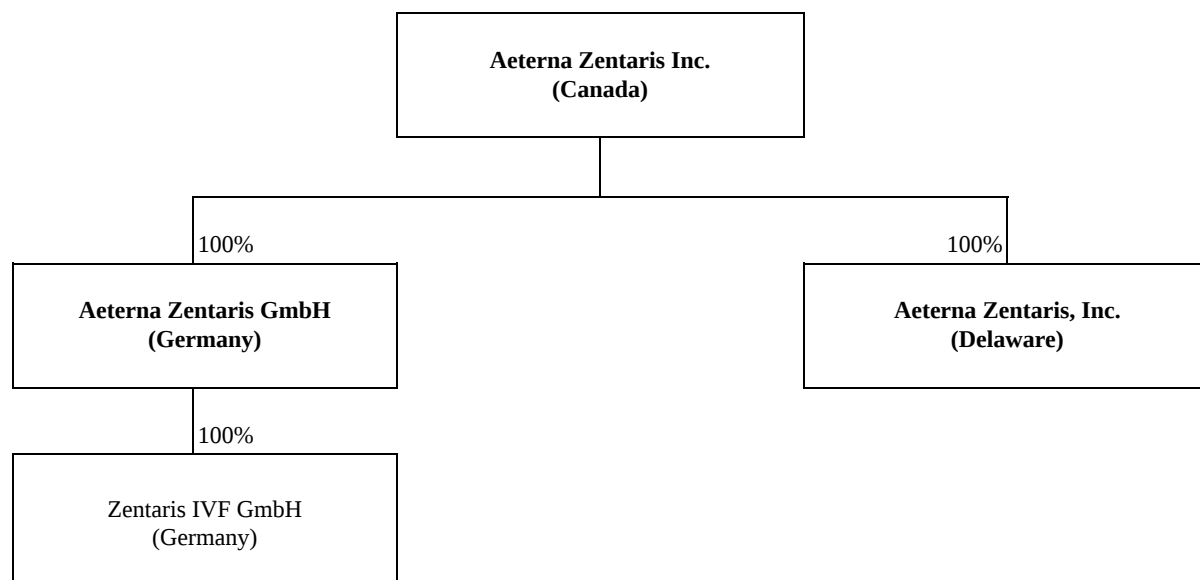
On April 6, 2005, our former subsidiary, Atrium Biotechnologies Inc. (now Atrium Innovations Inc.) ("Atrium"), completed its initial public offering in Canada and began trading on the TSX under the ticker symbol "ATB".

In 2006, we spun off our ownership interest in Atrium in two phases. As of January 2, 2007 we no longer held any ownership interest in Atrium.

In May 2007, we opened an office in the United States, located at 20 Independence Boulevard, Warren, New Jersey 07059-2731. The Company moved this office to a new location in December 2011 at 25 Mountainview Blvd., Suite 203, Basking Ridge, NJ 07920.

On October 2, 2012, we effected a 6-to-1 Share Consolidation (reverse stock split). Our common shares commenced trading on a consolidated and adjusted basis on both NASDAQ and TSX on October 5, 2012.

We currently have three wholly-owned direct and indirect subsidiaries, Aeterna Zentaris GmbH (Germany), based in Frankfurt, Germany, Zentaris IVF GmbH, a direct wholly-owned subsidiary of AEZS Germany based in Frankfurt, Germany, and Aeterna Zentaris, Inc., based in Basking Ridge, New Jersey in the United States.



Our current drug development strategy focuses mainly on our later-stage compounds AEZS-108 (doxorubicin Luteinizing Hormone-Releasing Hormone ("LHRH")-targeted conjugate compound) in oncology and AEZS-130 (oral ghrelin agonist) in endocrinology, as well as on strategic and targeted earlier-stage compounds, as depicted in the chart reproduced under the heading, "Our Product Pipeline".

Our common shares are listed for trading on the TSX under the trading symbol "AEZ" and on NASDAQ under the trading symbol "AEZS".

The Company's agent for service of process and SEC matters in the United States is its wholly-owned subsidiary, Aeterna Zentaris, Inc., located at 25 Mountainview Blvd., Suite 203, Basking Ridge, NJ 07920.

There have been no public takeover offers by third parties with respect to the Company or by the Company in respect of other companies' shares during the last or current fiscal year.

## **B. Business overview**

We are an oncology and endocrinology drug development company currently investigating treatments for various unmet medical needs.

Our pipeline encompasses compounds at all stages of development, from drug discovery through to marketed products. We also benefit from agreements and arrangements with strategic collaborators and licensee partners, which contribute to the development of our pipeline of product candidates and in the establishment of commercial activities in specific territories.

Over the years, the Company has incurred recurring operating losses, having invested significantly in our R&D activities, as well as supporting our general and administrative expenses. We have financed our operations through different sources including the issuance of common shares and warrants, the conclusion of strategic alliances with licensee partners and research and development grants awarded by governmental agencies. The Company expects to continue to incur operating losses and may require significant capital to fulfill our future obligations. See the capital disclosures and the liquidity risk sections.

In oncology, we are in the initiation process of a Phase 3 study under a Special Protocol Assessment ("SPA") with AEZS-108, a doxorubicin LHRH-targeted conjugate compound, in endometrial cancer, for which we have successfully completed a Phase 2 trial in advanced endometrial and advanced ovarian cancer. We are also advancing Phase 2 trials with AEZS-108 in triple-negative breast cancer, refractory bladder cancer and castration- and taxane-resistant prostate cancer.

Our oncology pipeline also encompasses other earlier-stage programs, including AEZS-112, an oral anticancer agent which involves three mechanisms of action (tubulin, topoisomerase II and angiogenesis inhibition), which has completed a Phase 1 trial in advanced solid tumors and lymphoma. Additionally, several novel targeted anticancer candidates such as AEZS-120, a live recombinant oral tumor vaccine candidate, as well as our PI3K/Erk inhibitors, including AEZS-129, AEZS-134 and AEZS-136, are currently in preclinical development.

In endocrinology, we are preparing the filing of an NDA in the U.S. for the registration of AEZS-130, an oral ghrelin agonist, as a diagnostic test for adult growth hormone deficiency ("AGHD"). A Phase 3 trial under a SPA with the FDA has been completed in this indication. Furthermore, AEZS-130 is in a Phase 2A trial for the treatment of cancer-induced cachexia.

### *Recent Developments*

On March 11, 2013, we announced that an independent Data Safety Monitoring Board ("DSMB") recommended discontinuing the Phase 3 study comparing the efficacy and safety of perifosine to placebo when combined with bortezomib (Velcade®) and dexamethasone in patients with relapsed or relapsed/refractory multiple myeloma. Based on the outcome of its preplanned interim analysis of efficacy and safety, the DSMB recommended that patient enrollment be stopped and the study discontinued. The DSMB reported that it was highly unlikely the study would achieve a significant difference in its primary endpoint, progression-free survival; no safety concerns were raised. Based on the foregoing, we determined to discontinue the Phase 3 study of perifosine in multiple myeloma.

For a complete description of our recent corporate and pipeline developments, refer to "Item 5. – Operating and Financial Review and Prospects – Key Developments in 2012".

### **Our Business Strategy**

Our primary business strategy is to advance, with the collaboration of our strategic partners, our product development pipeline with a focus on our principal product candidates in oncology and endocrinology. In addition, we continue to advance certain other clinical and preclinical programs as described below. Our vision is to become a fully-integrated specialty biopharmaceutical company.



## Our product pipeline

### Pipeline table

Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Commercial
~120,000 compound library	<p><b>AEZS-120</b> Prostate cancer vaccine (oncology)</p> <p><b>AEZS-129, 134 and 136</b> PI3K/Erk inhibitors (oncology)</p> <p><b>AEZS-137</b> (disorazol Z) (oncology)</p> <p><b>AEZS-125</b> (LHRH- disorazol Z) (oncology)</p>	<p><b>AEZS-112</b> (oncology)</p>	<p><b>AEZS-108</b></p> <ul style="list-style-type: none"> <li>• Triple-negative breast cancer</li> <li>• Ovarian cancer</li> <li>• Castration- and taxane-resistant prostate cancer</li> <li>• Refractory bladder cancer</li> </ul> <p><b>Ozarelix</b></p> <ul style="list-style-type: none"> <li>• Prostate cancer</li> </ul> <p><b>AEZS-130</b></p> <ul style="list-style-type: none"> <li>• Therapeutic in cancer cachexia</li> </ul> <p><b>Perifosine</b> (Phase 1/2)</p> <ul style="list-style-type: none"> <li>• Neuroblastoma</li> <li>• Glioma</li> <li>• Pediatric solid tumors</li> </ul>	<p><b>AEZS-108</b></p> <ul style="list-style-type: none"> <li>• Endometrial cancer (not yet recruiting)</li> </ul> <p><b>AEZS-130</b></p> <ul style="list-style-type: none"> <li>• Diagnostic in adult growth hormone deficiency (endocrinology)</li> </ul>	<p><b>Cetrotide®</b> (<i>in vitro</i> fertilization)</p>

### Licensee Partners and Territories by Product

#### Cetrotide®:

Merck Serono, World (except Japan) - **Nippon Kayaku/Shionogi**, Japan

#### Ozarelix:

**Spectrum Pharmaceuticals, Inc. ("Spectrum")**, World (ex-Japan, Korea and other Asian countries) - **Handok Pharmaceuticals ("Handok")**, Korea and other Asian countries for BPH indication - **Nippon Kayaku**, Japan for oncology indications

#### Perifosine:

**Yakult Honsha Co. Ltd ("Yakult")**, Japan - **Handok**, Korea - **Hikma Pharmaceuticals**, Middle East/North Africa

### Oncology

In oncology, we are in the initiation process of a Phase 3 study under a SPA with the FDA for AEZS-108 in endometrial cancer, for which we have successfully completed a Phase 2 trial in advanced endometrial and advanced ovarian cancer. We are also advancing Phase 2 trials with AEZS-108 in triple-negative breast cancer, refractory bladder cancer and castration- and taxane-resistant prostate cancer.

AEZS-108 represents a new targeting concept in oncology using a hybrid molecule composed of a synthetic peptide carrier and a well-known chemotherapy agent, doxorubicin. AEZS-108 is the first intravenous drug in advanced clinical development that directs the chemotherapy agent specifically to LHRH-receptor expressing tumors, resulting in more targeted treatment with less damage to healthy tissue. The product has successfully completed Phase 2 studies for the treatment of ovarian and endometrial cancer and the Company is initiating a Phase 3 trial in advanced endometrial cancer under a SPA with the FDA. AEZS-108 is also in Phase 2 trials in triple-negative breast cancer, refractory bladder cancer and castration- and taxane-resistant prostate cancer. AEZS-108 has been granted orphan drug designation by the FDA and orphan medicinal product designation from the European Medicines Agency for the treatment of ovarian cancer. We hold the worldwide rights to AEZS-108 pursuant to an exclusive license agreement with Tulane University, as licensor, and AEZS GmbH, as licensee. We also have a collaboration agreement with Ventana Medical Systems, Inc. ("Ventana"), a member of the Roche Group, to develop a companion diagnostic for the immunohistochemical determination of LHRH-receptor expression, for AEZS-108.

### **Endocrinology**

In endocrinology, we are preparing the filing of an NDA in the U.S. for the registration of AEZS-130, as a diagnostic test for AGHD. A Phase 3 trial under a SPA with the FDA has been completed in this indication. Furthermore, AEZS-130 is in a Phase 2A trial for the treatment of cancer-induced cachexia.

### **AEZS-130**

AEZS-130, a ghrelin agonist, is an orally available novel synthetic small molecule that stimulates the secretion of growth hormone. We completed a Phase 3 trial under a SPA obtained from the FDA and, following discussions with the FDA, we are preparing to file a NDA in the United States. AEZS-130 has been granted orphan-drug designation by the FDA. In addition to the diagnostic indication, we believe that AEZS-130 has potential application for the treatment of cachexia, a condition frequently associated with severe chronic diseases such as cancer, chronic obstructive pulmonary disease and Acquired Immune Deficiency Syndrome ("AIDS"). Furthermore, the FDA has granted an IND for the initiation of a Phase 2A trial in cancer-induced cachexia. The study is currently conducted under a cooperative research and development agreement ("CRADA") with the Michael E. DeBakey Veterans Affairs Medical Center that will be funding the study. We hold the worldwide rights to AEZS-130 pursuant to an exclusive license agreement with The French *Centre National de la Recherche Scientifique*, as licensor, and AEZS GmbH, as licensee.

### **Clinical and Preclinical Programs**

Our oncology pipeline also encompasses other earlier-stage programs, including AEZS-112, an oral anticancer agent that involves three mechanisms of action (tubulin, topoisomerase II and angiogenesis inhibition), which has completed a Phase 1 trial in advanced solid tumors and lymphoma. Additionally, several novel targeted anticancer candidates such as AEZS-120, a live recombinant oral tumor vaccine candidate, as well as our PI3K/Erk inhibitors, including AEZS-129, AEZS-134 and AEZS-136, are currently in preclinical development.

We also continue to perform targeted drug discovery activities from which we are able to derive preclinical candidates. This drug discovery includes high throughput screening systems and a library of more than 120,000 compounds.

We are currently at a stage in which some of our products and product candidates are being further developed or marketed jointly with strategic partners or with funding from governmental organizations.

## **1.0 ONCOLOGY**

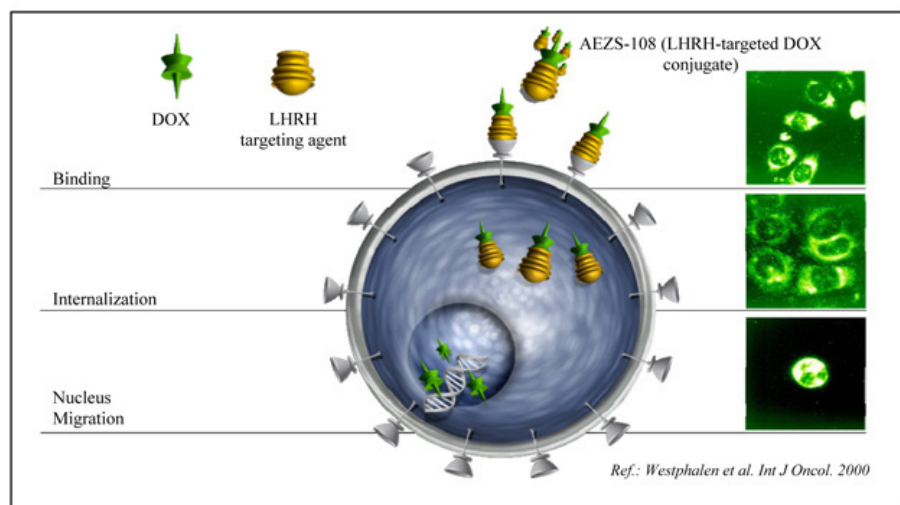
### **1.1 TUMOR TARGETING CYTOTOXIC CONJUGATES AND CYTOTOXICS**

#### **Cytotoxic conjugates**

In view of the non-specific toxicity of most chemotherapeutic agents against normal cells, targeting such drugs to cancerous tissue offers a potential benefit for patients with advanced or metastatic tumors. Targeted cytotoxic peptide conjugates are hybrid molecules composed of a cytotoxic moiety linked to a peptide carrier which binds to receptors on tumors. Cytotoxic conjugates are designed to achieve differential delivery, or targeting, of the cytotoxic agent to cancer vs. normal cells.

Our cytotoxic conjugates represent a novel oncological strategy to control and reduce toxicity and improve the effectiveness of cytotoxic drugs.

In AEZS-108, the most advanced of our cytotoxic conjugates, doxorubicin is chemically linked to an LHRH agonist, a modified natural hormone with affinity for the LHRH receptor. This design allows for the specific binding and selective uptake of the cytotoxic conjugate by LHRH receptor-positive tumors. Potential benefits of this targeted approach include a more favorable safety profile with lower incidence and severity of side effects, as normal tissues are spared from toxic effects of doxorubicin. In addition, the targeted approach may enable treatment of LHRH receptor-positive cancers that have become refractory to doxorubicin which has been administered in its non-targeted form.



### 1.1.1 AEZS-108 - Ovarian and Endometrial Cancer

In 2007, a Phase 2 open-label, non-comparative, multicenter two indication trial stratified with two stages Simon Design was prepared. The study was planned to involve up to 82 patients, with up to 41 patients each with a diagnosis of platinum-resistant ovarian cancer (stratum A) or disseminated endometrial cancer (stratum B). Under coordination by Prof. Günter Emons, M.D., Chairman of the Department of Obstetrics & Gynaecology at the University of Göttingen, Germany, this open-label, multicenter and multinational Phase 2 study "AGO-GYN 5" was conducted by the German AGO Study Group (Arbeitsgemeinschaft Gynäkologische Onkologie / Gynaecological Oncology Working Group), in cooperation with clinical sites in Europe. As part of a personalized healthcare approach, the study selected patients with tumors expressing LHRH receptors, the key element in the targeting mechanism of AEZS-108. An i.v. infusion of AEZS-108 (267 mg/m<sup>2</sup>) was administered over a period of two hours, every Day 1 of a 21-day (3-week) cycle. The proposed duration of the study treatment was six cycles. The study was performed with 14 centers of the German Gynaecological Oncology Working Group, in cooperation with three clinical sites in Europe. The primary efficacy endpoint was a response rate with a success criterion at the end of Stage II defined as five or more patients with partial or complete tumor responses according to RECIST and/or Gynaecologic Cancer Intergroup ("GCIG") guidelines. Secondary endpoints included TTP, survival, toxicity, as well as adverse effects. In October 2008, we announced that we had entered the second stage of patient recruitment for the Phase 2 trial in platinum-resistant ovarian cancer indication. This decision was taken following the report of two PR among patients with ovarian cancer. The second stage of patient recruitment for the endometrial cancer indication was reached in November 2008 and was based on the report of one CR and two PR among 14 patients with endometrial cancer.

On November 2, 2009, we announced positive preliminary efficacy data for the Phase 2 study in patients with LHRH-receptor positive platinum-resistant and taxane-pretreated ovarian cancer. All 43 patients who had entered the study had completed their treatment, and a preliminary evaluation had shown that the study had met its predefined primary efficacy endpoint of five or more responders in 41 evaluable patients. Responders, as well as patients with stable disease after completion of treatment with AEZS-108, were to be followed to assess the duration of response and, ultimately, OS.

On November 24, 2009, we announced positive results for the Phase 2 study in patients with endometrial cancer. Preliminary evaluation showed that the study met its predefined primary efficacy endpoint of five or more responders in endometrial cancer patients. Responders, as well as patients with stable disease after completion of treatment with AEZS-108, were to be followed to assess the duration of PFS and, ultimately, OS.

On May 6, 2010, we announced that we had received orphan drug designation from the FDA for AEZS-108 for the treatment of ovarian cancer.

On May 17, 2010, we announced that we had received a positive opinion for orphan medicinal product designation from the COMP of the EMA for AEZS-108 for the treatment of ovarian cancer.

On June 7, 2010, Prof. Günter Emons, Chairman, Department of Obstetrics & Gynaecology Georg-August University Göttingen, Germany, presented positive efficacy and safety data for AEZS-108 in ovarian cancer at the ASCO Annual Meeting. The poster (abstract #5035), was entitled "*Phase 2 study of AEZS-108, a targeted cytotoxic LHRH analog, in patients with LHRH receptor-positive platinum resistant ovarian cancer*".

42 patients with platinum-resistant ovarian cancer entered the study. Efficacy included PR in five patients (11.9%) and stable disease for more than twelve weeks in eleven patients (26.2%). Based on those data, a CBR of 38% was estimated. Median TTP and OS were evaluated as 3.5 months (104 days) and 15.6 months (475 days), respectively. OS compared favourably with data from Doxil<sup>®</sup> and topotecan (8-9 months). In all, tolerability of AEZS-108 was good and commonly allowed retreatment as scheduled. Only one patient (2.4%) had a dose reduction, and overall, 25 of 170 (14.7%) courses were given with a delay, including cases in which delay was not related to toxicity. Severe (Grade 3 or 4) toxicity was mainly restricted to rapidly reversible hematologic toxicity (leukopenia / neutropenia) associated with fever in three cases. Good tolerability of AEZS-108 was also reflected with only a few patients with non-hematological toxicities of Grade 3 (none with Grade 4), including single cases each of nausea, constipation, poor general condition, and an enzyme elevation. No cardiac toxicity was reported.

Final evaluation of the ovarian cancer study revealed six patients with PR based on tumor lesions, plus two responders with tumor marker response including one case with normalization, for an overall response rate of 19% (one unconfirmed CR and seven partial responses). Median TTP and OS were evaluated as three and twelve months, respectively.

On September 14, 2011, positive final Phase 2 efficacy and safety data for AEZS-108 in advanced endometrial cancer were presented at the European Society of Gynecological Oncology in Milan, Italy. The data showed that AEZS-108, administered as a single agent at a dosage of 267 mg/m<sup>2</sup> every three weeks was active, well tolerated and that OS was similar to that reported for modern triple combination chemotherapy, but was achieved with lower toxicity. The primary endpoint was the response rate as defined by the RECIST. Secondary endpoints included safety, TTP and OS.

In all, of 43 patients treated with AEZS-108, 39 were evaluable for efficacy. Efficacy confirmed by independent response review included two CR, ten PR, and 17 patients with SD. Based on those data, the estimated ORR (ORR = CR+PR) was 30.8% and the CBR (CBR = CR+PR+SD) was 74.4%. Responses in patients previously treated with chemotherapy included one CR, one PR and two SDs in eight of the patients with prior use of platinum/taxane regimens. Median TTP and OS were seven months and 13.7 months, respectively. A final evaluation, not excluding non-evaluable cases, revealed the following results: two CR, eleven PR (including three patients with PR not confirmed at subsequent time point), and 17 patients with SD, for an ORR of 30.2% and CBR of 70%; median TTP and OS at seven and 15 months, respectively.

Overall, tolerability of AEZS-108 was good and commonly allowed retreatment as scheduled. Severe (Grade 3 or 4) toxicity was mainly restricted to rapidly reversible leukopenia and neutropenia, associated with fever in only one patient who had been treated only three weeks after a surgery. Good tolerability of AEZS-108 was also reflected by a low rate of severe non-hematological and possibly drug-related adverse events which included single cases each of nausea, diarrhea, fatigue, general health deterioration, creatinine elevation, and blood potassium decrease. No cardiac toxicity was reported.

On December 28, 2012, we announced that we had reached an agreement with the FDA with respect to a SPA for an upcoming Phase 3 registration trial of AEZS-108 in endometrial cancer. The SPA agreement states that the proposed trial protocol design, clinical endpoints and planned analyses are acceptable to the FDA to support a regulatory submission. Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial. This will be an open-label, randomized, multicenter Phase 3 trial conducted in North America and Europe, comparing AEZS-108 with doxorubicin as second-line therapy for locally-advanced, recurrent or metastatic endometrial cancer. The trial will involve approximately 500 patients and the primary efficacy endpoint is Overall Survival.

#### *Competitors for AEZS-108 in Endometrial Cancer*

At present, the Company is not aware of any approved drug product for the treatment of advanced and recurrent metastatic endometrial cancer in the United States and Europe. There is also no systemic therapy approved in the United States and Europe (except Germany) for treating advanced or recurrent endometrial cancer.

The following products are among some of the many products currently in clinical trial in endometrial cancer:

Product / mode of action*	Company*	Development Status*
Ixabepilone / microtubule inhibitor	Bristol-Myers Squibb	Phase 3
Letrozole / non-steroidal aromatase inhibitor	Novartis	Phase 2 and Phase 3
SAR245408 (XL-147)/oral pan-PI3K inhibitor	Sanofi	Phase 2
BKM120/PI3K inhibitor	Novartis	Phase 2

\* Source: Competitor company's website and www.clinicaltrials.gov.

See also the risk factor entitled "Competition in our targeted markets is intense, and development by other companies could render our products or technologies non-competitive" in Item 3D of this annual report on Form 20-F.

#### Market Data - Endometrial Cancer

According to the American Cancer Society, endometrial cancer is the most common invasive gynecologic cancer in women in the United States, with an estimated 49,560 new cases expected to occur in 2013. This disease primarily affects postmenopausal women at an average age of 60 years at diagnosis. In the United States, it is estimated that approximately 8,190 women will die of endometrial cancer in 2013.

According to Datamonitor Healthcare (March 2010), a research and advisory firm focusing on therapeutic, strategic and health market analysis and competitive intelligence, the incidence of endometrial cancer in the seven major pharmaceutical markets was 94,061 patients in 2010 and is forecasted to reach approximately 98,500 cases by 2019.

#### 1.1.2 AEZS-108 - Triple-Negative Breast Cancer

On October 25, 2011, we announced that the FDA had granted Alberto J. Montero M.D. of the Sylvester Comprehensive Cancer Center, an IND approval for the initiation of a randomized Phase 2 trial in chemotherapy refractory triple-negative (ER/PR/HER2-negative) LHRH receptor-positive metastatic breast cancer with AEZS-108. Subsequently, the study was converted into a Company-sponsored study and is now conducted under our IND.

On February 20 2013, we announced that a first patient had been treated for the randomized Phase 2 trial in chemotherapy refractory triple-negative ("ER/PR/HER2-negative") luteinizing hormone-releasing hormone receptor ("LHRH-R")-positive metastatic breast cancer, with AEZS-108. Alberto J. Montero, MD, Assistant Professor, Department of Medicine, Division of Hematology/Oncology, Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine, is the lead investigator of this trial which also include sites at the Universities of Regensburg and Goettingen, in Germany.

This is an open-label, randomized, two-arm, multicenter Phase 2 study which will involve up to 74 patients. Patients will be randomized in a 1:1 ratio into one of the two treatment arms: [Arm A] AEZS-108 (267 mg/m<sup>2</sup> every 21 days) or [Arm B] SSC standard single agent cytotoxic chemotherapy at the discretion of the treating oncologist.

The primary study endpoint is median time of progression-free survival. Secondary endpoints include overall response rate, and overall survival. The study will also evaluate AEZS-108's toxicity profile and patients' quality of life relative to conventional cytotoxic chemotherapy.

#### 1.1.3 AEZS-108 - Bladder Cancer

On May 12, 2010, we announced that the FDA had approved our IND application for AEZS-108 in LHRH receptor-positive urothelial (bladder) cancer. Following this approval from the FDA, this trial will be conducted by Dr. Gustavo Fernandez at the Sylvester Comprehensive Cancer Center at the University of Miami's Miller School of Medicine, and will include up to 64 patients, male and female, with advanced LHRH receptor-positive urothelial (bladder) cancer. The study will be conducted in two parts: first, a dose-finding part in up to twelve patients; subsequently, the selected dose will be studied for its effect on PFS.

On December 14, 2010, we announced the initiation of the Phase 1/2 trial.

On July 26, 2012, we announced that preclinical data on AEZS-108 in urinary bladder cancer were published in the online edition of Oncotarget. The article underlined that AEZS-108 powerfully inhibited growth of bladder cancers in nude mice, exerted greater effects than doxorubicin ("DOX") and was less toxic. In contrast to DOX alone, which activated strong multidrug resistance mechanisms in RT-4 and HT-1197 cancers, AEZS-108 had no or fewer such effects. Polymerase Chain

Reaction ("PCR") assays and *in vitro* studies revealed differences in the action of AEZS-108 and DOX on the expression of genes involved in apoptosis.

#### 1.1.4 AEZS-108 - Prostate Cancer

On August 5, 2010, we announced that the The National Institutes of Health ("NIH") had awarded Dr. Jacek Pinski, Associate Professor of Medicine at the Norris Comprehensive Cancer Center of the University of Southern California, a grant of \$1.6 million over three years to conduct a Phase 1/2 study in refractory prostate cancer with AEZS-108. The study, entitled *A Phase I/II Trial of AN-152 [AEZS-108] in Castration- and Taxane-Resistant Prostate Cancer*, will enroll up to 55 patients and will be conducted in two portions: an abbreviated dose-escalation followed by a single arm, Simon Optimum two-stage design Phase 2 study using the dose selected in the Phase 1 portion. The primary objective of the Phase 2 portion is to evaluate the clinical benefit of AEZS-108 in men with castration- and taxane-resistant metastatic prostate cancer, for which the presence of LHRH receptors has been confirmed.

On December 14, 2010, we announced the initiation of the investigator initiated Phase 1/2 trial.

On September 26, 2011, we announced positive interim data for the Phase 1 portion of the Phase 1/2 trial with AEZS-108 in castration-and taxane-resistant prostate cancer at the ESMO meeting, Stockholm, Sweden. This is a single arm study with a Phase 1 lead-in to a Phase 2 clinical trial. The primary endpoint of the Phase 1 portion is safety. The primary objective of the Phase 2 portion is to evaluate the clinical benefit of AEZS-108 for these patients. Twelve patients entered the study: three patients each received AEZS-108 at the lower dose levels of 160 and 210 mg/m<sup>2</sup>, and six patients at 267 mg/m<sup>2</sup>. Data on ten patients were presented as two patients were too early for evaluation. AEZS-108 was generally well tolerated and there were no dose limiting toxicities so far. The only Grade 3 and 4 toxicities were hematologic in nature. At the time, there were three Grade 4 toxicities (two at 210 mg/m<sup>2</sup> and one at 267 mg/m<sup>2</sup>) all of which were asymptomatic. There were six Grade 3 toxicities including two cases of Grade 3 anemia after repeated courses (cycles five and six) and one case of febrile neutropenia that occurred during cycle one. Signs of therapeutic activity included five patients with Prostate Specific Antigen ("PSA") regression. One of these patients treated at the lowest dose level, received eight treatment cycles because he demonstrated continued clinical benefit. Three out of four evaluable patients with radiologic evaluable disease achieved stable disease per RECIST. The Phase 2 extension is planned after completion of the toxicity assessment in the final dose level of the Phase 1 portion of the study. In correlative studies, drug uptake was demonstrated for the first time in captured circulating tumor cells of patients, thus validating the principle of targeted tumor therapy with AEZS-108 in a clinical setting.

On February 3, 2012, we reported updated results for the Phase 1 portion of the ongoing Phase 1/2 study of AEZS-108 in prostate cancer.

The results were based on 13 patients who had been previously treated with androgen-deprivation therapy (LHRH agonist) and at least one taxane-based chemotherapy regimen, who were treated on three dose levels of AEZS-108: three at 160 mg/m<sup>2</sup>, three at 210 mg/m<sup>2</sup>, and seven at 267 mg/m<sup>2</sup>. Overall, AEZS-108 was well tolerated among this group of heavily pretreated older patients. There were two dose-limiting toxicities, each of which having been a case of asymptomatic Grade 4 neutropenia at the 267 mg/m<sup>2</sup> dose level and both patients fully recovered. The Grade 3 and 4 toxicities were primarily hematologic. There was minimal non-hematologic toxicity, most frequently fatigue and alopecia.

Despite the low doses of AEZS-108 in the first cohorts, there was some evidence of antitumor activity. One patient received eight cycles (at 210 mg/m<sup>2</sup>) due to continued benefit. Among the five evaluable patients with measurable disease, four achieved stable disease. At the time of submission of the abstract, a decrease in PSA was noted in six patients. Six of 13 (46%) treated patients received at least five cycles of therapy with no evidence of disease progression at twelve weeks. Correlative studies on circulating tumor cells ("CTC") demonstrated the uptake of AEZS-108 into the targeted tumor.

On November 12, 2012, we announced the initiation of the Phase 2 portion of the ongoing Phase 1/2 study of AEZS-108 in prostate cancer. The primary endpoint of the Phase 2 portion is to evaluate the clinical benefit of AEZS-108 for these patients. Secondary endpoints include toxicity, time to RECIST and PSA progression, RECIST response rate for patients with measurable disease, PSA response rate, pain palliation and overall survival.

#### 1.1.5 AEZS-108 - Companion Diagnostic Tool

On January 5, 2012, we announced that we had entered into a collaboration agreement, dated December 19, 2011, with Ventana, to develop a companion diagnostic for the immunohistochemical determination of LHRH receptor expression, for AEZS-108. According to the literature, in humans, LHRH receptors are expressed in a significant proportion of endometrial, ovarian, breast, bladder, prostate and pancreatic tumors. AEZS-108 specifically targets LHRH receptors and could therefore prove to be more efficient in treating patients with these types of LHRH receptor-positive cancers.

### 1.1.6 AEZS-137 (Disorazol Z) / AEZS-125 (LHRH-Disorazol Z)

In search of new antitumor agents, we found that disorazol Z (AEZS-137), isolated from the myxobacterium *Sorangium cellulosum*, possess cytotoxicity in the picomolar range in a panel of different tumor cell lines. Inhibition of tubulin polymerization, cell cycle arrest and efficient induction of apoptosis, have been identified as modes of action.

In order to obtain a specifically acting antitumor agent, we have linked disorazol Z to [D-Lys<sup>6</sup>] LHRH. The resulting conjugate, AEZS-125, has been characterized with respect to *in vitro* and *in vivo* antitumor activity. In CD 1 nu/nu mice xenografted with the LHRH receptor-positive, human ovarian carcinoma cell line OVCAR-3, we have shown tumor suppression by single administration of AEZS-125 in doses as low as 45 nmol/kg (0.1 mg/kg). Proof of concept for this approach is the far more efficient tumor suppression obtained with AEZS-125 in comparison to equimolar doses of disorazol Z itself. The results were published during the 99<sup>th</sup> AACR Annual Meeting in April 2008 in San Diego, California.

On March 24, 2011, we were awarded a \$1.5 million grant from the German Ministry of Education and Research to develop, up to the clinical stage, cytotoxic conjugates of the proprietary cytotoxic compound AEZS-137 and peptides targeting G-protein coupled receptors, including the LHRH receptors. The compounds being developed will combine the targeting principle successfully employed in Phase 2 with AEZS-108 (doxorubicin and LHRH receptor targeting agent) with the novel cytotoxic disorazol Z. Furthermore, diagnostic tools systematically assessing the receptor expression in tumor specimens will be developed to allow the future selection of patients and tumor types with the highest chance of benefiting from this personalized medicine approach. The grant will be payable as a partial reimbursement of qualifying expenditures over a three-year period. The qualified project will be performed with Morphisto GmbH and the Helmholtz Institute in Saarbrücken, Germany, which will receive additional funding of approximately US\$0.7 million. Researchers from the departments of Gynecology and Obstetrics at both the University of Göttingen and the University of Würzburg, Germany, will also be part of the collaboration.

On November 16, 2011, we announced the presentation of a poster at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on encouraging preclinical data for AEZS-137. The data showed that AEZS-137 possesses cytotoxicity in a highly diverse panel of 60 different tumor cell lines, and also underlined the identification of important aspects of this novel natural compound's mechanism of action. AEZS-137 has been identified as a tubulin binding agent with highly potent antitumor properties. Cell cycle analysis revealed that AEZS-137 arrested cells in the G2/M cell cycle phase and subsequently induced apoptosis with remarkable potency, as shown by sub-nanomolar EC50 values. Currently, experiments are under way to determine the tubulin binding site for disorazol Z and to identify further mechanisms of action of this novel highly potent agent. To expand our AEZS-108 technology platform, we aim to evaluate the utility of disorazol Z as a cytotoxic component in a drug-targeting approach utilizing GPCR ligands as the targeting moieties for the treatment of GPCR over-expressing cancers.

On November 8, 2012, we announced encouraging preclinical results for disorazol Z cytotoxic conjugates, such as AEZS-125 in ovarian cancer. All conjugates of D-Lys<sup>6</sup>-LHRH and disorazol Z analyzed demonstrated good potential regarding the treatment of LHRH-receptor positive tumors. For all conjugates including AEZS-125, a proof of concept was demonstrated in an LHRH-receptor positive ovarian cancer xenograft model. The data were presented at the 24<sup>th</sup> EORTC-NCI-AACR (ENA) Symposium. The study was funded through a grant from the German Ministry of Education and Research.

## 1.2 TUBULIN INHIBITORS / VASCULAR TARGETING AGENTS

### 1.2.1 AEZS-112 - Development of a Low Molecular Weight Tubulin Inhibitor with Antiangiogenic Properties

Tubulin is a protein found in all cells that plays an important role during cell division, in that it helps to transmit genetic information to the daughter cells. Inhibition of this process leads to the death of the affected cell. The antitumor agents taxol and vincristine, which are widely used in cancer therapy, are based on this principle. Both compounds are expensive natural substances and cause severe side effects when used in humans.

We are currently identifying and developing novel tubulin inhibitors which, compared with currently used products, exhibit improved efficacy in animal models, have a more acceptable side effect profile, an incomplete or no cross-resistance and are administered orally.

AEZS-112 is a drug development candidate with a favorable safety and tolerability profile showing excellent *in vivo* activity in various tumor models including mammary, colon, melanoma and leukemia cancers at acceptable and very well tolerated doses administered orally once weekly. This compound acts through three mechanisms of action. Strong anticancer activity is combined with proapoptotic and antiangiogenic properties. AEZS-112 inhibits the polymerization of tubulin, destroys the mitotic spindle of the cancer cells and, inhibits topoisomerase II activity. AEZS-112 arrests the cancer cells in the G2M cell cycle phase at a nanomolar concentration and induces apoptosis. AEZS-112 is not cross-resistant to cisplatin, vincristine and doxorubicin in cell lines resistant to these drugs. No findings with respect to cardiotoxicity and neurotoxicology parameters

could be observed during the toxicological evaluation in mice, rats and dogs. With this profile of activity, AEZS-112 is a promising candidate for further clinical development.

On January 8, 2007, we announced the initiation of a Phase 1 trial for AEZS-112 in patients with solid tumors and lymphoma. This open-label, dose-escalation, multicenter, intermittent treatment Phase 1 trial was conducted in the United States with Daniel D. Von Hoff, M.D., Senior Investigator at the Translational Genomics Research Institute in Phoenix, AZ, as the lead investigator. The trial included up to 50 patients with advanced solid tumors and lymphoma who have either failed standard therapy or for whom no standard therapy exists. Patients received a once-a-week oral administration of AEZS-112 for three consecutive weeks, followed by a one-week period without treatment. The cycles were repeated every four weeks based on tolerability and response, basically planned for up to four cycles, but allowing for continuation in case of potential benefit for the patient. The starting dose of AEZS-112 in this study was 13 mg/week, with doubling of doses in subsequent cohorts in the absence of significant toxicity. The primary endpoint of the Phase 1 trial focused on determining the safety and tolerability of AEZS-112 as well as establishing the recommended Phase 2 dose and regimen. Secondary endpoints were aimed at establishing the pharmacokinetics and determining the efficacy based on standard response criteria.

Results of this Phase 1 study were presented in April 2009 at the AACR meeting. In part I, 22 patients (twelve men / ten women) were studied on seven dose levels ranging from 13 to 800 mg/week. In all, 62 treatment cycles were administered. In part II, the weekly dose was split into three doses taken eight hours apart. Ultimately, 22 patients (twelve men / ten women) were studied on five dose levels ranging from 120 to 600 (= 200 x 3) mg/week. As at April 1, 2009, 62 treatment cycles had been administered (mean 3.2/patient) and treatment had been ongoing in eight patients. SD for more than twelve weeks was observed in 16 patients; four more patients were ongoing at less than twelve weeks. Prolonged courses of SD ranging from 20 to 35+ weeks were observed in nine patients with the following primary cancer types: trachea (39+), tongue (30+), thyroid (29+), prostate and melanoma (28), non-small cell lung cancer (26+), pancreas and 2x colorectal (20). Except for one patient with a background of gastrointestinal problems ("GI") who had dose-limiting GI reactions and electrolyte loss at a dose of 200 x 3 mg/week, no clinically relevant drug-related adverse events or changes in laboratory parameters were observed. AEZS-112 was shown to be metabolically stable in human plasma. As predicted by pharmacokinetic modelling based on data from part I of the study, the split-dose scheme led to a higher Cmax and trough values after administration of comparable doses. Those preliminary results showed that a maximum tolerated dose for weekly dosing has not been defined so far. However, prolonged courses of stable disease in both parts of the study were an encouraging observation.

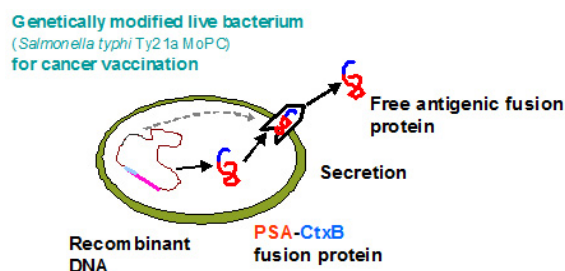
Completion of this Phase 1 trial was announced on September 21, 2009. Stable disease with time to failure ranging from 20 to 60+ weeks was achieved in twelve patients with various cancer types, including melanoma and cancers of the colon/rectum, lung, pancreas, prostate, tongue, trachea and thyroid. In several of these patients, the duration of stabilization exceeded the duration of disease control on previous treatment regimens. Except for a dose-limiting gastrointestinal reaction in a patient with pre-existing GI problems, no clinically relevant drug-related adverse events or changes in laboratory safety parameters were observed.

In 2011, we developed a higher concentration oral formulation of AEZS-112 in order to improve patient compliance.

### 1.3 IMMUNOTHERAPY / VACCINES

#### 1.3.1 AEZS-120

AEZS-120 is a tumor vaccine. The general principle of active tumor vaccines is the induction of a cellular and/or humoral immune response which is capable of attacking the tumor. AEZS-120 is a live recombinant oral tumor vaccine candidate based on *Salmonella typhi* Ty21a as a carrier strain. *Salmonella typhi* Ty21a is an approved oral typhoid vaccine which has been safely applied in more than 350 million doses. The molecular basis of AEZS-120 is the recombinant expression of the fusion protein between cholera toxin B (CtxB) and prostate specific antigen (PSA), and the recombinant expression of two components of the hemolysin secretion system (HlyB and HlyD) as well as the signal component HlyA which allow the secretion of the fusion protein by the attenuated approved carrier strain *S. typhi* Ty21a.





The relevant features with respect to activity as a tumor vaccine can be divided into two parts: A) adjuvant elements for optimal induction of innate and adaptive immunity; and B) the tumor antigen itself.

In the case of AEZS-120, the tumor antigen is PSA which is expressed in the majority of prostate cancer cases and is employed as a tumor antigen in several prostate cancer vaccines in development. Therefore, PSA can be considered as a valid antigen for prostate cancer vaccines.

The adjuvant activity is provided by three elements: the live bacterial carrier itself, the fusion to CtxB and the secretion of the antigen.

An important property of AEZS-120 is the oral application mode, which is based on the carrier *S. typhi* Ty21a. This strain is approved as a vaccine against typhoid fever and has preserved some features of virulent *S. typhi* strains which are relevant for the use of *S. typhi* Ty21a as a vaccine carrier. Virulent *S. typhi* is a pathogen which leads to systemic infection after oral uptake. Several virulence factors allow the survival within the gastro-intestinal tract and the crossing of the intestinal barrier. These features are, at least in part, also intact in the attenuated live vaccine *S. typhi* Ty21a allowing oral application with retained immunogenicity.

However, in particular, the cellular immune response against recombinantly expressed antigens, which is important for anti-tumor immunity, has been described as being suboptimal if the antigen is expressed within the carrier cell.

A substantial enhancement can be achieved via secretion of the recombinant antigen. In gram negative bacteria, like *Salmonellae*, protein secretion requires the activity of protein secretion machineries. Several types of secretion systems with different levels of complexity have been described. The principle of AEZS-120 is based on the recombinant expression of prostate-specific antigen fused to the B subunit of cholera toxin and a secretion signal in the presence of the *Escherichia coli* type I hemolysin secretion system. The proprietary system allows the secretion of the antigen together with an immunological adjuvant which has been demonstrated to be required for optimal induction of CD8 T-cell responses by recombinant Salmonella based bacterial vaccines. The proof-of-concept was already demonstrated for the mouse homologue of AEZS-120 in a mouse tumor challenge model and is supported by several patent applications filed in 2007 and 2009.

In 2007, the Company's PSA vaccine (AEZS-120) was selected as the first preclinical development candidate of an antitumor vaccine.

On July 20, 2011, we reached a key milestone in this non-clinical development program of AEZS-120, which 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. AEZS-120 has been developed through a research collaboration with the Department of Medical Radiation Biology and Cell Research, and the Department of Microbiology of the University of Würzburg, Germany. The collaboration was funded with a total of \$890,000 for us and \$870,000 for the university partner by the German Ministry of Education and Research (BMBF) for a period of three years. In accordance with this grant, 50% of our preclinical development costs and 100% of those of our university partner were reimbursed by the German Ministry of Science and Education. In addition, as part of the collaboration, a melanoma vaccine based on the recombinant expression of a modified B-Raf protein has been generated.

On October 2, 2012, we announced the presentation of a poster on AEZS-120 during the 32<sup>nd</sup> Congress of the *Société Internationale d'Urologie* in Fukuoka, Japan. The poster, entitled "Preclinical Proof of Concept and Characterization of AEZS-120, a Therapeutic Oral Prostate Cancer Vaccine Candidate Based on Live Recombinant Attenuated Salmonella", underlined the feasibility of an oral therapeutic vaccination approach against prostate cancer. The production, release, pharmacology, safety and toxicology program was conducted in agreement with the regulatory authorities and successfully finalized. The conclusions were:

- The proof-of-concept has been shown in a tumor-challenge mouse model using the anticipated clinical application schedule.
- Biosafety and biodistribution studies did not reveal a different safety profile compared to the carrier strain.
- Pharmacological and toxicological studies did not reveal differences to the approved carrier strain.
- In all, the non-clinical studies suggest that the safety and toxicological profile of AEZS-120 is similar to the approved carrier strain *S. typhi* Ty21a, which has already been safely applied in more than 250 million doses.

GMP material for clinical use has been produced and released, and a Clinical Trial Application ("CTA") filing in Europe for a Phase 1 clinical study is planned in 2013.

## 1.4 SIGNAL TRANSDUCTION INHIBITORS

### 1.4.1 Erk/PI3K inhibitors and dual kinase inhibitors

The Ras/Raf/Mek/Erk and the PI3K/Akt signaling pathways are prime targets for drug discovery in proliferative diseases such as cancer. The results of research to date indicate that both the MAPK and the PI3K signaling pathways represent therapeutic intervention points for the clinical treatment of malignant tumors.

Our multi-parameter optimization program for kinase inhibitor selectivity, cellular efficacy, physicochemical and *in vitro* ADMET properties has led to the identification of small molecular compounds with a unique kinase selectivity profile. Our kinase research program comprises the investigation of different compounds for single Erk inhibition, single PI3K inhibition and dual Erk/PI3K kinase inhibition.

#### 1.4.1.1 AEZS-126/129

On April 21, 2009, we presented two posters on AEZS-126, a promising compound for clinical intervention of the PI3K/Akt pathway in human tumors, at the AACR Annual Meeting. *In vivo* and *in vitro* data showed significant antitumor activity and a favorable *in vitro* pharmacologic profile which could lead to further *in vivo* profiling.

On November 17, 2010, we presented a poster on encouraging preclinical results for AEZS-129, a novel orally active compound with antitumor effects, at the 22<sup>nd</sup> EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Berlin, Germany. AEZS-129 has been identified as a highly potent and selective pan-PI3K inhibitor. The compound inhibits the PI3K/Akt signaling pathway both *in vitro* and *in vivo* and leads to growth inhibition of tumor cells. The compound was well tolerated during the four-week treatment period and showed substantial tumor growth inhibition in different mouse xenograft tumor models.

On March 22, 2011, we presented preclinical results for AEZS-129 at the Informa Life Sciences Protein Kinases Congress in Berlin, Germany. AEZS-129 was identified as a potent inhibitor of class I PI3Ks lacking activity against mTOR. Lack of mTOR activity is considered to potentially lead to a better safety profile. In biochemical and cellular assays, AEZS-129 demonstrated favorable properties in early *in vitro* ADMET screening, including microsomal stability, plasma stability and screening against a safety profile composed of receptors, enzymes and cardiac ion-channels. *In vitro*, the compound was shown to be a selective ATP-competitive inhibitor of PI3K with a broad antiproliferative activity against a broad panel of tumor cell lines. *In vivo*, AEZS-129 showed excellent plasma exposure and significant tumor growth inhibition in several tumor xenografts models, including A-549 (lung), HCT-116 (colon) and Hec1B (endometrium). These data suggest that AEZS-129 is a promising compound for clinical intervention of the PI3K/Akt pathway in human tumors.

#### 1.4.1.2 AEZS-136

On April 3, 2012, we announced that a poster on AEZS-136 showed the compound's unique inhibition and promising activity against PI3K and Erk signaling pathways, as well as being well tolerated. The poster, entitled "Dual inhibition of PI3K and Erk1/2 shows synergy and efficacy in human tumor cells, either by using drug combinations or novel dual PI3K/Erk inhibitors", was presented at the AACR Annual Meeting in Chicago.

The conclusions were as follows:

- Effective dual targeting of Raf-Mek-Erk and PI3K-Akt pathway
- Unique inhibitor with excellent activity against PI3K and Erk
- Induction of cell cycle arrest in G1 phase and apoptosis
- Broad anti-proliferative activity *in vitro*
- Favorable *in vitro* ADMET and *in vivo* PK profile
- Well tolerated up to daily doses of 90mg/kg for 4 weeks
- *In vivo* antitumor efficacy after oral administration

On August 13, 2012, we announced the presentation of a poster on AEZS-136 during the 244<sup>th</sup> National Meeting of the American Chemistry Society in Philadelphia. The data outlined the compound's unique inhibition and excellent preclinical activity against PI3K and Erk signaling pathways, as well as being well tolerated. AEZS-136 is an integral part of our kinase research program comprising the investigation of different compounds for single Erk inhibition, single PI3K inhibition and dual Erk/PI3K kinase inhibition. AEZS-136 selectively inhibits the kinase activity of Erk 1/2 and class 1 PI3Ks, enabling simultaneous inhibition of the Raf-Mek-Erk and the PI3K-Akt signaling cascades. AEZS-136 was discovered using our proprietary compound library and high throughput screening technology.

## 1.4.2 Perifosine

On April 2, 2012, we announced top-line Phase 3 results for perifosine in refractory colorectal cancer ("CRC"). The Phase 3 "X-PECT" (Xeloda® + Perifosine Evaluation in Colorectal Cancer Treatment) clinical trial evaluating perifosine + capecitabine in patients with refractory advanced CRC did not meet the primary endpoint of improving overall survival vs. capecitabine + placebo. The trial involving 468 patients in 65 sites in the U.S was conducted by our North American licensee partner, Keryx.

On March 11, 2013, we announced that an independent Data Safety Monitoring Board ("DSMB") recommended discontinuing the Phase 3 study comparing the efficacy and safety of perifosine to placebo when combined with bortezomib (Velcade®) and dexamethasone in patients with relapsed or relapsed/refractory multiple myeloma. Based on the outcome of its pre-planned interim analysis of efficacy and safety, the DSMB recommended that patient enrolment be stopped and the study discontinued. The DSMB reported that it was highly unlikely the study would achieve a significant difference in its primary endpoint, progression-free survival; no safety concerns were raised. Based on the foregoing, we determined to discontinue the Phase 3 study of perifosine in multiple myeloma.

Perifosine remains partnered with Yakult in Japan, Handok in Korea and Hikma in the MENA region for various cancer indications.

In addition, perifosine remains the object of certain investigator-initiated studies in different indications such as neuroblastoma, glioma, pediatric solid tumors and other indications.

## 2.0 ENDOCRINOLOGY

### 2.1 AEZS-130 - ORAL GHRELIN AGONIST

AEZS-130, a ghrelin agonist, is a novel orally active small molecule that stimulates the secretion of growth hormone by binding to the ghrelin receptor (GHSR-1a). It has potential uses in both endocrinology and in oncology indications. In endocrinology, we have completed a Phase 3 trial for its use as an oral diagnostic test for AGHD. AEZS-130 works by stimulating a patient's growth hormone secretion, which normally only occurs during sleep, after which a healthcare provider will measure how well the body responds to that stimulation based on the patient's growth hormone levels over a period of time. Low growth hormone levels, despite giving an effective stimulating agent, confirm a diagnosis of AGHD. AEZS-130 has been granted orphan-drug designation by the FDA for use as a diagnostic test for growth hormone deficiency. We own the worldwide rights to AEZS-130 which, if approved, would become the first orally administered diagnostic test for AGHD. In oncology, an IND has been granted for a Phase 2A trial with AEZS-130 in cancer induced cachexia, a disease which leads to significant weight loss and diminished functional performance. Since ghrelin agonists such as AEZS-130 have been shown to stimulate food intake and increase body weight in rats and mice, AEZS-130 could lead to better quality of life for patients with cancer induced cachexia. Ghrelin agonists have been in clinical trials for over a decade and have demonstrated good safety and efficacy profiles.

#### 2.1.1 AEZS-130 - Diagnostic test for AGHD

On October 19, 2009, we announced that we had initiated activities intended to complete the clinical development of AEZS-130 which could be the first oral diagnostic test approved for growth hormone deficiency ("GHD"). We had already assumed the sponsorship of the IND and discussed with the FDA the best way to complete the ongoing Phase 3 clinical trial and subsequently file a NDA for approval of AEZS-130 as a diagnostic test for AGHD.

The pivotal Phase 3 trial was designed to investigate the safety and efficacy of the oral administration of AEZS-130 as a growth hormone stimulation diagnostic test. It was accepted by the FDA that for the ongoing part of the study, AEZS-130 would not be tested against a comparator drug, as Geref® had been removed from the market.

On June 21, 2010, we presented positive data at the 92<sup>nd</sup> ENDO Meeting on AEZS-130 for diagnostic and therapeutic use. The preclinical data showed that AEZS-130 is a potent and safe oral synthetic GH-releasing compound with potential utility as a diagnostic test for growth hormone deficiencies.

On July 14, 2010, we announced the presentation of a poster on AEZS-130, entitled *Use of the Orally Active Ghrelin Mimetic AEZS-130 as a Simple Test for the Diagnosis of Growth Hormone (GH) Deficiency (GHD) in adults (AGHD)*. Merriam G.R., Yuen K., Bonert V., Dobs A, Garcia J., Kipnes M., Molitch M., Swerdloff R., Wang C., Cook D., Altemose I. and Biller B. This poster was presented at the Seventh International Congress of Neuroendocrinology, in Rouen, France.

On October 5, 2010, we announced at the Fifth International Congress of the Growth Hormone Research Society and the Insulin-like Growth Factors Society, after the interim Phase 3 analysis, that AEZS-130 demonstrated the potential to provide a simple, well tolerated and safe oral diagnostic test for AGHD.

On December 20, 2010, we announced we had reached agreement with the FDA on a SPA for AEZS-130, enabling the Company to complete the ongoing registration study required to gain approval as a diagnostic test for AGHD.

### Study Design

The Phase 3 study was completed according to the modifications agreed with the FDA.

### Original Study

The first part of the study conducted by our former partner, Ardana, was a two-way cross-over study and included 42 patients with confirmed AGHD or multiple pituitary hormone deficiencies and a low insulin-like growth factor-I. A control group of 10 subjects without AGHD were matched to patients for age, gender, body mass index and (for females) estrogen status.

On July 26, 2011, we announced the completion of the Phase 3 study of AEZS-130 as a first oral diagnostic test for AGHD and the decision to meet with the FDA for the future filing of a NDA for the registration of AEZS-130 in the United States.

On August 30, 2011, we announced favorable top-line results of our completed Phase 3 study with AEZS-130 as a first oral diagnostic test for AGHD. The results showed that AEZS-130 had reached its primary endpoint demonstrating >90% area-under-the-curve ("AUC") of the Receiver Operating Characteristic ("ROC") curve, which determines the level of specificity and sensitivity of the product. Importantly, the primary efficacy parameters show that the study achieved both specificity and sensitivity at a level of 90% or greater. In addition, eight of the ten newly enrolled AGHD patients were correctly classified by a pre-specified peak GH threshold level. The use of AEZS-130 was shown to be safe and well tolerated overall throughout the completion of this trial.

On June 26, 2012, we announced that the final results from a multicenter, open-label Phase 3 trial for AEZS-130 showed that the drug is safe and effective in diagnosing AGHD. Jose M. Garcia, MD, PhD, of the Baylor College of Medicine and the Michael E. DeBakey VA Medical Center, disclosed these data during an oral presentation at the 94<sup>th</sup> ENDO Annual Meeting and Expo in Houston. The study had originally been designed as a cross-over trial of AEZS-130 vs. growth hormone-releasing hormone (GHRH) + L-Arginine (ARG) in AGHD patients and in controls matched for body mass index ("BMI"), estrogen status, gender and age. After 43 AGHD patients and ten controls had been tested, GHRH became unavailable. The study was completed by testing ten more AGHD patients and 38 controls with AEZS-130 alone. Of the 53 AGHD subjects enrolled, 52 received AEZS-130, and 50 who had confirmed AGHD prior to study entry were included in this analysis, along with 48 controls. Two AGHD subjects could not be matched due to the combination of young age, high BMI and estrogen use. The objective of this clinical trial was to determine the efficacy and safety of AEZS-130 in the diagnosis of AGHD. Mean peak growth hormone ("GH") levels in AGHD patients and controls following AEZS-130 administration were 2.36ng/mL (range 0.03-33) and 17.71ng/mL (range 10.5-94), respectively. The ROC plot analysis yielded an optimal GH cut-point of 2.7ng/mL, with 82% sensitivity, 92% specificity and a 13% misclassification rate. Obesity (BMI>30) was present in 58% of cases and controls, and peak GH levels were inversely associated with BMI in controls. Adverse events ("AE") were seen in 37% of AGHD patients and in 21% of controls following AEZS-130. In contrast, 61% of AGHD subjects and 30% of controls experienced AEs with L ARG+GHRH. The most common AEs after AEZS-130 were unpleasant taste (19.2%) and diarrhea (3.8%) for the AGHD patients and unpleasant taste (4.2%) and diarrhea (4.2%) for the matched controls. No clinically meaningful changes from baseline in ECG results during the study for AGHD patients; however, one control subject had an ECG change (T wave abnormality and QTc interval prolongation) one hour after treatment with AEZS-130 that was considered a serious treatment-related adverse event and resolved spontaneously within 24 hours. The subject had been pre-treated with citalopram, a drug that was later reported by the FDA to be associated with QT prolongation, although the patient had stopped this medication seven days prior to dosing. Overall, this study demonstrated that AEZS-130 is safe and effective in diagnosing growth hormone deficiency in adults.

On August 7, 2012, the United States Patent and Trademark Office granted us a patent for the use of AEZS-130 (EP1572) as a diagnostic test for AGHD. Filed on February 19, 2007, the patent (US 8,192,719 B2), entitled "Methods and Kits to Diagnose Growth Hormone Deficiency by Oral Administration of EP1572 or EP1573 Compounds", became effective as of June 5, 2012 and will expire on October 12, 2027. The corresponding composition of matter patent (US 6,861,409 B2), filed on June 13, 2001 and granted on March 1, 2005, will expire on August 1, 2022, with the possibility of a patent term extension of up to five years.

On September 25, 2012, the European Patent Office granted us a patent for the use of AEZS-130 related to methods and kits for use in relation to the diagnosis of GHD in a human or animal subject. Filed on February 19, 2007, the patent, (EP #1 984 744 B1) entitled "Methods and Kits to Diagnose Growth Hormone Deficiency", was effective as of September 19, 2012 following its publication in the European Patent Bulletin, and it will expire on February 19, 2027.

On September 26, 2012, we received notification from the FDA that Fast Track designation previously filed had not been granted for AEZS-130 as a diagnostic test for AGHD.

On October 18, 2012, we announced that results from a multicenter open-label Phase 3 trial for AEZS-130 demonstrated that the drug is safe and effective in diagnosing AGHD. George R. Merriam, MD, Director of the Clinical Study Unit at the Veterans Affairs Puget Sound Health Care System, and Professor of Medicine at the University of Washington, Seattle and Tacoma, WA, disclosed these data at the 6<sup>th</sup> International Congress of the GRS and IGF Society in Munich, Germany. His presentation confirmed data previously presented by Jose M. Garcia, MD, Ph.D., of the Baylor College of Medicine and the Michael E. DeBakey Veterans Affairs Medical Center, at the 94<sup>th</sup> ENDO Meeting in Houston, Texas in June 2012. Dr. Merriam's presentation drew attention to the effect of BMI on optimizing the cut-off values to improve the sensitivity and specificity of the test. Responses in normal subjects classified as obese, with BMI's above 30, were significantly lower than in leaner subjects. Since GH deficiency can lead to increased body fat, many of the patients also met criteria for obesity, and therefore, a lower peak GH cut-off is more accurate in separating obese normals from obese patients. Based upon these study results, a cut-off of 2.7 µg/L was optimal for subjects with a BMI≥30 and a cut-off of 6.8 µg/L for subjects with a BMI<30. Age had a weaker effect on test performance and gender made no difference. Thus GH stimulation with oral AEZS-130 may provide a simple, rapid, safe, and well-tolerated diagnostic test for AGHD, with accuracy comparable to that of the GHRH-ARG test.

#### *Competitors for AEZS-130 as a Diagnostic Test*

Competitors for AEZS-130 as a diagnostic test for AGHD are principally the diagnostic tests currently performed by endocrinologists, although none of these tests are approved by the FDA for this purpose.

The most commonly used diagnostics tests for GHD are:

- Measurement of blood levels of Insulin Growth Factor ("IGF")-1, which is typically used as the first test when GHD is suspected. However, this test is not used to definitively rule out GHD as many growth hormone deficient patients show normal IGF-1 levels;
- Insulin Tolerance Test ("ITT"), which is considered to be the "gold standard" for GH secretion provocative tests but requires constant patient monitoring while the test is administered and is contra-indicated in patients with seizure disorders, with cardiovascular disease and in brain injured patients and elderly patients. ITT is administered i.v.;
- GHRH + Arginine test, which is an easier test to perform in an office setting and has a good safety profile but is considered to be costly to administer compared to ITT and Glucagon. This test is contra-indicated in patients with renal failure. GHRH + Arginine is approved in the EU and has been proposed to be the best alternative to ITT, but it is no longer available in the United States. This test is administered i.v.; and
- Glucagon test, which is simple to perform and is considered relatively safe by endocrinologists but is contraindicated in malnourished patients and patients who have not eaten for more than 48 hours. Since there is a suspicion that this test may cause hypoglycemia, it may not be appropriate in diabetic populations. This test is administered i.m.

Oral administration of AEZS-130 offers more convenience and simplicity over the current GHD tests used, requiring either i.v. or i.m. administration. Additionally, AEZS-130 may demonstrate a more favorable safety profile than existing diagnostic tests, some of which may be inappropriate for certain patient populations e.g. diabetes mellitus or renal failure, and have demonstrated a variety of side effects which AEZS-130 has not thus far. These factors may be limiting the use of GHD testing and may enable AEZS-130 to become the diagnostic test of choice for GHD.

#### *Market Data - AGHD*

According to the Hormone Foundation, in the United States, about 35,000 adults have GHD, with about 6,000 newly diagnosed each year (source: Hormone Foundation Website). In addition, in patients with traumatic brain injury ("TBI"), a GHD is frequent and may contribute to the cognitive sequel and to a reduction in quality of life. According to the CDC (Center for Disease Control and Prevention – MMWR – Surveillance for traumatic brain injury – related deaths USA, May 6, 2011), of the 1.7 million TBIs occurring each year in the USA, 80.7% were emergency department visits, 16.3% were hospitalizations and 3% were deaths. GHD develops in approximately 18% of patients with complicated mild, moderate or severe TBI (source: Kelly *et al.* Journal of Neurotrauma, 2006).

## 2.1.2 AEZS-130 - Cancer Cachexia

On November 28, 2011, we announced that the FDA had granted Jose M. Garcia, M.D., Ph.D., Assistant Professor, Division of Diabetes Endocrinology and Metabolism, Departments of Medicine and Molecular and Cell Biology, Baylor College of Medicine and Michael E. DeBakey Veterans Affairs Medical Center, in Houston Texas, an IND approval for the initiation of a Phase 2A trial to assess the safety and efficacy of repeated doses of AEZS-130, in patients with cancer cachexia. Cachexia, which is characterized by diminished appetite and food intake in cancer patients, is defined as an involuntary weight loss of at least 5% of the pre-illness body weight over the previous 6 months.

On March 8, 2012, we announced that the Michael E. DeBakey Veterans Affairs Medical Center, in Houston, Texas, had initiated the Phase 2A trial assessing the safety and efficacy of repeated doses of AEZS-130 in patients with cancer cachexia. The study is conducted under a CRADA with the Michael E. DeBakey Veterans Affairs Medical Center, which is funding the study. This is a double-blind, randomized, placebo-controlled Phase 2A trial to test the effects of different doses of AEZS-130 in 18 to 26 patients with cancer cachexia. The study will involve three sequential groups receiving differing doses of AEZS-130. Each dose group will have six patients who will receive AEZS-130 and 2-4 patients who will receive a placebo. The primary objective of the study is to evaluate the safety and efficacy of repeated oral administration of AEZS-130 at different doses daily for one week in view of developing a treatment for cachexia.

On August 28, 2012, we announced that a first patient had been recruited for a Phase 2A trial in cancer-induced cachexia with AEZS-130.

## 2.2 LHRH ANTAGONISTS

### 2.2.1 Cetrorelix

Cetrorelix is a peptide-based active substance which was developed in cooperation with Nobel Laureate Professor Andrew Schally presently of the United States Veterans Administration-Miami, University of Miami, and formerly of Tulane University in New Orleans. This compound is a LHRH (also known as GnRH) antagonist that blocks the pituitary LHRH receptors resulting in a rapid decrease of sexual hormone levels. Moreover, cetrorelix allows the LHRH receptors on the pituitary gland to be blocked gradually. Conversely, the side effects usually associated with the use of agonists and resulting from total hormone withdrawal can be avoided in conditions that do not require a castrating degree of hormone withdrawal. Therefore, in contrast to treatment with agonists, LHRH antagonists permit dose-dependent hormone suppression which is of critical importance for the tolerability of hormonal therapy.

#### 2.2.1.1 Cetrorelix *In Vitro* Fertilization (Controlled Ovulation Stimulation/Assisted Reproductive Technologies ("COS/ART"))

##### *Cetrotide*<sup>®</sup>

Cetrorelix was the first LHRH antagonist approved for therapeutic use as part of fertilization programs in Europe and was launched on the market under the trade name *Cetrotide*<sup>®</sup> (cetrorelix acetate) in 1999. In women who undergo controlled ovarian stimulation for recovery of oocytes for subsequent fertilization, *Cetrotide*<sup>®</sup> helps prevent premature ovulation. LHRH is a naturally occurring hormone produced by the brain to control the secretion of LH and, therefore, final egg maturation and ovulation. *Cetrotide*<sup>®</sup> is designed to prevent LH production by the pituitary gland and to delay the hormonal event, known as the "LH surge" which could cause eggs to be released too early in the cycle, thereby reducing the opportunity to retrieve the eggs for the assisted reproductive techniques procedure.

In comparison with LHRH agonists that require a much longer pre-treatment, the use of *Cetrotide*<sup>®</sup>, permits the physician to interfere in the hormone regulation of the women undergoing treatment much more selectively and within a shorter time.

*Cetrotide*<sup>®</sup> is the only LHRH antagonist that is available in two dosing regimens. With an immediate onset of action, *Cetrotide*<sup>®</sup> permits precise control - a single dose (3 mg), which controls the LH surge for up to four days, or a daily dose (0.25 mg) given over a short period of time (usually five to seven days).

*Cetrotide*<sup>®</sup> is marketed in a 3 mg and a 0.25 mg subcutaneous injection as cetrorelix acetate by Merck Serono in the United States and Europe. In September 2006, we announced the launch of *Cetrotide*<sup>®</sup> in Japan for *in vitro* fertilization. *Cetrotide*<sup>®</sup> is marketed in Japan by our partner Shionogi. We receive revenue from the supply of *Cetrotide*<sup>®</sup> to our Japanese partners. The market competitor is ganirelix (Antagon<sup>™</sup>/Orgalutran<sup>®</sup>) from Merck indicated for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation.

In August 2000, we entered into a commercialization agreement with Merck Serono for Cetrotide®. Under the terms of this agreement, we granted an exclusive license to Merck Serono to commercialize Cetrotide® for IVF/COS/ART worldwide ex-Japan and we are entitled to receive fixed and sales royalties from Merck Serono. The Japanese rights for this indication are held by Shionogi whereby, according to a commercialization agreement, we received transfer pricing from Shionogi.

In November 2008, we sold our rights to royalties on future sales of Cetrotide® covered by our license agreement with Merck Serono for \$52.5 million to HRP less transaction costs of \$1.0 million, resulting in initial net proceeds to us of \$51.5 million. In addition, upon net sales of Cetrotide® having reached a specified level in 2010, we received an additional payment of \$2.5 million from HRP in February 2011. Furthermore, under the terms of the agreement, we agreed to make a one-time cash payment to HRP in an amount ranging from \$5 million up to a maximum of \$15 million in the event cetrotide is approved for sale by the European regulatory authorities in an indication other than *in vitro* fertilization. The amount which would be due to HRP will be higher the earlier the product receives European regulatory approval. Since cetrotide development has been terminated, we do not expect to make this one-time cash payment to HRP.

Cetrotide clinical development has been terminated in all indications other than *in vitro* fertilization (COS/ART). Furthermore, we focus on our manufacturing on behalf of Merck Serono and Shionogi.

### 2.2.2 Ozarelix

Ozarelix is a modified LHRH antagonist which is a linear decapeptide sequence. Ozarelix is a fourth-generation LHRH antagonist designed to extend the suppression of testosterone levels, which does not require a sophisticated depot formulation for long-lasting activity.

On August 12, 2004, we entered into a licensing and collaboration agreement with Spectrum for ozarelix and its potential to treat hormone-dependent cancers as well as benign proliferative disorders, such as BPH and endometriosis for all potential indications in North America (including Canada and Mexico) and India while keeping the rights for the rest of the world. In addition, Spectrum is entitled to receive 50% of upfront and milestone payments and royalties received from our Japanese partner, Nippon Kayaku, that are generated in the Japanese market for oncological indications. In November 2010, this agreement with Spectrum was amended. Under the terms of the amended agreement, Spectrum is entitled to use our patent rights and know-how to develop, use, make, have made, sell, offer for sale, have sold, import, export and commercialize ozarelix in all worldwide territories except Japan, Korea, Indonesia, Malaysia, the Philippines and Singapore. Under the terms of the amended agreement, Spectrum granted, as further consideration, 326,956 shares of its common stock, with an equivalent fair value at the time of approximately \$1,263,000, as an upfront nonrefundable license fee payment to us. Also per the amended agreement, we will be entitled to receive a total of approximately \$22,765,000 in cash payments, as well as approximately \$670,000 in Spectrum common stock, upon achieving certain regulatory milestones in various markets. Furthermore, we will be entitled to receive royalties (scale-up royalties from high single to low double-digit) on future net sales of ozarelix products in the named territories.

In July 2006, we entered into a licensing and collaboration agreement with Nippon Kayaku for ozarelix (oncological indication) in Japan.

During the third quarter of 2008, we entered into a commercialization agreement with Handok for ozarelix (BPH indication) for the Korean market.

#### 2.2.2.1 Prostate Cancer Clinical Trials

In August 2006, we announced positive Phase 2 results for ozarelix in hormone-dependent inoperable prostate cancer. This open-label, randomized-controlled dose-finding trial enrolled 64 patients receiving different IM dosage regimens of ozarelix to assess its safety and efficacy. The study achieved its primary endpoint of defining a tolerable dosage regimen of ozarelix that would ensure continuous suppression of testosterone at castration level for a three-month test period. A secondary efficacy endpoint aimed at assessing tumor response as determined by a 50% or greater reduction of serum PSA level, compared to baseline, was also achieved. The best results regarding the primary endpoint of continuous suppression were obtained with a dose of 130 mg per cycle where all patients remained suppressed to castration until at least day 85. In patients with continuous testosterone suppression below castration level, tumor response as measured by PSA levels was 97%.

On August 3, 2006, we announced a licensing and collaboration agreement with Nippon Kayaku for ozarelix. Under the terms of the agreement, we granted Nippon Kayaku an exclusive license to develop and market ozarelix for all potential oncological indications in Japan. In return, we received an upfront payment upon signature and are eligible to receive payments upon

achievement of certain development and regulatory milestones, in addition to low double-digit royalties on potential net sales. Spectrum is entitled to receive 50% of the upfront, milestone payments and royalties received from Nippon Kayaku.

Our partner, Spectrum, is currently recruiting patients in Phase 2 trial for the treatment of prostate cancer. This is an international, multicenter, open-label, randomized study assessing the safety and efficacy of a monthly dosing regimen of oza-relix versus goserelin depot in men with prostate cancer (source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)).

## **RAW MATERIALS**

Raw materials and supplies are generally available in quantities adequate to meet the needs of our business. We are dependent on third-party manufacturers for the pharmaceutical products that we market. An interruption in the availability of certain raw materials or ingredients, or significant increases in the prices paid by us for them, could have a material adverse effect on our business, financial condition, liquidity and operating results.

## **DISTRIBUTION**

We currently have a lean sales and marketing staff. In order to commercialize our product candidates successfully, we would need to make arrangements with third parties to perform some or all of these services in certain territories.

We contract with third parties for the sales and marketing of our products. We are currently dependent on strategic partners and may enter into future collaborations for the research, development and commercialization of our product candidates. Our arrangements with these strategic partners may not provide us with the benefits we expect and may expose us to a number of risks.

## **REGULATORY COMPLIANCE**

Governmental authorities in Canada, the United States, Europe and other countries extensively regulate the preclinical and clinical testing, manufacturing, labeling, storage, record keeping, advertising, promotion, export, marketing and distribution, among other things, of our product candidates. Under the laws of the United States, the countries of the European Union, and other countries, we and the institutions at which we sponsor research are subject to obligations to ensure that our clinical trials are conducted in accordance with GCP guidelines and the investigational plan and protocols contained in an IND application, or comparable foreign regulatory submission. The Japanese regulatory process for approval of new drugs is similar to the FDA approval process described below except that Japanese regulatory authorities request bridging studies to verify that foreign clinical data are applicable to Japanese patients and also require the tests to determine appropriate dosages for Japanese patients to be conducted on Japanese patient volunteers. Due to these requirements, delays of two to three years in introducing a drug developed outside of Japan to the Japanese market are possible. Set forth below is a brief summary of the material government regulations affecting the Company in the major markets in which we intend to market our products.

### **Canada**

In Canada, the Canadian Therapeutic Products Directorate is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the *Food and Drugs Act* and other legislation and regulations. The requirements for the development and sale of pharmaceutical drugs in Canada are substantially similar to those in the United States, which are described below.

### **United States**

In the United States, the FDA under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations, subject pharmaceutical products to rigorous review.

In order to obtain approval of a new product from the FDA, we must, among other requirements, submit proof of safety and efficacy as well as detailed information on the manufacture and composition of the product. In most cases, this proof entails extensive preclinical, clinical, and laboratory tests. Before approving a new drug or marketing application, the FDA also typically conducts pre-approval inspections of the company, its contract research organizations and/or its clinical trial sites to ensure that clinical, safety, quality control, and other regulated activities are compliant with Good Clinical Practices, or GCP, or Good Laboratory Practices, or GLP, for specific non-clinical toxicology studies. Manufacturing facilities used to produce a product are also subject to ongoing inspection by the FDA. The FDA may also require confirmatory trials, post-marketing testing, and extra surveillance to monitor the effects of approved products, or place conditions on any approvals that could restrict the commercial applications of these products. Once approved, the labeling, advertising, promotion, marketing, and distribution of a drug or biologic product must be in compliance with FDA regulatory requirements.



The first stage required for ultimate FDA approval of a new biologic or drug involves completion of preclinical studies and the submission of the results of these studies to the FDA. This, together with proposed clinical protocols, manufacturing information, analytical data, and other information in an IND, must become effective before human clinical trials may commence. Preclinical studies involve laboratory evaluation of product characteristics and animal studies to assess the efficacy and safety of the product. The FDA regulates preclinical studies under a series of regulations called the current GLP regulations. If the sponsor violates these regulations, the FDA may require that the sponsor replicate those studies.

After the IND becomes effective, a sponsor may commence human clinical trials. The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap. In Phase 1 trials, the sponsor tests the product in a small number of patients or healthy volunteers, primarily for safety at one or more doses. Phase 1 trials in cancer are often conducted with patients who have end-stage or metastatic cancer. In Phase 2, in addition to safety, the sponsor evaluates the efficacy of the product in a patient population somewhat larger than Phase 1 trials. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at geographically dispersed test sites. The sponsor must submit to the FDA a clinical plan, or "protocol", accompanied by the approval of the institutions participating in the trials, prior to commencement of each clinical trial. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time. In the case of product candidates for cancer, the initial human testing may be done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease, such studies may provide results traditionally obtained in Phase 2 studies. Accordingly, these studies are often referred to as "Phase 1/2" studies. Even if patients participate in initial human testing and a Phase 1/2 study is carried out, the sponsor is still responsible for obtaining all the data usually obtained in both Phase 1 and Phase 2 studies.

The sponsor must submit to the FDA the results of the preclinical and clinical testing, together with, among other things, detailed information on the manufacture and composition of the product, in the form of a NDA or, in the case of a biologic, a BLA. In a process that can take a year or more, the FDA reviews this application and, when and if it decides that adequate data are available to show that the new compound is both safe and effective for a particular indication and that other applicable requirements have been met, approves the drug or biologic for marketing. The amount of time taken for this approval process is a function of a number of variables, including the quality of the submission and studies presented and the potential contribution that the compound will make in improving the treatment of the disease in question.

Orphan-drug designation is granted by the FDA Office of Orphan Drug Products to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity if the drug is the first of its type approved for the specified indication or if it demonstrates superior safety, efficacy or a major contribution to patient care versus another drug of its type previously granted the designation for the same indication. We have been granted orphan drug designations for perifosine in the MM and neuroblastoma indications, for AEZS-108 for the treatment of advanced ovarian cancer and for AEZS-130 for the diagnosis of growth hormone deficiency.

Under the Hatch-Waxman Act, newly-approved drugs and indications may benefit from a statutory period of non-patent data exclusivity. The Hatch-Waxman Act provides five-year data exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active pharmaceutical ingredient, or active moiety. Although protection under the Hatch-Waxman Act will not prevent the submission or approval of another full NDA, such an NDA applicant would be required to conduct its own preclinical and adequate, well controlled clinical trials to demonstrate safety and effectiveness.

The Hatch-Waxman Act also provides three years of data exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) applications, for, among other things, new indications, dosage forms, routes of administration, or strengths of an existing drug, or for a new use, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application. This exclusivity, which is sometimes referred to as clinical investigation exclusivity, would not prevent the approval of another application if the applicant has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of a generic product that did not incorporate the exclusivity-protected changes of the approved drug product.

The labeling, advertising, promotion, marketing, and distribution of a drug or biologic product must be in compliance with FDA regulatory requirements. Failure to comply with applicable requirements can lead to the FDA demanding that production and shipment cease and, in some cases, that the manufacturer recall products, or to enforcement actions that can include seizures, injunctions, and criminal prosecution. These failures can also lead to FDA withdrawal of approval to market a product.

## European Union

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

### *Centralized procedure*

The European Union has implemented a centralized procedure coordinated by the EMA for the approval of human medicines, which results in a single marketing authorization issued by the European Commission that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

### *National authorization procedures*

There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:

**Decentralized procedure.** Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.

The application will be reviewed by a selected Reference Member State ("RMS"). The Marketing Authorization granted by the RMS will then be recognized by the other Member States involved in this procedure.

**Mutual recognition procedure.** In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

For more information about the regulatory risks associated with the Company's business operations, see "Item 3. – Key Information – Risk Factors".

## DRUG DISCOVERY

There is an increasing demand on the world market for active substances. Our internal drug discovery unit provides an important prerequisite for the provision of new patented active substances, which can then be developed further or licensed to third parties.

Our drug discovery unit concentrates on the search for active substances for innovative targets, which open the door to the introduction of new therapeutic approaches. Further, this unit searches for new active substances having improved properties for clinically validated targets for which drugs are already being used in humans and which produce inadequate effects, cause severe side effects, are not economical or are not available in a patient-friendly form.

To this end, we possess an original substance library for the discovery of active compounds with a comprehensive range of promising natural substances which can serve as models for the construction of synthetic molecules. The initial tests involve 120,000 samples from our internal substance library in the form of high-throughput screening. The "hits", which are the first active compounds found in the library, are tested further and built up specifically into potential lead structures. Based on two to three lead structures, they are then optimized in a further step to potential development candidates.

## INTELLECTUAL PROPERTY - PATENTS

We believe that we have a solid intellectual property portfolio that covers compounds, manufacturing processes, compositions and methods of medical use for our lead drugs and drug candidates. Our patent portfolio consists of approximately 50 owned and in-licensed patent families (issued, granted or pending in the United States, Europe and other jurisdictions). Independent of the original patent expiry date, additional exclusivity is possible in the United States, Europe and several other countries by data protection for new chemical entities, by orphan drug designation, or by patent term extension respective supplementary protection certificate.

In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent, in which the patentee may file an application for yearly interim extensions within five years if the patent will expire and the FDA has not yet approved the NDA. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended.

Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In these jurisdictions however no interim extensions exist and the marketing approval must be granted before the patent expires. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. While we anticipate that any such applications for patent term extensions will likely be granted, we cannot predict the precise length of the time for which such patent terms would be extended in the United States, Europe or other jurisdictions. If we are not able to secure patent term extensions on patents covering our products for meaningful periods of additional time, we may not achieve or sustain profitability, which would adversely affect our business.

Of the issued or granted patents, the protective rights described below form the core of our patent portfolio with regard to our lead drugs and drug candidates.

#### **AEZS-108:**

- U.S. patent 5,843,903 provides protection in the United States for the compound AEZS-108 and other related targeted cytotoxic anthracycline analogs, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of cancer. This U.S. patent expires in November 2015. A patent term extension of up to five years may be possible.
- European patent 0 863 917 B1 provides protection in Europe for the compound AEZS-108 and other related targeted cytotoxic anthracycline analogs, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This European patent expires in November 2016. A patent term extension of up to five years may be possible in case approval has been achieved prior to patent expiration.
- Japanese patent 3 987 575 provides protection in Japan for the compound AEZS-108 and other related targeted cytotoxic anthracycline analogs, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This Japanese patent expires in November 2016. A patent term extension of up to five years may be possible in case approval has been achieved prior to patent expiration.

#### **AEZS-120:**

- European patent 2 092 067 B1 provides protection in Europe for microorganisms as carriers of heterogeneous nucleotide sequences coding for antigens and protein toxins, a process of manufacturing thereof as well as corresponding plasmids or expression vectors, useful as medicaments, in particular as tumor vaccines for the treatment of various tumors. This European patent expires in November 2027. A patent term extension of up to five years may be possible.
- U.S. and Japanese patent applications have been filed for AEZS-120 in November 2007. Patent applications are still pending. Granted patents will expire in November 2027.

#### **AEZS-130:**

- U.S. patent 6,861,409 protects the compound AEZS-130 and U.S. patent 7,297,681 protects other related growth hormone secretagogue compounds, each also protecting pharmaceutical compositions comprising the compounds as well as their medical use for elevating the plasma level of growth hormone. This U.S. patent 6,861,409 expires in August 2022. A patent term extension of up to five years may be possible.
- European patent 1 289 951 protects the compound AEZS-130 and European patent 1 344 773 protects other related growth hormone secretagogue compounds, pharmaceutical compositions comprising the compounds as well as their medical use for elevating the plasma level of growth hormone. This European patent 1 289 951 expires in June 2021. A patent term extension of up to five years by SPC may be possible.
- Japanese patent 3 522 265 protects the compound AEZS-130 and pharmaceutical compositions comprising the compounds as well as their medical use for elevating the plasma level of growth hormone. This Japanese patent expires in June 2021. A patent term extension of up to five years may be possible.

- U.S. patent 8,192,719 protects a method of assessing pituitary-related growth hormone deficiency in a human or animal subject comprising an oral administration of the compound AEZS-130 and determination of the level of growth hormone in the sample and assessing whether the level of growth hormone in the sample is indicative of growth hormone deficiency. This U.S. patent 8,192,719 expires in October 2027.
- European patent 1 984 744 protects a method of assessing pituitary-related growth hormone deficiency by oral administration of AEZS-130. The European patent 1 984 744 expires in February 2027.
- Japanese patent 4 852 728 protects a method of assessing pituitary-related growth hormone deficiency by oral administration of AEZS-130. The Japanese patent 4 852 728 expires in February 2027.

#### **Cetrotide®:**

- European patent 0 299 402 provides protection in European countries for the compound cetrorelix and other LHRH antagonists. This patent will expire in July 2013 pursuant to granted requests for SPC.
- U.S. patent 5,198,533 provided protection in U.S.A. for the compound cetrorelix per se. This patent expired in extended status in October 2010.
- Japanese patent 2 944 669 provides protection in Japan for the compound cetrorelix and other LHRH antagonists. This patent will expire in July 2013 pursuant to granted requests for patent term extension.
- U.S. patent 6,828,415 protects a method for preparing sterile lyophilizate formulations of cetrorelix. It specifically protects the lyophilization process used to manufacture Cetrotide®. This U.S. patent will expire in December 2021.
- European patent 0 611 572 protects a method for preparing sterile lyophilizate formulations of cetrorelix. It specifically protects the lyophilization process used to manufacture Cetrotide®. This patent will expire in February 2014.
- Japanese patent 4 033 919 protects a method for preparing sterile lyophilizate formulations of cetrorelix. It specifically protects the lyophilization process used to manufacture Cetrotide®. This patent will expire in February 2014.
- U.S. patent 7,790,686 protects an aqueous injectable solution of the compound cetrorelix or other LHRH antagonists in an organic, pharmaceutically acceptable acid. This patent will expire in October 2023.
- European patent 1 448 221 protects an aqueous injectable solution of the compound cetrorelix or other LHRH antagonists in an organic, pharmaceutically acceptable acid. This patent will expire in November 2022.

#### **Ozarelix:**

- U.S. patent 6,627,609 provides protection in the United States for the compound ozarelix and related third-generation LHRH antagonists and pharmaceutical compositions comprising them. This U.S. patent will expire in March 2020. A patent term extension of up to five years may be possible.
- European patent 1 163 264 provides protection in Europe for the compound ozarelix and related third-generation LHRH antagonists and pharmaceutical compositions comprising them. This European patent will expire in March 2020. A SPC of up to five years may be possible.
- Japanese patent 3 801 867 provides protection in Japan for the compound ozarelix and related third-generation LHRH antagonists and pharmaceutical compositions comprising them. This Japanese patent will expire in March 2020. A patent term extension of up to five years may be possible.

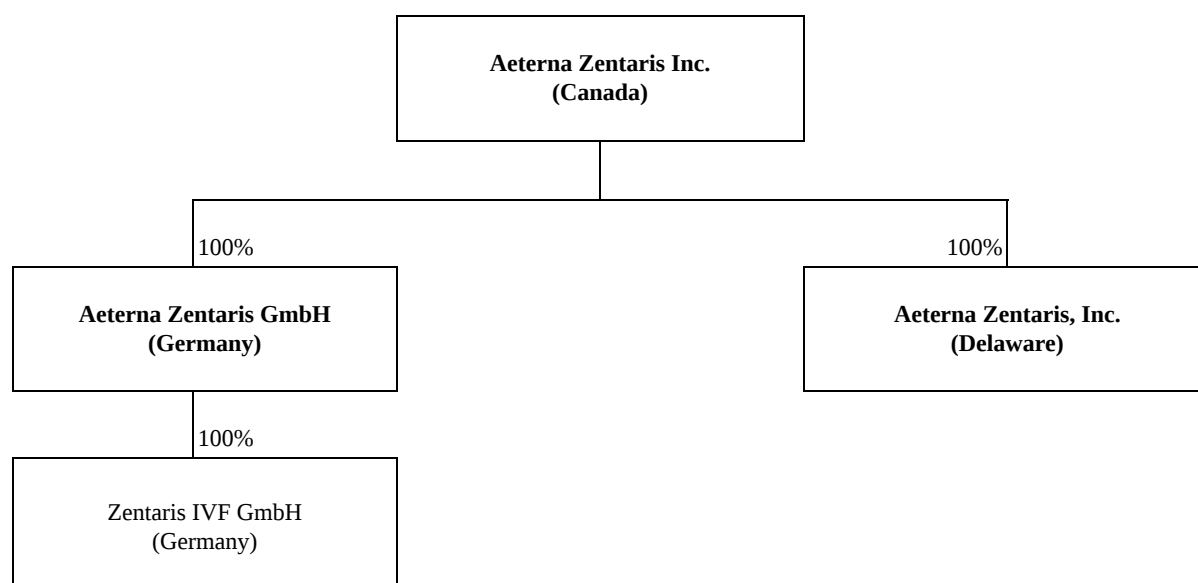
The table below lists some of our issued or granted patents in the United States, Europe and Japan:

<b>Patent No.</b>	<b>Title</b>	<b>Country</b>	<b>Expiry Date</b>
<b><u>AEZS-108</u></b>			
U.S. 5,843,903	Targeted cytotoxic anthracycline analogs	United States	2015-11-27
EP 0 863 917	Targeted cytotoxic anthracycline analogs	Europe	2016-11-14
JP 3 987 575	Targeted cytotoxic anthracycline analogs	Japan	2016-11-14
<b><u>AEZS-120</u></b>			
EP 2 092 067	Microorganisms as carriers of nucleotide sequences	Europe	2027-11-13
<b><u>AEZS-130</u></b>			
U.S. 6,861,409	Growth hormone secretagogues	United States	2022-08-01
EP 1 289 951	Growth hormone secretagogues	Germany, United Kingdom, France, Switzerland and others	2021-06-13
JP 3 522 265	Growth hormone secretagogues	Japan	2021-06-13
U.S. 8,192,719	Method and kit to diagnose growth hormone deficiency	United States	2027-10-12
EP 1 984 744	Method and kit to diagnose growth hormone deficiency	Europe	2027-02-19
JP 4 852 728	Method and kit to diagnose growth hormone deficiency	Japan	2027-02-19
<b><u>Cetrotide®</u></b>			
EP 0 299 402	LHRH antagonists	Germany, United Kingdom, France, Switzerland and others	2013-07-10*
EP 0 611 572	Process to prepare a cetrorelix lyophilised composition	Germany, United Kingdom, France, Switzerland and others	2014-02-04
U.S. 6,828,415	Oligopeptide lyophilisate, their preparation and use	United States	2021-12-07
U.S. 6,716,817	Method of treatment of female infertility	United States	2014-02-22
U.S. 6,863,891	Oligopeptide lyophilisate, their preparation and use	United States	2014-02-22
U.S. 6,867,191	Preparation and use of oligopeptide lyophilisate for gonad protection	United States	2014-02-22
U.S. 7,605,121	Oligopeptide lyophilisate, their preparation and use	United States	2014-02-22
U.S. 7,790,686	Injection solution of an LHRH antagonist	United States	2023-10-28
<b><u>AEZS-112</u></b>			
U.S. 7,365,081	Indole derivatives and their use as medicaments	United States	2017-09-08
EP 1 309 585	Indole derivatives and their use as medicaments	Germany, United Kingdom, France, Switzerland and others	2021-07-26
<b><u>Ozarelix</u></b>			
U.S. 6,627,609	LHRH antagonists having improved solubility properties	United States	2020-03-14
EP 1 163 264	LHRH antagonists having improved solubility properties	Germany, United Kingdom, France, Switzerland and others	2020-03-11
JP 3 801 867	LHRH antagonists having improved solubility properties	Japan	2020-03-11

\* Includes Patent Term Extension.

**C. Organizational structure**

The following chart presents our corporate structure, the jurisdiction of incorporation of our direct and indirect subsidiaries and the percentage of shares that we held in those subsidiaries as at December 31, 2012.



**D. Property, plants and equipment**

Our corporate head office and facilities are located in Quebec City, Province of Quebec, Canada. The following table sets forth information with respect to our main facilities as at March 21, 2013.

Location	Use of space	Square Footage	Type of interest
1405 du Parc Technologique Blvd., Quebec City (Quebec), Canada	Fully occupied for management, R&D and administration	4,400	Leased
25 Mountainview Blvd., Suite 203, Basking Ridge, NJ 07920	Fully occupied for management, R&D and administration	3,188	Leased
Weismüllerstr. 50 D-60314 Frankfurt-am-Main, Germany	Fully occupied for management, R&D, business development and administration	46,465	Leased

**Item 4A Unresolved Staff Comments**

None.

**Item 5. Operating and Financial Review and Prospects**

**Key Developments in 2012**

**AEZS-108 (Doxorubicin Peptide Conjugate)**

- Special Protocol Assessment ("SPA") was granted by the United States Food and Drug Administration ("FDA") for the initiation of a Phase 3 study in advanced recurrent endometrial cancer. This study is an open-label, randomized, and multicenter trial which will be conducted in North America and Europe, comparing AEZS-108 with doxorubicin as second-line therapy for locally-advanced, recurrent or metastatic endometrial cancer. The trial will involve approximately 500 patients and the primary efficacy endpoint is improvement in median overall survival.

- Initiation of the Phase 2 portion of the Phase 1/2 trial in castration- and taxane-resistant prostate cancer ("CRPC"). The National Institutes of Health ("NIH") awarded a three-year \$1.6 million grant to an investigator in order to support this study. Results for the Phase 1 portion demonstrated that AEZS-108 was well tolerated and early evidence of antitumor activity was observed in men with CRPC.

#### ***AEZS-130 (Oral Ghrelin Agonist)***

- Phase 3 trial results for AEZS-130, as a diagnostic test for adult growth hormone deficiency ("AGHD") presented at the 6<sup>th</sup> International Congress of the Growth Hormone Research ("GRS") and Insulin-like Growth Factor ("IGF") Society in Munich, Germany. The data expanded on the previously disclosed data in June 2012 at the 94<sup>th</sup> ENDO Annual Meeting and Expo ("ENDO"). Both sets of data confirm AEZS-130's potential of possibly becoming the first approved oral diagnostic test for AGHD.
- Subsequent to year-end, New Drug Application ("NDA") as a diagnostic test for AGHD remains in preparation.

#### ***Perifosine (Oral AKT Inhibitor)***

- Phase 3 trial results for perifosine + capecitabine ("Xeloda<sup>®</sup>") showed no benefit in overall survival and in progression-free survival in the refractory colorectal cancer ("CRC") setting.
- On March 11, 2013, we announced that an independent DSMB recommended discontinuing the Phase 3 study comparing the efficacy and safety of perifosine to placebo when combined with bortezomib ("Velcade<sup>®</sup>") and dexamethasone in patients with relapsed or relapsed/refractory multiple myeloma. Based on the outcome of its preplanned interim analysis of efficacy and safety, the DSMB recommended that patient enrollment be stopped and the study discontinued. The DSMB reported that it was highly unlikely the study would achieve a significant difference in its primary endpoint, progression-free survival; no safety concerns were raised. Based on the foregoing, we determined to discontinue the Phase 3 study of perifosine in multiple myeloma.

#### ***Corporate Developments***

##### ***At-the-Market Issuance Program***

- During the year 2012, we issued a total of 1.2 million common shares (retroactively adjusted to reflect the Share Consolidation described below) under the January 2012 At-The-Market ("ATM") Program for aggregate gross proceeds of \$8.8 million.

##### ***Share Consolidation and NASDAQ Minimum Bid Price Compliance***

- We consolidated our issued and outstanding common shares on a 6-to-1 basis (the "Share Consolidation"), effective as of October 2, 2012, in order to regain compliance with The NASDAQ Stock Market ("NASDAQ") minimum bid price requirement. Our common shares began trading on a consolidated basis on October 5, 2012 and we regained NASDAQ compliance on October 19, 2012.

##### ***Public Offering***

- On October 17, 2012, we completed a public offering (the "Offering") of 6.6 million units at a purchase price of \$2.50 per unit, generating net proceeds of \$15.1 million.

#### **Introduction**

This Management's Discussion and Analysis ("MD&A") provides a review of the results of operations, financial condition and cash flows of Aeterna Zentaris Inc. for the year ended December 31, 2012. In this MD&A, "Aeterna Zentaris", the "Company", "we", "us", "our" and the "Group" mean Aeterna Zentaris Inc. and its subsidiaries. This discussion should be read in conjunction with the information contained in the Company's consolidated financial statements and related notes as at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010. Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

All amounts in this MD&A are presented in U.S. dollars, except for share, option and warrant data, per share and per warrant data and as otherwise noted.

All shares, options and share purchase warrants as well as per share, option and share purchase warrant information for periods preceding October 2, 2012 have been adjusted, including proportionate adjustments being made to each stock option and share purchase warrant exercise price, to reflect and give effect to the Share Consolidation described above.

### **About Forward-Looking Statements**

This document contains forward-looking statements, which reflect our current expectations regarding future events. Forward-looking statements may include words such as "anticipate", "assuming", "believe", "could", "expect", "foresee", "goal", "guidance", "intend", "may", "objective", "outlook", "plan", "seek", "should", "strive", "target" and "will".

Forward-looking statements involve risks and uncertainties, many of which are discussed in this MD&A. Results or performance may differ significantly from expectations. For example, the results of current clinical trials cannot be foreseen, nor can changes in policy or actions taken by regulatory authorities such as the FDA, the European Medicines Agency ("EMA"), the Therapeutic Products Directorate of Health Canada or any other organization responsible for enforcing regulations in the pharmaceutical industry.

Given these uncertainties and risk factors, readers are cautioned not to place undue reliance on any forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce 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.

### **About Material Information**

This MD&A includes information that we believe to be material to investors after considering all circumstances, including potential market sensitivity. We consider information and disclosures to be material if they result in, or would reasonably be expected to result in, a significant change in the market price or value of our securities, or where it is likely that a reasonable investor would consider the information and disclosures to be important in making an investment decision.

The Company is a reporting issuer under the securities legislation of all of the provinces of Canada, and its securities are registered with the United States Securities and Exchange Commission. The Company is therefore required to file or furnish continuous disclosure information such as interim and annual financial statements, MD&A, proxy circulars, annual reports on Form 20-F, material change reports and press releases with the appropriate securities regulatory authorities. Copies of these documents may be obtained free of charge upon request from the Company's Investor Relations department or on the Internet at the following addresses: [www.aezsinc.com](http://www.aezsinc.com), [www.sedar.com](http://www.sedar.com) and [www.sec.gov](http://www.sec.gov).

### **Company Overview**

Aeterna Zentaris Inc. (NASDAQ: AEZS and TSX: AEZ) is an oncology and endocrinology drug development company currently investigating treatments for various unmet medical needs. Our pipeline encompasses compounds at all stages of development, from drug discovery through to marketed products. We also benefit from agreements and arrangements with strategic collaborators and licensee partners; which contribute to the development of our pipeline of product candidates and in the establishment of commercial activities in specific territories.

Over the years, the Company has incurred recurring operating losses, having invested significantly in our R&D activities, as well as supporting our general and administrative expenses. We have financed our operations through different sources including the issuance of common shares and warrants, the conclusion of strategic alliances with licensee partners and research and development grants awarded by governmental agencies. The Company expects to continue to incur operating losses and may require significant capital to fulfill our future obligations. See the capital disclosures and the liquidity risk sections below.

In oncology, we are in the initiation process of a Phase 3 study under a Special Protocol Assessment ("SPA") with AEZS-108, a doxorubicin Luteinizing Hormone Releasing Hormone ("LHRH")-targeted conjugate compound, in endometrial cancer, for which we have successfully completed a Phase 2 trial in advanced endometrial and advanced ovarian cancer. We are also advancing Phase 2 trials with AEZS-108 in triple-negative breast cancer, refractory bladder cancer and castration- and taxane-resistant prostate cancer.

Our oncology pipeline also encompasses other earlier-stage programs, including AEZS-112, an oral anticancer agent which involves three mechanisms of action (tubulin, topoisomerase II and angiogenesis inhibition), which has completed a Phase 1 trial in advanced solid tumors and lymphoma. Additionally, several novel targeted anticancer candidates such as AEZS-120, a live recombinant oral tumor vaccine candidate, as well as our PI3K/Erk inhibitors, including AEZS-129, AEZS-134 and AEZS-136, are currently in preclinical development.



In endocrinology, we are preparing the filing of an NDA in the United States ("U.S.") for the registration of AEZS-130, an oral ghrelin agonist, as a diagnostic test for AGHD. A Phase 3 trial under an SPA with the FDA has been completed in this indication. Furthermore, AEZS-130 is in a Phase 2A trial for the treatment of cancer-induced cachexia.

## Status of Our Drug Pipeline

Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Commercial
~120,000 compound library	<p><b>AEZS-120</b> Prostate cancer vaccine (oncology)</p> <p><b>AEZS-129, 134 and 136</b> PI3K/Erk inhibitors(oncology)</p> <p><b>AEZS-137</b> (disorazol Z) (oncology)</p> <p><b>AEZS-125</b> (LHRH- disorazol Z) (oncology)</p>	<p><b>AEZS-112</b> (oncology)</p>	<p><b>AEZS-108</b></p> <ul style="list-style-type: none"> <li>• Triple-negative breast cancer</li> <li>• Ovarian cancer</li> <li>• Castration- and taxane-resistant prostate cancer</li> <li>• Refractory bladder cancer</li> </ul> <p><b>Ozarelix</b></p> <ul style="list-style-type: none"> <li>• Prostate cancer</li> </ul> <p><b>AEZS-130</b></p> <ul style="list-style-type: none"> <li>• Therapeutic in cancer cachexia</li> </ul> <p><b>Perifosine</b> (Phase 1/2)</p> <ul style="list-style-type: none"> <li>• Neuroblastoma</li> <li>• Glioma</li> <li>• Pediatric solid tumors</li> </ul>	<p><b>AEZS-108</b></p> <ul style="list-style-type: none"> <li>• Endometrial cancer (not yet recruiting)</li> </ul> <p><b>AEZS-130</b></p> <ul style="list-style-type: none"> <li>• Diagnostic in adult growth hormone deficiency (endocrinology)</li> </ul>	<p><b>Cetrotide®</b> (<i>in vitro</i> fertilization)</p>

## Licensee Partners and Territories by Product

### Cetrotide®:

Merck Serono, World (except Japan) – **Nippon Kayaku/Shionogi**, Japan

### Ozarelix:

**Spectrum Pharmaceuticals**, World (ex-Japan, Korea and other Asian countries) – **Handok Pharmaceuticals**, Korea and other Asian countries for BPH indication – **Nippon Kayaku**, Japan for oncology indications

### Perifosine:

**Yakult Honsha**, Japan – **Handok Pharmaceuticals**, Korea – **Hikma Pharmaceuticals**, Middle East/North Africa

## Consolidated Statements of Comprehensive Loss Information

(in thousands, except share and per share data)	Three-month periods ended December 31,		Years ended December 31,		
	2012	2011	2012	2011	2010
	\$	\$	\$	\$	\$
<b>Revenues</b>					
Sales and royalties	9,165	9,317	31,538	31,306	24,857
License fees and other	380	3,310	2,127	4,747	2,846
	<u>9,545</u>	<u>12,627</u>	<u>33,665</u>	<u>36,053</u>	<u>27,703</u>
<b>Operating expenses</b>					
Cost of sales	7,489	8,114	26,820	27,560	18,700
Research and development costs, net of refundable tax credits and grants	5,523	7,793	20,604	24,517	21,257
Selling, general and administrative expenses	3,469	5,408	13,245	16,170	12,552
	<u>16,481</u>	<u>21,315</u>	<u>60,669</u>	<u>68,247</u>	<u>52,509</u>
<b>Loss from operations</b>	<b>(6,936)</b>	<b>(8,688)</b>	<b>(27,004)</b>	<b>(32,194)</b>	<b>(24,806)</b>
Finance income	689	1,434	6,974	6,231	1,792
Finance costs	(700)	(2)	(382)	—	(5,437)
<b>Net finance (costs) income</b>	<b>(11)</b>	<b>1,432</b>	<b>6,592</b>	<b>6,231</b>	<b>(3,645)</b>
Loss before income taxes	(6,947)	(7,256)	(20,412)	(25,963)	(28,451)
Income tax expense	—	(263)	—	(1,104)	—
<b>Net loss</b>	<b>(6,947)</b>	<b>(7,519)</b>	<b>(20,412)</b>	<b>(27,067)</b>	<b>(28,451)</b>
<b>Other comprehensive loss:</b>					
Items that may be reclassified subsequently to profit or loss					
Foreign currency translation adjustments	(204)	169	(504)	(789)	1,001
Items that will not be reclassified to profit or loss					
Actuarial loss on defined benefit plans	(3,705)	(1,335)	(3,705)	(1,335)	191
<b>Comprehensive loss</b>	<b>(10,856)</b>	<b>(8,685)</b>	<b>(24,621)</b>	<b>(29,191)</b>	<b>(27,259)</b>
<b>Net loss per share</b>					
Basic	(0.29)	(0.44)	(1.03)	(1.72)	(2.26)
Diluted	(0.29)	(0.44)	(1.03)	(1.72)	(2.26)
<b>Weighted average number of shares outstanding</b>					
Basic	24,181,462	17,185,156	19,775,073	15,751,331	12,609,902
Diluted	24,181,462	17,185,156	19,775,073	15,751,331	12,609,902

## 2012 compared to 2011

### Revenues

**Revenues** are derived primarily from sales and royalties as well as from license fees. Sales are derived from Cetrotide® (cetrotirelix acetate solution for injection), marketed for reproductive health assistance for *in vitro* fertilization, as well as from Active Pharmaceutical Ingredients ("API"). Royalties are derived indirectly from ARES Trading S.A.'s ("Merck Serono") net sales of Cetrotide® and represent the periodic amortization, under the units-of-revenue method, of the proceeds received in connection with the 2008 sale to Healthcare Royalty Partners L.P. (formerly Cowen Healthcare Royalty Partners L.P.) ("HRP") of the underlying future royalty stream.

License fees include periodic milestone payments, research and development ("R&D") contract fees and the amortization of upfront payments received from our licensing partners.

Sales and royalties were \$9.2 million and \$31.5 million for the three-month period and the year ended December 31, 2012, respectively, compared to \$9.3 million and \$31.3 million for the same periods in 2011.

License fees and other revenues were \$0.4 million and \$2.1 million for the three-month period and the year ended December 31, 2012, respectively, as compared to \$3.3 million and \$4.7 million for the same periods in 2011. Such decreases in license fees and other revenues are mainly due to the recording of a \$2.6 million milestone payment from Yakult with respect to the initiation of a Phase 1 trial with perifosine in CRC in Japan during the last quarter of the year 2011.

Excluding the impact of foreign exchange rate fluctuations, revenues are expected to remain at similar levels in 2013 as compared to 2012.

### Operating Expenses

**Cost of sales** were \$7.5 million and \$26.8 million for the three-month period and the year ended December 31, 2012, respectively, as compared to \$8.1 million and \$27.6 million for the same periods in 2011.

For the three-month period ended December 31, 2012, cost of sales as a percentage of sales and royalties decreased to approximately 81.7%, as compared to 87.1% in the fourth quarter of 2011. The improved margin is attributable to a comparative increase of Cetrotide® lot sizes delivered that have a lower production cost by unit.

For the year ended December 31, 2012, cost of sales as a percentage of sales and royalties decreased to approximately 85.0%, as compared to 88.0% for the same period in 2011. The improved margin is attributable to an increase of Cetrotide® lot sizes delivered that have a lower production cost by unit, as well as to the higher margin on the API sold during the second quarter of 2012.

**R&D costs, net of refundable tax credits and grants**, were \$5.5 million and \$20.6 million for the three-month period and the year ended December 31, 2012, respectively, compared to \$7.8 million and \$24.5 million for the same periods in 2011.

For each of the three-month period and the year ended December 31, 2012, the decreases are attributable to lower employee compensation and benefit costs, as no annual cash bonuses were recorded during the fourth quarter of 2012, as well as to continued cost-saving measures resulting in a lower number of employees. The decreases are also related to comparative lower third-party costs associated with the development of PI3K/Erk inhibitors and other products during the fourth quarter of 2012 and to lower third-party costs associated with the development of most of our products except for AEZS-108 and perifosine and the weakening of the euro against the U.S. dollar.

The following table summarizes our net R&D costs by nature of expense:

<i>(in thousands)</i>	Three-month periods ended December 31,		Years ended December 31,		
	2012	2011	2012	2011	2010
	\$	\$	\$	\$	\$
Employee compensation and benefits	2,145	3,152	8,590	10,028	9,226
Third-party costs	2,345	3,576	8,679	10,244	8,138
Facilities rent and maintenance	401	459	1,661	1,835	1,773
Other costs*	744	661	2,542	2,793	2,807
R&D tax credits and grants	(112)	(55)	(868)	(383)	(687)
	<u>5,523</u>	<u>7,793</u>	<u>20,604</u>	<u>24,517</u>	<u>21,257</u>

\* Includes depreciation and amortization charges.

The following table summarizes primary third-party R&D costs, by product candidate, incurred by the Company during the three-month periods ended December 31, 2012 and 2011.

<i>(in thousands, except percentages)</i>	Product	Status	Three-month periods ended December 31,			
			2012		2011	
			\$	%	\$	%
Perifosine	Phases 2 and 3	1,434	61.2	1,366	38.2	
AEZS-108	Phase 2 and 3	282	12.0	510	14.3	
AEZS-130	Phase 3	30	1.3	101	2.8	
PI3K/Erk inhibitors	Preclinical	199	8.5	589	16.5	
Other	Preclinical	400	17.0	1,010	28.2	
		<u>2,345</u>	<u>100.0</u>	<u>3,576</u>	<u>100.0</u>	

The following table summarizes primary third-party R&D costs, by product candidate, incurred by the Company during the years ended December 31, 2012, 2011 and 2010.

<i>(in thousands, except percentages)</i>	Product	Status	Years ended December 31,					
			2012		2011		2010	
			\$	%	\$	%	\$	%
Perifosine	Phases 2 and 3	3,801	43.8	3,726	36.4	968	11.9	
AEZS-108	Phase 2 and 3	2,133	24.6	1,652	16.1	2,089	25.7	
AEZS-130	Phase 3	112	1.3	1,156	11.3	865	10.6	
PI3K/Erk inhibitors	Preclinical	1,727	19.9	1,860	18.2	923	11.4	
Other	Preclinical and clinical	906	10.4	1,850	18.0	3,293	40.4	
		<u>8,679</u>	<u>100.0</u>	<u>10,244</u>	<u>100.0</u>	<u>8,138</u>	<u>100.0</u>	

Excluding the impact of foreign exchange rate fluctuations, we expect net R&D costs for 2013 to increase, compared to 2012, due to the advancement of our lead projects listed above. Excluding the impact of unforeseen foreign exchange rate fluctuations, we expect that we will incur net R&D costs of between \$20 million and \$22 million for the year 2013, particularly given our primary focus on developing AEZS-108, AEZS-130, AEZS-120 and certain earlier-stage compounds. We note, however, that our R&D estimates may be revised as we continue to advance our development activities and as new information becomes available.

**Selling, general and administrative ("SG&A") expenses** were \$3.5 million and \$13.2 million for the three-month period and the year ended December 31, 2012, respectively, compared to \$5.4 million and \$16.2 million for the same periods in 2011.

For the three-month period ended December 31, 2012, the comparative decrease in SG&A expenses is mainly related to 2011 events. During the three-month period ended December 31, 2011, we recognized an impairment loss on property, plant and equipment (\$0.3 million), an increase in onerous lease provision (\$0.2 million) and we incurred marketing expenses in Europe (\$0.5 million), as described below. In addition, the quarter-to-quarter decrease is attributable to the employee benefits expense decrease (\$0.4 million) and the related foreign exchange loss decrease (\$0.5 million), partly offset by transaction costs related to share purchase warrants (\$0.4 million).

For the year ended December 31, 2012, the comparative decrease in SG&A expenses is mainly related to 2011 events. During the year ended December 31, 2011, we recognized an impairment loss on our Cetrotide® asset (\$1.1 million), an impairment loss on property, plant and equipment (\$0.3 million), an increase in onerous lease provision (\$0.2 million) and we incurred marketing expenses in Europe (\$0.9 million), as described below. In addition, the year-over-year decrease in SG&A expenses is attributable to the decreases in employee benefit expenses (\$0.8 million) and royalty expenses (\$0.2 million), as well as the weakening of the euro against the U.S. dollar, partly offset by transaction costs related to share purchase warrants (\$0.4 million), share-based compensation costs related to collaborators (\$0.3 million) and an increase in legal fees (\$0.3 million).

We expect SG&A expenses to decrease in 2013, as compared to 2012, assuming lower royalty expenses, lower transaction costs related to share purchase warrants, lower legal and audit fees, as well as lower share-based compensation costs related to collaborators combined with continued costs reduction in human resources.

**Net finance (costs) income** are comprised predominantly of the change in fair value of warrant liability, net gains (losses) due to changes in foreign currency exchange rates and the gain on our short-term investment. For the three-month period and the year ended December 31, 2012, net finance (costs) income totalled \$nil and \$6.6 million, respectively, as compared to \$1.4 million and \$6.2 million for the same periods in 2011, as presented below.

(in thousands)	Three-month periods ended		Years ended December 31,		
	December 31,				
	2012	2011	2012	2011	2010
	\$	\$	\$	\$	\$
<b>Finance income</b>					
Net gains due to changes in foreign currency exchange rates	—	1,118	—	2,197	932
Change in fair value of warrant liability	634	221	6,746	2,533	—
Interest income	55	93	228	223	173
Gain on held-for-trading financial instrument	—	—	—	1,278	687
	<b>689</b>	<b>1,432</b>	<b>6,974</b>	<b>6,231</b>	<b>1,792</b>
<b>Finance costs</b>					
Net losses due to changes in foreign currency exchange rates	(700)	—	(382)	—	—
Change in fair value of warrant liability	—	—	—	—	(5,437)
	<b>(700)</b>	<b>—</b>	<b>(382)</b>	<b>—</b>	<b>(5,437)</b>
	<b>(11)</b>	<b>1,432</b>	<b>6,592</b>	<b>6,231</b>	<b>(3,645)</b>

The significant fluctuation in net finance (costs) income, as compared to the same periods in 2011, is mainly due to the change in fair value of our warrant liability and to (losses) or gains due to changes in foreign currency exchange rates. The change in fair value of our warrant liability results from the periodic "mark-to-market" revaluation, via the application of the Black-Scholes option pricing model, of currently outstanding share purchase warrants. The Black-Scholes "mark-to-market" warrant valuation most notably has been impacted by the market price of our common shares, which, on NASDAQ, has fluctuated from \$10.32 on January 3, 2011 to \$2.38 on December 31, 2012. The (losses) or gains due to changes in foreign currency exchange rates are mainly related to the period-over-period continued weakness of the euro against the U.S. dollars, as presented below.

	Three-month periods ended December 31,		Years ended December 31,		
	2012	2011	2012	2011	2010
Euro to US\$ average conversion rate	1.2975	1.3477	1.2858	1.3919	1.3273

**Income tax expense** was \$nil for the year ended December 31, 2012, as compared to \$1.1 million for the same period in 2011. The year-over-year decrease consists of foreign withholding taxes related to an upfront payment received from a partner and to milestone license fee revenues recorded in 2011.

**Net loss** for the three-month period and the year ended December 31, 2012 was \$6.9 million and \$20.4 million, or \$0.29 and \$1.03 per basic and diluted share, respectively, compared to \$7.5 million and \$27.1 million, or \$0.44 and \$1.72 per basic and diluted share for the same periods in 2011.

The decrease in net loss for the three-month period ended December 31, 2012, as compared to the same period in 2011, is largely due to lower net R&D costs, SG&A expenses and income tax expense, as well as to higher margin contribution from Cetrotide®, partly offset by the significant decrease in license fee revenues, and in net finance income.

The decrease in net loss for the year ended December 31, 2012, as compared to the year ended December 31, 2011, is largely due to lower net R&D costs, SG&A expenses and income tax expense, as well as to higher margin contribution from sales and higher net finance income, partly offset by the significant decrease in license fee revenues.

#### **2011 compared to 2010**

##### **Revenues**

Sales and royalties were \$31.3 million for the year ended December 31, 2011, compared to \$24.9 million for the year ended December 31, 2010. This increase is largely attributable to comparatively higher deliveries of Cetrotide® to Merck Serono.

License fees and other revenues were \$4.7 million for the year ended December 31, 2011, compared to \$2.8 million for the year ended December 31, 2010. This increase is mainly due to the recording in 2011 of a milestone payment from a partner, as described above.

##### **Operating Expenses**

**Cost of sales** was \$27.6 million for the year ended December 31, 2011, compared to \$18.7 million for the year ended December 31, 2010. This increase is largely attributable to the comparative increase in volume of sales of Cetrotide® to Merck Serono, as discussed above. Additionally, cost of sales as a percentage of sales and royalties increased to approximately 88.0% for the year ended December 31, 2011, compared to 75.2% for the year ended December 31, 2010. Our lower comparative margins are largely attributable to a decrease of \$3.4 million of royalties in 2011, as compared to 2010.

**R&D costs, net of refundable tax credits and grants**, were \$24.5 million for the year ended December 31, 2011, compared to \$21.3 million for the year ended December 31, 2010. The comparative increase is mainly attributable to an increase in third-party costs incurred in connection with the advancement of perifosine, AEZS-130 and Erk/PI3K compounds (AEZS-129, AEZS-131, AEZS-132) related activities.

**SG&A expenses** were \$16.2 million for the year ended December 31, 2011, compared to \$12.6 million for the year ended December 31, 2010. SG&A expenses were higher during the year 2011 mainly due to the recognition of impairment losses and due to the initiation of pre-launch and marketing efforts related to the potential commercialization of perifosine in Europe.

During the year 2011, we recognized an impairment loss (\$1.1 million) following impairment testing that was performed on our Cetrotide® asset. The impairment loss was recognized predominantly to take into account management's lower trend estimates related to the commercialization of Cetrotide®, due to changes in the competitive environment in the Japanese market.

In addition, during the year 2011, following the relocation of one of the Company's offices, we recognized an impairment loss on property plant and equipment (leasehold improvements and furniture and fixtures (\$0.3 million)) and an additional onerous lease provision (\$0.2 million).

Furthermore, we initiated our pre-launch and marketing efforts related to the potential marketing by the Company of perifosine in Europe. During the year 2011, we incurred approximately \$0.9 million in connection with the preparation of a launch plan, including market research, pricing expectations and forecast calculations.

**Net finance (costs) income** for the year ended December 31, 2011 totalled \$6.2 million, compared to (\$3.6 million) for the year ended December 31, 2010, as presented above.

The significant increase in net finance income, as compared to the same period in 2010, is mainly due to the change in fair value of our warrant liability. That change results from the periodic "mark-to-market" revaluation, via the application of the Black-Scholes option pricing model, of currently outstanding share purchase warrants. The Black-Scholes "mark-to-market" warrant valuation most notably has been impacted by the market price of our common shares, which, on NASDAQ, has fluctuated from \$4.84 as at January 4, 2010 to \$10.32 as at December 31, 2010, and \$9.24 as at December 30, 2011.

Additionally, our net finance income increased during the year 2011 from the same period in 2010 due to higher foreign exchange gains, which in turn resulted primarily from the overall substantial weakening, during 2011, of the euro against the U.S. dollar, as compared to an overall lower weakening of the euro against the U.S. dollar within the 2010 period. As a result, during the twelve-month period ended December 31, 2011, we recorded foreign exchange gains on transactions and on cash and cash equivalent balances denominated in U.S. dollars.

The increase in our net finance income during the year ended December 31, 2011, as compared to the year ended December 31, 2010, also included gains on our short-term investment, which was sold during the year 2011.

**Income tax expense** was \$1.1 million for the year ended December 31, 2011, as compared to \$nil for the same period in 2010. The year-over-year increase consists of foreign withholding taxes related to an upfront payment received from a partner and milestone license fees revenues recorded in 2011.

**Net loss** for the year ended December 31, 2011 was \$27.1 million, or \$1.72 per basic and diluted share, compared to \$28.5 million, or \$2.26 per basic and diluted share for the year ended December 31, 2010.

The decrease in net loss for the year ended December 31, 2011, as compared to the year ended December 31, 2010, is largely due to the significant increase in license fees revenues, as well as net finance income, partly offset by lower margin contribution from Cetrotide<sup>®</sup>, higher net R&D costs and SG&A expenses, combined with the recording of income tax expense of \$1.1 million in 2011, as discussed above.

## Quarterly Consolidated Results of Operations Information

(in thousands, except for per share data)

	Quarters ended			
	December 31, 2012	September 30, 2012	June 30, 2012	March 31, 2012
	\$	\$	\$	\$
Revenues	9,545	7,139	7,471	9,510
Loss from operations	(6,936)	(5,680)	(7,600)	(6,788)
Net (loss) income	(6,947)	(6,554)	4,540	(11,451)
Net (loss) income per share*				
Basic	(0.29)	(0.35)	0.25	(0.65)
Diluted	(0.29)	(0.35)	0.25	(0.65)

	Quarters ended			
	December 31, 2011	September 30, 2011	June 30, 2011	March 31, 2011
	\$	\$	\$	\$
Revenues	12,627	9,514	6,523	7,389
Loss from operations	(8,688)	(8,244)	(7,971)	(7,291)
Net (loss) income	(7,519)	1,078	(10,569)	(10,057)
Net (loss) income per share*				
Basic	(0.44)	0.07	(0.70)	(0.72)
Diluted	(0.44)	0.06	(0.70)	(0.72)

\* Net (loss) income per share is based on the weighted average number of shares outstanding during each reporting period, which may differ on a quarter-to-quarter basis. As such, the sum of the quarterly net (loss) income per share amounts may not equal year-to-date net (loss) income per share.

First and second quarter revenues of 2012 increased, when compared quarter-over-quarter to each of the corresponding periods in 2011, mainly due to higher deliveries of Cetrotide® to Merck Serono, partly offset by the weakening of the euro against the U.S. dollar.

Third and fourth quarter revenues decreased, when compared quarter-over-quarter to each of the corresponding periods in 2011. The decreases are largely attributable to comparative lower deliveries of Cetrotide® to certain customers in the third quarter, to a decrease in license fee revenues from a partner in the fourth quarter and to the relative weakening of the euro against the U.S. dollar.

In the last eight quarters, net (loss) income has been impacted by revenues, as mentioned above, by the comparative level of net R&D costs in connection with the advancement of perifosine, AEZS-108, AEZS-130 and certain earlier stage compounds. Net R&D costs increased in the first quarter, as compared to the same quarter of 2011 and decreased when compared quarter-over-quarter for each of the other corresponding periods in 2012 vs. 2011. The quarter-over-quarter periods net (loss) income were also impacted by the recognition of impairment losses in the third and fourth quarters of 2011, as well as in the fourth quarter of 2012, by the initiation of prelaunch and marketing efforts related to the potential commercialization of perifosine in Europe in the third and fourth quarters of 2011, by gains on our short-term investment recorded during the first, second and third quarters of 2011, by foreign exchange gains or losses and changes in fair value of our warrant liability, as well as by the income tax expense in the first and fourth quarters of 2011.



## Consolidated Statement of Financial Position Information

(in thousands)	As at December 31,	
	2012	2011
	\$	\$
Cash and cash equivalents	39,521	46,881
Trade and other receivables and other current assets	13,780	13,258
Restricted cash	826	806
Property, plant and equipment	2,147	2,512
Other non-current assets	11,391	11,912
<b>Total assets</b>	<b>67,665</b>	<b>75,369</b>
Payables and other current liabilities	15,675	17,784
Long-term payable (current and non-current portions)	30	88
Warrant liability (current and non-current portions)	6,176	9,204
Non-financial non-current liabilities*	52,479	52,839
<b>Total liabilities</b>	<b>74,360</b>	<b>79,915</b>
<b>Shareholders' deficiency</b>	<b>(6,695)</b>	<b>(4,546)</b>
<b>Total liabilities and shareholders' deficiency</b>	<b>67,665</b>	<b>75,369</b>

\* Comprised mainly of non-current portion of deferred revenues, employee future benefits and provision.

The decrease in cash and cash equivalents as at December 31, 2012, as compared to December 31, 2011, is due to the recurring disbursements and other variations in components of our working capital, partially offset by: the receipt of a milestone payment of \$2.6 million in connection with our development, commercialization and licensing agreement entered into with a partner, the receipt of net proceeds of \$23.6 million pursuant to a public offering and drawdowns made under our January 2012 ATM Program, as discussed above, and the relative strengthening as at December 31, 2012 of the euro against the U.S. dollar, as compared to December 31, 2011.

Payables and other current liabilities decreased from December 31, 2011 to December 31, 2012, mainly due to decreases of approximately \$1.4 million in trade accounts payable, \$1.3 million in accrued salaries and \$0.3 million in income taxes payable, which in turn were partly offset by an increase of approximately \$0.7 million in accrued liabilities in connection with deliveries of Cetrotide® and with the R&D expenses resulting from the advancement of perifosine, AEZS-108, AEZS-130 and Erk/PI3K compounds and by the impact of foreign exchange rate fluctuations.

Our warrant liability decreased from December 31, 2011 to December 31, 2012 predominantly due to the change in fair value pursuant to the periodic "mark-to-market" revaluation of the underlying outstanding share purchase warrants, as discussed above, partly offset by the grant of 2,970,000 share purchase warrants during the fourth quarter of 2012.

Non-financial liabilities were slightly lower as at December 31, 2012, as compared to December 31, 2011, mainly as a result of the recurring amortization of deferred revenues of \$4.6 million and the utilization amount of onerous lease provisions, partially offset by the change of \$4.4 million in the employee benefit obligations. That change predominantly resulted from the 2012 actuarial loss which was mainly related to the change in the discount rate assumption.

The increase in shareholders' deficiency from December 31, 2011 to December 31, 2012 is mainly attributable to the increase in our deficit due to the net loss and the actuarial loss on defined benefit plans for the year 2012. This is partly offset by an increase in share capital representing the proceeds from the issuance of common shares pursuant to the aforementioned public offering and drawdowns made under our January 2012 ATM Program, and the exercise of warrants and stock options, as well as the recording of share-based compensation costs.

### Financial Liabilities, Obligations and Commitments

We have certain contractual leasing obligations and purchase obligation commitments as well as long-term obligations. Purchase obligation commitments mainly include R&D services and manufacturing agreements related to the production of Cetrotide® and other R&D programs. Long-term obligations are related to unfunded benefit pension plans and unfunded post-employment benefit plans. The following tables summarize future cash requirements with respect to these obligations.

Future minimum lease payments and future minimum sublease payments expected to be received under non-cancellable operating leases (subleases), as well as future payments in connection with utility service agreements are as follows:

<i>(in thousands)</i>	<b>As at December 31, 2012</b>		
	<b>Minimum lease payments</b>	<b>Minimum sublease payments</b>	<b>Utilities</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
Less than 1 year	1,669	(226)	610
1 – 3 years	3,215	(451)	861
4 – 5 years	997	(451)	105
More than 5 years	29	(19)	—
<b>Total</b>	<b>5,910</b>	<b>(1,147)</b>	<b>1,576</b>

Service and manufacturing commitments given, which consist of R&D service agreements and manufacturing agreements for Cetrotide<sup>®</sup>, are as follows:

<i>(in thousands)</i>	<b>As at December 31,</b>
	<b>2012</b>
	<b>\$</b>
Less than 1 year	10,123
1 – 3 years	6,693
4 – 5 years	—
More than 5 years	—
<b>Total</b>	<b>16,816</b>

In accordance with the assumptions used in the employee future benefits obligation calculation as at December 31, 2012, future benefits expected to be paid are as follows:

<i>(in thousands)</i>	<b>As at December 31,</b>
	<b>2012</b>
	<b>\$</b>
Less than 1 year	485
1 – 3 years	1,075
4 – 5 years	1,151
More than 5 years	3,254
<b>Total</b>	<b>5,965</b>

### Outstanding Share Data

As at March 21, 2013, we had 25,329,288 common shares issued and outstanding, as well as 2,040,267 stock options outstanding. Warrants outstanding as at March 21, 2013 represented a total of 4,407,410 equivalent common shares. The foregoing outstanding share, option and warrant data reflect and give effect to the Share Consolidation.

### Capital Disclosures

Our objective in managing capital, primarily composed of shareholders' deficiency and cash and cash equivalents, is to ensure sufficient liquidity to fund R&D activities, general and administrative expenses, working capital and capital expenditures.

In the past, we have had access to liquidity through non-dilutive sources, including the sale of non-core assets, investment tax credits and grants, interest income, licensing and related services and royalties. Since 2009, we have raised capital via public equity offerings and drawdowns under various ATM sales programs.

Our capital management objective remains the same as that of previous periods. The policy on dividends is to retain cash to keep funds available to finance the activities required to advance our product development pipeline.

We are not subject to any capital requirements imposed by any regulators or by any other external source.

## Liquidity, Cash Flows and Capital Resources

Our operations and capital expenditures have been financed through cash flows from operating activities, public equity offerings, as well as from the drawdowns under various ATM programs, as discussed above.

Our cash and cash equivalents amounted to \$39.5 million as at December 31, 2012, compared to \$46.9 million as at December 31, 2011. As at December 31, 2012, cash and cash equivalents included €6.0 million, denominated in euro.

Based on our assessment, which took into account current cash levels, as well as our strategic plan and corresponding budgets and forecasts, we believe that we have sufficient liquidity and financial resources to fund planned expenditures and other working capital needs for at least, but not limited to, the 12-month period following the statement of financial position date of December 31, 2012.

We may endeavour to secure additional financing, as required, through strategic alliance arrangements or through other activities, as well as via the issuance of new share capital.

The variations in our liquidity by activity are explained below.

### Operating Activities

#### *2012 compared to 2011*

**Cash flows used in operating activities** were \$8.8 million and \$30.8 million for the three-month period and the year ended December 31, 2012, respectively, compared to \$8.7 million and \$26.2 million of cash flows used during the same periods in 2011. The increase in cash used in operating activities for the year ended December 31, 2012, as compared to the same period in 2011, is mainly due to the receipt, during the first quarter of 2011, of an \$8.4 million upfront payment in connection with our development, commercialization and licensing agreement entered into with Yakult for the rights related to perifosine in Japan, partially offset by a lower loss from operations for the year ended December 31, 2012.

We expect net cash used in operating activities to range from \$30 million to \$32 million during 2013, as we increase our investment in AEZS-108, AEZS-130, AEZS-120 and certain earlier-stage compounds.

#### *2011 compared to 2010*

**Cash flows used in operating activities** totalled \$26.2 million for the year ended December 31, 2011, as compared to \$31.7 million for the year ended December 31, 2010. The decrease in cash used in operating activities is due in large part to the receipt, during the year 2011, of nearly \$8.4 million in connection with our development, commercialization and licensing agreement entered into with Yakult, as discussed above, as well as to lower trade accounts payable settlements, partially offset by lower trade accounts receivable settlements.

### Financing Activities

#### *2012 compared to 2011*

**Cash flows provided by financing activities** were \$15.1 million and \$24.2 million for the three-month period and the year ended December 31, 2012, respectively, as compared to \$8.0 million and \$38.6 million for the same periods in 2011. The fourth quarter increase is primarily due to higher proceeds from the issuance of common shares and warrants, discussed above, which resulted in the receipt of net cash proceeds of \$15.1 million for the three-month period ended December 31, 2012, as compared to \$7.9 million for the same period in 2011. The year-over-year decrease is primarily due to lower proceeds from the issuance of common shares and warrants, as discussed above, which resulted in the receipt of net cash proceeds of \$23.6 million for the year ended December 31, 2012, as compared to \$36.3 million for the same period in 2011 and to lower proceeds received following the exercise of share purchase warrants.

#### *2011 compared to 2010*

**Cash flows provided by financing activities** increased to \$38.6 million for the year ended December 31, 2011, as compared to \$26.0 million for the year ended December 31, 2010. The increase is primarily due to the receipt of higher net proceeds from offerings such as the drawdowns under our ATM Sales Agreements, as well as to the increase in proceeds received following the exercise of share purchase warrants.

## Investing Activities

### *2012 compared to 2011*

**Cash flows used in investing activities** reached \$0.3 million for the year December 31, 2012, as compared to cash flows provided by investing activities of nearly \$2.5 million for the year ended December 31, 2011. The decrease in cash provided by investing activities is due to 2011 events, as described below.

### *2011 compared to 2010*

**Cash flows provided by investing activities** reached \$2.5 million for the year ended December 31, 2011, as compared to cash flows used in investing activities of nearly \$0.5 million for the year ended December 31, 2010. The increase in cash provided by investing activities is due to the increase in cash proceeds received on the sale of our short-term investment, partly offset by cash disbursements made in connection with the purchases of laboratory and other equipment used in ongoing R&D activities.

## Critical Accounting Policies, Estimates and Judgments

Our consolidated financial statements as at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010 have been prepared in accordance with IFRS.

The consolidated financial statements were approved by our Board of Directors on March 21, 2013.

Additionally, the preparation of consolidated financial statements in accordance with IFRS requires management to make judgments, estimates and assumptions that affect the reported amounts of the Company's assets, liabilities, revenues, expenses and related disclosures. Judgments, estimates and assumptions are based on historical experience, expectations, current trends and other factors that management believes to be relevant at the time at which the Company's consolidated financial statements are prepared.

Management reviews, on a regular basis, the Company's accounting policies, assumptions, estimates and judgments in order to ensure that the consolidated financial statements are presented fairly and in accordance with IFRS. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

A summary of those critical estimates and judgments used in applying accounting policies in the preparation of our consolidated financial statements can be found in note 3 to our consolidated financial statements as at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010.

## Recent Accounting Pronouncements

There are no IFRSs or International Financial Reporting Interpretations Committee ("IFRIC") that are effective for the first time in 2012 that would be expected to have a material impact on the Company.

### Adopted in 2012

In June 2011, the IASB amended IAS 1, *Presentation of Financial Statements* ("IAS 1"), to change the disclosure of items presented in other comprehensive income into two groups, based on whether those items may be recycled to profit or loss in the future. The amendments to IAS 1 apply to financial statements for annual periods beginning after July 1, 2012, with early adoption permitted.

### Not yet adopted

In November 2009 and October 2010, the IASB issued IFRS 9, *Financial Instruments* ("IFRS 9"), which represents the completion of the first part of a three-part project to replace IAS 39, *Financial Instruments: Recognition and Measurement*, with a new standard. Per the new standard, an entity choosing to measure a liability at fair value will present the portion of the change in its fair value due to changes in the entity's own credit risk in the other comprehensive income or loss section of the entity's statement of comprehensive loss, rather than within profit or loss in case where the fair value option is taken for financial liabilities. Additionally, IFRS 7 Amendment includes revised guidance related to the derecognition of financial instruments. IFRS 9 applies to financial statements for annual periods beginning on or after January 1, 2015, with early adoption permitted. The Company currently is evaluating any impact that this new standard may have on the Company's consolidated financial statements.

In May 2011, the IASB issued IFRS 10, *Consolidated Financial Statements* ("IFRS 10"), which builds on existing principles by identifying the concept of control as the determining factor in whether an entity should be included within the consolidated financial statements of a parent company. IFRS 10 also provides additional guidance to assist in the determination of control.

where this is difficult to assess. IFRS 10 applies to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new guidance may have on the Company's consolidated financial statements.

In May 2011, the IASB issued IFRS 11, *Joint Arrangements* ("IFRS 11"), which enhances accounting for joint arrangements, particularly by focusing on the rights and obligations of the arrangement, rather than the arrangement's legal form. IFRS 11 also addresses inconsistencies in the reporting of joint arrangements by requiring a single method to account for interests in jointly controlled entities and prohibits proportionate consolidation. IFRS 11 applies to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new guidance may have on the Company's consolidated financial statements.

In May 2011, the IASB issued IFRS 12, *Disclosure of Interests in Other Entities* ("IFRS 12"), which is a comprehensive standard on disclosure requirements for all forms of interests in other entities, including joint arrangements, associates, special purpose vehicles and other off-balance sheet vehicles. IFRS 12 applies to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new guidance may have on the Company's consolidated financial statements.

In May 2011, the IASB issued IFRS 13, *Fair Value Measurement* ("IFRS 13"), which defines fair value, sets out in a single IFRS a framework for measuring fair value and requires disclosures about fair value measurements. IFRS 13 does not determine when an asset, a liability or an entity's own equity instrument is measured at fair value. Rather, the measurement and disclosure requirements of IFRS 13 apply when another IFRS requires or permits the item to be measured at fair value (with limited exceptions). IFRS 13 applies to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new guidance may have on the Company's consolidated financial statements.

In June 2011, the IASB issued an amended version of IAS 19, *Employee Benefits* ("IAS 19"), including the elimination of the option to defer the recognition of actuarial gains and losses (known as the "corridor method"), the streamlining of the presentation of changes in assets and liabilities arising from defined benefit plans and the enhancement of the disclosure requirements for defined benefit plans, including additional information about the characteristics of defined benefit plans and the risks to which entities are exposed through participation in those plans. The amendments to IAS 19 apply to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new standard may have on the Company's consolidated financial statements.

## **Outlook for 2013**

### **AEZS-108**

We expect to advance our Phase 3 study in endometrial cancer under an SPA recently granted by the FDA. Patient recruitment is expected to be initiated in the coming weeks.

We expect to continue our Phase 2 studies in triple-negative breast cancer and refractory bladder cancer.

We expect to continue the Phase 2 study in castration- and taxane-resistant prostate cancer, for which the investigator of this study was awarded a grant from the NIH.

We expect to continue our companion diagnostic program.

### **AEZS-130**

We expect to finalize our NDA and thereafter, file the corresponding NDA for AEZS-130 as a diagnostic test for AGHD in the U.S.

We expect to continue the Phase 2A study in cancer-induced cachexia, which is conducted under a Cooperative Research Development Agreement ("CRADA") with the Michael E. DeBakey Veterans Affairs Medical Center, which is funding this study.

### **AEZS-120**

We expect to file a CTA in Europe and initiate a Phase 1 study in prostate cancer.

## **Revenue expectations**

Revenues are expected to remain at similar levels in 2013, as compared to 2012.

## R&D expenses

During 2013, as described above, we expect to continue to focus our R&D efforts mainly on our later-stage compounds, namely AEZS-108 and AEZS-130. We anticipate that earlier-stage projects will be associated with grants, R&D credits or collaboration agreements. With our focused strategy, we currently expect our R&D expenses to total between \$20 million and \$22 million for the year 2013, as compared to \$20.6 million in 2012.

We expect that our overall operating burn in 2013 will range from \$30 million to \$32 million, primarily as we increase our investment in AEZS-108, AEZS-130, AEZS-120 and certain earlier-stage compounds.

## Financial Risk Factors and Other Instruments

### Fair value risk

The change in fair value of our warrant liability, which is measured at Fair Value through Profit or Loss ("FVTPL"), results from the periodic "mark-to-market" revaluation, via the application of the Black-Scholes option pricing model, of currently outstanding share purchase warrants. The Black-Scholes valuation is impacted, among other inputs, by the market price of our common shares. As a result, the change in fair value of the warrant liability, which is reported as finance income (costs) in the accompanying consolidated statements of comprehensive income (loss), has been and may continue in future periods to be materially affected most notably by changes in our common share price, which has ranged from \$1.87 to \$12.90 on NASDAQ during the year ended December 31, 2012.

If variations in the market price of our common shares of -10% and +10% were to occur, the impact on our net (loss) income for warrant liability held at December 31, 2012 would be as follows:

	Carrying amount	-10%	+10%
	\$	\$	\$
Warrant liability	6,176	768	(783)
<b>Total impact on net loss – decrease / (increase)</b>		<b>768</b>	<b>(783)</b>

### Foreign currency risk

Since we operate internationally, we are exposed to currency risks as a result of potential exchange rate fluctuations related to non-intragroup transactions. In particular, fluctuations in the U.S. and CA dollar exchange rates against the euro could have a potentially significant impact on our results of operations.

If foreign exchange rate variations of -5% (depreciation of the EUR) and +5% (appreciation of the EUR) against the US\$ and the CA\$, from period-end rates of EUR1 = US\$1.3185 and of EUR1=CA\$1.3118 were to occur, the impact on our net (loss) income for each category of financial instruments held at December 31, 2012 would be as follows:

	Carrying amount	Balances denominated in US\$	
	\$	-5%	+5%
	\$	\$	\$
Cash and cash equivalents	24,551	1,228	(1,228)
Warrant liability	6,176	(309)	309
<b>Total impact on net loss – decrease / (increase)</b>		<b>919</b>	<b>(919)</b>

	Carrying amount	Balances denominated in CA\$	
	\$	-5%	+5%
	\$	\$	\$
Cash and cash equivalents	7,064	353	(353)
<b>Total impact on net loss – decrease / (increase)</b>		<b>353</b>	<b>(353)</b>

## **Liquidity risk**

Liquidity risk is the risk that we will not be able to meet our financial obligations as they become due. We manage this risk through the management of our capital structure. We also manage liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors reviews and approves our operating and capital budgets, as well as any material transactions out of the ordinary course of business. We have adopted an investment policy in respect of the safety and preservation of our capital to ensure our liquidity needs are met. The instruments are selected with regard to the expected timing of expenditures and prevailing interest rates.

We believe that we have sufficient funds to pay our ongoing general and administrative expenses, to pursue our R&D activities and to meet our liabilities, obligations and existing commitments as they fall due for the ensuing twelve months. In assessing whether the going concern assumption is appropriate, we take into account all available information about the future, which is at least, but not limited to, twelve months from the end of the reporting period. We expect to continue to incur operating losses and may require significant capital to fulfill our future obligations. Our ability to continue future operations beyond December 31, 2012 and fund our activities is dependent on our ability to secure additional financings which may be completed in a number of ways including but not limited to licensing deals, partnerships, share and other equity issuances and other financing activities. We will pursue such additional sources of financing when required, and while we have been successful in securing financing in the past, there can be no assurance we will be able to do so in the future or that these sources of funding or initiatives will be available for the Company or that they will be available on terms which are acceptable to us.

## **Credit risk**

Credit risk is the risk of an unexpected loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. We regularly monitor credit risk exposure and take steps to mitigate the likelihood of this exposure resulting in losses. Our exposure to credit risk currently relates to cash and cash equivalents, to trade and other receivables and to restricted cash. We invest our available cash in amounts that are readily convertible to known amounts of cash and deposit our cash balances with financial institutions that are rated the equivalent of "A3" and above. This information is supplied by independent rating agencies where available and, if not available, we use publicly available financial information to ensure we invest our cash in creditworthy and reputable financial institutions.

As at December 31, 2012, trade accounts receivable for an amount of approximately \$7.3 million were with two customers.

As at December 31, 2012, no trade accounts receivable were past due or impaired.

Generally, we do not require collateral or other security from customers for trade accounts receivable; however, credit is extended following an evaluation of creditworthiness. In addition, we perform ongoing credit reviews of all our customers and establish an allowance for doubtful accounts when accounts are determined to be uncollectible.

The maximum exposure to credit risk approximates the amount recognized on the statement of financial position.

## **Related Party Transactions and Off-Balance Sheet Arrangements**

We did not enter into transactions with any related parties during the year ended December 31, 2012.

As at December 31, 2012, we did not have any interests in special purpose entities or any other off-balance sheet arrangements.

## Item 6. Directors, Senior Management and Employees

### A. Directors and senior management

The following table sets forth information about our directors and corporate officers as at March 21, 2013.

<u>Name and Place of Residence</u>	<u>Position with Aeterna Zentaris</u>
Aubut, Marcel Quebec, Canada	Director
Blake, Paul Pennsylvania, United States	Senior Vice President and Chief Medical Officer
Dorais, José P. Quebec, Canada	Director
Egbert, Carolyn Texas, United States	Director
Engel, Juergen Alzenau, Germany	President and Chief Executive Officer and Director
Ernst, Juergen Brussels, Belgium	Chairman of the Board and Director
Lapalme, Pierre Quebec, Canada	Director
Limoges, Gérard Quebec, Canada	Director
Métivier, Amélie Quebec, Canada	Assistant Secretary
Meyers, Michael California, United States	Director
Pelliccione, Nicholas New York, United States	Senior Vice President, Regulatory Affairs and Quality Assurance
Shapiro, Elliot Quebec, Canada	Corporate Secretary
Turpin, Dennis Quebec, Canada	Senior Vice President and Chief Financial Officer

There are no family relationships among any of the directors or executive officers of the Company and its subsidiaries. The following is a brief biography of each of our directors and senior officers.

*Marcel Aubut* has served as a director on our Board since 1996. Mr. Aubut is a managing partner of Heenan Blaikie Aubut LLP, a law firm. The countless companies and boards with which Marcel Aubut has been involved over the years demonstrate his versatility and, above all, his vast experience in the world of business. These include, among others, Atomic Energy of Canada, Olymel L.P. (Olybro), Boralex Power Income Fund, Triton Electronik, Whole Foods Market Canada, Hydro-Québec (Executive Committee), Purolator Courier Ltd., Tremblant Resort, Cinar Inc., La Laurentienne générale, La Laurentienne vie, Investors Group Inc., Transforce Inc., Intra Continental Insurers Ltd., the National Hockey League Pension Society, Boréal Entreprises Premier CDN Ltée, Les Industries Amisco Ltée, Donohue Matane Inc., La Société de développement du Loisir et du Sport du Québec, the Canadian Olympic Committee, the Canadian Olympic Foundation, member of VANOC's Audit Committee, Governance and Ethics Committee and Observer Team, Sodic Québec Inc., Innovatech Québec, Textile Dionne, Canada's Sports Hall of Fame, the Committee for the 2002 Quebec City Olympic Games Bid, the Committee for the 2015 Toronto Pan American Games Bid, la Fondation Nordiques, etc. He has also presided over the establishment of numerous industrial projects in the greater region of Quebec City.



*Paul Blake* was appointed our Senior Vice President and Chief Medical Officer in August 2007. Prior to joining us, Dr. Blake was Chief Medical Officer of Avigenics, Inc. (now Synageva BioPharma) since January 2007. In 2005, he was Senior Vice President, Clinical Research and Regulatory Affairs at Cephalon, Inc. before being promoted to Executive Vice President, Worldwide Medical & Regulatory Operations. From 1992 to 1998, he held the position of Senior Vice President and Medical Director, Clinical Research and Development at SmithKline Beecham Pharmaceuticals (now GSK). Dr. Blake earned a medical degree from the London University, Royal Free Hospital. He was elected Fellow of the American College of Clinical Pharmacology, Fellow of the Faculty of Pharmaceutical Medicine, Royal College of Physicians in the UK, and he is a Fellow of the Royal College of Physicians in the UK. Dr. Blake is also a Director of Oxford BioMedica (non-executive) and Chairman of its remuneration committee.

*José P. Dorais* has served as a director on our Board since 2006. Mr. Dorais is a partner of Miller Thomson LLP where he mainly practices administrative, corporate, business and international trade law. Over his 35-year career, he has worked in both the private and public sectors; in the latter he acted as Secretary to the Minister of Justice and as Secretary of the consulting committee on the Free Trade Agreement for the Quebec Provincial Government. Mr. Dorais has been a member of numerous boards of directors, including the Société des Alcools du Québec, Armand-Frappier Institute, Biochem Pharma and St-Luc Hospital in Montreal. He was until recently a member of the Board of Directors of Alliance Films Inc. and Investissement Québec. He is Chairman of the Board of Foster Wheeler Énergie Inc. He holds a law degree from the University of Ottawa and is a member of the *Barreau du Québec*.

*Carolyn Egbert* has served as a director on our Board since August 2012. After enjoying the private practice of law as a defense litigator in Michigan and Washington, D.C., she joined Solvay America, Inc. ("Solvay") (a chemical and pharmaceutical company) in Houston, Texas. Over the course of a twenty-year career with Solvay, she held the positions of Vice President, Human Resources, President of Solvay Management Services, Global Head of Human Resources and Senior Executive Vice President of Global Ethics and Compliance. During her tenure with Solvay, she served as a director on the Board of Directors of seven subsidiary companies. After retirement in 2010, she established a consulting business providing expertise in corporate governance, ethics and compliance, organizational development and strategic human resources. She holds a Bachelor of Sciences degree in Biological Sciences from George Washington University, Washington D.C. and a Juris Doctor degree from Seattle University, Seattle, Washington. She also was a Ph.D. candidate in Pharmacology at both Georgetown University Medical School at Washington, D.C. and Northwestern University Medical School at Chicago, Illinois. She remains an active member of both the Michigan State Bar and the District of Columbia Bar, Washington, D.C.

*Juergen Engel* was appointed President and Chief Executive Officer, effective September 1, 2008, after having up to such time served as our Executive Vice President and Chief Scientific Officer. He became a director on our Board in 2003. Dr. Engel has been Managing Director of AEZS Germany, the Company's principal operating subsidiary, since the beginning of 2001. Before that, he was in charge of all research and development activities of ASTA Medica AG. He is a member of the Advisory Board of GIG, Berlin and ElexoPharm, Saarbrücken. He served as a member of the Board of Directors of Isotechnika Pharma Inc until February 2011. He is also a member of the Board of the German Pharmaceutical Association (BPI) and the German Chemical Association (VCI) for the state of Hesse.

*Juergen Ernst* was appointed Chairman of the Board, effective August 13, 2007, after having been Interim President and Chief Executive Officer from April 11, 2008 until August 31, 2008. He has served as a director on our Board since 2005. A seasoned executive with more than 20 years of pharmaceutical industry expertise mainly in the field of corporate development and pharmaceutical product marketing, Mr. Ernst was worldwide General Manager, Pharmaceutical Sector of Solvay S.A., before retiring in 2004. He has served as a director of Pharming Group N.V., Leiden, Netherlands since April 15, 2009.

*Pierre Lapalme* has served as a director on our Board since December 2009. Mr. Lapalme has over the course of his career held numerous senior management positions in various global life sciences companies. He is former Senior Vice-President, Sales and Marketing for Ciba-Geigy (which subsequently became Novartis) and former Chief Executive Officer and Chairman of the Board of Rhone-Poulenc Pharmaceuticals Inc. in Canada and in North America, as well as Executive Vice-President and Chief Executive Officer of Rhone-Poulenc-Rorer Inc. North America (now sanofi-aventis), where he supervised the development, manufacturing and sales of prescription products in North and Central America. Mr. Lapalme served on the Board of the National Pharmaceutical Council USA and was a Board member of the Pharmaceutical Manufacturers Association of Canada, where he played a leading role in reinstating patent protection for pharmaceuticals. Until recently, he was Board member and Chairman of the Board of Sciele Pharma Inc. which was acquired by Shionogi and Co. Ltd. Mr. Lapalme is currently Chairman of the Board of Biomarin Inc., Chairman of the Board of Pediapharm Inc., Board member of Algorithme Pharma Inc. and Insy's Therapeutics Inc., a Phoenix-Arizona based specialty pharma company. He studied at the University of Western Ontario and at INSEAD, France.

*Gérard Limoges*, has served as a director on our Board since 2004. Mr. Limoges served as the Deputy Chairman of Ernst & Young LLP Canada until his retirement in September 1999. After a career of 37 years with Ernst & Young, Mr. Limoges has been devoting his time as a director of a number of companies. Mr. Limoges began his career with Ernst & Young in Montreal in 1962. After graduating from the Management Faculty of *Université de Montréal* (HEC Montreal) in 1966, he wrote the CICA exams the same year (Honors: Governor General of Canada; Gold Medal for the highest marks in Canada and Gold Medal of the *Ordre des Comptables Agréés du Québec*). He became a chartered accountant in 1967 and partner of Ernst & Young in 1971. After practicing as auditor since 1962 and partner since 1971, he was appointed Managing Partner of the Montreal Office in 1979 and Chairman for Quebec in 1984 when he also joined the National Executive Committee. In 1992, he was appointed Vicechairman of Ernst & Young Canada and the following year, Deputy Chairman of the Canadian firm. After retirement from public practice at the end of September 1999, he was appointed Trustee of the School board of Greater Montreal (1999), member of the Quebec Commission on Health Care and Social Services (2000-2001) and special advisor to the Rector of the University de Montreal and affiliate schools (2000-2003). Mr. Limoges, at the request of the Board of the University of Montreal, has participated in the selection of the Dean of the Faculty of Medicine in 2011. Mr. Limoges is a board member or trustee and chairman of the audit committees of the following public companies: Aeterna Zentaris Inc. (TSX and NASDAQ), Atrium Innovations Inc. (TSX), Hartco Inc. (TSX), Hart Stores Inc. (TSXV) and PRO Real Estate Investment Trust ("PRO REIT") (TSX Venture). He is also a board member of various private companies and charities. Mr. Limoges became an FCA (Fellow) in 1984 and received the Order of Canada in 2002.

*Amélie Métivier*, Assistant Secretary. Ms. Métivier has served as our Assistant Secretary since April 2009. In addition, Ms. Métivier is currently a lawyer at the law firm of Norton Rose Canada LLP with a business law and transaction-oriented practice, where she has worked since 2003. She is a member of the *Barreau du Québec* and holds an LL.B. (2004) degree from Université de Montréal.

*Michael Meyers* has served as a director on our Board since March 2011. He is a co-founding member, Chief Executive Officer and Chief Investment Officer of Arcoda Capital Management LP ("Arcoda"), a private investment fund manager. Prior to founding Arcoda in 2007, Mr. Meyers was a Partner and Portfolio Manager of two other money management firms located in New York. Between 2000 and 2003 Mr. Meyers was a Managing Director, Partner and Director of a life sciences venture capital firm located in New York and Zurich, Switzerland. Between 1997 and 2000, Mr. Meyers was Director, Biotechnology and Pharmaceutical Investment Banking at Merrill Lynch & Co. Between 1993 and 1997, Mr. Meyers was Vice President, Health Care Investment Banking at Cowen & Company. Prior to Cowen & Company, Mr. Meyers was Special Assistant to the Chief Executive Officer of St. Barnabas Hospital System. Mr. Meyers began his career as a Biotechnology and Medical Device Research Associate at Hambrecht & Quist in New York. Mr. Meyers holds an M.P.H. in Health Policy and Management from Columbia University and an A.B. in Biology from Brandeis University in Massachusetts. Mr. Meyers has also served on the Board of Directors of six companies at various times.

*Nicholas J. Pelliccione* was appointed our Senior Vice President, Regulatory Affairs and Quality Assurance in May 2007. In previous roles, Dr. Pelliccione has been responsible for the clinical/preclinical and CMC regulatory aspects of new drugs in the oncology, anti-infectives, cytokines and cardiovascular therapy areas, leading to several approvals. He served as Senior Vice President, Regulatory and Pharmaceutical Sciences at Chugai Pharma USA from May 2005 until March 2007. Prior to his experience at Chugai, Dr. Pelliccione spent more than 15 years at Schering Plough Corporation holding positions with increasing responsibility from Manager of Regulatory Affairs, Oncology to Vice President, Global Regulatory Affairs, Chemistry, Manufacturing and Controls. Dr. Pelliccione holds a Ph.D. in Biochemistry from Mount Sinai School of Medicine, New York and a BS in Chemistry from Polytechnic University.

*Elliot Shapiro* was appointed our Corporate Secretary in April 2009. In addition, Mr. Shapiro is currently a partner and a lawyer at the law firm of Norton Rose Canada LLP with a business law and transaction-oriented practice, where he has worked since 1999. He is a member of the *Barreau du Québec*. Mr. Shapiro holds B.C.L. (1999), LL.B. (1999) and B.A. (1993) degrees from McGill University.

*Dennis Turpin* was appointed our Senior Vice President and Chief Financial Officer in August 2007. Prior to that, he served as our Vice President and Chief Financial Officer since June 1999. Mr. Turpin joined Aeterna Zentaris in August 1996 as Director of Finance. Prior to that, he was Director in the tax department at Coopers Lybrand, now PricewaterhouseCoopers, from 1988 to 1996 and worked as an auditor from 1985 to 1988. Mr. Turpin earned his Bachelor's degree in Accounting from Laval University in Québec. He obtained his license in accounting in 1985 and became a chartered accountant in 1987.

## B. Compensation

Our executive officers are generally paid in their home country's currency. Unless otherwise indicated, all directors' and executive compensation information included in this document is presented in US dollars and, to the extent a director or officer has been paid in a currency other than US dollars (Canadian dollars or euros), the amounts have been converted from such person's home country currency to US dollars based on the following average exchange rates: for the financial year ended December 31, 2012: €1.000 = US\$1.286 and CAN\$1.000 = US\$1.001; for the financial year ended December 31, 2011: €1.000 = US\$1.392 and CAN\$1.000 = US\$1.011; and for the financial year ended December 31, 2010: €1.000 = US\$1.326 and CAN\$1.000 = US\$0.970.

### 1. Compensation of Outside Directors

The compensation paid to the Company's directors is designed to (i) attract and retain the most qualified people to serve on the Board and its committees, (ii) align the interests of the Company's directors with those of its shareholders, and (iii) provide appropriate compensation for the risks and responsibilities related to being an effective director. This compensation is recommended to the Board by the Corporate Governance, Nominating and Human Resources Committee ("Governance Committee"). The Governance Committee is composed of four (4) directors, each of whom is independent, namely Messrs. José P. Dorais (Chair), Juergen Ernst, Gérard Limoges and Ms. Carolyn Egbert. One of the members of the Governance Committee, Juergen Ernst, is the Chairman of the Board.

The Board has adopted a formal mandate for the Governance Committee, which is available on our website at [www.aezsinc.com](http://www.aezsinc.com). The mandate of the Governance Committee provides that it is responsible for (i) assisting the Board in developing our approach to corporate governance issues, (ii) proposing new Board nominees, (iii) assessing the effectiveness of the Board and its committees, their respective chairs and individual directors and (iv) making recommendations to the Board with respect to directors' compensation.

We did not employ the services of any external compensation consultant in or with respect to the financial year ended December 31, 2012.

### Annual Retainers and Attendance Fees

Annual retainers and attendance fees are paid on a quarterly basis to the members of the Board who are not employees of the Company or its subsidiaries ("Outside Directors") on the following basis.

Type of Compensation	Annual compensation for the year 2012 (in units of home country currency)
Chairman's Retainer	45,000
Board Retainer	15,000
Board Meeting Attendance Fees	1,000 per meeting
Audit Committee Chair Retainer	15,000
Audit Committee Member Retainer	4,000
Audit Committee Meeting Attendance Fees	1,000 per meeting
Governance Committee Chair Retainer	12,000
Governance Committee Member Retainer	2,000
Governance Committee Meeting Attendance Fees	1,000 per meeting

All amounts in the above table are paid to Board and committee members in their home country currency.

The President and Chief Executive Officer is the only member of the Board who is not an Outside Director and as such, is not compensated in his capacity as a director. The Chairman is an Outside Director and is compensated as such. Outside Directors are reimbursed for travel and other out-of-pocket expenses incurred in attending Board or committee meetings.

## Outstanding Option-Based Awards and Share-Based Awards

The following table shows all awards outstanding to each Outside Director up to the end of the financial year ending and as at December 31, 2012:

Name	Option-based Awards					Share-based Awards		
	Issuance Date	Number of Securities Underlying Unexercised Options <sup>(1)</sup>	Option Exercise Price	Option Expiration Date	Value of Unexercised In-the-money Options <sup>(2)</sup>	Issuance Date	Number of Shares or Units of Shares that have Not Vested	Market or Payout Value of Share-based Awards that have Not Vested
	(mm-dd-yyyy)	(#)	(CAN\$ or US\$)	(mm-dd-yyyy)	(CAN\$ or US\$)	(mm-dd-yyyy)	(#)	(\$)
Aubut, Marcel	12/11/2003	5,000	CAN\$10.44	12/10/2013	—	—	—	—
	12/14/2004	2,500	CAN\$34.98	12/13/2014	—	—	—	—
	12/13/2005	2,500	CAN\$21.18	12/12/2015	—	—	—	—
	01/04/2007	833	CAN\$27.90	01/03/2017	—	—	—	—
	12/11/2007	4,166	CAN\$10.92	12/10/2017	—	—	—	—
	12/08/2008	2,500	CAN\$3.30	12/08/2018	—	—	—	—
	12/09/2009	3,333	CAN\$5.70	12/08/2019	—	—	—	—
	12/08/2010	5,000	CAN\$9.12	12/07/2020	—	—	—	—
	12/07/2011	8,333	US\$10.44	12/06/2021	—	—	—	—
	05/09/2012	10,000	US\$3.54	05/08/2022	—	—	—	—
Dorais, José P.	12/08/2010	5,000	CAN\$9.12	12/07/2020	—	—	—	—
	12/07/2011	8,333	US\$10.44	12/06/2021	—	—	—	—
	05/09/2012	10,000	US\$3.54	05/08/2022	—	—	—	—
Egbert, Carolyn	12/06/2012	7,500	US\$2.17	12/05/2022	US\$1,575	—	—	—
Ernst, Juergen	02/25/2005	2,500	CAN\$30.54	02/24/2015	—	—	—	—
	12/13/2005	2,500	CAN\$21.18	12/12/2015	—	—	—	—
	01/04/2007	833	CAN\$27.90	01/03/2017	—	—	—	—
	12/11/2007	4,166	CAN\$10.92	12/10/2017	—	—	—	—
	11/14/2008	16,666	CAN\$3.90	11/13/2018	—	—	—	—
	12/08/2008	2,500	CAN\$3.30	12/08/2018	—	—	—	—
	12/09/2009	3,333	CAN\$5.70	12/08/2019	—	—	—	—
	12/08/2010	5,000	CAN\$9.12	12/07/2020	—	—	—	—
	12/07/2011	8,333	US\$10.44	12/06/2021	—	—	—	—
	05/09/2012	10,000	US\$3.54	05/08/2022	—	—	—	—
Lapalme, Pierre	12/09/2009	3,333	CAN\$5.70	12/08/2019	—	—	—	—
	12/08/2010	5,000	CAN\$9.12	12/07/2020	—	—	—	—
	12/07/2011	8,333	US\$10.44	12/06/2021	—	—	—	—
	05/09/2012	10,000	US\$3.54	05/08/2022	—	—	—	—
Limoges, Gérard	12/14/2004	2,500	CAN\$34.98	12/13/2014	—	—	—	—
	12/13/2005	2,500	CAN\$21.18	12/12/2015	—	—	—	—
	01/04/2007	833	CAN\$27.90	01/03/2017	—	—	—	—
	12/11/2007	4,166	CAN\$10.92	12/10/2017	—	—	—	—
	12/08/2008	2,500	CAN\$3.30	12/08/2018	—	—	—	—
	12/09/2009	3,333	CAN\$5.70	12/08/2019	—	—	—	—
	12/08/2010	5,000	CAN\$9.12	12/07/2020	—	—	—	—
	12/07/2011	8,333	US\$10.44	12/06/2021	—	—	—	—
Meyers, Michael	05/27/2011	3,333	US\$14.16	05/26/2021	—	—	—	—
	12/07/2011	6,666	US\$10.44	12/06/2021	—	—	—	—
	05/09/2012	10,000	US\$3.54	05/08/2022	—	—	—	—

(1) The number of securities underlying unexercised options represent all awards outstanding as at December 31, 2012.

(2) "Value of unexercised in-the-money options" at financial year-end is calculated based on the difference between the closing prices of the common shares on the TSX or NASDAQ, as applicable, on the last trading day of the fiscal year (December 31, 2012) of CAN\$2.37 and US\$2.38, respectively, and the exercise price of the options, multiplied by the number of unexercised options.

See "Summary of the Stock Option Plan" below for more details on the Stock Option Plan (as defined below).

## Total Compensation of Outside Directors

The table below summarizes the total compensation earned by the Outside Directors during the financial year ended December 31, 2012 (all amounts are in US dollars):

Name	Fees earned (\$)		Share-based Awards (\$)	Option-based Awards <sup>(2)</sup> (\$)	Non-Equity Incentive Plan Compensation (\$)	Pension Value (\$)	All Other Compensation <sup>(3)</sup> (\$)	Total (\$)
	Retainer <sup>(1)</sup>	Attendance <sup>(1)</sup>						
Aubut, Marcel	15,009	4,503	—	27,672	—	—	—	47,184
Dorais, José P.	27,016	8,005	—	27,672	—	—	—	62,693
Egbert, Carolyn <sup>(4)</sup>	5,707	3,500	—	13,374	—	—	—	22,581
Ernst, Juergen	79,720	10,286	—	27,672	—	—	2,572	120,250
Lapalme, Pierre	19,011	9,506	—	27,672	—	—	—	56,189
Limoges, Gérard	32,019	11,507	—	27,672	—	—	—	71,198
Meyers, Michael	19,000	8,000	—	27,672	—	—	—	54,672

(1) These amounts represent the portion paid in cash to the Outside Directors and are paid in each director's home country currency.

(2) The value of option-based awards represents the closing price of the common shares on NASDAQ on the last trading day preceding the date of grant (US\$3.54 for options granted on May 9, 2012 and US\$2.17 for options granted to Carolyn Egbert on December 6, 2012) multiplied by the Black-Scholes factor as at such date (78.17% for options granted on May 9, 2012 and 82.174% for options granted to Carolyn Egbert on December 6, 2012) and the number of stock options granted on such date.

(3) These amounts represent fees paid in cash for special tasks or overseas travelling and are also paid in each director's home country currency.

(4) Carolyn Egbert was appointed director on August 14, 2012 and has been a member of the Governance Committee since December 6, 2012.

During the financial year ended December 31, 2012, the Company paid an aggregate amount of \$255,361 to all of its Outside Directors for services rendered in their capacity as directors, excluding reimbursement of out-of-pocket expenses and the value of option-based awards granted in 2012.

## 2. Compensation of Executive Officers

The mandate of the Governance Committee provides that it is responsible for taking all reasonable measures to ensure that appropriate human resources systems and procedures, such as hiring policies, competency profiles, training policies and compensation structures are in place so that we can attract, motivate and retain the quality of senior management required to meet our business objectives.

The Governance Committee also assists the Board in discharging its responsibilities relating to executive and other human resources hiring, assessment, compensation and succession planning matters.

Thus, the Governance Committee recommends the appointment of senior officers, including the terms and conditions of their appointment and termination, and reviews the evaluation of the performance of such senior officers, including recommending their compensation and overseeing risk identification and management in relation to executive compensation policies and practices. The Board, which includes the members of the Governance Committee, reviews the corporate goals and objectives that are set annually and evaluates the Chief Executive Officer's performance and compensation in light of such goals and objectives.

The Governance Committee recognizes that the industry and competitive environment in which the Company operates requires a balanced level of risk-taking to promote and achieve the performance expectations of executives of a development-stage biopharmaceutical company. The Governance Committee is of the view that the Company's executive compensation program should not encourage senior executives to take excessive risk. In this regard, the Governance Committee recommends the implementation of compensation methods that tie a portion of senior executive compensation to each of the short-term and longer-term performance of both the Company as well as that of each individual executive officer and that take into account the advantages and risks associated with such compensation methods. The Governance Committee is also responsible for creating compensation policies that are intended to reward the creation of shareholder value while reflecting a balance between the short-term and longer-term performance of the Company and of each executive officer.

## Compensation Discussion & Analysis

### *Compensation Philosophy and Objectives*

The Company's executive compensation program is designed to attract, motivate and retain high performing senior executives, encourage and reward superior performance and align the executives' interests with those of our shareholders by:

- providing the opportunity for an executive to earn compensation that is competitive with the compensation received by executives employed by a group of comparable North American companies;
- providing executives with an equity-based incentive plan, namely a stock option plan;
- aligning employee compensation with company corporate objectives; and
- attracting and retaining highly qualified individuals in key positions.

### *Risk Assessment of Executive Compensation Program*

The Board, through the Governance Committee, oversees the implementation of compensation methods that tie a portion of executive compensation to each of the short-term and longer-term performance of the Company and of each executive officer and that take into account the advantages and risks associated with such compensation methods. In addition, the Board oversees the creation of compensation policies that are intended to reward the creation of shareholder value while reflecting a balance between the short-term and longer-term performance of the Company and of each executive officer.

The Governance Committee has considered in general terms the concept of risk as it relates to the Company's executive compensation program.

Base salaries are fixed in amount to provide a steady income to the executive officers regardless of share price and thus do not encourage or reward risk-taking to the detriment of other important business, operational or clinical metrics or milestones. The variable compensation elements (annual bonuses and stock options) are designed to reward both short and long-term performance. For short-term performance, a discretionary annual bonus may be awarded based on the timing and level of attainment of specific operational and corporate goals that the Governance Committee believes to be challenging, yet does not encourage unnecessary or excessive risk-taking. While the Company's bonus payments are generally based on annual performance, a maximum bonus payment is pre-fixed for each senior executive officer and represents only a portion of each individual's overall total compensation opportunities. In exceptional circumstances, a particular executive officer may be awarded a bonus that exceeds his or her maximum pre-fixed bonus amount. Finally, a significant portion of executive compensation is provided in the form of stock options, which is intended to further align the interests of executives with those of shareholders. The Governance Committee believes that these awards do not encourage unnecessary or excessive risk-taking since the ultimate value of the awards is tied to the Company's share price, and in the case of grants under the long-term incentive compensation plan, are generally subject to long-term vesting schedules to help ensure that executives generally have significant value tied to long-term share price performance.

The Governance Committee believes that the variable compensation elements (annual bonuses and stock options) represent a percentage of overall compensation that is sufficient to motivate the Company's executive officers to produce superior short-term and long-term corporate results, while the fixed compensation element (base salary) is also sufficient to discourage executive officers from taking unnecessary or excessive risks. The Governance Committee and the Board also generally have the discretion to adjust annual bonuses and stock option grants based on individual performance and any other factors they may determine to be appropriate in the circumstances. Such factors may include, where necessary or appropriate, the level of risk-taking a particular executive officer may have engaged in during the preceding year.

Based on the foregoing, the Governance Committee has not identified any specific risks associated with the Company's executive compensation program that are reasonably likely to have a material adverse effect on the Company. The Governance Committee believes that the Company's executive compensation program does not encourage or reward any unnecessary or excessive risk-taking behaviour.

The Board of Directors, based on the Governance Committee's recommendation, set goals for the Company at the end of 2011, which constitute the performance objectives for the Chief Executive Officer and the Company's other executive officers. The performance objectives are not established for individual executive officers but rather by function(s) exercised within the Company, many of which are carried out by or fall within the responsibility of the Company's President and Chief Executive Officer, the Chief Financial Officer and the three (3) other most highly compensated executive officers of the Company during the most recently completed financial year (collectively, the "Named Executive Officers").

In December 2012, the Governance Committee determined that despite the fact that activities in 2012 were marked by the negative outcome of the Phase 3 perifosine trial in refractory colorectal cancer, the Company nonetheless made considerable progress with its other development candidates, and the Company's executive officers as a group met or exceeded each of the objectives set forth in the table below as follows:

Objectives for 2012	Results for 2012
<b>Clinical / Regulatory</b>	
Advancement of product pipeline / Optimize regulatory strategy with lead authorities	
<sup>1</sup> Perifosine	<sup>1</sup> Despite the negative results of perifosine in refractory colorectal cancer, the Company: <ul style="list-style-type: none"> <li>- regained in full the North American rights to perifosine from Keryx and continued the Phase 3 trial in multiple myeloma following the review of different opinion leaders;</li> <li>- successfully managed alliances with partners Yakult Honsha Co. Ltd. (Japan), Handok Pharmaceuticals (South Korea) and Hikma Pharmaceuticals (MENA region); and</li> <li>- initiated a Phase 1 bridging study in Japan by the Company's partner for the Japanese market, Yakult Honsha Co. Ltd.</li> </ul>
<sup>1</sup> AEZS-108	<sup>1</sup> Special Protocol Assessment (SPA) was granted by the Food and Drug Administration (FDA) for the initiation of a Phase 3 study in advanced recurrent endometrial cancer
	<sup>1</sup> Initiated the Phase 2 portion of a Phase 1/2 trial in castration- and taxane-resistant prostate cancer supported by the NIH
<sup>1</sup> AEZS-130	<sup>1</sup> Presented at 2 international conferences the Phase 3 results for AEZS-130, as a diagnostic test for AGHD
	<sup>1</sup> Initiated a Phase 2 study in cancer-induced cachexia under CRADA with the Michael E. DeBakey Veterans Affairs Medical Center, which is funding the study
<sup>1</sup> AEZS-120	<sup>1</sup> Continued the preparation of the filing of a New Drug Application (NDA) for the registration of AEZS-130 as a diagnostic test for AGHD
<sup>1</sup> Cetrotide®	<sup>1</sup> Presented preclinical data at an international conference underlining the feasibility of an oral therapeutic vaccination approach against prostate cancer
	<sup>1</sup> Successful management of higher Cetrotide® demand; reduction of cost of goods
<b>Business Development/Alliance Management</b>	
<sup>1</sup> Ensure successful alliance management with existing drug development and commercialization partners	<sup>1</sup> Continued to maintain excellent relations with alliance partners and identified new partners for potential alliances
<b>Financial</b>	
<sup>1</sup> Ensure the continued funding of ongoing drug development programs for a minimum period of time while maintaining flexibility to execute different forms of financing	<sup>1</sup> Completed At-the-Market Financing (ATM) for aggregate net proceeds of \$8.5 million
	<sup>1</sup> Completed a registered follow-on financing generating net proceeds of \$15.1 million
<sup>1</sup> Budget management	<sup>1</sup> Cash and cash equivalents as of December 31, 2012 totaled \$39.5 million
	<sup>1</sup> Tight budget control, effective management of liquidity and capital resources, including proceeds generated in financings described in the above bullet points
<b>Investor Relations</b>	
<sup>1</sup> Increase awareness: volume	<sup>1</sup> Initiation and continuation of coverage by several analysts
<sup>1</sup> Improve targeted investors	<sup>1</sup> Presented at several strategic healthcare and partnership conferences and continued to build the Company's investor base and awareness
<b>Human Resources</b>	
<sup>1</sup> Maintain high level of motivation at all levels (and sites) of the Company and low level staff turnover	<sup>1</sup> Maintained HR-attrition policy while progressing development pipeline

The determination of individual performance does not involve quantitative measures using a mathematical calculation in which each individual performance objective is given a numerical weight. Instead, the Governance Committee's determination of individual performance is a subjective determination as to whether a particular executive officer substantially achieved the stated objectives or over-performed or under-performed with respect to corporate objectives that were deemed to be important to the Company's success.

While the Company has not formally adopted a policy prohibiting or restricting its executive officers and directors from purchasing financial instruments, including, for greater certainty, pre-paid variable forward contracts, equity swaps, collars, or units of exchange funds, which are designed to hedge or offset a decrease in market value of equity securities granted as executive compensation or directors' remuneration, the Company's executive officers and directors have not historically engaged in such financial instruments or transactions. In addition, the Company's disclosure and trading policy requires that all "reporting insiders", including executive officers and directors, pre-clear with the Company's Corporate Secretary each trade relating to the Company's securities, which would include the entering into of any such financial instrument or transaction, hedge, swap or forward contract.

### **Benchmarking**

In order to attain the Company's objectives of providing market competitive compensation opportunities, the Company's executive compensation plan, based on a study provided by AON Consulting (and updated annually), is benchmarked against market compensation data gathered from organizations of comparable size and/or stage of development or other companies that the Company competes with for executive talent (the "Reference Group"). The Company did not, however, pay AON Consulting any fee or other remuneration in 2012. An overview of the characteristics of the Reference Group is provided in the following table:

(In millions of US\$)

	<b>Aeterna Zentaris</b>	<b>Survey Reference Group</b>
<b>Location</b>	North America and Europe	North America
<b>Industries</b>	Biopharmaceutical	Biopharmaceutical
<b>Revenues</b> Last fiscal year	36.1 <sup>(1)</sup>	24.8 <sup>(2)</sup>
<b>Market Capitalization</b> As at October 31, 2012	54.5	257.7
<b>Net Loss</b> Last fiscal year	27.1 <sup>(1)</sup>	24.6 <sup>(2)</sup>

(1) For the year ended December 31, 2011, as presented in the Company's 2011 audited consolidated financial statements, which were presented in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

(2) The Reference Group for the financial year ended December 31, 2012 was selected in October 2012 and these data are based on their most recently completed fiscal year at such time.

The Reference Group used in respect of the financial year ended December 31, 2012 was composed of the following companies: Acadia Pharmaceuticals Inc.; Array Biopharma Inc.; Biocryst Pharmaceuticals, Inc.; BioSanté Pharmaceuticals, Inc.; Cell Therapeutics Inc.; Cel-Sci Corporation; Enzon Pharmaceuticals Inc.; Genomic Health Inc.; Ligand Pharmaceuticals Inc.; Neurocrine Biosciences Inc.; Nps Pharmaceuticals Inc.; OncoGenex Pharmaceuticals Inc.; Onyx Pharmaceuticals, Inc.; Savient Pharmaceuticals Inc.; Xoma Ltd.; and Ziopharm Oncology, Inc.

### **Positioning**

The Company's compensation policy is for executive compensation to be generally aligned with the 50<sup>th</sup> percentile of the Reference Group. The Governance Committee uses discretion and judgment when determining compensation levels as they apply to a specific executive officer. Individual compensation may be positioned above or below median, based on individual experience and performance or other criteria deemed important by the Governance Committee. The total cash target payment (base salary and, if applicable or awarded in cash, annual bonus) for the Company's executive officers generally falls within the 50<sup>th</sup> percentile competitive range of the Reference Group.



## ***Compensation Elements***

An executive compensation policy has been established to acknowledge and reward the contributions of the executive officers to the Company's success and to ensure competitive compensation, in order that the Company may benefit from the expertise required to pursue its objectives.

The Company's executive compensation policy is comprised of both fixed and variable components. The variable components include equity and non-equity incentive plans. Each compensation component is intended to serve a different function, but all elements are intended to work in concert to maximize both corporate and individual performance by establishing specific, competitive operational and corporate goals and by providing financial incentives to employees based on their level of attainment of these goals.

The Company's current executive compensation program is comprised of the following four basic components:

- (i) base salary;
- (ii) non-equity incentives - consisting of an annual bonus linked to both individual and corporate performance;
- (iii) long-term equity incentives - consisting solely of stock options under the Company's Stock Option Plan established for the benefit of its directors, executive officers and employees (the "Stock Option Plan"); and
- (iv) other elements of compensation - consisting of benefits, perquisites and retirement benefits.

### ***Base Salary***

Salaries of the Company's executive officers are based on a comparison with competitive benchmark positions. The starting point to determine executive base salaries is the median of executive salaries in the Reference Group. In determining individual base salaries, the Governance Committee takes into consideration individual circumstances that may include the scope of an executive's position, the executive's relevant competencies or experience and retention risk. The Governance Committee also takes into consideration the fulfillment of the corporate objectives of the Company as well as the individual performance of the executive.

### ***Short-Term Incentive Compensation***

The short-term incentive compensation plan sets out the allocation of incentive awards based on the advancement of the Company's product pipeline, its financial position as well as strategic objectives.

In the case of executive officers, a program is designed to maximize both corporate and individual performance by establishing specific operational, clinical, regulatory, financial and corporate goals and to provide financial incentives to executive officers based on their level of attainment of these goals. The granting of incentives requires the approval of both the Governance Committee and the Board and is based upon an assessment of each individual's performance, as well as the performance of the Company. The underlying objectives are set at the end of each financial year as part of the annual review of corporate strategies.

For the financial year ended December 31, 2012, the Governance Committee recommended, and the Board approved, in the best interests of the Company, that, to the extent earned, all bonuses awarded to the Company's executive officers in respect of the 2012 year be payable entirely in the form of stock options (i.e., no cash bonuses were awarded to executive officers), whereby \$1.00 generally equals 0.6 stock option, such that the dollar amount of the pre-fixed cash bonus amount was determined to be paid in the form of stock options to vest in equal one-third tranches at six-month intervals, with the first one-third to vest on the six-month anniversary of the date of grant. The accelerated vesting of these stock options granted to employees and executives is intended to allow these grants to serve their purpose as replacements for annual cash bonuses. For the Company's European executives, as in prior years, the number of options was "grossed up" by a multiple of 1.27 to reflect the then prevailing US\$ to € exchange rate. See Section "Summary of the Stock Option Plan" for more details on the Stock Option Plan.

In making decisions related to the short-term incentive compensation for the Named Executive Officers, other than the President and Chief Executive Officer, the Governance Committee concluded as follows, based on the goals and results for 2012, as described in Section "Risk Assessment of Executive Compensation Program".

Mr. Turpin's 2012 goals were aligned with the Company's overall objectives, with an emphasis on financial objectives. In respect of the 2012 year, the Governance Committee determined that Mr. Turpin's individual performance surpassed his objectives. Under Mr. Turpin's financial direction, the Company completed a successful ATM financing generating net proceeds of \$8.4 million, and a registered follow on financing generating net proceeds of \$15.1 million which, in addition to Mr. Turpin's tight operating budget control, enabled the Company to end the year with cash and cash equivalents that significantly exceeded the budgeted amount. In light of the foregoing, the Governance Committee determined that Mr. Turpin's contributions to the

achievement of the Company's goals merited an equity-based bonus in an amount of \$140,000 paid through the granting of 84,000 stock options, representing a non-cash bonus payout of 117% of his maximum bonus amount.

Dr. Blake's and Dr. Pelliccione's 2012 respective goals were aligned with the Company's overall objectives, with an emphasis on overseeing and supporting the attainment of the Company's clinical and regulatory objectives. In respect of the 2012 year, the Governance Committee determined that both Dr. Blake's and Dr. Pelliccione's individual performance exceeded expectations, particularly in respect of the advancement of the product pipeline and the optimization of the Company's regulatory strategy with the principal regulatory authorities. The Governance Committee determined that Dr. Blake's and Dr. Pelliccione's contributions to the achievement of the Company's goals merited a non-cash, equity-based bonus payout of 100% of the amounts previously established by the Governance Committee, in an amount of \$134,500 in the case of Dr. Blake, paid through the granting of 80,700 stock options, and in an amount of \$116,833 in the case of Dr. Pelliccione, paid through the granting of 70,100 stock options.

As Mr. Seeber voluntarily left the Company effective December 31, 2012, no bonus was awarded to Mr. Seeber in respect of the 2012 year. See Section "Item 10.C – Material Contracts" for more details on Mr. Seeber's departure arrangement.

For the financial year ended December 31, 2012, the stock options granted to all executive officers under the short-term incentive compensation plan in replacement of the annual cash bonuses represented a non-cash payout of 104% of the aggregate maximum bonus amounts previously established by the Governance Committee.

### ***Long-Term Equity Compensation Plan of Executive Officers***

The long-term component of the compensation of the Company's executive officers is based exclusively on the Stock Option Plan, which permits the award of a number of options based on the contribution of the officers and their responsibilities. To encourage retention and focus management on developing and successfully implementing the continuing growth strategy of the Company, stock options have historically vested over a period of three years, with the first third vesting on the first anniversary of the date of grant. However, as described in Section "Short-Term Incentive Compensation" above, the vesting schedule for certain stock options granted to senior executives in the financial years ended December 2012, 2011, 2010 and 2009 was accelerated from three years to 18 months since a portion of these grants were intended to serve as a partial or total replacement for cash bonuses. Stock options are usually granted to executive officers in December of each year.

For the financial year ended December 31, 2012, the Governance Committee recommended that no stock options be granted to executive officers under the long-term equity compensation plan. See Section "Short-Term Incentive Compensation" for details on stock options granted in replacement of cash bonuses in 2012.

### ***Summary of the Stock Option Plan***

We established the Stock Option Plan in order to attract and retain directors, officers, employees of the Company or any of its subsidiaries, as the case may be, and suppliers of ongoing services, who will be motivated to work towards ensuring the success of the Company. The Board has full and complete authority to interpret the Stock Option Plan, to establish applicable rules and regulations and to make all other determinations it deems necessary or useful for the administration of the Stock Option Plan, provided that such interpretations, rules, regulations and determinations are consistent with the rules of all stock exchanges and quotation systems on which our securities are then traded and with all relevant securities legislation.

Individuals eligible to participate under the Stock Option Plan are determined from time to time by either the Board or the Governance Committee.

The maximum number of common shares issuable under the Stock Option Plan is fixed at 11.4% of the issued and outstanding common shares at any given time, which, as at March 21, 2013, represented 2,887,538 common shares. There are currently 2,040,267 options outstanding under the Stock Option Plan representing approximately 8.1% of all issued and outstanding common shares on March 21, 2013.

Under the Stock Option Plan, as amended on March 21, 2013 (as explained below), (i) the number of securities issuable to insiders, at any time, or issued within any one-year period, under all of the Company's security-based compensation arrangements, cannot exceed 10% of the Company's issued and outstanding securities and (ii) no single option holder may hold options to purchase, from time to time, more than 5% of the Company's issued and outstanding common shares.

Options granted under the Stock Option Plan may be exercised at any time within a maximum period of ten years following the date of their grant (the "Outside Expiry Date"). The Board or the Governance Committee, as the case may be, designates, at its discretion, the individuals to whom stock options are granted under the Stock Option Plan and determines the number of common shares covered by each of such option grants, the grant date, the exercise price of each option, the expiry date, the vesting schedule and any other matter relating thereto, in each case in accordance with the applicable rules and regulations of

the regulatory authorities. The price at which the common shares may be purchased may not be lower than the greater of the closing prices of the common shares on the TSX or NASDAQ, as applicable, on the last trading day preceding the date of grant of the option. Options granted under the Stock Option Plan generally vest in equal tranches over a three-year period (one-third each year, starting on the first anniversary of the grant date) or as otherwise determined by the Board or the Governance Committee, as the case may be, although, as described above, under section "Short-Term Non-Equity Incentive Compensation", a certain number of stock options granted to executive officers since 2009 have an accelerated vesting schedule of 18 months.

Unless the Board or the Governance Committee decides otherwise, option holders cease to be entitled to exercise their options under the Stock Option Plan: (i) immediately, in the event an option holder who is an officer or employee resigns or voluntarily leaves his or her employment with the Company or one of its subsidiaries or the employment with the Company or one of its subsidiaries is terminated with cause and, in the case of an optionee who is a non-employee director of the Company or one of its subsidiaries, the date on which such optionee ceases to be a member of the relevant board of directors; (ii) six months following the date on which employment is terminated as a result of the death of an option holder who is an officer or employee and, in the case of an optionee who is a non-employee director of the Company or one of its subsidiaries, six months following the date on which such optionee ceases to be a member of the relevant board of directors by reason of death; (iii) 30 days following the date on which an option holder's employment with the Company or any of its subsidiaries is terminated for a reason other than those mentioned in (i) or (ii) above including, without limitation, upon the disability, long-term illness, retirement or early retirement of the option holder; and (iv) where the option holder is a service supplier, 30 days following the date on which such option holder ceases to act as such, for any cause or reason (each, an "Early Expiry Date").

The Stock Option Plan also provides that, if the expiry date of an option(s) (whether an Early Expiry Date or an Outside Expiry Date) occurs during a "blackout period" or within the seven business days immediately after a blackout period imposed by the Company, the expiry date will be automatically extended to the date that is seven business days after the last day of the blackout period. For the purposes of the foregoing, "blackout period" means the period during which trading in the Company's securities is restricted in accordance with its corporate policies.

Option holders may not assign their options (nor any interest therein) other than by will or in accordance with the applicable laws of estates and succession.

In the event that, at any time, an offer to purchase is made to holders of all our common shares, notice of such offer shall be given by the Company to each optionee and all unexercised options will become exercisable immediately at their respective exercise prices, but only to the extent necessary to enable optionees to tender their common shares in response to such offer.

The Stock Option Plan currently provides that the following amendments may be made to the plan upon approval of each of the Board and our shareholders as well as receipt of all required regulatory approvals:

- any amendment to Section 3.2 of the Stock Option Plan (which sets forth the limit on the number of options that may be granted to insiders) that would have the effect of permitting, without having to obtain shareholder approval on a "disinterested vote" at a duly convened shareholders' meeting, the grant of any option(s) under the Stock Option Plan otherwise prohibited by Section 3.2;
- any amendment to the number of securities issuable under the Stock Option Plan (except for certain permitted adjustments, such as in the case of stock splits, consolidations or reclassifications);
- any amendment which would permit any option granted under the Stock Option Plan to be transferable or assignable other than by will or in accordance with the applicable laws of estates and succession;
- the addition of a cashless exercise feature, payable in cash or securities, which does not provide for a full deduction of the number of underlying securities from the Stock Option Plan reserve;
- the addition of a deferred or restricted share unit component or any other provision which results in employees receiving securities while no cash consideration is received by the Company;
- with respect to any option holder whether or not such option holder is an "insider" and except in respect of certain permitted adjustments, such as in the case of stock splits, consolidations or reclassifications:
  - any reduction in the exercise price of any option after the option has been granted, or
  - any cancellation of an option and the re-grant of that option under different terms;
- any extension to the term of an option beyond its Outside Expiry Date to an option holder who is an "insider" (except for extensions made in the context of a "blackout period");

- any amendment to the method of determining the exercise price of an option granted pursuant to the Stock Option Plan;
- the addition of any form of financial assistance or any amendment to a financial assistance provision which is more favourable to employees; and
- any amendment to the foregoing amending provisions requiring Board, shareholder and regulatory approvals.

The Stock Option Plan further currently provides that the following amendments may be made to the Stock Option Plan upon approval of the Board and upon receipt of all required regulatory approvals, but without shareholder approval:

- amendments of a "housekeeping" or clerical nature or to clarify the provisions of the Stock Option Plan;
- amendments regarding any vesting period of an option;
- amendments regarding the extension of an option beyond an Early Expiry Date in respect of any option holder, or the extension of an option beyond the Outside Expiry Date in respect of any option holder who is a "non-insider" of the Company;
- adjustments to the number of issuable common shares underlying, or the exercise price of, outstanding options resulting from a split or a consolidation of the common shares, a reclassification, the payment of a stock dividend, the payment of a special cash or non-cash distribution to our shareholders on a pro rata basis provided such distribution is approved by our shareholders in accordance with applicable law, a recapitalization, a reorganization or any other event which necessitates an equitable adjustment to the outstanding options in proportion with corresponding adjustments made to all outstanding common shares;
- discontinuing or terminating the Stock Option Plan; and
- any other amendment which does not require shareholder approval under the terms of the Stock Option Plan.

On March 21, 2013, the Board of Directors approved, subject to obtaining shareholder approval, certain changes to the Stock Option Plan's amending provision that would have the effect of requiring shareholder approval of certain amendments to the plan or to options granted thereunder, in order to comply with good governance practices. The TSX has approved this amendment to the Stock Option Plan and shareholders will be asked at our Annual Meeting of Shareholders to adopt the Stock Option Renewal Resolution approving such changes.

The Board of Directors also approved, on March 21, 2013, amendments to the Stock Option Plan of a "housekeeping" or clerical nature, which amendments are not subject to shareholder approval, and which were approved by the TSX. The first of such amendments rectifies the wording of Section 3.2 of the Stock Option Plan, to the effect that the number of securities issuable to insiders, at any time, or issued within any one-year period, under all of the Company's security-based compensation arrangements, cannot exceed 10% of the Company's issued and outstanding securities (the previous wording of the provision stated that the number of securities issued to insiders, at any time, or issuable within any one-year period, under all of the Company's security-based compensation arrangements, could not exceed 10% of the Company's issued and outstanding securities).

The second amendment of a "housekeeping" or clerical nature clarifies Section 4.2 of the Stock Option Plan, to the effect that non-employee directors are eligible to receive a total of up to 60,000 stock options per year (the previous wording of the provision stated that directors were eligible to receive grants of up to 40,000 options upon or in connection with their election or appointment to the Board and were eligible to receive grants of up to 20,000 options for each and every year thereafter).

## Outstanding Option-Based Awards and Share-Based Awards

The following table shows all awards outstanding to the Named Executive Officers as of December 31, 2012:

Name	Option-based Awards					Share-based Awards		
	Issuance Date	Number of Securities Underlying Unexercised Options <sup>(1)</sup>	Option Exercise Price	Option Expiration Date	Value of Unexercised In-the-money Options <sup>(2)</sup>	Issuance Date	Number of Shares or Units of shares that have Not Vested	Market or Payout Value of Share-based Awards that have Not Vested
	(mm-dd-yyyy)	(#)	(CAN\$ or US\$)	(mm-dd-yyyy)	(CAN\$ or US\$)		(#)	(\$)
Engel, Juergen	12/11/2003	10,000	CAN\$10.44	12/10/2013	—	—	—	—
	12/14/2004	16,666	CAN\$34.98	12/13/2014	—	—	—	—
	12/13/2005	8,333	CAN\$21.18	12/12/2015	—	—	—	—
	01/04/2007	8,333	CAN\$27.90	01/03/2017	—	—	—	—
	12/11/2007	8,333	CAN\$10.92	12/10/2017	—	—	—	—
	11/14/2008	33,333	CAN\$3.90	11/13/2018	—	—	—	—
	12/08/2008	12,500	CAN\$3.30	12/08/2018	—	—	—	—
	12/09/2009	27,500	CAN\$5.70	12/08/2019	—	—	—	—
	12/08/2010	37,125	CAN\$9.12	12/07/2020	—	—	—	—
	12/07/2011	44,499	US\$10.44	12/06/2021	—	—	—	—
	12/06/2012	133,400	US\$2.17	12/05/2022	US\$28,014	—	—	—
Turpin, Dennis	12/11/2003	10,000	CAN\$10.44	12/10/2013	—	—	—	—
	12/14/2004	15,000	CAN\$34.98	12/13/2014	—	—	—	—
	12/13/2005	8,333	CAN\$21.18	12/12/2015	—	—	—	—
	01/04/2007	8,333	CAN\$27.90	01/03/2017	—	—	—	—
	12/11/2007	8,333	CAN\$10.92	12/10/2017	—	—	—	—
	12/09/2009	19,166	CAN\$5.70	12/08/2019	—	—	—	—
	12/08/2010	9,475	CAN\$9.12	12/07/2020	—	—	—	—
	12/07/2011	17,353	US\$10.44	12/06/2021	—	—	—	—
		12/06/2012	84,000	US\$2.17	12/05/2022	US\$17,640	—	—
Blake, Paul	07/27/2007	7,500	US\$18.30	07/26/2017	—	—	—	—
	12/11/2007	8,333	US\$10.92	12/10/2017	—	—	—	—
	12/08/2008	8,333	CAN\$3.30	12/08/2018	—	—	—	—
	12/09/2009	18,333	CAN\$5.70	12/08/2019	—	—	—	—
	12/08/2010	10,675	CAN\$9.12	12/07/2020	—	—	—	—
	12/07/2011	18,071	US\$10.44	12/06/2021	—	—	—	—
		12/06/2012	80,700	US\$2.17	12/05/2022	US\$16,947	—	—
Seeber, Matthias <sup>(3)</sup>	—	—	—	—	—	—	—	—
Pelliccione, Nicholas J.	05/07/2007	4,166	US\$23.76	05/06/2017	—	—	—	—
	12/11/2007	8,333	US\$10.92	12/10/2017	—	—	—	—
	12/08/2008	3,333	CAN\$3.30	12/08/2018	—	—	—	—
	12/09/2009	10,000	CAN\$5.70	12/08/2019	—	—	—	—
	12/08/2010	8,333	CAN\$9.12	12/07/2020	—	—	—	—
	12/07/2011	17,218	US\$10.44	12/06/2021	—	—	—	—
		12/06/2012	70,100	US\$2.17	12/05/2022	US\$14,721	—	—

(1) The number of securities underlying unexercised options represents all awards outstanding at December 31, 2012.

(2) "Value of unexercised in-the-money options" at financial year-end is calculated based on the difference between the closing prices of the common shares on the TSX or NASDAQ, as applicable, on the last trading day of the year (December 31, 2012) of CAN\$2.37 and US\$2.38, respectively, and the exercise price of the options, multiplied by the number of unexercised options.

(3) All stock options held by Mr. Seeber were forfeited on December 31, 2012 in connection with his voluntary departure from the Company.

## Incentive Plan Awards - Value Vested or Earned During the Year

The following table shows the incentive plan awards value vested or earned for each Named Executive Officer for the financial year ended December 31, 2012.

Name	Option-based awards - Value vested during the year <sup>(1)</sup>	Share-based awards - Value vested during the year	Non-equity incentive plan compensation - Value earned during the year
	(\$)	(\$)	(\$)
Engel, Juergen	—	—	—
Turpin, Dennis	—	—	—
Seeber, Matthias <sup>(2)</sup>	—	—	—
Blake, Paul	—	—	—
Pelliccione, Nicholas J.	—	—	—

(1) Represents the aggregate dollar value that would have been realized if the options had been exercised on the vesting date, based on the difference between the closing price of the common shares on the TSX or NASDAQ, as applicable, and the exercise price on such vesting date.

(2) All stock options held by Mr. Seeber were forfeited on December 31, 2012 in connection with his voluntary departure from the Company.

## Other Forms of Compensation

### Benefits and Perquisites

The Company's executive employee benefits program also includes life, medical, dental and disability insurance. Perquisites consist of a car allowance and human resources counselling. These benefits and perquisites are designed to be competitive overall with equivalent positions in comparable North American organizations in the life sciences industry.

### Pension Plan

Dr. Juergen Engel, the President and Chief Executive Officer, participates in a non-contributory defined benefit pension plan. Benefits payable under this plan correspond to 40% of the executive officer's average salary of the last twelve months before leaving the Company or reaching retirement age. This amount is unchanged during the first five working years of the executive officer and increases by 0.4% for each additional year of employment before the executive officer reaches the age of 65.

As the normal retirement age is 65 years, first payments under the pension plan were made to Dr. Engel as of September 1, 2010. The following table shows total annual pension benefits payable to Dr. Engel pursuant to this plan. Upon the death of a participant, the surviving spouse of the participant will be entitled to a benefit equal to 60% of the benefits to which such participant was entitled. All benefits payable under this plan are in addition to German governmental social security benefits.

### Defined Benefit Plans Table as at December 31, 2012

Name	Number of years of credited service (#)	Annual benefits payable		Accrued obligation at start of year (\$)	Compensatory change <sup>(1)</sup> (\$)	Non-compensatory change (\$)	Accrued obligation at year end <sup>(1)(2)</sup> (\$)
		At year end <sup>(1)</sup> (\$)	At age 65 <sup>(1)</sup> (\$)				
Engel, Juergen	34	206,089	202,755	3,569,399	818,155	58,676	4,240,141

(1) By way of exception to other currency conversions in this document, all amounts in the above table have been converted from euros to US\$ based on the exchange rate on December 31, 2012, which was €1.000 = US\$1.319.

(2) The figure in the column "Accrued obligation at year end" was further reduced by an amount of \$206,089 representing the amount of mandatory pension payments made to Dr. Engel during 2012.

All figures in the above table were calculated using the assumptions and methods used for financial statement reporting purposes under the accounting principles used to prepare the Company's financial statements filed with the Canadian securities regulatory authorities and available at [www.sedar.com](http://www.sedar.com) and furnished to the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov).

## Employer Contribution to Employees' Retirement Plan

In 2008, the Board approved a plan whereby the Company would contribute to its employees' retirement plans both in Canada (RRSP) and the United States (401(k)) to the extent of 50% of the employee's contribution up to a maximum of \$7,750 annually for Canadian employees under 50 years old and \$8,500 for those in the United States. The plan also includes a contribution for employees over 50 years old up to a maximum of \$10,250 for Canadian employees and \$11,250 for those in the United States. Employees based in Frankfurt, Germany also benefit from certain employer contributions into the employees' pension funds (DUPK/RUK). The Company's executive officers, including the Named Executive Officers, are eligible to participate in such employer-contribution plans to the same extent and in the same manner as all other employees of the Company.

## Summary Compensation Table

The Summary Compensation Table set forth below shows compensation information for the Named Executive Officers for services rendered in all capacities during each of the financial years ended December 31, 2012, 2011 and 2010.

### SUMMARY COMPENSATION TABLE

Name and principal position	Years	Salary (\$)	Share based awards (\$)	Option based awards <sup>(1)</sup> (\$)	Non-equity incentive plan compensation		Pension Value (\$)	All other compensation <sup>(2)</sup> (\$)	Total compensation (\$)
					Annual incentive plan (\$)	Long-term incentive plans (\$)			
Engel, Juergen President and CEO	2012	443,601 <sup>(3)</sup>	—	237,876	—	—	797,849	200,974 <sup>(4)</sup>	1,680,300
	2011	505,260	—	336,420	160,764	—	590,136	214,212 <sup>(4)</sup>	1,806,792
	2010	419,348	—	265,763	109,395	—	34,605	68,593 <sup>(5)</sup>	897,704
Turpin, Dennis Senior Vice President and CFO	2012	341,605	—	149,787	—	—	—	—	491,392
	2011	332,434	—	131,198	80,509	—	—	5,056 <sup>(6)</sup>	549,197
	2010	309,978	—	67,828	55,169	—	—	7,518 <sup>(6)</sup>	440,493
Seeber, Matthias Former Senior Vice President, Administration and Legal Affairs	2012	327,879	—	—	—	—	—	135,172 <sup>(7)</sup>	463,051
	2011	342,512	—	131,576	82,818	—	—	56,966 <sup>(8)</sup>	613,872
	2010	288,162	—	62,011	51,051	—	—	38,217 <sup>(8)</sup>	439,441
Blake, Paul Senior Vice President and Chief Medical Officer	2012	384,300	—	143,902	—	—	—	11,000 <sup>(9)</sup>	539,202
	2011	370,223	—	136,622	89,670	—	—	11,000 <sup>(9)</sup>	607,515
	2010	359,876	—	76,418	64,050	—	—	11,000 <sup>(9)</sup>	511,344
Pelliccione, Nicholas J. Senior Vice President Regulatory Affairs and Quality Assurance	2012	333,600	—	125,000	—	—	—	11,000 <sup>(9)</sup>	469,600
	2011	321,062	—	130,178	77,739	—	—	11,000 <sup>(9)</sup>	539,979
	2010	311,992	—	59,655	50,001	—	—	11,000 <sup>(9)</sup>	432,648

- (1) The value of option-based awards represents the closing price of the common shares on NASDAQ on the last trading day preceding the date of grant (US\$2.17 for options granted on December 6, 2012, US\$10.44 for options granted on December 7, 2011 and CAN\$9.12 equivalent to US\$8.82 for options granted on December 8, 2010) multiplied by the Black-Scholes factor as at such dates (82,174% for options granted on December 6, 2012, 72.414% for options granted on December 7, 2011 and 80.921% for options granted on December 8, 2010) and the number of stock options granted on such dates.
- (2) "All Other Compensation" represents perquisites and other personal benefits which, in the aggregate, amount to \$50,000 or more, or are equivalent to 10% or more of a Named Executive Officer's total salary for the financial year ended December 31, 2012. The type and amount of each perquisite, the value of which exceeds 25% of the total value of perquisites, is separately disclosed for each Named Executive Officer, if applicable. In the case of the President and CEO, "All Other Compensation" also includes mandatory pension payments paid to him commencing in 2010. See note (4) below.
- (3) In accordance with Dr. Engel's employment agreement, he was entitled to be paid a base salary in the amount of \$501,462 (converted from euros to US\$ based on an annual salary of €390,000) for 2012. However, Dr. Engel voluntarily offered to reduce his salary by an amount of \$57,861 in 2012.
- (4) Represents mandatory pension payments made to Dr. Engel in each of 2012 and 2011.
- (5) Represents DUPK/RUK (Germany) employer contributions to Dr. Engel's retirement savings plans from January 1, 2010 to August 31, 2010. The reported amount also includes \$67,169 in mandatory pension payments made to Dr. Engel after attaining age 65 commencing on September 1, 2010 for the remainder of 2010. See Section 6.5.2, "Pension Plan", above.
- (6) Represents RRSP employer contribution to Mr. Turpin's retirement savings plan.
- (7) Represents DUPK/RUK (Germany) employer contribution to Mr. Seeber's retirement savings plan. The reported amount also includes \$64,290 paid to Mr. Seeber upon his departure on December 31, 2012 in recognition of his contribution and service over the years with the Company.
- (8) Represents DUPK/RUK (Germany) employer contribution to Mr. Seeber's retirement savings plan.
- (9) Represents 401(k) employer contributions to Messrs. Blake's and Pelliccione's retirement savings plans.

## *Compensation of the Chief Executive Officer*

The compensation of the President and Chief Executive Officer is governed by the Company's executive compensation policy described in Section "Compensation of Executive Officers", and the President and Chief Executive Officer participates together with the other Named Executive Officers in all of the Company's incentive plans.

Dr. Engel's total earned salary for 2012 was \$443,601, which places him at approximately 10% below the 50<sup>th</sup> percentile in the Reference Group.

Based upon the results attained versus established goals for 2012, as described in Section "Short-Term Incentive Compensation", the Governance Committee determined that the individual performance of Dr. Engel surpassed expectations in a number of key strategic areas, including alliance management and business development with existing and potential partners and collaborators. See Section "Risk Assessment of Executive Compensation Program" above for more details on such goals.

The Governance Committee recommended, and the Board approved, in the best interests of the Company and considering its financial situation, that any bonus awarded to Dr. Engel in respect of the 2012 year be payable entirely in the form of stock options. Based on the foregoing, the Governance Committee determined that Dr. Engel's contributions to the achievement of the Company's goals merited an equity-based bonus in an amount of \$225,015, paid through the granting of 133,400 stock options, representing a non-cash bonus payout of 100% of his maximum bonus amount. The terms of such stock option grant provide for accelerated vesting conditions, in order to allow these stock options to serve their purpose as a replacement for the CEO's 2012 annual bonus that would otherwise have been paid in cash. See Section "Short-Term Incentive Compensation" above for more details on such grants.

For the financial year ended December 31, 2012, the Governance Committee recommended that no stock options be granted to the President and Chief Executive Officer under the long-term equity compensation plan. See Section "Long-Term Equity Compensation Plan of Executive Officers-Summary of the Stock Option Plan", for a complete description of the Stock Option Plan.

### **C. Board Practices**

Our Articles provide that our Board shall be composed of a minimum of five and a maximum of 15 directors. Directors are elected annually by our shareholders, but the directors may from time to time appoint one or more directors, provided that the total number of directors so appointed does not exceed one-third of the number of directors elected at the last annual meeting of shareholders. Each elected director will remain in office until termination of the next annual meeting of the shareholders or until his or her successor is duly elected or appointed, unless his or her post is vacated earlier. For information regarding Dr. Engel's employment agreement with the Company, which provides for benefits on termination of his employment, see "Item 10.C – Material Contracts". None of the other directors are party to any directors' service contracts with the Company providing for benefits on termination of employment.

### **Committees of the Board of Directors**

#### Audit Committee

Our Board has established an Audit Committee and a Governance Committee.

The Audit Committee assists the Board in fulfilling its oversight responsibilities. The Audit Committee reviews the financial reporting process, the system of internal control, the audit process, and the Company's process for monitoring compliance with laws and regulations and with our Code of Ethical Conduct. In performing its duties, the Audit Committee will maintain effective working relationships with the Board, management, and the external auditors. To effectively perform his or her role, each committee member will obtain an understanding of the detailed responsibilities of committee membership as well as the Company's business, operations and risks.

The function of the Audit Committee is oversight and while it has the responsibilities and powers set forth in its charter (incorporated by reference to Exhibit 11.2), it is neither the duty of the committee to plan or to conduct audits or to determine that the Company's financial statements are complete, accurate and in accordance with generally accepted accounting principles, nor to maintain internal controls and procedures.

The current members of the Audit Committee are Pierre Lapalme, Gérard Limoges and Michael Meyers.



## Governance Committee

The mandate of the Governance Committee provides that it is responsible for taking all reasonable measures to ensure that appropriate human resources systems and procedures, such as hiring policies, competency profiles, training policies and compensation structures are in place so that the Company can attract, motivate and retain the quality of personnel required to meet its business objectives.

The Governance Committee also assists the Board in discharging its responsibilities relating to executive and other human resources hiring, assessment, compensation and succession planning matters.

Thus, the Governance Committee recommends the appointment of senior officers, including the terms and conditions of their appointment and termination, and reviews the evaluation of the performance of our senior officers, including recommending their compensation and overseeing risk identification and management in relation to executive compensation policies and practices. The Board, which includes the members of the Governance Committee, reviews the Chief Executive Officer's corporate goals and objectives and evaluates his or her performance and compensation in light of such goals and objectives.

The current members of the Governance Committee are Juergen Ernst, José P. Dorais, Carolyn Egbert and Gérard Limoges.

### **D. Employees**

As at March 1, 2013, we had a total of 81 full time equivalents ("FTE") (as compared to 89 as at March 1, 2012 and 88 as at March 1, 2011), of which 66 are based in Frankfurt, Germany, 6 in New Jersey, United States, and 9 in Quebec City, Canada. Of these, 52 are involved in discovery, preclinical, clinical and pharmaceutical development, 8 are involved in regulatory affairs, quality assurance and intellectual property, and 21 are involved in business operations, communications, finance, information technology, human resources, project management and legal affairs. We have agreements with our employees covering confidentiality, loyalty, non-competition, and assignment to the Company of all intellectual property rights developed during the employment period.

### **E. Share ownership**

The information in the table below is provided as at December 31, 2012 and, to the Company's knowledge, no change occurred in such share ownership figures between December 31, 2012 and March 21, 2013:

Name	No. of common shares owned or held	Percent <sup>(1)</sup>	No. of stock options held <sup>(2)</sup>	No. of currently exercisable options
Marcel Aubut	18,750	*	44,165	26,945
Paul Blake	11,725	*	151,945	61,334
José P. Dorais	—	*	23,333	6,113
Carolyn Egbert	—	*	7,500	—
Juergen Engel	33,333	*	340,022	180,678
Juergen Ernst	9,808	*	55,831	38,611
Pierre Lapalme	—	*	26,666	9,446
Gérard Limoges	1,499	*	39,165	21,945
Nicholas J. Pelliccione	4,625	*	121,483	41,757
Dennis Turpin	3,541	*	179,993	86,322
Matthias Seeber <sup>(3)</sup>	—	*	—	—
<b>Total</b>	<b>83,281</b>	<b>0.33</b>	<b>990,103</b>	<b>473,151</b>

\* Less than 1%

(1) Based on 25,329,288 common shares outstanding as at March 21, 2013.

(2) For information regarding option expiration dates and exercise price refer to the tables included under Item 6.B.

(3) All stock options held by Mr. Seeber were forfeited on December 31, 2012 in connection with his voluntary departure from the Company.

**Item 7. Major Shareholders and Related Party Transactions****A. Major shareholders**

We are not directly or indirectly owned or controlled by another corporation or by any foreign government. Based on filings with the Securities and Exchange Commission and the Canadian securities regulatory authorities, as at March 21, 2013, set out below are the only persons/entities who beneficially owned, directly or indirectly, or exercised control or direction over our common shares carrying more than 5% of the voting rights attached to all our common shares. As used in the table below, "beneficial ownership" means sole or shared power to vote or direct the voting of the security, or the sole or shared investment power with respect to a security (i.e., the power to dispose, or direct a disposition, of a security). A person is deemed at any date to have "beneficial ownership" of any security that the person has a right to acquire within 60 days. More than one person may be deemed to have beneficial ownership of the same securities.

Name of Shareholder	Common Shares	Total Percentage of Voting Rights
1 Globe Capital LLC	1,796,433	7.09%

The shareholder named in the above table has identical voting rights to all other shareholders.

**United States Shareholders**

As at December 31, 2012, there were a total of 46 holders of record of our common shares, of which two were registered with addresses in the United States holding in the aggregate approximately 87.92% of our outstanding common shares. We believe that the number of beneficial owners of our common shares is substantially greater than the number of record holders, because the overwhelming majority of our common shares are held in broker "street names".

**B. Related party transactions**

None.

**C. Interests of experts and counsel**

Not applicable.

**Item 8. Financial Information****A. Consolidated statements and other financial information**

The financial statements filed as part of this annual report on Form 20-F are presented under "Item 18. – Financial Statements".

**B. Significant changes**

No significant changes occurred since the date of our annual consolidated financial statements included elsewhere in this annual report on Form 20-F.

**Item 9. The Offering and Listing****A. Offer and listing details**

Not Applicable, except for Item 9A(4).

Our common shares are listed and posted for trading on NASDAQ under the symbol "AEZS" and on the TSX under the symbol "AEZ". The following table indicates, for the relevant periods, the high and low closing prices of our common shares on NASDAQ and on the TSX:

	NASDAQ (US\$)		TSX (CAN\$)	
	High	Low	High	Low
2012	12.90	1.87	12.84	1.87
2011	15.48	8.58	15.06	8.46
2010	12.54	4.74	12.84	4.80
2009	16.98	2.76	18.66	3.42
2008	10.80	2.40	11.10	2.64
<b>2011</b>				
Fourth quarter	10.68	8.58	10.80	8.82
Third quarter	14.10	8.58	13.56	8.46
Second quarter	15.48	10.92	15.06	10.50
First quarter	11.98	9.30	11.58	9.24
<b>2012</b>				
Fourth quarter	4.12	1.87	4.08	1.87
Third quarter	5.06	2.35	5.04	2.34
Second quarter	4.80	2.29	4.80	2.40
First quarter	12.90	9.36	12.84	9.42
<b>Most recent 6 months</b>				
March 2013 <sup>(1)</sup>	2.62	1.91	2.67	1.95
February 2013	3.04	2.41	3.03	2.45
January 2013	3.23	2.53	3.27	2.48
December 2012	2.47	2.17	2.49	2.14
November 2012	2.32	1.87	2.29	1.87
October 2012	4.12	2.15	4.08	2.07
September 2012	5.06	2.90	5.04	2.82

(1) Up to and including March 19, 2013

**B. Plan of distribution**

Not applicable.

**C. Markets**

Our common shares are listed and posted for trading on NASDAQ under the symbol "AEZS" and on the TSX under the symbol "AEZ".

**D. Selling shareholders**

Not applicable.

**E. Dilution**

Not applicable.

**F. Expenses of the issuer**

Not applicable.

**Item 10. Additional Information**

**A. Share capital**

Not applicable.

**B. Memorandum and articles of association**

The Company is governed by its restated articles of incorporation (the "Restated Articles of Incorporation") under the CBCA and by articles of amendment dated October 2, 2012 (together with the Restated Articles of Incorporation, the "Articles") and by its bylaws (the "bylaws"). The Company's Articles are on file with the Corporations Directorate of Industry Canada under Corporation Number 264271-9. The Articles do not include a stated purpose and do not place any restrictions on the business that the Company may carry on.

**Inspection Rights of Shareholders**

Under the CBCA, shareholders are entitled to be provided with a copy of the list of registered shareholders of the Company. In order to obtain the shareholder list, the Company must be provided with an affidavit including, among other things, a statement that the list will only be used for the purposes permitted by the CBCA. These permitted purposes include an effort to influence the voting of shareholders of the Company, an offer to acquire securities of the Company and any other matter relating to the affairs of the Company. The Company is entitled to charge a reasonable fee for the provision of the shareholder list and must deliver that list no more than ten days after receipt of the affidavit described above.

Under the CBCA, shareholders have the right to inspect certain corporate records, including its Articles and bylaws and minutes of meetings and resolutions of the shareholders. Shareholders have no statutory right to inspect minutes of meetings and resolutions of directors of the Company. Shareholders of the Company have the right to certain financial information respecting the Company. In addition to the annual and quarterly financial statements required to be filed under applicable securities laws, under the CBCA the Company is required to place before every annual meeting of shareholders its audited comparative annual financial statements. In addition, shareholders have the right to examine the financial statements of each of our subsidiaries and any other corporate entity whose accounts are consolidated in the financial statements of the Company.

**Directors**

The minimum number of directors of the Company is five and the maximum number is 15. In accordance with the CBCA, a majority of its directors must be residents of Canada. In order to serve as a director, a person must be a natural person at least 18 years of age, of sound mind, not bankrupt, and must not be prohibited by any court from holding the office of director. None of the Articles, the bylaws and the CBCA imposes any mandatory retirement requirements for directors.

The directors are elected by a majority of the votes cast at the annual meeting at which an election of directors is required, to hold office until the election of their successors except in the case of resignations or if their offices become vacant by death or otherwise. Subject to the provisions of the Company's bylaws, all directors may, if still qualified to serve as directors, stand for re-election. The Board is not replaced at staggered intervals but is elected annually.

There is no provision in the Company's bylaws or its Articles that requires that a director of the Company must be a shareholder.

The directors are entitled to remuneration as shall from time to time be determined by the Board or by a committee to which the Board may delegate the power to do so. Under the mandate of the Company's Governance Committee, such committee, comprised of a majority of independent directors, is tasked with making recommendations to the Board concerning director remuneration.

The CBCA provides that a director who is a party to, or who is a director or officer of, or has a material interest in, any person who is a party to a material contract or transaction or proposed material contract or transaction with the Company must disclose to the Company the nature and extent of his or her interest at the time and in the manner provided by the CBCA, or request that same be entered in the minutes of the meetings of the Board, even if such contract, in connection with the normal business activity of the Company, does not require the approval of either the directors or the shareholders. At the request of the president

or any director, the director placed in a situation of conflict of interest must leave the meeting while the Board discusses the matter. The CBCA prohibits such a director from voting on any resolution to approve the contract or transaction unless the contract or transaction:

- relates primarily to his or her remuneration as a director, officer, employee or agent of the Company or an affiliate;
- is for indemnity or insurance for director's liability as permitted by the CBCA; or
- is with an affiliate of the Company.

The CBCA provides that the Board may, on behalf of the Company and without authorization of its shareholders:

- borrow money upon the credit of the Company;
- issue, reissue, sell or pledge debt obligations of the Company;
- give a guarantee on behalf of the Company to secure performance of an obligation of any person; and
- mortgage, hypothecate, pledge or otherwise create a security interest in all or any property of the Company, owned or subsequently acquired, to secure any obligation of the Company.

The shareholders have the ability to restrict such powers through the Company's Articles or bylaws (or through a unanimous shareholder agreement), but no such restrictions are in place.

The CBCA prohibits the giving of a guarantee to any shareholder, director, officer or employee of the Company or of an affiliated corporation or to an associate of any such person for any purpose or to any person for the purpose of or in connection with a purchase of a share issued or to be issued by the Company or its affiliates, where there are reasonable grounds for believing that the Company is or, after giving the guarantee, would be unable to pay its liabilities as they become due, or the realizable value of the Company's assets in the form of assets pledged or encumbered to secure a guarantee, after giving the guarantee, would be less than the aggregate of the Company's liabilities and stated capital of all classes. These borrowing powers may be varied by the Company's bylaws or its Articles. However, the Company's bylaws and Articles do not contain any restrictions on or variations of these borrowing powers.

Pursuant to the CBCA, the directors of the Company manage and administer the business and affairs of the Company and exercise all such powers and authority as the Company is authorized to exercise pursuant to the CBCA, the Articles and the bylaws. The general duties of a director or officer of the Company under the CBCA are to act honestly and in good faith with a view to the best interests of the Company and to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances. Any breach of these duties may lead to liability to the Company and its shareholders for breach of fiduciary duty. In addition, a breach of certain provisions of the CBCA, including the improper payment of dividends or the improper purchase or redemption of shares, will render the directors who authorized such action liable to account to the Company for any amounts improperly paid or distributed.

The Company's bylaws provide that the Board may, from time to time, appoint from amongst their number committees of the Board, and delegate to any such committee any of the powers of the Board except those which pursuant to the CBCA a committee of the Board has no authority to exercise. As such, the Board has two standing committees: the Audit Committee and the Governance Committee.

Subject to the limitations provided by the CBCA, the Company's bylaws provide that the Company shall, to the full extent provided by law, indemnify a director or an officer of the Company, a former director or officer of the Company or a person who acts or acted at the Company's request as a director or officer of a body corporate of which the Company is or was a shareholder or creditor, and his or her heirs and legal representatives, against all costs, losses, charges and expenses, including an amount paid to settle an action or satisfy a judgment, reasonably incurred by him or her in respect of any civil, criminal or administrative action or proceeding to which he or she is made a party by reason of having been a director or officer of the Company or such body corporate, provided:

- (a) he or she acted in good faith in the best interests of the Company; and
- (b) in the case of a criminal or an administrative action or proceeding that is enforced by a monetary penalty, he or she had reasonable grounds to believe that his or her conduct was lawful.

The directors of the Company are authorized to indemnify from time to time any director or other person who has assumed or is about to assume in the normal course of business any liability for the Company or for any corporation controlled by the Company, and to secure such director or other person against any loss by the pledge of all or part of the movable or immovable property of the Company through the creation of a hypothec or any other real right in all or part of such property or in any other manner.

## **Share Capitalization**

Our authorized share capital structure consists of an unlimited number of shares of the following classes (all classes are without nominal or par value): common shares; and first preferred shares (the "First Preferred Shares") and second preferred shares (the "Second Preferred Shares" and, together with the First Preferred Shares, the "Preferred Shares"), both issuable in series. As at March 21, 2013, there were 25,329,288 common shares outstanding. No Preferred Shares of the Company have been issued to date. The Company has also issued warrants to acquire common shares in connection with certain equity financings.

### **Common Shares**

The holders of the common shares are entitled to one vote for each common share held by them at all meetings of shareholders, except meetings at which only shareholders of a specified class of shares are entitled to vote. In addition, the holders are entitled to receive dividends if, as and when declared by the Company's Board of Directors on the common shares. Finally, the holders of the common shares are entitled to receive the remaining property of the Company upon any liquidation, dissolution or winding-up of the affairs of the Company, whether voluntary or involuntary. Shareholders have no liability to further capital calls as all shares issued and outstanding are fully paid and non-assessable.

### **Preferred Shares**

The First and Second Preferred Shares are issuable in series with rights and privileges specific to each class. The holders of Preferred Shares are generally not entitled to receive notice of or to attend or vote at meetings of shareholders. The holders of First Preferred Shares are entitled to preference and priority to any participation of holders of Second Preferred Shares, common shares or shares of any other class of shares of the share capital of the Company ranking junior to the First Preferred Shares with respect to dividends and, in the event of the liquidation of the Company, the distribution of its property upon its dissolution or winding-up, or the distribution of all or part of its assets among the shareholders, to an amount equal to the value of the consideration paid in respect of such shares outstanding, as credited to the issued and paid-up share capital of the Company, on an equal basis, in proportion to the amount of their respective claims in regard to such shares held by them. The holders of Second Preferred Shares are entitled to preference and priority to any participation of holders of common shares or shares of any other class of shares of the share capital of the Company ranking junior to the Second Preferred Shares with respect to dividends and, in the event of the liquidation of the Company, the distribution of its property upon its dissolution or winding-up, or the distribution of all or part of its assets among the shareholders, to an amount equal to the value of the consideration paid in respect of such shares outstanding, as credited to the issued and paid-up share capital of the Company, on an equal basis, in proportion to the amount of their respective claims in regard to such shares held by them.

Our Board of Directors may, from time to time, provide for additional series of Preferred Shares to be created and issued, but the issuance of any Preferred Shares is subject to the general duties of the directors under the CBCA to act honestly and in good faith with a view to the best interests of the Company and to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

### **Shareholder Actions**

The CBCA provides that shareholders of the Company may, with leave of a court, bring an action in the name of and on behalf of the Company for the purpose of prosecuting, defending or discontinuing an action on behalf of the Company. In order to grant leave to permit such an action, the CBCA provides that the court must be satisfied that the directors of the Company were given adequate notice of the application, the shareholder is acting in good faith and that it appears to be in the Company's best interests that the action be brought.

### **Shareholder Rights Plan**

The Company's Board of Directors adopted a shareholder rights plan on March 23, 2010, which was initially confirmed and ratified by the Company's shareholders on May 13, 2010 (the "Rights Plan").

Under the terms of the Rights Plan, its continued existence must be reconfirmed by the Company's shareholders at the Company's annual meeting of shareholders to be held on May 8, 2013 (the "Meeting"). If not reconfirmed, the Rights Plan and the rights issued thereunder will terminate at the close of the Meeting, unless earlier terminated.

#### *Objectives and Background of the Shareholder Rights Plan*

The fundamental objectives of the Rights Plan are to provide adequate time for our Board and shareholders to assess an unsolicited take-over bid for the Company, to provide the Board with sufficient time to explore and develop alternatives for maximizing shareholder value if a take-over bid is made, and to provide shareholders with an equal opportunity to participate in a take-over bid.

The Rights Plan encourages a potential acquiror who makes a take-over bid to proceed either by way of a "Permitted Bid", as described below, which requires a take-over bid to satisfy certain minimum standards designed to promote fairness, or with the concurrence of our Board. If a take-over bid fails to meet these minimum standards and the Rights Plan is not waived by the Board, the Rights Plan provides that holders of common shares, other than the acquiror, will be able to purchase additional common shares at a significant discount to market, thus exposing the person acquiring common shares to substantial dilution of its holdings.

#### *Summary of the Rights Plan*

The following is a summary of the principal terms of the Rights Plan, which summary is qualified in its entirety by reference to the terms thereof. Capitalized terms not otherwise defined in this summary shall have the meaning ascribed to such terms in the Shareholder Rights Plan Agreement which sets forth the Rights Plan. The Rights Plan is filed as an exhibit to this annual report on Form 20-F.

#### *Operation of the Rights Plan*

Pursuant to the terms of the Rights Plan, one right was issued in respect of each common share outstanding at 5:01 p.m. on March 29, 2010 (the "Effective Date"). In addition, one right will be issued for each additional common share issued after the Record Time and prior to the earlier of the Separation Time (as defined below) and the Expiration Time (as defined below). The rights have an initial exercise price equal to the Market Price (as defined below) of the common shares as determined at the Separation Time, multiplied by five, subject to certain anti-dilution adjustments (the "Exercise Price"), and they are not exercisable until the Separation Time. Upon the occurrence of a Flip-in Event, each right will entitle the holder thereof, other than an Acquiring Person or any other person whose rights are or become void pursuant to the provisions of the Rights Plan, to purchase from the Company, effective at the close of business on the eighth trading day after the Stock Acquisition Date, upon payment to the Company of the Exercise Price, common shares having an aggregate Market Price equal to twice the Exercise Price on the date of consummation or occurrence of such Flip-in Event, subject to certain anti-dilution adjustments.

#### *Definition of Market Price*

Market Price is generally defined in the Rights Plan, on any given day on which a determination must be made, as the volume weighted average trading price of the common shares for the five consecutive trading days (i.e. days on which the TSX is open for the transaction of business, subject to certain exceptions), through and including the trading day immediately preceding such date of determination, subject to certain exceptions.

#### *Trading of Rights*

Until the Separation Time (or the earlier termination or expiration of the rights), the rights trade together with the common shares and are represented by the same share certificates as the common shares or an entry in the Company's securities register in respect of any outstanding common shares. From and after the Separation Time and prior to the Expiration Time, the rights are evidenced by rights certificates and trade separately from the common shares. The rights do not carry any of the rights attaching to the common shares such as voting or dividend rights.

#### *Separation Time*

The rights will separate from the common shares to which they are attached and become exercisable at the time (the "Separation Time") of the close of business on the eighth business day after the earliest to occur of:

1. the first date (the "Stock Acquisition Date") of a public announcement of facts indicating that a person has become an Acquiring Person; and
2. the date of the commencement of, or first public announcement of the intention of any person (other than the Company or any of its subsidiaries) to commence a take-over bid or a share exchange bid for more than 20% of the outstanding common shares of the Company other than a Permitted Bid or a Competing Permitted Bid (as defined below), so long as such take-over bid continues to satisfy the requirements of a Permitted Bid or a Competing Permitted Bid), as the case may be.

The Separation Time can also be such later time as may from time to time be determined by the Board, provided that if any such take-over bid expires, or is cancelled, terminated or otherwise withdrawn prior to the Separation Time, without securities deposited thereunder being taken up and paid for, it shall be deemed never to have been made and if the Board determines to waive the application of the Rights Plan to a Flip-in Event, the Separation Time in respect of such Flip-in Event shall be deemed never to have occurred.

From and after the Separation Time and prior to the Expiration Time, each right entitles the holder thereof to purchase one common share upon payment to the Company of the Exercise Price.

#### *Flip-in Event*

The acquisition by a person (an "Acquiring Person"), including others acting jointly or in concert with such person, of more than 20% of the outstanding common shares, other than by way of a Permitted Bid, a Competing Permitted Bid or in certain other limited circumstances described in the Rights Plan, is referred to as a "Flip-in Event".

In the event that, prior to the Expiration Time, a Flip-in Event which has not been waived occurs (see "Waiver and Redemption" below), each right (other than those held by or deemed to be held by the Acquiring Person) will thereafter entitle the holder thereof, effective as at the close of business on the eighth trading day after the Stock Acquisition Date, to purchase from the Company, upon payment of the Exercise Price and otherwise exercising such right in accordance with the terms of the Rights Plan, that number of common shares having an aggregate Market Price on the date of consummation or occurrence of the Flip-in Event equal to twice the Exercise Price, for an amount in cash equal to the Exercise Price (subject to certain anti-dilution adjustments described in the Rights Plan).

A bidder may enter into Lock-up Agreements with the Company's shareholders ("Locked-up Persons") who are not affiliates or associates of the bidder and who are not, other than by virtue of entering into such agreement, acting jointly or in concert with the bidder, whereby such shareholders agree to tender their common shares to the take-over bid (the "Lock-up Bid") without the bidder being deemed to beneficially own the common shares deposited pursuant to the Lock-up Bid. Any such agreement must include a provision that permits the Locked-up Person to withdraw the common shares to tender to another take-over bid or to support another transaction that will either provide greater consideration to the shareholder than the Lock-up Bid or provide for a right to sell a greater number of shares than the Lock-up Bid contemplates (provided that the Lock-up Agreement may require that such greater number exceed the number of shares under the Locked-up Bid by a specified percentage not to exceed 7%).

The Lock-up Agreement may require that the consideration under the other transaction exceed the consideration under the Lock-up Bid by a specified amount. The specified amount may not be greater than 7%. For greater certainty, a Lock-up Agreement may contain a right of first refusal or require a period of delay (or other similar limitation) to give a bidder an opportunity to match a higher price in another transaction as long as the limitation does not preclude the exercise by the Locked-up Person of the right to withdraw the common shares during the period of the other take-over bid or transaction.

The Rights Plan requires that any Lock-up Agreement be made available to the Company and the public. The definition of Lock-up Agreement also provides that under a Lock-up Agreement, no "break up" fees, "topping" fees, penalties, expenses or other amounts that exceed in aggregate the greater of (i) 21/2% of the price or value of the aggregate consideration payable under the Lock-up Bid, and (ii) 50% of the amount by which the price or value of the consideration received by a Locked-up Person under another take-over bid or transaction exceeds what such Locked-up Person would have received under the Lock-up Bid, can be payable by such Locked-up Person if the Locked-up Person fails to deposit or tender common shares to the Lock-up Bid or withdraws common shares previously tendered thereto in order to deposit such common shares to another take-over bid or support another transaction.

#### *Permitted Bid Requirements*

The requirements of a Permitted Bid include the following:

1. the take-over bid must be made by means of a take-over bid circular;
2. the take-over bid must be made to all holders of common shares wherever resident, on identical terms and conditions, other than the bidder;
3. the take-over bid must not permit common shares tendered pursuant to the bid to be taken up or paid for:
  - a) prior to the close of business on a date which is not less than 60 days following the date of the bid, and
  - b) then only if at such date more than 50% of the then outstanding common shares held by shareholders other than any other Acquiring Person, the bidder, the bidder's affiliates or associates, persons acting jointly or in concert with the bidder and any employee benefit plan, deferred profit-sharing plan, stock participation plan or trust for the benefit of employees of the Company or any of its subsidiaries, unless the beneficiaries of such plan or trust direct the manner in which the common shares are to be voted or direct whether the common shares are to be tendered to a take-over bid (the "Independent Shareholders"), have been deposited or tendered to the take-over bid and not withdrawn;



4. the take-over bid must allow common shares to be deposited, unless the take-over bid is withdrawn, at any time up to the close of business on the date that the common shares are to be first taken up and paid for;
5. the take-over bid must allow common shares to be withdrawn until taken up and paid for; and
6. if more than 50% of the then outstanding common shares held by Independent Shareholders are deposited or tendered to the take-over bid within the 60-day period and not withdrawn, the bidder must make a public announcement of that fact and the take-over bid must remain open for deposits and tenders of common shares for not less than ten days from the date of such public announcement.

A Permitted Bid need not be a bid for all outstanding common shares not held by the bidder, i.e., a Permitted Bid may be a partial bid. The Rights Plan also allows a competing Permitted Bid (a "Competing Permitted Bid") to be made while a Permitted Bid is in existence. A Competing Permitted Bid must satisfy all the requirements of a Permitted Bid other than the requirement set out in clause 3(a) above and must not permit common shares tendered or deposited pursuant to the bid to be taken up or paid for prior to the close of business on a date which is earlier than 35 days (or such longer minimum period of days that the bid must be open for acceptance after the date of the bid under applicable Canadian provincial securities legislation) and the 60th day after the earliest date on which any other Permitted Bid or Competing Permitted Bid that is then in existence was made.

#### *Waiver and Redemption*

The Board may, prior to the occurrence of a Flip-in Event, waive the dilutive effects of the Rights Plan in respect of, among other things, a particular Flip-in Event resulting from a take-over bid made by way of a take-over bid circular to all holders of common shares of the Company. In such an event, such waiver shall also be deemed to be a waiver in respect of any other Flip-in Event occurring under a take-over bid made by way of a take-over bid circular to all holders of common shares prior to the expiry of the first mentioned take-over bid.

The Board may, with the approval of a majority of Independent Shareholders (or, after the Separation Time has occurred, holders of rights, other than rights which are void pursuant to the provisions of the Rights Plan or which, prior to the Separation Time, are held otherwise than by Independent Shareholders), at any time prior to the occurrence of a Flip-in Event which has not been waived, elect to redeem all, but not less than all, of the then outstanding rights at a price of \$0.00001 each, appropriately adjusted as provided in the Rights Plan (the "Redemption Price").

Where a take-over bid that is not a Permitted Bid or Competing Permitted Bid is withdrawn or otherwise terminated after the Separation Time has occurred and prior to the occurrence of a Flip-in Event, the Board may elect to redeem all the outstanding rights at the Redemption Price without the consent of the holders of the common shares or the rights and reissue rights under the Rights Plan to holders of record of common shares immediately following such redemption. Upon the rights being so redeemed and reissued, all the provisions of the Rights Plan will continue to apply as if the Separation Time had not occurred, and the Separation Time will be deemed not to have occurred and the Company shall be deemed to have issued replacement rights to the holders of its then outstanding common shares.

#### *Amendment to the Rights Plan*

The Rights Plan may be amended to correct any clerical or typographical error or to make such changes as are required to maintain the validity of the Rights Plan as a result of any change in any applicable legislation, regulations or rules thereunder, without the approval of the holders of the common shares or rights. Prior to the Separation Time, the Company may, with the prior consent of the holders of common shares, amend, vary or delete any of the provisions of the Rights Plan in order to effect any changes which the Board, acting in good faith, considers necessary or desirable. The Company may, with the prior consent of the holders of rights, at any time after the Separation Time and before the Expiration Time, amend, vary or delete any of the provisions of the Rights Plan.

#### *Protection Against Dilution*

The Exercise Price, the number and nature of securities which may be purchased upon the exercise of rights and the number of rights outstanding are subject to adjustment from time to time to prevent dilution in the event of stock dividends, subdivisions, consolidations, reclassifications or other changes in the outstanding common shares, *pro rata* distributions to holders of common shares and other circumstances where adjustments are required to appropriately protect the interests of the holders of rights.

### *Fiduciary Duty of Board*

The Rights Plan will not detract from or lessen the duty of the Board to act honestly and in good faith with a view to the best interests of the Company and its shareholders. The Board will continue to have the duty and power to take such actions and make such recommendations to the Company's shareholders as are considered appropriate.

### *Exemptions for Investment Advisors*

Fund managers, investment advisors (for fully-managed accounts), trust companies (acting in their capacities as trustees and administrators), statutory bodies whose business includes the management of funds, and administrators of registered pension plans are exempt from triggering a Flip-in Event, provided that they are not making, or are not part of a group making, a take-over bid.

### *Term*

The Rights Plan will expire (the "Expiration Time") on the earlier of the first annual meeting of shareholders of the Company following March 29, 2016, being the sixth anniversary of the Effective Date and the time at which the right to exercise rights shall terminate pursuant to the provisions of the Rights Plan pertaining to the redemption of rights and the waiver of the application of the Rights Plan, after which time it will automatically terminate. The Rights Plan will also expire if the Company's shareholders do not confirm and ratify it at the Company's annual meeting of shareholders to be held on May 8, 2013.

### **Action Necessary to Change Rights of Shareholders**

In order to change the rights of its shareholders, the Company would need to amend its Articles to effect the change. Such an amendment would require the approval of holders of two-thirds of the issued and outstanding shares cast at a duly called special meeting. For certain amendments such as those creating a class of Preferred Shares, a shareholder is entitled under the CBCA to dissent in respect of such a resolution amending the Articles and, if the resolution is adopted and the Company implements such changes, demand payment of the fair value of its shares.

### **Disclosure of Share Ownership**

In general, under applicable securities regulation in Canada, a person or company who beneficially owns, or who directly or indirectly exercises control or direction over voting securities of a reporting issuer, voting securities of an issuer or a combination of both, carrying more than ten percent of the voting rights attached to all the issuer's outstanding voting securities is an insider and must, within ten days of becoming an insider, file a report in the required form effective the date on which the person became an insider, disclosing any direct or indirect beneficial ownership of, or control or direction over, securities of the reporting issuer.

Additionally, securities regulation in Canada provides for the filing of a report by an insider of a reporting issuer whose holdings change, which report must be filed within five days from the day on which the change takes place.

Section 13 of the *United States Securities Exchange Act of 1934* (the "Exchange Act") imposes reporting requirements on persons who acquire beneficial ownership (as such term is defined in the Rule 13d-3 under the Exchange Act) of more than five percent of a class of an equity security registered under Section 12 of the Exchange Act. The Company's common shares are so registered. In general, such persons must file, within ten days after such acquisition, a report of beneficial ownership with the SEC containing the information prescribed by the regulations under Section 13 of the Exchange Act. This information is also required to be sent to the issuer of the securities and to each exchange where the securities are traded.

### **Meeting of Shareholders**

An annual meeting of shareholders is held each year for the purpose of considering the financial statements and reports, electing directors, appointing auditors and fixing or authorizing the Board to fix their remuneration and for the transaction of other business as may properly come before a meeting of shareholders. Any annual meeting may also constitute a special meeting to take cognizance and dispose of any matter of which a special meeting may take cognizance and dispose. Under the bylaws, the Chief Executive Officer or the President of the Company has the power to call a meeting of shareholders.

The CBCA provides that the holders of not less than 5% of the outstanding voting shares of the Company may requisition the directors of the Company to call a meeting of shareholders for the purpose stated in the requisition. Except in limited circumstances, including where a meeting of shareholders has already been called and a notice of meeting already given or where it is clear that the primary purpose of the requisition is to redress a personal grievance against the Company or its directors, officers or shareholders, the directors of the Company, on receipt of such requisition, must call a meeting of

shareholders. If the directors fail to call a meeting of shareholders within twenty-one days after receiving the requisition, any shareholder who signed the requisition may call the meeting of shareholders and, unless the shareholders resolve otherwise at the meeting, the Company shall reimburse the shareholders for the expenses reasonably incurred by them in requisitioning, calling and holding the meeting of shareholders.

The CBCA also provides that, except in limited circumstances, a resolution in writing signed by all of the shareholders entitled to vote on that resolution at a meeting of shareholders is as valid as if it had been passed at a meeting of shareholders.

A quorum of shareholders is present at an annual or special meeting of shareholders, regardless of the number of persons present in person at the meeting, if the holder(s) of shares representing at least 10% of the outstanding voting shares at such meeting are present in person or represented in accordance with the Company's bylaws. In the case where the CBCA, the Articles or the bylaws of the Company require or permit the vote by class of holders of a given class of shares of the share capital of the Company, the quorum at any meeting will be one or more persons representing 10% of the outstanding shares of such class.

Notice of the time and place of each annual or special meeting of shareholders must be given not less than 21 days, nor more than 50 days, before the date of each meeting to each director, to the auditor and to each shareholder entitled to vote thereat. If the address of any shareholder, director or auditor does not appear in the books of the Company, the notice may be sent to such address as the person sending the notice may consider to be most likely to reach such shareholder, director or auditor promptly. Every person who, by operation of the CBCA, transfers or by any other means whatsoever, becomes entitled to any share, shall be bound by every notice given in respect of such share which, prior to the entry of his or her name and address on the register of the Company, is given to the person whose name appears on the register at the time such notice is sent. Notice of meeting of shareholders called for any other purpose other than consideration of the financial statements and auditor's report, election of directors and reappointment of the incumbent auditor, must state the nature of the business in sufficient detail to permit the shareholder to form a reasoned judgment on and must state the text of any special resolution or bylaw to be submitted to the meeting.

On March 21, 2013, the Board of Directors approved an amendment to the Company's bylaws in order to include an advance notice provision (the "Advance Notice Requirement") and concurrently approved an amendment to and restatement of the Company's bylaws giving effect to the Advance Notice Requirement (the "Amended and Restated Bylaws"). The Advance Notice Requirement applies in certain circumstances where nominations of persons for election to the Board of Directors are made by shareholders of the Company other than pursuant to: (a) a requisition of a meeting made pursuant to the provisions of the CBCA; or (b) a shareholder proposal made pursuant to the provisions of the CBCA.

Among other things, the Advance Notice Requirement fixes a deadline by which shareholders must submit a notice of director nominations to the Company prior to any annual or special meeting of shareholders where directors are to be elected and sets forth the information that a shareholder must include in the notice for it to be valid. In the case of an annual meeting of shareholders, notice to the Company must be given not less than 30 nor more than 65 days prior to the date of the annual meeting; provided, however, that in the event that the annual meeting is to be held on a date that is less than 50 days after the date on which the first public announcement of the date of the annual meeting was made, notice may be made not later than the close of business on the 10<sup>th</sup> day following such public announcement. In the case of a special meeting of shareholders (which is not also an annual meeting), notice to the Company must be given not later than the close of business on the 15<sup>th</sup> day following the day on which the first public announcement of the date of the special meeting was made.

The Board of Directors may, in its sole discretion, waive any requirement of the Advance Notice Requirement.

### **Limitations on Right to Own Securities**

Neither Canadian law nor the Company's Restated Articles of Incorporation or bylaws limit the right of a non-resident to hold or vote common shares, other than as provided in the *Investment Canada Act* (the "Investment Act"). The Investment Act prohibits implementation of certain direct reviewable investments by an individual, government or agency thereof, corporation, partnership, trust or joint venture that is not a "Canadian", as defined in the Investment Act (a "non-Canadian"), unless, after review, the minister responsible for the Investment Act is satisfied or is deemed to be satisfied that the investment is likely to be of net benefit to Canada. An investment in the common shares of the Company by a non-Canadian (other than a "WTO Investor", as defined below) would be reviewable under the Investment Act if it were an investment to acquire direct control of the Company, and the book value of the assets of the Company were CAN\$5 million or more (provided that immediately prior to the implementation of the investment the Company was not controlled by WTO Investors). Subject to the Amendments (as defined below), an investment in common shares of the Company by a WTO Investor would be reviewable under the Investment Act if it were an investment to acquire direct control of the Company and the value of the assets of the Company equalled or exceeded CAN\$344 million (for 2013). A non-Canadian, whether a WTO Investor or otherwise, would be deemed to acquire control of the Company for purposes of the Investment Act if he or she acquired a majority of the common shares of

the Company. The acquisition of less than a majority, but at least one-third of the shares, would be presumed to be an acquisition of control of the Company, unless it could be established that the Company was not controlled in fact by the acquirer through the ownership of the shares. In general, an individual is a WTO Investor if he or she is a "national" of a country (other than Canada) that is a member of the World Trade Organization ("WTO Member") or has a right of permanent residence in a WTO Member. A corporation or other entity will be a "WTO Investor" if it is a "WTO Investor-controlled entity", pursuant to detailed rules set out in the Investment Act. The United States is a WTO Member. Certain transactions involving the common shares would be exempt from the Investment Act, including: (a) an acquisition of the shares if the acquisition were made in the ordinary course of that person's business as a trader or dealer in securities; (b) an acquisition of control of the Company in connection with the realization of a security interest granted for a loan or other financial assistance and not for any purpose related to the provisions of the Investment Act; and (c) an acquisition of control of the Company by reason of an amalgamation, merger, consolidation or corporate reorganization, following which the ultimate direct or indirect control in fact of the Company, through the ownership of voting interests, remains unchanged.

The Canadian Federal Government adopted certain amendments (the "Amendments") to the Investment Act in 2009. Some of the Amendments, which came into force on February 6, 2009, introduce a national security test and review process, authorizing the Canadian Minister of Industry to review investments that "could be injurious to national security", regardless of the size of the transaction. Some of the other Amendments will come into force on a day to be fixed by order of the Canadian Governor in Council, including the increase to the thresholds that trigger governmental review for WTO Investors. Therefore, the thresholds for the review of direct acquisitions of control by WTO Investors would increase from the current CAN\$344 million (based on book value) to CAN\$600 million (to be based on the "enterprise value" of the Canadian business) for the two years after such Amendments come into force, to CAN\$800 million in the following two years and then to CAN\$1 billion for the next two years. Thereafter, the thresholds are to be adjusted to account for inflation. A number of the Amendments still require additional definition and details, which will be set forth in regulations promulgated under the Investment Act.

There are no limits on the rights of non-Canadians to exercise voting rights on their common shares of the Company.

### **C. *Material contracts***

Other than as disclosed herein under "Shareholder Rights Plan" and below, and except for contracts entered into in the ordinary course of business, there are no material contracts to which the Company or any of its subsidiaries is a party.

### **Employment Agreements**

The Company and/or its subsidiaries have entered into employment agreements (the "Employment Agreements") with each of the Named Executive Officers. The Employment Agreements provide that we will pay the Named Executive Officers a base salary and an annual bonus and that such executives will be eligible to receive long-term incentive grants in the form of stock options which will be reviewed annually in accordance with our policies. Annual bonuses are paid in either cash, stock options or a combination thereof. The Employment Agreements have an indefinite term. However, in addition to his Employment Agreement, Dr. Engel had previously entered into a service contract in his prior capacity as Managing Director with AEZS GmbH, our Company's principal operating subsidiary, which service contract has an indefinite term. Each of the Employment Agreements provides that, if we terminate the employment of a Named Executive Officer without cause, then the executive will be entitled to receive, in the case of Dr. Engel, a lump-sum payment, less statutory deductions, of the equivalent of 24 months of his then applicable base salary, an amount equivalent to twice the annual bonus received for the most recently completed year and an amount equivalent to twelve months of the cost of the other benefits to which he is entitled. In the case of Mr. Turpin, the lump-sum payment will be equivalent to 18 months of his then applicable base salary, 1.5 times the annual bonus of the preceding year and 18 months of the value of the other benefits to which he is entitled. In the case of Dr. Blake and Dr. Pelliccione, they are entitled to receive, upon termination of employment without cause, a lump-sum payment equivalent to twelve months of their then applicable base salaries, an amount equivalent to the annual bonus received for the preceding year and twelve months of the value of the other benefits to which they are entitled.

Furthermore, each of Messrs. Turpin, Blake and Pelliccione shall not, for a period equal to one year following such executive's termination of employment with the Company, directly or indirectly, compete with the Company; solicit any of the Company's customers; permit the use of his name in order to solicit said clients or do anything whatsoever to induce or to lead any person to decide to put an end, in whole or in part, to their business relations with the Company; induce, attempt to induce or otherwise solicit the personnel of the Company to leave their employment with the Company or hire the personnel of the Company for any enterprise in which the executive has an interest.

Matthias Seeber voluntarily left the Company effective December 31, 2012 and, consequently, he was not entitled to any form of termination benefit upon his departure, although he did receive payment of an amount of \$64,290 in recognition of his contribution and service over the years with the Company. All stock options held by Mr. Seeber were forfeited on

December 31, 2012 in connection with his voluntary departure from the Company. See Section "Summary Compensation Table", for more information on Mr. Seeber's compensation for the year ended December 31, 2012.

Pursuant to the Employment Agreements, each of the Named Executive Officers is also entitled to certain payments (the "Change of Control Payments") in the event (i) a "Change of Control" occurs and (ii) during the twelve-month period following the Change of Control, either the Company terminates the employment of the executive "without Cause" or if the executive terminates his or her employment "for Good Reason".

The Change of Control Payments are as follows:

- for Dr. Engel, (i) the equivalent of 24 months of his then prevailing annual base salary, (ii) an amount equivalent to twice the annual bonus, if any, which he would have been entitled to receive in the year during which the Change of Control occurred, and (iii) an amount equivalent to 24 months of the value of the benefits which were in force at the time of termination of his employment, calculated on a yearly basis, including car allowance, but excluding operating costs;
- for Mr. Turpin, the Change of Control Payment would be the same as in the context of a termination of employment described above, except that the 1.5 multiple of his bonus payment would be based on his potential bonus for the year in which the Change of Control occurs as opposed to his actual bonus received for the preceding financial year; and
- for Dr. Blake and Dr. Pelliccione (i) the equivalent of 18 months of their then prevailing annual base salaries, (ii) an amount equivalent to 1.5 times the annual bonus, if any, which the executive would have been entitled to receive in the year during which the Change of Control occurred, and (iii) an amount equivalent to 18 months of the value of the benefits which were in force at the time of termination of the executive's employment, calculated on a yearly basis, including car allowance, but excluding operating costs.

All Change of Control Payments described above are subject to applicable statutory withholdings. In addition, any outstanding stock options held by a Named Executive Officer are unaffected by the change of control provisions included in the Employment Agreements and, in the event of a Change of Control followed by termination of employment within twelve months, such stock options will be treated in accordance with the applicable provisions of the Stock Option Plan described elsewhere in this annual report on Form 20-F.

For the purposes of the Employment Agreements (including the annexes and schedules thereto):

- a "Change of Control" shall be deemed to have occurred in any of the following circumstances: (i) subject to certain exceptions, upon the acquisition by a person (or one or more persons who are affiliates of one another or who are acting jointly or in concert) of a beneficial interest in securities of the Company representing in any circumstance 50% or more of the voting rights attaching to the then outstanding securities of the Company; (ii) upon a sale or other disposition of all or substantially all of the Company's assets; (iii) upon a plan of liquidation or dissolution of the Company; or (iv) if, for any reason, including an amalgamation, merger or consolidation of the Company with or into another company, the individuals who, as at the date of the relevant Employment Agreement, constituted the Board (and any new directors whose appointment by the Board or whose nomination for election by the Company's shareholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors as at the date of the relevant Employment Agreement or whose appointment or nomination for election was previously so approved) cease to constitute a majority of the members of the Board;
- termination of employment by the Company "for Cause" includes (but is not limited to) (i) if the executive commits any fraud, theft, embezzlement or other criminal act of a similar nature, and (ii) if the executive is guilty of serious misconduct or willful negligence in the performance of his duties; and
- termination of employment by the executive officer for "Good Reason" means the occurrence, without the executive's express written consent, of any of the following acts: (i) a material reduction of the executive's total compensation (including annual base salary plus annual bonus, benefits and number of stock options) as in effect on the date of the relevant Employment Agreement or as same may be increased from time to time; (ii) a material reduction or change in the executive's duties, authority, responsibilities, accountability or a change in the business or corporate structure of the Company which materially affects his or her authority, compensation or ability to perform duties or responsibilities (such as shifting from a policy-making to a policy-implementation position); (iii) a forced relocation; or (iv) a material change in the terms and conditions of the change of control provisions included in the relevant Employment Agreement.

## Other Material Contracts

### Cetrotide®

In November 2008, we signed a definitive agreement to sell to HRP our rights to royalties on future sales of Cetrotide® covered by our license agreement with Merck Serono. This license agreement was signed in 2000 and amended in 2003 and granted Merck Serono exclusive rights to market, distribute and sell Cetrotide® worldwide, with the exception of Japan, in the field of *in vitro* fertilization. On closing, we received \$52.5 million from HRP (less transaction costs of \$1.0 million) and, upon net sales of Cetrotide® having reached a specified level in 2010, we received an additional payment of \$2.5 million from HRP in February 2011. Under the terms of the agreement, if cetrorelix is approved for sale by the European regulatory authorities in an indication other than *in vitro* fertilization, we have agreed to make a one-time cash payment to HRP in an amount ranging from \$5 million up to \$15 million.

### D. Exchange controls

Canada has no system of exchange controls. There are no exchange restrictions on borrowing from foreign countries or on the remittance of dividends, interest, royalties and similar payments, management fees, loan repayments, settlement of trade debts or the repatriation of capital.

### E. Taxation

THE FOLLOWING SUMMARY IS OF A GENERAL NATURE ONLY AND IS NOT INTENDED TO BE, NOR SHOULD IT BE CONSTRUED TO BE, LEGAL OR TAX ADVICE TO ANY PARTICULAR HOLDER. CONSEQUENTLY, HOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS FOR ADVICE AS TO THE TAX CONSEQUENCES OF AN INVESTMENT IN THE COMMON SHARES HAVING REGARD TO THEIR PARTICULAR CIRCUMSTANCES.

#### Material Canadian Income Tax Considerations

The following summary describes the principal Canadian federal income tax considerations to a holder who acquires common shares (a "holder") and who, for the purposes of the Canadian federal Income Tax Act, R.S.C. 1985, as amended (the "Tax Act"), and at all relevant times, deals at arm's length with, and is not affiliated with, the Company and holds their common shares as capital property. Common shares will generally be considered to be capital property to a holder for purposes of the Tax Act unless either the holder holds such common shares in the course of carrying on a business of trading or dealing in securities, or the holder has held or acquired such common shares in a transaction or transactions considered to be an adventure in the nature of trade.

This summary is not applicable to a holder (i) that is a "financial institution", as defined in the Tax Act for purposes of the mark-to-market rules, (ii), that is a "specified financial institution", as defined in the Tax Act, (iii) an interest in which would be a "tax shelter investment" as defined in the Tax Act, or (iv) that has made a functional currency reporting election for purposes of the Tax Act. Such holders should consult their own tax advisors.

Additional considerations, not discussed herein, may be applicable to a holder that is a corporation resident in Canada, and is, or becomes, controlled by a non-resident corporation for the purposes of the "foreign affiliate dumping" rules in section 212.3 of the Tax Act. Such holders should consult their tax advisors with respect to the consequences of acquiring common shares.

This summary is based upon the current provisions of the Tax Act and the regulations promulgated thereunder (the "Regulations") and the Company's understanding of the current published administrative policies and assessing practices of the Canada Revenue Agency ("CRA"). It also takes into account all proposed amendments to the Tax Act and the Regulations publicly released by the Minister of Finance (Canada) prior to the date hereof ("Tax Proposals"), and assumes that all such Tax Proposals will be enacted as currently proposed. No assurance can be given that the Tax Proposals will be enacted in the form proposed or at all. This summary does not otherwise take into account or anticipate any changes in law or administrative or assessing practice or policy of the CRA, whether by legislative, regulatory, judicial or administrative action or interpretation, nor does it address any provincial, local, territorial or foreign tax considerations.

#### Holders Not Resident in Canada

The following discussion applies to a holder of common shares who, at all relevant times, for purposes of the Tax Act, is neither resident nor deemed to be resident in Canada and does not, and is not deemed to, use or hold common shares in carrying on a business or part of a business in Canada (a "Non-Resident holder"). In addition, this discussion does not apply to an insurer who carries on an insurance business in Canada and elsewhere or to an authorized foreign bank (as defined in the Tax

Act).

## Disposition of Common Shares

A Non-Resident holder generally will not be subject to tax under the Tax Act in respect of any capital gain realized by such Non-Resident holder on a disposition or deemed disposition of common shares unless such shares constitute "taxable Canadian property" (as defined in the Tax Act) of the Non-Resident holder at the time of disposition and the gain is not exempt from tax pursuant to the terms of an applicable income tax treaty or convention.

As long as the common shares are listed on a designated stock exchange (which currently includes NASDAQ and the TSX) at the time of their disposition, the common shares generally will not constitute taxable Canadian property of a Non-Resident holder, unless at any time during the 60-month period immediately preceding the disposition: (i) the Non-Resident holder, persons with whom the Non-Resident holder did not deal at arm's length, or the Non-Resident holder together with all such persons, owned 25% or more of the issued shares of any class or series of shares of the corporation; and (ii) more than 50% of the fair market value of the shares of the corporation was derived directly or indirectly from one or any combination of real or immovable property situated in Canada, "Canadian resource properties" (as defined in the Tax Act), "timber resource properties" (as defined in the Tax Act) or options in respect of, or interests in, or for civil law rights in, such property whether or not such property exists.

A Non-Resident holder's capital gain (or capital loss) in respect of common shares that constitute or are deemed to constitute taxable Canadian property (and are not "treaty-protected property" as defined for purposes of the Tax Act) will generally be computed in the manner described below under the heading "*Holders Resident in Canada - Disposition of Common Shares*".

If the common shares were to cease being listed on NASDAQ, the TSX or another "recognized stock exchange", a Non-Resident holder who disposes of common shares that are taxable Canadian property may be required to fulfill the requirements of section 116 of the Tax Act.

Non-Resident holders whose common shares are taxable Canadian property should consult their own tax advisors.

## Taxation of Dividends on Common Shares

Dividends paid or credited or deemed to be paid or credited to a Non-Resident holder by the corporation are subject to Canadian withholding tax at the rate of 25% unless reduced by the terms of an applicable tax treaty or convention.

Under the Canada - United States Tax Convention (1980) (the "Convention") as amended, the rate of withholding tax on dividends paid or credited to a Non-Resident holder who is the beneficial owner of the dividends, is resident in the U.S. for purposes of the Convention and entitled to the benefits of the Convention (a "U.S. holder") is generally limited to 15% of the gross amount of the dividend (or 5% in the case of a U.S. holder that is a company beneficially owning at least 10% of the corporation's voting shares). Non-Resident holders should consult their own tax advisors.

## Holders Resident in Canada

The following discussion applies to a holder of common shares who, at all relevant times, for purposes of the Tax Act, is or is deemed to be resident in Canada (a "Canadian holder"). Certain Canadian holders whose common shares might not otherwise qualify as capital property may, in certain circumstances, treat the common shares and every other "Canadian security" (as defined in the Tax Act) owned by the Canadian holder as capital property by making an irrevocable election provided by subsection 39(4) of the Tax Act.

## Taxation of Dividends on Common Shares

Dividends received or deemed to have been received on the common shares will be included in a Canadian holder's income for purposes of the Tax Act. Such dividends received or deemed to have been received by a Canadian holder that is an individual (other than certain trusts) will be subject to the gross-up and dividend tax credit rules generally applicable under the Tax Act in respect of dividends received on shares of taxable Canadian corporations. Generally, a dividend will be eligible for the enhanced gross-up and dividend tax credit if the corporation designates the dividend as an "eligible dividend" (within the meaning of the Tax Act) in accordance with the provisions of the Tax Act. There may be limitations on the ability of the Company to designate dividends as eligible dividends. A Canadian holder that is a corporation will be required to include such dividends in computing its income and will generally be entitled to deduct the amount of such dividends in computing its taxable income. A Canadian holder that is a "private corporation" or a "subject corporation" (as such terms are defined in the Tax Act), may be liable under Part IV of the Tax Act to pay a refundable tax of 33 1/3% on dividends received or deemed to have been received on the common shares to the extent such dividends are deductible in computing the holder's taxable income.



## Disposition of Common Shares

A disposition, or a deemed disposition, of a common share by a Canadian holder will generally give rise to a capital gain (or a capital loss) equal to the amount by which the proceeds of disposition of the share, net of any reasonable costs of disposition, exceed (or are less than) the adjusted cost base of the share to the holder. Such capital gain (or capital loss) will be subject to the treatment described below under "Taxation of Capital Gains and Capital Losses".

## Additional Refundable Tax

A Canadian holder that is a "Canadian-controlled private corporation" (as such term is defined in the Tax Act) may be liable to pay an additional refundable tax of 6 2/3% on certain investment income including amounts in respect of "Taxable Capital Gains", as defined below.

## Taxation of Capital Gains and Capital Losses

In general, one half of any capital gain (a "Taxable Capital Gain") realized by a Canadian holder in a taxation year will be included in the holder's income in the year. Subject to and in accordance with the provisions of the Tax Act, one half of any capital loss (an "Allowable Capital Loss") realized by a Canadian holder in a taxation year must be deducted from Taxable Capital Gains realized by the holder in the year and Allowable Capital Losses in excess of Taxable Capital Gains may be carried back and deducted in any of the three preceding taxation years or carried forward and deducted in any subsequent taxation year against net Taxable Capital Gains realized in such years. The amount of any capital loss realized by a Canadian holder that is a corporation on the disposition or deemed disposition of a common share may be reduced by the amount of dividends received or deemed to have been received by it on such common share (or on a share for which the common share has been substituted) to the extent and under the circumstances prescribed by the Tax Act. Similar rules may apply where a corporation is a member of a partnership or a beneficiary of a trust that owns common shares, directly or indirectly, through a partnership or a trust.

## Alternative Minimum Tax

A Taxable Capital Gain realized and taxable dividends received or deemed to have been received by a Canadian holder who is an individual (including a trust, other than certain specified trusts) may give rise to liability for alternative minimum tax.

## Certain Material U.S. Federal Income Tax Considerations

The following discussion is a summary of certain material U.S. federal income tax consequences applicable to the ownership and disposition of common shares by a U.S. Holder (as defined below), but does not purport to be a complete analysis of all potential U.S. federal income tax effects. This summary is based on the Internal Revenue Code of 1986, as amended (the "Code"), U.S. Treasury regulations promulgated thereunder, IRS rulings and judicial decisions in effect on the date hereof. All of these are subject to change, possibly with retroactive effect, or different interpretations. This summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation that, if enacted, could be applied on a retroactive basis. This summary is not binding on the IRS, and the IRS is not precluded from taking a position that is different from, and contrary to, the positions taken in this summary.

This summary does not address all aspects of U.S. federal income taxation that may be relevant to particular U.S. Holders in light of their specific circumstances (for example, U.S. Holders subject to the alternative minimum tax or Medicare contribution tax provisions of the Code) or to holders that may be subject to special rules under U.S. federal income tax law, including:

- dealers in stocks, securities or currencies;
- securities traders that use a mark-to-market accounting method;
- banks and financial institutions;
- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- tax-exempt organizations;
- retirement plans, individual plans, individual retirement accounts and tax-deferred accounts;



- partnerships or other pass-through entities for U.S. federal income tax purposes and their partners or members;
- persons holding common shares as part of a hedging or conversion transaction straddle or other integrated or risk reduction transaction;
- persons who or that are, or may become, subject to the expatriation provisions of the Code;
- persons whose functional currency is not the U.S. dollar; and
- direct, indirect or constructive owners of 10% or more of the total combined voting power of all classes of our voting stock.

This summary also does not address the tax consequences of holding, exercising or disposing of warrants in the Company. If the Company is a PFIC, as described below, U.S. Holders of its warrants will be subject to adverse tax rules and will not be able to make the mark-to-market or the QEF election described below with respect to such warrants. U.S. Holders of warrants should consult their tax advisors with regard to the U.S. federal income tax consequences of holding, exercising or disposing of warrants in the Company, including in the situation in which the Company is classified as a PFIC.

This summary also does not discuss any aspect of state, local or foreign law, or estate or gift tax law as applicable to U.S. Holders. In addition, this discussion is limited to U.S. Holders holding common shares as capital assets. For purposes of this summary, "U.S. Holder" means a beneficial holder of common shares who or that for U.S. federal income tax purposes is:

- an individual citizen or resident of the United States;
- a corporation or other entity classified as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (a) a court within the United States is able to exercise primary supervision over the administration of such trust and one or more "U.S. persons" (within the meaning of the Code) have the authority to control all substantial decisions of the trust, or (b) a valid election is in effect to be treated as a U.S. person for U.S. federal income tax purposes.

If a partnership or other entity or arrangement classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner generally will depend on the status of the partner and the activities of the partnership. This summary does not address the tax consequences to any such partner. Such a partner should consult its own tax advisor as to the tax consequences of the partnership owning and disposing of common shares.

**U.S. HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH REGARD TO THE APPLICATION OF THE TAX CONSEQUENCES DESCRIBED BELOW TO THEIR PARTICULAR SITUATIONS AS WELL AS THE APPLICATION OF ANY STATE, LOCAL, FOREIGN OR OTHER TAX LAWS, INCLUDING GIFT AND ESTATE TAX LAWS.**

### ***Dividends***

Subject to the PFIC rules discussed below, any distributions paid by the Company out of current or accumulated earnings and profits (as determined for U.S. federal income tax purposes), before reduction for any Canadian withholding tax paid with respect thereto, will generally be taxable to a U.S. Holder as foreign source dividend income, and will not be eligible for the dividends received deduction generally allowed to corporations. Distributions in excess of current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in the common shares and thereafter as capital gain. U.S. Holders should consult their own tax advisors with respect to the appropriate U.S. federal income tax treatment of any distribution received from the Company.

Dividends paid by the Company should be taxable to a non-corporate U.S. Holder at the special reduced rates normally applicable to long-term capital gains, provided that certain conditions are satisfied. A U.S. Holder will not be able to claim a reduced rate if the Company is treated as a PFIC for the taxable year in which the dividend is paid or the preceding year. See "Passive Foreign Investment Company Considerations" below.

Under current law, payments of dividends by the Company to non-Canadian investors are generally subject to a 25% Canadian withholding tax. The rate of withholding tax applicable to U.S. Holders that are eligible for benefits under the Canada-United States Tax Convention (the "Convention") is reduced to a maximum of 15%. This reduced rate of withholding will not apply if the dividends received by a U.S. Holder are effectively connected with a permanent establishment of the U.S. Holder in Canada. For U.S. federal income tax purposes, U.S. Holders will be treated as having received the amount of Canadian taxes

withheld by the Company, and as then having paid over the withheld taxes to the Canadian taxing authorities. As a result of this rule, the amount of dividend income included in gross income for U.S. federal income tax purposes by a U.S. Holder with respect to a payment of dividends may be greater than the amount of cash actually received (or receivable) by the U.S. Holder from the Company with respect to the payment.

Subject to certain limitations, a U.S. Holder will generally be entitled, at the election of the U.S. Holder, to a credit against its U.S. federal income tax liability, or a deduction in computing its U.S. federal taxable income, for Canadian income taxes withheld by the Company. This election is made on a year-by-year basis and applies to all foreign taxes paid (whether directly or through withholding) by a U.S. Holder during a year. For purposes of the foreign tax credit limitation, dividends paid by the Company generally will constitute foreign source income in the "passive category income" basket. The foreign tax credit rules are complex and prospective purchasers should consult their tax advisors concerning the availability of the foreign tax credit in their particular circumstances.

Dividends paid in Canadian dollars will be included in the gross income of a U.S. Holder in a U.S. dollar amount calculated by reference to the exchange rate in effect on the date the U.S. Holder (actually or constructively) receives the dividend, regardless of whether such Canadian dollars are actually converted into U.S. dollars at that time. If the Canadian dollars received are not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a tax basis in the Canadian dollars equal to their U.S. dollar value on the date of receipt. Gain or loss, if any, realized on a sale or other disposition of the Canadian dollars will generally be U.S. source ordinary income or loss to a U.S. Holder.

The Company generally does not pay any dividends and does not anticipate paying any dividends in the foreseeable future.

#### *Sale, Exchange or Other Taxable Disposition of Common Shares*

Subject to the PFIC rules discussed below, upon a sale, exchange or other taxable disposition of common shares, a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference, if any, between the amount realized on the sale, exchange or other taxable disposition and the U.S. Holder's adjusted tax basis in the common shares.

This capital gain or loss will be long-term capital gain or loss if the U.S. Holder's holding period in the common shares exceeds one year. The deductibility of capital losses is subject to limitations. Any gain or loss will generally be U.S. source for U.S. foreign tax credit purposes.

#### *Passive Foreign Investment Company Considerations*

A foreign corporation will be classified as a PFIC for any taxable year in which, after taking into account the income and assets of the corporation and certain subsidiaries pursuant to applicable "look-through rules", either (i) at least 75% of its gross income is "passive income" or (ii) at least 50% of the average value of its assets is attributable to assets which produce passive income or are held for the production of passive income. Passive income generally includes dividends, interest, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income.

The Company believes it was not a PFIC for the 2012 taxable year. However, the fair market value of the Company's assets may be determined in large part by the market price of the common shares, which is likely to fluctuate, and the composition of the Company's income and assets will be affected by how, and how quickly, the Company spends any cash that is raised in any financing transaction. Thus, no assurance can be provided that the Company will not be classified as a PFIC for the 2013 taxable year and for any future taxable year. U.S. Holders should consult their tax advisors regarding the Company's PFIC status.

If the Company is classified as a PFIC for any taxable year during which a U.S. Holder owns common shares, the U.S. Holder, absent certain elections (including the mark-to-market election described below), will generally be subject to adverse rules (regardless of whether the Company continues to be classified as a PFIC) with respect to (i) any "excess distributions" (generally, any distributions received by the U.S. Holder on the common shares in a taxable year that are greater than 125% of the average annual distributions received by the U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period for the common shares) and (ii) any gain realized on the sale or other disposition of the common shares.

Under these adverse rules (a) the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period, (b) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which the Company is

classified as a PFIC will be taxed as ordinary income, and (c) the amount allocated to each of the other taxable years during which the Company was classified as a PFIC will be subject to tax at the highest rate of tax in effect for the applicable category of taxpayer for that year and an interest charge will be imposed with respect to the resulting tax attributable to each such other taxable year. A U.S. Holder that is not a corporation will be required to treat any such interest paid as "personal interest", which is not deductible.

U.S. Holders can avoid the adverse rules described above in part by making a mark-to-market election with respect to the common shares, provided that the common shares are "marketable". The common shares will be marketable if they are "regularly traded" on a "qualified exchange" or other market within the meaning of applicable U.S. Treasury regulations. For this purpose, the common shares generally will be considered to be regularly traded during any calendar year during which they are traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. The common shares are currently listed on NASDAQ, which constitutes a qualified exchange; however, there can be no assurance that the common shares will be treated as regularly traded for purposes of the mark-to-market election on a qualified exchange. If the common shares were not regularly traded on NASDAQ or were delisted from NASDAQ and were not traded on another qualified exchange for the requisite time period described above, the mark-to-market election would not be available.

A U.S. Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year an amount equal to the excess, if any, of the fair market value of the U.S. Holder's common shares at the close of the taxable year over the U.S. Holder's adjusted tax basis in the common shares. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted tax basis in the common shares over the fair market value of the common shares at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains previously included in income. A U.S. Holder that makes a mark-to-market election generally will adjust such U.S. Holder's tax basis in the common shares to reflect the amount included in gross income or allowed as a deduction because of such mark-to-market election. Gains from an actual sale or other disposition of the common shares will be treated as ordinary income, and any losses incurred on a sale or other disposition of the common shares will be treated as ordinary losses to the extent of any net mark-to-market gains previously included in income.

If the Company is classified as a PFIC for any taxable year in which a U.S. Holder owns common shares but before a mark-to-market election is made, the adverse PFIC rules described above will apply to any mark-to-market gain recognized in the year the election is made. Otherwise, a mark-to-market election will be effective for the taxable year for which the election is made and all subsequent taxable years. The election cannot be revoked without the consent of the IRS unless the common shares cease to be marketable, in which case the election is automatically terminated.

If the Company is classified as a PFIC, a U.S. Holder of common shares will generally be treated as owning stock owned by the Company in any direct or indirect subsidiaries that are also PFICs and will be subject to similar adverse rules with respect to distributions to the Company by, and dispositions by the Company of, the stock of such subsidiaries. A mark-to-market election is not permitted for the shares of any subsidiary of the Company that is also classified as a PFIC. U.S. Holders should consult their tax advisors regarding the availability of, and procedure for making, a mark-to-market election.

In some cases, a shareholder of a PFIC can avoid the interest charge and the other adverse PFIC consequences described above by making a QEF election to be taxed currently on its share of the PFIC's undistributed income. The Company does not, however, expect to provide the information regarding its income that would be necessary in order for a U.S. Holder to make a QEF election with respect to common shares if the Company is classified as a PFIC.

If the Company is classified as a PFIC and then ceases to be so classified, a U.S. Holder may make an election (a "deemed sale election") to be treated for U.S. federal income tax purposes as having sold such U.S. Holder's common shares on the last day of the taxable year of the Company during which it was a PFIC. A U.S. Holder that made a deemed sale election would then cease to be treated as owning stock in a PFIC by reason of ownership of common shares in the Company. However, gain recognized as a result of making the deemed sale election would be subject to the adverse rules described above and loss would not be recognized.

If the Company is a PFIC in any year with respect to a U.S. Holder, the U.S. Holder will be required to file an annual information return on IRS Form 8621 regarding distributions received on common shares and any gain realized on the disposition of common shares.

In addition, under U.S. tax legislation and subject to future guidance, if the Company is a PFIC, U.S. Holders will be required to file an annual information return with the IRS (also on IRS Form 8621, which PFIC shareholders will be required to file with their U.S. federal income tax or information returns) relating to their ownership of common shares. Pursuant to IRS Notice 2011-55, the IRS has suspended this new filing requirement for U.S. Holders that are not otherwise required to file the current version of the IRS Form 8621 until the IRS releases a subsequent revision of IRS Form 8621, modified to reflect the U.S. tax legislation. Guidance has not yet been issued regarding the information required to be included on such form.

This new filing requirement is in addition to the pre-existing reporting requirements described above that apply to a U.S. Holder's interest in a PFIC (which the recently enacted tax legislation and IRS Notice 2011-55 do not affect).

U.S. Holders should consult their tax advisors regarding the potential application of the PFIC regime and any reporting obligations to which they may be subject under that regime.

#### *Information Reporting and Backup Withholding*

Payments made within the United States, or by a U.S. payor or U.S. middleman, of dividends on, and proceeds arising from sales or other dispositions of common shares, generally will be reported to the IRS and to the U.S. Holder as required under applicable regulations. Backup withholding tax may apply to these payments if the U.S. Holder fails to timely provide in the appropriate manner an accurate taxpayer identification number or otherwise fails to comply with, or establish an exemption from, such backup withholding tax requirements. Certain U.S. Holders are not subject to the information reporting or backup withholding tax requirements described herein. U.S. Holders should consult their tax advisors as to their qualification for exemption from backup withholding tax and the procedure for establishing an exemption.

Backup withholding tax is not an additional tax. U.S. Holders generally will be allowed a refund or credit against their U.S. federal income tax liability for amounts withheld, provided the required information is timely furnished to the IRS.

Subject to certain exceptions and future guidance, U.S. tax legislation generally requires a U.S. Holder that is a specified individual or, to the extent provided in recently proposed and temporary U.S. Treasury regulations, a domestic entity, to report annually to the IRS on IRS Form 8938 such U.S. Holder's interests in stock or securities issued by a non-U.S. person (such as the Company). Pursuant to IRS Notice 2013-10, reporting under this legislation will not be required by domestic entities any earlier than taxable years beginning after December 31, 2012. U.S. Holders should consult their tax advisors regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of common shares.

#### **F. Dividends and paying agents**

Not applicable.

#### **G. Statement by experts**

Not applicable.

#### **H. Documents on display**

In addition to placing our audited comparative annual financial statements before every annual meeting of shareholders as described above, we are subject to the information requirements of the Securities Exchange Act of 1934, as amended. In accordance with these requirements, we file and furnish reports and other information with the SEC. These materials, including this annual report on Form 20-F and the exhibits thereto, may be inspected and copied at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. The public may obtain information on the operation of the SEC's Public Reference Room by calling the SEC in the United States at 1-800-SEC-0330. The SEC also maintains a website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy statements and other information regarding registrants that file electronically with the SEC. The Company's annual reports and some of the other information submitted by the Company to the SEC may be accessed through this website. In addition, material filed by the Company can be inspected on the Canadian Securities Administrators' electronic filing system, SEDAR, accessible at the website [www.sedar.com](http://www.sedar.com). This material includes the Company's Management Information Circular for its annual meeting to be held on May 8, 2013 to be furnished to the SEC on Form 6-K, which provides information including directors' and officers' remuneration and indebtedness and principal holders of securities. Additional financial information is provided in our audited annual financial statements for the year ended December 31, 2012 and our MD&A relating to these statements included elsewhere in this annual report on Form 20-F. These documents are also accessible on SEDAR ([www.sedar.com](http://www.sedar.com)) and on EDGAR ([www.sec.gov](http://www.sec.gov)).

#### **I. Subsidiary information**

The subsidiaries of the Company are set forth under "Item 4C. – Organizational Structure".

## Item 11. Quantitative and Qualitative Disclosures About Market Risk

We have not entered into any forward currency contracts or other financial derivatives to hedge foreign exchange risk. We are therefore subject to foreign currency transaction and translation gains and losses.

### Fair value

The Company classifies its financial instruments in the following categories: "Financial assets at fair value through profit or loss ("FVTPL")"; "Loans and receivables"; "Financial liabilities at FVTPL"; and "Other financial liabilities".

- The Company's loans and receivables are comprised of cash and cash equivalents, trade and other receivables and restricted cash.
- Financial liabilities at FVTPL are currently comprised of the Company's warrant liability.
- Other financial liabilities include trade accounts payable and accrued liabilities, long-term payable and other long-term liabilities.

The carrying values of all of the aforementioned financial instruments, excluding cash and cash equivalents, restricted cash and warrant liability which are stated at fair value, approximate their fair values due to their short-term maturity or to the prevailing interest rates of these instruments, which are comparable to those of the market.

### Financial risk factors

The following provides disclosures relating to the nature and extent of the Company's exposure to risks arising from financial instruments, including credit risk, liquidity risk and market risk (share price risk and currency risk), and how the Company manages those risks.

#### (a) Credit risk

Credit risk is the risk of an unexpected loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. The Company regularly monitors credit risk exposure and takes steps to mitigate the likelihood of this exposure resulting in losses. The Company's exposure to credit risk currently relates to cash and cash equivalents, to trade and other receivables and to restricted cash. The Company invests its available cash in amounts that are readily convertible to known amounts of cash and deposits its cash balances with financial institutions that are rated the equivalent of "A3" and above. This information is supplied by independent rating agencies where available and, if not available, the Company uses publicly available financial information to ensure it invests its cash in creditworthy and reputable financial institutions.

As at December 31, 2012, trade accounts receivable for an amount of approximately \$7.3 million were with two external customers or partners.

As at December 31, 2012, no trade accounts receivable were past due or impaired.

Generally, the Company does not require collateral or other security from customers for trade accounts receivable; however, credit is extended following an evaluation of creditworthiness. In addition, the Company performs ongoing credit reviews of all its customers and establishes an allowance for doubtful accounts when accounts are determined to be uncollectible.

The maximum exposure to credit risk approximates the amount recognized on the statement of financial position.

#### Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they become due. As indicated in the capital disclosures section (see "Item 5 – Operating and Financial Review and Prospects") the Company manages this risk through the management of its capital structure. It also manages liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors reviews and approves the Company's operating and capital budgets, as well as any material transactions out of the ordinary course of business. The Company has adopted an investment policy in respect of the safety and preservation of its capital to ensure the Company's liquidity needs are met. The instruments are selected with regard to the expected timing of expenditures and prevailing interest rates.

(b) *Market risk*

*Share price risk*

The change in fair value of our warrant liability, which is measured at FVTPL, results from the periodic "mark-to-market" revaluation, via the application of the Black-Scholes option pricing model, of currently outstanding share purchase warrants. The Black-Scholes valuation is impacted, among other inputs, by the market price of our common shares. As a result, the change in fair value of the warrant liability, which is reported as finance income (costs) in the accompanying interim consolidated statements of comprehensive income (loss), has been and may continue in future periods to be materially affected most notably by changes in our common share price, which has ranged from \$1.87 to \$12.90 on NASDAQ during the year ended December 31, 2012.

If variations in the market price of our common shares of -10% and +10% were to occur, the impact on our net (loss) income for warrant liability held at December 31, 2012 would be as follows:

	<b>Carrying amount</b>	<b>-10%</b>	<b>+10%</b>
	\$	\$	\$
Warrant liability	6,176	768	(783)
<b>Total impact on net loss – decrease/(increase)</b>		<b>768</b>	<b>(783)</b>

*Foreign currency risk*

Since we operate internationally, we are exposed to currency risks as a result of potential exchange rate fluctuations related to non-intragroup transactions. In particular, fluctuations in the U.S. and CA dollar exchange rates against the euro could have a potentially significant impact on our results of operations.

If foreign exchange rate variations of -5%<sup>(1)</sup> (depreciation of the EUR) and +5%<sup>(1)</sup> (appreciation of the EUR) against the US\$ and the CA\$, from period-end rates of EUR1 = US\$1.3185 and of EUR1=CA\$1.3118 were to occur, the impact on our net (loss) income for each category of financial instruments held at December 31, 2012 would be as follows:

	<b>Carrying amount</b>	<b>Balances denominated in US\$</b>	
	\$	-5%	+5%
	\$	\$	\$
Cash and cash equivalents	24,551	1,228	(1,228)
Warrant liability	6,176	(309)	309
<b>Total impact on net loss – decrease/(increase)</b>		<b>919</b>	<b>(919)</b>

	<b>Carrying amount</b>	<b>Balances denominated in CA\$</b>	
	\$	-5%	+5%
	\$	\$	\$
Cash and cash equivalents	7,064	353	(353)
<b>Total impact on net loss – decrease/(increase)</b>		<b>353</b>	<b>(353)</b>

(1) Hypothetical change based on historical quarterly closing rates analysis.

**Item 12. Description of Securities Other than Equity Securities**

**A. Debt securities**

Not applicable.

**B. Warrants and rights**

Not applicable.

**C. Other securities**

Not applicable.

**D. American depositary shares**

Not applicable.

## PART II

### Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

### Item 14. Material Modification to the Rights of Security Holders and Use of Proceeds

None.

### Item 15. Controls and Procedures

Under the supervision of and with the participation of the Registrant's management, including the Chief Executive Officer and Chief Financial Officer, we have conducted an evaluation pursuant to Rule 13a-15, promulgated under the Securities Exchange Act of 1934, as amended, of the effectiveness of our disclosure controls and procedures as at December 31, 2012. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective as at December 31, 2012.

#### Management's Annual Report on Internal Control over Financial Reporting

The Registrant's management is responsible for establishing and maintaining adequate internal control over financial reporting. The Registrant's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS.

The Registrant's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Registrant's assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS, and that receipts and expenditures of the Registrant are being made only in accordance with authorizations of the Registrant's management; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Registrant's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management conducted an evaluation of the effectiveness of the Registrant's internal control over financial reporting based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that the Registrant's internal control over financial reporting was effective as at December 31, 2012.

#### Attestation Report of the Independent Auditors

The effectiveness of the Registrant's internal control over financial reporting as of December 31, 2012, has been audited by PricewaterhouseCoopers LLP, independent auditors, as stated in their report which is included under "Item 18. – Financial Statements".

#### Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the year ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### Item 16A. Audit Committee Financial Expert

The Board of the Registrant has determined that the Registrant has at least one audit committee financial expert (as defined in paragraph (b) of Item 16A to Form 20-F). The name of the audit committee financial expert of the Registrant is Mr. Gérard Limoges, FCA, the Audit Committee's Chairman. The Commission has indicated that the designation of Mr. Limoges as the audit committee financial expert of the Registrant does not: (i) make Mr. Limoges an "expert" for any purpose, including



without limitation for purposes of Section 11 of the Securities Act of 1933, as amended, as a result of this designation; (ii) impose any duties, obligations or liability on Mr. Limoges that are greater than those imposed on him as a member of the Audit Committee and the Board in the absence of such designation; or (iii) affect the duties, obligations or liability of any other member of the Audit Committee or the Board. The other members of the Audit committee are Mr. Pierre Lapalme and Michael Meyers, each of whom, along with Mr. Limoges, is independent, as that term is defined in the NASDAQ listing standards. For a description of their respective education and experience, please refer to "Item 6. – Directors, Senior Management and Employees".

#### **Item 16B. Code of Ethics**

On March 29, 2004, the Board adopted a "Code of Ethical Conduct", which has been amended by the Board on November 3, 2004, December 13, 2005, March 2, 2007 and March 10, 2009. The December 13, 2005 amendment incorporates changes to the duty to report violations consistent with applicable laws. The Registrant has selected an independent third party supplier to provide a confidential and anonymous communication channel for reporting concerns about possible violations to the Registrant's Code of Ethical Conduct as well as financial and/or accounting irregularities or fraud. A copy of the Code of Ethical Conduct, as amended, is included as Exhibit 11.1 to this annual report on Form 20-F and is also available on the Registrant's Web site at [www.aezsinc.com](http://www.aezsinc.com) under the Investors - Governance tab. The Code of Ethical Conduct is a "code of ethics" as defined in paragraph (b) of Item 16B to Form 20-F. The Code of Ethical Conduct applies to all of the Registrant's employees, directors and officers, including the Registrant's principal executive officer, principal financial officer, and principal accounting officer or controller, or persons performing similar functions, and includes specific provisions dealing with integrity in accounting matters, conflicts of interest and compliance with applicable laws and regulations. The Registrant will provide this document without charge to any person or company upon request to the Chief Financial Officer of the Registrant, at its head office at 1405 du Parc-Technologique Boulevard, Quebec City, Quebec, G1P 4P5, Canada.

#### **Item 16C. Principal Accountant Fees and Services**

*(All amounts are in US dollars)*

##### **A. Audit Fees**

During the financial years ended December 31, 2012 and 2011, the Registrant's principal accountant, PricewaterhouseCoopers LLP, billed \$364,442 and \$650,460, respectively, for the audit of the Registrant's annual consolidated financial statements and for services rendered in connection with the Registrant's statutory and regulatory filings.

##### **B. Audit-related Fees**

During the financial years ended December 31, 2012 and 2011, the Registrant's principal accountant, PricewaterhouseCoopers LLP, billed \$79,652 and \$76,822, respectively, for audit or attest services not required by statute or regulation, for accounting consultations on proposed transactions, for the review of prospectuses and prospectus supplements, including the delivery of customary consent and comfort letters in connection therewith, as well as evaluations of accounting policy decisions and adjustments related to the Registrant's transition to IFRS.

##### **C. Tax Fees**

During the financial years ended December 31, 2012 and 2011, the Registrant's principal accountant, PricewaterhouseCoopers LLP, billed \$52,726 and \$50,282, respectively, for services related to tax compliance, tax planning and tax advice.

##### **D. All Other Fees**

During the financial years ended December 31, 2012 and 2011, the Registrant's principal accountant, PricewaterhouseCoopers LLP, billed \$Nil and \$Nil, respectively, for services not included in audit fees, audit-related fees and tax fees.

##### **E. Audit Committee Pre-Approval Policies and Procedures**

Under applicable Canadian securities regulations, the Registrant is required to disclose whether its Audit Committee has adopted specific policies and procedures for the engagement of non-audit services and to prepare a summary of these policies and procedures. The Audit Committee Charter (included as Exhibit 11.2 to this annual report on Form 20-F) provides that it is

such committee's responsibility to approve all audit engagement fees and terms as well as reviewing policies for the provision of non-audit services by the external auditors and, when required, the framework for pre-approval of such services. The Audit Committee delegates to its Chairman the pre-approval of such non-audit fees. The pre-approval by the Chairman is then presented to the Audit Committee at its first scheduled meeting following such pre-approval.

For each of the years ended December 31, 2012 and 2011, none of the non-audit services provided by the Registrant's external auditor were approved by the Audit Committee pursuant to the "de minimis exception" to the pre-approval requirement for non-audit services.

During the financial year ended on December 31, 2012, only full-time, permanent employees of the Registrant's principal accountant, PricewaterhouseCoopers LLP, performed audit work on the Registrant's financial statements.

**Item 16D. Exemptions from the Listing Standards for Audit Committees**

None.

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

**Item 16F. Changes in Registrant's Certifying Accountant**

None.

**Item 16G. Corporate Governance**

The Registrant is in compliance with the corporate governance requirements of NASDAQ except as described below. The Registrant is not in compliance with the NASDAQ requirement that a quorum for a meeting of the holders of the common stock of the Registrant be no less than 33 1/3% of such outstanding shares. The by-laws of the Registrant provide that a quorum for purposes of any meeting of shareholders of the Registrant consists of at least 10% of the outstanding voting shares. The Registrant benefits from an exemption from NASDAQ from this quorum requirement because the quorum provided for in the by-laws of the Registrant complies with the requirements of the CBCA, the Registrant's governing corporate statute, and with the rules of TSX, the home country exchange on which the Registrant's voting shares are traded.

In addition, the Registrant follows certain of its home country practices in lieu of compliance with the NASDAQ requirements that: (i) independent directors of the Registrant have regularly scheduled meetings at which only independent directors are present ("executive sessions"); (ii) the compensation of the chief executive officer and the other executive officers of the Registrant be determined, or recommended to the Registrant's Board for determination, by a compensation committee comprised solely of independent directors; and (iii) the director nominees be selected, or recommended for selection by the Registrant's Board, by a nominations committee comprised solely of independent directors. The Chairman of the Board of the Registrant from time to time ensures that directors hold meetings at which senior management is not present, and the Registrant's Corporate Governance, Nominating and Human Resources Committee, which serves as the Registrant's compensation and nominations committee, is comprised of three members, each of whom is independent. In accordance with applicable current NASDAQ requirements, the Registrant has in the past provided to NASDAQ letters from outside counsel certifying that these practices are not prohibited by the Registrant's home country law.

**Item 16H. Mine Safety Disclosure**

None.

## **PART III**

### **Item 17 Financial Statements**

We have elected to provide financial statements pursuant to Item 18.

### **Item 18. Financial Statements**

The financial statements appear on pages 104 through 150.

# **Aeterna Zentaris Inc.**

Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended  
December 31, 2012, 2011 and 2010

(presented in thousands of US dollars)

March 21, 2013

## **Independent Auditor's Report**

### **To the Shareholders of**

#### **Aeterna Zentaris Inc.**

We have completed integrated audits of Aeterna Zentaris Inc. and its subsidiaries' 2012 and 2011 consolidated financial statements and their internal control over financial reporting as at December 31, 2012 and an audit of their 2010 consolidated financial statements. Our opinions, based on our audits, are presented below.

#### **Report on the consolidated financial statements**

We have audited the accompanying consolidated financial statements of Aeterna Zentaris Inc. and its subsidiaries, which comprise the consolidated statements of financial position as at December 31, 2012 and December 31, 2011 and the consolidated statements of changes in shareholders' deficiency, comprehensive loss and cash flows for each of the three years in the period ended December 31, 2012, and the related notes, which comprise a summary of significant accounting policies and other explanatory information.

#### **Management's responsibility for the consolidated financial statements**

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### **Auditor's responsibility**

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with Canadian generally accepted auditing standards and the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform an audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement. Canadian generally accepted auditing standards also require that we comply with ethical requirements.

An audit involves performing procedures to obtain audit evidence, on a test basis, about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained in our audits is sufficient and appropriate to provide a basis for our audit opinion on the consolidated financial statements.

#### **Opinion**

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Aeterna Zentaris Inc. and its subsidiaries as at December 31, 2012 and December 31, 2011 and their financial performance and their cash flows for each of the three years in the period ended December 31, 2012 in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

.....  
*PricewaterhouseCoopers LLP/s.r.l./s.e.n.c.r.l.*  
*1250 René-Lévesque Boulevard West, Suite 2800, Montréal, Québec, Canada H3B 2G4*  
*T: +1 514 205 5000, F: +1 514 876 1502*

"PwC" refers to PricewaterhouseCoopers LLP/s.r.l./s.e.n.c.r.l., an Ontario limited liability partnership.

**Report on internal control over financial reporting**

We have also audited Aeterna Zentaris Inc. and its subsidiaries' internal control over financial reporting as at December 31, 2012, based on criteria established in *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

**Management's responsibility for internal control over financial reporting**

Management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the section entitled "Management's Annual Report on Internal Control over Financial Reporting" included on page 100 of this Annual Report on Form 20-F.

**Auditor's responsibility**

Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we consider necessary in the circumstances.

We believe that our audit provides a reasonable basis for our audit opinion on the company's internal control over financial reporting.

**Definition of internal control over financial reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

**Inherent limitations**

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

**Opinion**

In our opinion, Aeterna Zentaris Inc. and its subsidiaries maintained, in all material respects, effective internal control over financial reporting as at December 31, 2012 based on criteria established in *Internal Control - Integrated Framework* issued by COSO.

*PricewaterhouseCoopers LLP*<sup>1</sup>

Montréal, Québec, Canada

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<sup>1</sup> CPA auditor, CA, public accountancy permit No. A123498

# Aeterna Zentaris Inc.

## Consolidated Statements of Financial Position

(in thousands of US dollars)

	December 31, 2012	December 31, 2011
	\$	\$
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents (note 6)	39,521	46,881
Trade and other receivables (note 7)	7,993	8,325
Inventory (note 8)	4,084	3,456
Prepaid expenses and other current assets	1,703	1,477
	<u>53,301</u>	<u>60,139</u>
<b>Restricted cash (note 9)</b>	826	806
<b>Property, plant and equipment (note 10)</b>	2,147	2,512
<b>Other non-current assets</b>	797	830
<b>Identifiable intangible assets (note 11)</b>	1,128	1,769
<b>Goodwill (note 12)</b>	9,466	9,313
	<u>67,665</u>	<u>75,369</u>
<b>LIABILITIES</b>		
<b>Current liabilities</b>		
Payables and accrued liabilities (note 13)	10,440	12,257
Current portion of deferred revenues (note 5)	5,235	5,310
Income taxes (note 21)	—	259
Current portion of long-term payable	30	59
	<u>15,705</u>	<u>17,885</u>
<b>Deferred revenues (note 5)</b>	34,663	39,242
<b>Warrant liability (note 14)</b>	6,176	9,162
<b>Long-term payable</b>	—	29
<b>Employee future benefits (note 18)</b>	17,231	12,880
<b>Provision and other non-current liabilities (note 15)</b>	585	717
	<u>74,360</u>	<u>79,915</u>
<b>SHAREHOLDERS' DEFICIENCY</b>		
<b>Share capital (note 16)</b>	122,791	101,884
<b>Other capital</b>	83,892	82,327
<b>Deficit</b>	(213,086)	(188,969)
<b>Accumulated other comprehensive (loss) income</b>	(292)	212
	<u>(6,695)</u>	<u>(4,546)</u>
	<u>67,665</u>	<u>75,369</u>

Commitments, contingencies and guarantee (note 24)

Subsequent events (note 28)

The accompanying notes are an integral part of these consolidated financial statements.

Approved by the Board of Directors



Juergen Ernst  
Director



Gérard Limoges  
Director

## Aeterna Zentaris Inc.

### Consolidated Statements of Changes in Shareholders' Deficiency

For the years ended December 31, 2012, 2011 and 2010

(in thousands of US dollars, except share data)

	Common shares (number of) <sup>1,2</sup>	Share capital	Other capital	Deficit	Accumulated other comprehensive income (loss)	Total
		\$	\$	\$	\$	\$
<b>Balance - January 1, 2012</b>	<b>17,460,349</b>	<b>101,884</b>	<b>82,327</b>	<b>(188,969)</b>	<b>212</b>	<b>(4,546)</b>
Net loss		—	—	(20,412)	—	(20,412)
Other comprehensive loss:						
Foreign currency translation adjustments		—	—	—	(504)	(504)
Actuarial loss on defined benefit plans (note 18)		—	—	(3,705)	—	(3,705)
Comprehensive loss		—	—	(24,117)	(504)	(24,621)
Share issuance in connection with a public offering (note 16)	6,600,000	11,265	—	—	—	11,265
Share issuances in connection with "At-the-Market" drawdowns (note 16)	1,190,973	8,382	—	—	—	8,382
Share issuances pursuant to the exercise of warrants (note 14)	52,383	819	—	—	—	819
Share issuances pursuant to the exercise of stock options (note 16)	25,583	441	(232)	—	—	209
Share-based compensation costs	—	—	1,797	—	—	1,797
<b>Balance - December 31, 2012</b>	<b>25,329,288</b>	<b>122,791</b>	<b>83,892</b>	<b>(213,086)</b>	<b>(292)</b>	<b>(6,695)</b>

	Common shares (number of) <sup>1,2</sup>	Share capital	Other capital	Deficit	Accumulated other comprehensive income (loss)	Total
		\$	\$	\$	\$	\$
<b>Balance - January 1, 2011</b>	<b>13,904,986</b>	<b>60,900</b>	<b>81,091</b>	<b>(160,567)</b>	<b>1,001</b>	<b>(17,575)</b>
Net loss		—	—	(27,067)	—	(27,067)
Other comprehensive loss:						
Foreign currency translation adjustments		—	—	—	(789)	(789)
Actuarial loss on defined benefit plans (note 18)		—	—	(1,335)	—	(1,335)
Comprehensive loss		—	—	(28,402)	(789)	(29,191)
Share issuances in connection with "At-the-Market" drawdowns, net of transaction costs	3,244,094	35,881	—	—	—	35,881
Share issuances pursuant to the exercise of warrants (note 14)	284,545	4,861	—	—	—	4,861
Share issuances pursuant to the exercise of stock options (note 16)	26,724	242	(97)	—	—	145
Share-based compensation costs	—	—	1,333	—	—	1,333
<b>Balance - December 31, 2011</b>	<b>17,460,349</b>	<b>101,884</b>	<b>82,327</b>	<b>(188,969)</b>	<b>212</b>	<b>(4,546)</b>

<sup>1</sup> Issued and paid in full

<sup>2</sup> Adjusted to reflect the October 2, 2012 6-to-1 share consolidation (see note 1 – Summary of business, liquidity risk, reporting entity and basis of preparation and note 16 – Share capital)

The accompanying notes are an integral part of these consolidated financial statements.



## Aeterna Zentaris Inc.

### Consolidated Statements of Changes in Shareholders' Deficiency

For the years ended December 31, 2012, 2011 and 2010

(in thousands of US dollars, except share data)

	Common shares (number of) <sup>1,2</sup>	Share capital	Other capital	Deficit	Accumulated other comprehensive income (loss)	Total
		\$	\$	\$	\$	\$
<b>Balance - January 1, 2010</b>	<b>10,514,992</b>	<b>41,524</b>	<b>79,943</b>	<b>(132,307)</b>	<b>—</b>	<b>(10,840)</b>
Net loss		—	—	(28,451)	—	(28,451)
Other comprehensive income:						
Foreign currency translation adjustments		—	—	—	1,001	1,001
Actuarial gain on defined benefit plans (note 18)		—	—	191	—	191
Comprehensive loss		—	—	(28,260)	1,001	(27,259)
Issuances pursuant to registered direct offerings, net of transaction costs	3,319,513	18,391	—	—	—	18,391
Issuance pursuant to the exercise of warrants (note 14)	49,803	829	—	—	—	829
Issuance pursuant to the exercise of stock options (note 16)	20,678	156	(44)	—	—	112
Share-based compensation costs	—	—	1,192	—	—	1,192
<b>Balance - December 31, 2010</b>	<b>13,904,986</b>	<b>60,900</b>	<b>81,091</b>	<b>(160,567)</b>	<b>1,001</b>	<b>(17,575)</b>

<sup>1</sup> Issued and paid in full

<sup>2</sup> Adjusted to reflect the October 2, 2012 6-to-1 share consolidation (see note 1 – Summary of business, liquidity risk, reporting entity and basis of preparation and note 16 – Share capital)

The accompanying notes are an integral part of these consolidated financial statements.

**Aeterna Zentaris Inc.**

## Consolidated Statements of Comprehensive Loss

For the years ended December 31, 2012, 2011 and 2010

(in thousands of US dollars, except share and per share data)

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
<b>Revenues</b>			
Sales and royalties	31,538	31,306	24,857
License fees and other	2,127	4,747	2,846
	<u>33,665</u>	<u>36,053</u>	<u>27,703</u>
<b>Operating expenses (note 17)</b>			
Cost of sales	26,820	27,560	18,700
Research and development costs, net of refundable tax credits and grants	20,604	24,517	21,257
Selling, general and administrative expenses (notes 10 and 11)	13,245	16,170	12,552
	<u>60,669</u>	<u>68,247</u>	<u>52,509</u>
<b>Loss from operations</b>	<u>(27,004)</u>	<u>(32,194)</u>	<u>(24,806)</u>
Finance income (note 19)	6,974	6,231	1,792
Finance costs (note 19)	(382)	—	(5,437)
<b>Net finance (costs) income</b>	<u>6,592</u>	<u>6,231</u>	<u>(3,645)</u>
Loss before income taxes	(20,412)	(25,963)	(28,451)
Income tax expense (notes 5 and 21)	—	(1,104)	—
<b>Net loss</b>	<u>(20,412)</u>	<u>(27,067)</u>	<u>(28,451)</u>
<b>Other comprehensive loss:</b>			
Items that may be reclassified subsequently to profit or loss			
Foreign currency translation adjustments	(504)	(789)	1,001
Items that will not be reclassified to profit or loss			
Actuarial loss on defined benefit plans	(3,705)	(1,335)	191
<b>Comprehensive loss</b>	<u>(24,621)</u>	<u>(29,191)</u>	<u>(27,259)</u>
<b>Net loss per share (note 25)</b>			
Basic	<u>(1.03)</u>	<u>(1.72)</u>	<u>(2.26)</u>
Diluted	<u>(1.03)</u>	<u>(1.72)</u>	<u>(2.26)</u>
<b>Weighted average number of shares outstanding (notes 16 and 25)</b>			
Basic	<u>19,775,073</u>	<u>15,751,331</u>	<u>12,609,902</u>
Diluted	<u>19,775,073</u>	<u>15,751,331</u>	<u>12,609,902</u>

The accompanying notes are an integral part of these consolidated financial statements.

**Aeterna Zentaris Inc.**

## Consolidated Statements of Cash Flows

For the years ended December 31, 2012, 2011 and 2010

(in thousands of US dollars)

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
<b>Cash flows from operating activities</b>			
Net loss	(20,412)	(27,067)	(28,451)
Items not affecting cash and cash equivalents			
Change in fair value of warrant liability (note 14)	(6,746)	(2,533)	5,437
Depreciation, amortization and impairment (notes 10 and 11)	1,319	2,876	1,573
Share-based compensation costs (note 16)	1,797	1,333	1,192
Non-cash consideration received in connection with an amended licensing agreement	—	—	(1,263)
Gain on held-for-trading financial instrument	—	(1,278)	(687)
Employee future benefits (note 18)	335	492	249
Amortization of deferred revenues	(5,252)	(5,840)	(5,873)
Foreign exchange (gain) loss on items denominated in foreign currencies	614	(1,955)	(965)
(Gain) loss on disposal of property, plant and equipment	—	(26)	28
Amortization of prepaid expenses and other non-cash items	5,124	4,207	4,587
Changes in operating assets and liabilities (note 20)	(7,594)	3,548	(7,539)
Net cash used in operating activities	<b>(30,815)</b>	<b>(26,243)</b>	<b>(31,712)</b>
<b>Cash flows from financing activities</b>			
Proceeds from issuances of common shares and warrants, net of cash transaction costs of \$1,665 in 2012, \$1,204 in 2011 and \$1,506 in 2010 (note 16)	23,619	36,250	25,580
Proceeds from the exercise of share purchase warrants (note 14)	437	2,222	396
Proceeds from the exercise of stock options (note 16)	209	145	112
Repayment of long-term payable	(57)	(61)	(59)
Net cash provided by financing activities	<b>24,208</b>	<b>38,556</b>	<b>26,029</b>
<b>Cash flows from investing activities</b>			
Proceeds from the sale of short-term investment	—	3,242	—
Purchase of identifiable intangible assets (note 11)	—	(69)	—
Purchase of property, plant and equipment (note 10)	(272)	(736)	(82)
Disposals of property, plant and equipment (note 10)	—	26	32
Net cash provided by (used in) investing activities	<b>(272)</b>	<b>2,463</b>	<b>(50)</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>(481)</b>	<b>107</b>	<b>(369)</b>
<b>Net change in cash and cash equivalents</b>	<b>(7,360)</b>	<b>14,883</b>	<b>(6,102)</b>
<b>Cash and cash equivalents – Beginning of the year</b>	<b>46,881</b>	<b>31,998</b>	<b>38,100</b>
<b>Cash and cash equivalents – End of the year</b>	<b>39,521</b>	<b>46,881</b>	<b>31,998</b>
<b>Cash and cash equivalents components (note 6):</b>			
Cash	15,441	15,112	12,922
Cash equivalents	24,080	31,769	19,076
	<b>39,521</b>	<b>46,881</b>	<b>31,998</b>

The accompanying notes are an integral part of these consolidated financial statements.

# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

### 1 Summary of business, liquidity risk, reporting entity, share consolidation and basis of preparation

#### Summary of business

Aeterna Zentaris Inc. ("Aeterna Zentaris" or the "Company") is a global biopharmaceutical company specializing in oncology and endocrine therapy with expertise in drug discovery, development and commercialization. The Company's pipeline encompasses compounds at all stages of development, from drug discovery through to marketed products. The Company benefits from strategic collaborators and licensee partners to contribute to the development of its pipeline of product candidates and to establish commercial activities in specific territories.

#### Liquidity risk

Over the years, the Company has incurred recurring operating losses having invested significantly in its research and development ("R&D") activities as well as supporting its general and administrative expenses. It has financed its operations through different sources including the issuance of common shares and the conclusion of strategic alliances with licensee partners. The Company expects to continue to incur operating losses and may require significant capital to fulfill its future obligations. See note 22 – Capital disclosures and note 23 – Financial instruments and financial risk management – Liquidity risk.

#### Reporting entity

The accompanying consolidated financial statements include the accounts of Aeterna Zentaris Inc., an entity incorporated under the *Canada Business Corporations Act*, and its wholly-owned subsidiaries (collectively referred to as the "Group"). Aeterna Zentaris Inc. is the parent company of the Group and represents the ultimate parent of the Group.

The Company currently has three wholly-owned direct and indirect subsidiaries, Aeterna Zentaris GmbH ("AEZS Germany"), based in Frankfurt, Germany, Zentaris IVF GmbH, a direct wholly-owned subsidiary of AEZS Germany based in Frankfurt, Germany, and Aeterna Zentaris, Inc., based in Basking Ridge, New Jersey in the United States.

The address of the Company is 1405 du Parc-Technologique Blvd., Québec, Canada, G1P 4P5.

The Company's common shares are listed on both the Toronto Stock Exchange and the NASDAQ Global Market (the "NASDAQ").

#### Share consolidation

On October 2, 2012, the Company completed a consolidation of its issued and outstanding common shares on a 6-to-1 basis ("Share Consolidation"). The Share Consolidation affected all shareholders, optionholders and warrant holders uniformly and thus did not materially affect any securityholder's percentage of ownership interest. All references in these consolidated financial statements to common shares, options and share purchase warrants have been retroactively adjusted to reflect the Share Consolidation. See note 16 – Share capital, for additional information.

#### Basis of preparation

##### (a) Statement of compliance

The consolidated financial statements as at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010 (the "Consolidated Financial Statements") have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

These consolidated financial statements were approved by the Company's Board of Directors on March 21, 2013.

The accompanying consolidated financial statements were prepared on a going concern basis, under the historical cost convention, except for held-for-trading financial assets and of the warrant liability derivatives, which are measured at fair value through profit or loss ("FVTPL").

# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

The preparation of financial statements in accordance with IFRS requires the use of certain critical accounting estimates and the exercise of management's judgment in applying the Company's accounting policies. Areas involving a high degree of judgment or complexity and areas where assumptions and estimates are significant to the Company's consolidated financial statements are discussed in note 3 – Critical accounting estimates and judgments.

### (b) Principles of consolidation

These consolidated financial statements include all entities over which the Company has the power to govern the financial and operating policies generally accompanying a shareholding of more than one half of the voting rights. Entities are included in the consolidation from the date control is obtained by the Company, while entities are deconsolidated from the consolidation from the date that control ceases. The purchase method of accounting is used to account for acquisitions. All intercompany balances and transactions are eliminated on consolidation.

### (c) Foreign currency

The accompanying consolidated financial statements are presented in thousands of US dollars, which is the Company's presentation currency.

Assets and liabilities of Group entities are translated from euro at the period end rates of exchange, and the results of their operations are translated from euro at average rates of exchange for the period. The resulting translation adjustments are included in accumulated other comprehensive income within shareholders' deficiency.

Items included in the financial statements of the Group's entities are measured using the currency of the primary economic environment in which the entities operate (the "functional currency"), which is the euro ("EUR"). Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transaction. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities not denominated in euro are recognized in the consolidated statement of comprehensive loss.

Foreign exchange gains and losses that relate to cash and cash equivalents, the short-term investment and the warrant liability are presented within finance income or finance costs in the consolidated statement of comprehensive loss. All other foreign exchange gains and losses are presented in the consolidated statement of comprehensive loss within operating expenses.

## 2 Summary of significant accounting policies

The accounting policies set out below have been applied consistently to all years presented in these consolidated financial statements, and have been applied consistently by Group entities.

### Cash and cash equivalents

Cash and cash equivalents consists of unrestricted cash on hand and balances with banks, as well as three months or less interest-bearing deposits (including a money market account) that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

### Inventory

Inventory is valued at the lower of cost and net realizable value, which is defined as the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated selling costs. Cost is determined on a first-in, first-out basis. The cost of finished goods and work in progress includes raw materials, labour and manufacturing overhead under the absorption costing method.

### Restricted cash

Restricted cash is comprised of a bank deposit, related to a long-term operating lease obligation that cannot be used for current purposes.

# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

### Property, plant and equipment and depreciation

Items of property, plant and equipment are recorded at cost, net of related government grants and accumulated depreciation and impairment charges. Depreciation is calculated using the following methods, annual rates and period:

	Methods	Annual rates and period
Equipment	Declining balance and straight-line	20%
Furniture and fixtures	Declining balance and straight-line	10% and 20%
Computer equipment	Straight-line	25% and 33 1/3%
Leasehold improvements	Straight-line	Remaining lease term

Depreciation expense is allocated to the appropriate expense categories to which the underlying items of property, plant and equipment relate, and is recorded under the captions cost of sales, selling, general and administrative expenses, and R&D on the statement of comprehensive income.

### Identifiable intangible assets

Identifiable intangible assets with finite useful lives consist of in-process R&D that were acquired in business combinations, patents and trademarks, technology and other. In-process R&D acquired in business combinations are recognised at fair value at the acquisition date. Patents and trademarks are comprised of costs, including professional fees incurred in connection with the filing of patents and the registration of trademarks for product marketing and manufacturing purposes, net of related government grants, impairment losses, where applicable, and accumulated amortization. Identifiable intangible assets with finite useful lives are amortized from the time they are available for use on a straight-line basis over their estimated useful lives of eight to fifteen years for in-process R&D and patents and ten years for trademarks. Amortization expense is allocated to the appropriate expense categories to which the underlying identifiable intangible assets relate, and recorded under the captions selling, general and administrative expenses, and R&D on the statement of comprehensive income.

### Goodwill

Goodwill represents the excess of the purchase price over the fair values of the net assets of entities acquired at their respective dates of acquisition. Goodwill is carried at cost less accumulated impairment losses. Goodwill is allocated to each cash-generating unit ("CGU") or group of CGUs that are expected to benefit from the related business combination.

### Impairment of assets

Items of property, plant and equipment and identifiable intangible assets with finite lives subject to depreciation or amortization, respectively, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. Management is required to assess at each reporting date whether there is any indication that an asset may be impaired. Where such an indication exists, the asset's recoverable amount is compared to its carrying value, and an impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows, or CGU. In determining value in use of a given asset or CGU, estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. Impairment losses are allocated to the appropriate expense categories to which the underlying identifiable intangible assets relate, and recorded under the captions selling, general and administrative expenses, and R&D on the statement of comprehensive income.

Items of property, plant and equipment and amortizable identifiable intangible assets with finite lives that suffered impairment are reviewed for possible reversal of the impairment if there has been a change, since the date of the most recent impairment test, in the estimates used to determine the impaired asset's recoverable amount. However, an asset's

# **Aeterna Zentaris Inc.**

## **Notes to Consolidated Financial Statements**

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

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(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

carrying amount, increased due to the reversal of a prior impairment loss, must not exceed the carrying amount that would have been determined, net of depreciation or amortization, had the original impairment not occurred.

Goodwill is not subject to amortization and instead is tested for impairment annually or more often if there is an indication that the CGU to which the goodwill has been allocated may be impaired. Impairment is determined for goodwill by assessing whether the carrying value of a CGU, including the allocated goodwill, exceeds its recoverable amount, which is the higher of fair value less costs to sell and value in use. In the event that the carrying amount of goodwill exceeds its recoverable amount, an impairment loss is recognized in an amount equal to the excess. Impairment losses related to goodwill are not subsequently reversed.

### **Share purchase warrants**

Share purchase warrants are classified as liabilities, since the Company does not have the unconditional right to avoid delivering cash to the holders in the future. Each of the Company's share purchase warrants contains a written put option, arising upon the occurrence of a Fundamental Transaction, as that term is defined in the share purchase warrant agreement, and also upon a change of control. As a result of the existence of these put options, despite the fact that the repurchase feature is conditional on a defined contingency, the share purchase warrants are required to be classified as a financial liability, since such contingency could ultimately result in the transfer of assets by the Company.

The warrant liability is initially measured at fair value, and any subsequent changes in fair value are recognized as gains or losses through profit or loss. Any transaction costs related to the share purchase warrants are expensed as incurred.

The warrant liability is classified as non-current, unless the underlying share purchase warrants are expected to expire or be settled within 12 months from the end of a given reporting period.

### **Employee benefits**

#### *Salaries and other short-term benefits*

Salaries and other short-term benefit obligations are measured on an undiscounted basis and are recognized in the consolidated statement of comprehensive loss over the related service period or when the Company has a present legal or constructive obligation to make payments as a result of past events and when the amount payable can be estimated reliably.

#### *Post-employment benefits*

The Company's subsidiary in Germany maintains defined contribution and unfunded defined benefit plans, as well as other benefit plans for its employees. For defined benefit pension plans and other post-employment benefits, net periodic pension expense is actuarially determined on an annual basis using the projected unit credit method. The cost of pension and other benefits earned by employees is determined by applying certain assumptions, including discount rates, the projected age of employees upon retirement, the expected rate of future compensation and employee turnover.

The employee future benefits liability is recognized at its present value, which is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid and that have terms to maturity approximating the terms of the related future benefit liability. Actuarial gains and losses that arise in calculating the present value of the defined benefit obligation are recognized in other comprehensive loss, net of tax, in the deficit in the consolidated statement of financial position in the year in which the actuarial gains and losses arise and without recycling to the consolidated statement of comprehensive loss in subsequent periods.

For defined contribution plans, expenses are recorded in the consolidated statement of comprehensive loss as incurred—namely, over the period that the related employee service is rendered.

# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

### *Termination benefits*

Termination benefits are recognized in the consolidated statement of comprehensive loss when the Company is demonstrably committed, without the realistic possibility of withdrawal, to a formal detailed plan either to terminate employment before the normal retirement date or to provide termination benefits as a result of an offer made to encourage voluntary redundancy. Termination benefit liabilities expected to be settled after 12 months from the end of a given reporting period are discounted to their present value, where material.

### **Financial instruments**

The Company classifies its financial instruments in the following categories: "Financial assets at FVTPL"; "Loans and receivables"; "Financial liabilities at FVTPL"; and "Other financial liabilities".

Financial assets and liabilities are offset, and the net amount is reported in the consolidated statement of financial position, when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle on a net basis or realize the asset and settle the liability simultaneously.

#### (a) Classification

##### *Financial assets at fair value through profit or loss*

Financial assets at FVTPL are financial assets held for trading. Fair value is defined as the amount at which the financial assets could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. A financial asset is classified as at FVTPL if the instrument is acquired or received as consideration principally for the purpose of selling in the short-term. Financial assets at FVTPL are classified as current assets if expected to be settled within 12 months from the end of a given reporting period; otherwise, the assets are classified as non-current.

As at December 31, 2012 and 2011, the Company holds no asset classified as financial assets at FVTPL.

##### *Loans and receivables*

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Loans and receivables are included in current assets, except for instruments with maturities greater than 12 months after the end of a given reporting period or where restrictions apply that limit the Company from using the instrument for current purposes, which are classified as non-current assets.

The Company's loans and receivables are comprised of cash and cash equivalents, trade and other receivables and restricted cash.

##### *Financial liabilities at fair value through profit or loss*

Financial liabilities at FVTPL are financial liabilities held for trading. A financial liability is classified as at FVTPL if the instrument is acquired or incurred principally for the purpose of selling or repurchasing in the short-term or where the Company does not have the unconditional right to avoid delivering cash or another financial asset to the holders in certain circumstances. Financial liabilities at FVTPL are classified as current liabilities if expected or potentially required to be settled within 12 months from the end of a given reporting period; otherwise, the liabilities are classified as non-current.

Financial liabilities at FVTPL are currently comprised of the Company's warrant liability.

##### *Other financial liabilities*

Other financial liabilities include trade accounts payable and accrued liabilities, long-term payable and other long-term liabilities.



# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

### (b) Recognition and measurement

#### *Financial assets at fair value through profit or loss*

Financial assets at FVTPL are recognized on the settlement date, which is the date on which the asset is delivered to the Company. Financial assets at FVTPL are initially recognized at fair value, and transaction costs are expensed immediately in the consolidated statement of comprehensive loss. Financial assets at FVTPL are derecognized when the right to receive cash flows from the underlying investment have expired or have been transferred and when the Group has transferred substantially all risks and rewards of ownership. Gains and losses arising from changes in the fair value of financial assets at FVTPL are presented in the consolidated statement of comprehensive loss within finance income or finance costs in the period in which they arise.

#### *Loans and receivables*

Loans and receivables are recognized on the settlement date and are measured initially at fair value and subsequently at amortized cost using the effective interest rate method.

#### *Financial liabilities at fair value through profit or loss*

Financial liabilities at FVTPL are recognized on the settlement date. Financial liabilities at FVTPL are initially recognized at fair value, and transaction costs are expensed immediately in the consolidated statement of comprehensive loss. Gains and losses arising from changes in the fair value of financial liabilities at FVTPL are presented in the consolidated statement of comprehensive loss within finance income or finance costs in the period in which they arise.

#### *Other financial liabilities*

Financial instruments classified as "Other financial liabilities" are measured initially at fair value and subsequently at amortized cost using the effective interest rate method.

### (c) Impairment

Financial assets measured at amortized cost are reviewed for impairment at each reporting date. Where there is objective evidence that impairment exists for a financial asset measured at amortized cost, an impairment charge equivalent to the difference between the asset's carrying amount and the present value of estimated future cash flows is recorded in the consolidated statement of comprehensive loss. The expected cash flows exclude future credit losses that have not been incurred and are discounted at the financial asset's original effective interest rate.

Impairment charges of financial assets carried at amortized cost are reversed if, in a subsequent period, the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognized. However, the reversal cannot result in a carrying amount of the financial asset that exceeds what the amortized cost would have been had the impairment not been recognized at the date the impairment is reversed.

## Share capital

The Company has authorized an unlimited number of common shares (being voting and participating shares) with no par value, as well as an unlimited number of preferred, first and second ranking shares, issuable in series, with rights and privileges specific to each class, with no par value.

Common shares are classified as equity. Incremental costs that are directly attributable to the issue of common shares and stock options are recognized as a deduction from equity, net of any tax effects.

Where offerings result in the issuance of units (where each unit is comprised of a common share of the Company and a share purchase warrant, exercisable in order to purchase a common share or fraction thereof), proceeds received in connection with those offerings are allocated between Share capital and Share purchase warrants based on the residual method. Proceeds are allocated to warrant liability based on the share purchase warrants fair value, and the residual

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amount of proceeds is allocated to Share capital. Transaction costs in connection with such offerings are allocated to the liability and equity units components in proportion to the allocation of proceeds.

### Provisions

Provisions represent liabilities to the Company for which the amount or timing is uncertain. Provisions are recognized when the Company has a present legal or constructive obligation as a result of past events, when it is probable that an outflow of resources will be required to settle the obligation and where the amount can be reliably estimated. Provisions are not recognized for future operating losses.

Provisions are made for any contracts, including lease arrangements, which are deemed onerous. A contract is onerous if the unavoidable costs of meeting the obligations under the contract exceed the economic benefits expected to be received under it. Provisions for onerous contracts are measured at the present value of the lower of the expected cost of terminating the contract and the expected net cost of continuing with the contract. Present value is determined based on expected future cash flows that are discounted at a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The unwinding of the discount is recognized in finance costs.

### Revenue recognition

#### *Sales of products*

Revenues from the sale of goods are recognized when the Company has transferred to the buyer the significant risks and rewards of ownership of the goods (which is at the time the goods are shipped), when the Company retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold, when the amount of revenues can be measured reliably, when it is probable that the economic benefits associated with the transaction will flow to the Company and when the costs incurred or to be incurred in respect of the transaction can be measured reliably.

#### *Royalty revenues*

The Company has deferred recognition of proceeds received in December 2008 from Healthcare Royalty Partners L.P. (formerly Cowen Healthcare Royalty Partners L.P.) ("HRP") relating to the Company's rights to royalties on future sales of Cetrotide<sup>®</sup> covered by a license agreement with ARES Trading S.A. ("Merck Serono") in which the latter had been granted worldwide marketing, distribution and selling rights, except in Japan, for Cetrotide<sup>®</sup>, a compound used for *in vitro* fertilization. Royalties on Merck Serono's net sales of Cetrotide<sup>®</sup>, formerly payable to the Company, are now payable directly to HRP.

The Company recognized the proceeds received from HRP as royalty revenues over the life of the underlying royalty sale arrangement, pursuant to the "units-of-revenue" method. Under that method, periodic royalty revenues are calculated as the ratio of the remaining deferred revenue amount to the total estimated remaining royalties that Merck Serono is expected to pay to HRP over the term of the underlying arrangement multiplied by the royalty payments due to HRP for the period.

#### *Licensing revenues and multiple element arrangements*

The Company is currently in a phase in which certain potential products are being further developed or marketed jointly with strategic partners. Existing licensing agreements usually foresee one-time payments (upfront payments), payments for R&D services in the form of cost reimbursements, milestone payments and royalty receipts for licensing and marketing product candidates. Revenues associated with those multiple-element arrangements are allocated to the various elements based on their relative fair value.

Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered obligation(s). The consideration received is allocated among the separate units based on each unit's fair value, and the applicable revenue recognition criteria are applied to each of the separate units.

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License fees representing non-refundable payments received at the time of signature of license agreements are recognized as revenue upon signature of the license agreements when the Company has no significant future performance obligations and collectibility of the fees is probable. Upfront payments received at the beginning of licensing agreements are deferred and recognized as revenue on a systematic basis over the period during which the related services are rendered and all obligations are performed.

### *Milestone payments*

Milestone payments, which are generally based on developmental or regulatory events, are recognized as revenue when the milestones are achieved, collectibility is assured, and when the Company has no significant future performance obligations in connection with the milestones.

### **Cost of sales**

Cost of sales represents the cost of goods sold and represents almost exclusively the amount of inventory recognized as an expense during the year. This amount includes the cost of raw materials, supplies, manufacturing fees as well as write-down of inventories.

### **Share-based compensation costs**

The Company operates an equity-settled share-based compensation plan under which the Company receives services from directors, senior executives, employees and other collaborators as consideration for equity instruments of the Company.

The Company accounts for all forms of directors, senior executives, employees and other collaborators stock-based compensation using the fair value-based method. Fair value of stock options is determined at the date of grant using the Black-Scholes option pricing model, which includes estimates of the number of awards that are expected to vest over the vesting period. Where granted share options vest in installments over the vesting period (defined as graded vesting), the Company treats each installment as a separate share option grant. Share-based compensation expense is recognized over the vesting period, or as specified vesting conditions are satisfied, and credited to Other Capital.

Any consideration received by the Company in connection with the exercise of stock options is credited to Share Capital. Any Other Capital component of the stock-based compensation is transferred to Share Capital upon the issuance of shares.

### **Current and deferred income tax**

The tax expense for the period comprises current and deferred tax. Tax is recognized in profit or loss, except that a change attributable to an item of income or expense recognized as other comprehensive income (loss) or directly in equity (deficit) is also recognized directly in other comprehensive income (loss) or directly in equity (deficit). Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

The current income tax charge is calculated on the basis of tax rates and laws that have been enacted or substantively enacted by the reporting date in the countries where the company's subsidiaries operate and generate taxable income.

Deferred income tax is recognized on temporary differences (other than temporary differences associated with unremitted earnings from foreign subsidiaries and associates to the extent that the investment is essentially permanent in duration, or temporary differences associated with the initial recognition of goodwill) arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements and on unused tax losses or R&D non-refundable tax credits in the group. Deferred income tax is determined using tax rates and laws that have been enacted or substantively enacted by the reporting date.

Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilised.

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Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income taxes assets and liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities where there is an intention to settle the balances on a net basis.

### **Research and development costs**

Research costs are expensed as incurred. Development costs are expensed as incurred except for those which meet generally accepted criteria for deferral, in which case, the costs are capitalized and amortized to operations over the estimated period of benefit. No costs have been deferred during any of the periods presented.

### **Research and development refundable tax credits and grants**

The Company's German subsidiary is entitled to receive research grants from the German Federal Ministry of Education and Research. Funding is earned on qualified projects, and corresponding expenses are reimbursed at a rate of 51% of eligible base amounts.

Refundable R&D tax credits and grants are accounted for using the cost reduction method. Accordingly, refundable R&D tax credits and grants are recorded as a reduction of the related expenses or capital expenditures in the period the expenses are incurred, provided that the Company has reasonable assurance the refundable R&D tax credits or grants will be realized.

### **Net loss per share**

Basic net loss per share is calculated using the weighted average number of common shares outstanding during the year.

Diluted net loss per share is calculated based on the weighted average number of common shares outstanding during the year, plus the effects of dilutive common share equivalents, such as stock options and share purchase warrants. This method requires that diluted net loss per share be calculated using the treasury stock method, as if all common share equivalents had been exercised at the beginning of the reporting period, or period of issuance, as the case may be, and that the funds obtained thereby were used to purchase common shares of the Company at the average trading price of the common shares during the period.

## **3 Critical accounting estimates and judgments**

The preparation of consolidated financial statements in accordance with IFRS requires management to make judgments, estimates and assumptions that affect the reported amounts of the Company's assets, liabilities, revenues, expenses and related disclosures. Judgments, estimates and assumptions are based on historical experience, expectations, current trends and other factors that management believes to be relevant at the time at which the Company's consolidated financial statements are prepared.

Management reviews, on a regular basis, the Company's accounting policies, assumptions, estimates and judgments in order to ensure that the consolidated financial statements are presented fairly and in accordance with IFRS. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

### **a) Critical accounting estimates and assumptions**

Critical accounting estimates and assumptions are those that have a significant risk of causing material adjustment and are often applied to matters or outcomes that are inherently uncertain and subject to change. As such, management cautions that future events often vary from forecasts and expectations and that estimates routinely require adjustment.

The following discusses the most significant accounting estimates and assumptions that the Company has made in the preparation of the consolidated financial statements.

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### *Revenue recognition*

Royalty revenues calculated under the "units-of-revenue" method are dependent upon certain assumptions, including expected future third-party net sales of Cetrotide®. Any future changes in the assumptions utilized to determine the amortization of deferred revenues could result in a change in the timing of the Company's royalty revenue recognition.

### *Fair value of the warrant liability and stock options*

Determining the fair value of the warrant liability and stock options requires judgment related to the choice of a pricing model, the estimation of stock price volatility and the expected term of the underlying instruments. Any changes in the estimates or inputs utilized to determine fair value could result in a significant impact on the Company's future operating results, liabilities or other components of shareholders' deficiency. Fair value assumptions used are described in notes 14 – Warrant liability and 16 – Share capital.

### *Identifiable intangible assets and goodwill impairment*

The values associated with identifiable intangible assets with finite lives and goodwill are determined by applying significant estimates and assumptions, including those related to cash flow projections, economic risk, discount rates and asset useful lives.

Valuations performed in connection with post-acquisition assessments of impairment of identifiable intangible assets are based on estimates that include risk-adjusted future cash flows, which are discounted using appropriate interest rates. Projected cash flows are based on business forecasts, trends and expectations and are therefore inherently judgmental. Future events could cause the assumptions utilized in impairment assessments to change, resulting in a potentially significant effect on the Company's future operating results due to increased impairment charges, or reversals thereof, or adjustments to amortization charges. Additional information is included in note 11 – Identifiable intangible assets.

The annual impairment assessment related to goodwill is based on estimates that are derived from current market capitalization and on other factors, including assumptions related to recent industry-specific market analyses. Future events, including a significant reduction in the Company's share price, could cause the assumptions utilized in the impairment tests to change, resulting in a potentially adverse effect on the Company's future results due to increased impairment charges.

### *Employee future benefits*

The determination of expense and obligations associated with employee future benefits requires the use of assumptions, such as the discount rate to measure obligations, the projected age of employees upon retirement, the expected rate of future compensation and estimated employee turnover. Because the determination of the cost and obligations associated with employee future benefits requires the use of various assumptions, there is measurement uncertainty inherent in the actuarial valuation process. Actual results will differ from results that are estimated based on the aforementioned assumptions. Additional information is included in note 18 – Employee future benefits.

### *Income taxes*

The estimation of income taxes includes evaluating the recoverability of deferred tax assets based on an assessment of Group entities' ability to utilize the underlying future tax deductions against future taxable income prior to expiry of those deductions. Management assesses whether it is probable that some or all of the deferred income tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income, which in turn is dependent upon the successful commercialization of the Company's products. To the extent that management's assessment of any Group entity's ability to utilize future tax deductions changes, the Company would be required to recognize more or fewer deferred tax assets, and future income tax provisions or recoveries could be affected. Additional information is included in note 21 – Income taxes.

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- b) Critical judgement in applying the entity's accounting policies

### *Revenue recognition*

Management's assessments related to the recognition of revenues related to arrangements containing multiple elements are based on judgment. Judgment is necessary to identify separate units of accounting and to allocate related consideration to each separate unit of accounting. Where deferral of upfront payments or license fees is deemed appropriate, subsequent revenue recognition is often determined based upon the assessment of the Company's continuing involvement in the arrangement, the benefits expected to be derived by the customer and expected patent lives. Additional information is included in note 5 – Development, commercialization and license agreement.

## 4 Recent accounting pronouncements

There are no IFRSs or International Financial Reporting Interpretations Committee ("IFRIC") that are effective for the first time in 2012 that would be expected to have a material impact on the Company.

### Adopted in 2012

In June 2011, the IASB amended IAS 1, *Presentation of Financial Statements* ("IAS 1"), to change the disclosure of items presented in other comprehensive income into two groups, based on whether those items may be recycled to profit or loss in the future. The amendments to IAS 1 apply to financial statements for annual periods beginning after July 1, 2012, with early adoption permitted.

### Not yet adopted

In November 2009 and October 2010, the IASB issued IFRS 9, *Financial Instruments* ("IFRS 9"), which represents the completion of the first part of a three-part project to replace IAS 39, *Financial Instruments: Recognition and Measurement*, with a new standard. Per the new standard, an entity choosing to measure a liability at fair value will present the portion of the change in its fair value due to changes in the entity's own credit risk in the other comprehensive income or loss section of the entity's statement of comprehensive loss, rather than within profit or loss in case where the fair value option is taken for financial liabilities. Additionally, IFRS 7 Amendment includes revised guidance related to the derecognition of financial instruments. IFRS 9 applies to financial statements for annual periods beginning on or after January 1, 2015, with early adoption permitted. The Company currently is evaluating any impact that this new standard may have on the Company's consolidated financial statements.

In May 2011, the IASB issued IFRS 10, *Consolidated Financial Statements* ("IFRS 10"), which builds on existing principles by identifying the concept of control as the determining factor in whether an entity should be included within the consolidated financial statements of a parent company. IFRS 10 also provides additional guidance to assist in the determination of control where this is difficult to assess. IFRS 10 applies to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new guidance may have on the Company's consolidated financial statements.

In May 2011, the IASB issued IFRS 11, *Joint Arrangements* ("IFRS 11"), which enhances accounting for joint arrangements, particularly by focusing on the rights and obligations of the arrangement, rather than the arrangement's legal form. IFRS 11 also addresses inconsistencies in the reporting of joint arrangements by requiring a single method to account for interests in jointly controlled entities and prohibits proportionate consolidation. IFRS 11 applies to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new guidance may have on the Company's consolidated financial statements.

In May 2011, the IASB issued IFRS 12, *Disclosure of Interests in Other Entities* ("IFRS 12"), which is a comprehensive standard on disclosure requirements for all forms of interests in other entities, including joint arrangements, associates, special purpose vehicles and other off-balance sheet vehicles. IFRS 12 applies to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new guidance may have on the Company's consolidated financial statements.

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In May 2011, the IASB issued IFRS 13, *Fair Value Measurement* ("IFRS 13"), which defines fair value, sets out in a single IFRS a framework for measuring fair value and requires disclosures about fair value measurements. IFRS 13 does not determine when an asset, a liability or an entity's own equity instrument is measured at fair value. Rather, the measurement and disclosure requirements of IFRS 13 apply when another IFRS requires or permits the item to be measured at fair value (with limited exceptions). IFRS 13 applies to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new guidance may have on the Company's consolidated financial statements.

In June 2011, the IASB issued an amended version of IAS 19, *Employee Benefits* ("IAS 19"), including the elimination of the option to defer the recognition of actuarial gains and losses (known as the "corridor method"), the streamlining of the presentation of changes in assets and liabilities arising from defined benefit plans and the enhancement of the disclosure requirements for defined benefit plans, including additional information about the characteristics of defined benefit plans and the risks to which entities are exposed through participation in those plans. The amendments to IAS 19 apply to financial statements for annual periods beginning on or after January 1, 2013, with early adoption permitted. The Company currently is evaluating any impact that this new standard may have on the Company's consolidated financial statements.

### 5 Development, commercialization and license agreement

On March 8, 2011, the Company entered into an agreement with Yakult Honsha Co. Ltd. ("Yakult") for the development, manufacture and commercialization of perifosine in all human uses, excluding leishmaniasis, in Japan. Under the terms of this agreement, Yakult made an initial, non-refundable gross upfront payment to the Company of €6,000,000 (approximately \$8,412,000). Also per the agreement, the Company is entitled to receive up to a total of €44,000,000 (approximately \$58,015,000) upon achieving certain pre-established milestones, including the occurrence of certain clinical and regulatory events in Japan. Furthermore, the Company will be entitled to receive double-digit royalties on future net sales of perifosine in the Japanese market.

On November 23, 2011, the Company entered into an agreement with Hikma Pharmaceuticals LLC. ("Hikma") for the development and commercialization of perifosine in all oncology uses in certain countries in the Middle East and North Africa ("MENA"). Under the terms of this agreement, Hikma made an initial, non-refundable gross upfront payment to the Company of \$200,000. Also per the agreement, the Company will be entitled to receive up to a total of \$850,000, as amended on December 18, 2012, upon achieving certain pre-established milestones, including the occurrence of certain regulatory events in certain countries in the MENA region. Furthermore, the Company will be entitled to receive double-digit royalties on future net sales of perifosine in the MENA market.

The Company has substantial continuing involvement in the aforementioned arrangements, including the use of commercially reasonable efforts to develop, apply for and obtain relevant regulatory approval for, manufacture and commercialize perifosine outside Japan and MENA region, which will facilitate the ultimate commercialization process within Japan and MENA region. Additionally, the Company will ensure a stable supply of perifosine and related trial products to Yakult and Hikma throughout the ongoing development process and will maintain relevant patent rights over the term of the arrangements. Lastly, per the terms of the aforementioned agreements, the Company has agreed to supply perifosine, on a cost-plus basis, to Yakult and Hikma following regulatory approvals.

The Company has applied the provisions of IAS 18, Revenue, and has determined that all deliverables and performance obligations contemplated by the agreements with Yakult and Hikma should be accounted for as a single unit of accounting, limited to amounts that are not contingent upon the delivery of additional items or the meeting of other specified performance conditions which are not known, probable or estimable at the time at which the agreements with Yakult and Hikma were entered into.

The Company has deferred the non-refundable license fees and is amortizing the related payments as revenue on a straight-line basis over the duration of the Company's continuing involvement in the arrangements, which approximate the estimated life cycle of the product that is currently under development and the expected period over which Yakult and Hikma will derive value from the use of, and access to, the underlying licenses.

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In determining the period over which license revenues are to be recognized, and in addition to due consideration of the Company's continuing involvement, as discussed above, the Company considered the remaining expected life of applicable patents as the most reasonable basis for estimating the underlying product's life cycle. However, the Company may adjust the amortization period based on appropriate facts and circumstances not yet known, including, but not limited to, the extension(s) of patents, the granting of new patents, the economic lives of competing products and other events that would significantly change the duration of the Company's continuing involvement and performance obligations or benefits expected to be derived by Yakult and Hikma. Additional information is included in note 28 – Subsequent events.

Future milestones will be recognized as revenue individually and in full upon the actual achievement of the related milestone, given the substantive nature of each milestone. Lastly, upon initial commercialization and sale of the developed product, the Company will recognize royalty revenues as earned, based on the contractual percentage applied to the actual net sales achieved by Yakult and Hikma, as per the aforementioned agreement.

The Company was required to remit to the Japanese tax authorities \$1,104,000 of the gross proceeds received from Yakult. These amounts, which were withheld at the source, were recognized as income tax expense in the consolidated statement of comprehensive loss in accordance with the provision of IAS 12, *Income Taxes*.

### 6 Cash and cash equivalents

	As at December 31,	
	2012	2011
	\$	\$
Cash on hand and balances with banks	15,441	15,112
Three months or less interest-bearing deposits	24,080	31,769
	<u>39,521</u>	<u>46,881</u>

### 7 Trade and other receivables

	As at December 31,	
	2012	2011
	\$	\$
Trade accounts receivable	7,323	7,716
Value added tax	428	439
Other	242	170
	<u>7,993</u>	<u>8,325</u>

### 8 Inventory

	As at December 31,	
	2012	2011
	\$	\$
Raw materials	1,691	1,608
Work in progress	1,931	1,848
Finished goods	462	—
	<u>4,084</u>	<u>3,456</u>



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#### 9 Restricted cash

In support of the Company's long-term operating lease obligation in Germany and in replacement of a related bank guarantee, the Company transferred approximately \$826,000 (\$806,000 in 2011) to a restricted cash account. The fixed amount, including any interest earned thereon, is restricted for as long as the underlying lease arrangement (note 24 – Commitments, contingencies and guarantee) has not expired and therefore cannot be utilized for current purposes as at December 31, 2012.

#### 10 Property, plant and equipment

Components of the Company's property, plant and equipment are summarized below.

	Cost				
	Equipment	Furniture and fixtures	Computer equipment	Leasehold improvements	Total
	\$	\$	\$	\$	\$
At January 1, 2011	8,939	1,551	1,738	1,156	13,384
Additions	684	—	46	6	736
Disposals / Retirements	(96)	—	(2)	—	(98)
Impact of foreign exchange rate changes	(330)	(49)	(58)	(37)	(474)
At December 31, 2011	9,197	1,502	1,724	1,125	13,548
Additions	180	87	5	—	272
Disposals / Retirements	(79)	—	(3)	—	(82)
Impact of foreign exchange rate changes	146	26	28	19	219
At December 31, 2012	9,444	1,615	1,754	1,144	13,957

	Accumulated depreciation				
	Equipment	Furniture and fixtures	Computer equipment	Leasehold improvements	Total
	\$	\$	\$	\$	\$
At January 1, 2011	6,749	1,352	1,672	515	10,288
Disposals / Retirements	(96)	—	(2)	—	(98)
Impairment loss	—	134	—	178	312
Recurring depreciation expense	728	39	50	101	918
Impact of foreign exchange rate changes	(255)	(47)	(56)	(26)	(384)
At December 31, 2011	7,126	1,478	1,664	768	11,036
Disposals / Retirements	(79)	—	(3)	—	(82)
Impairment loss	—	—	—	—	—
Recurring depreciation expense	564	8	34	57	663
Impact of foreign exchange rate changes	128	25	26	14	193
At December 31, 2012	7,739	1,511	1,721	839	11,810

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#### Carrying amount

	Equipment	Furniture and fixtures	Computer equipment	Leasehold improvements	Total
	\$	\$	\$	\$	\$
At December 31, 2011	2,071	24	60	357	2,512
At December 31, 2012	1,705	104	33	305	2,147

Depreciation of \$663,000 (\$918,000 in 2011) is included in the statement of comprehensive loss: \$85,000 (nil in 2011) in cost of sales, \$555,000 (\$824,000 in 2011) in R&D and \$23,000 (\$94,000 in 2011) in selling, general and administrative expenses.

During the year ended December 31, 2011, an impairment loss was recognized based on the results of impairment testing of the Company's Leasehold improvements and Furniture and fixtures assets. The impairment loss was recognized predominantly to take into account the relocation of one of the Company's offices. Following management's analyses, which demonstrated that the remaining carrying value of these assets was no longer recoverable, an impairment charge of approximately \$312,000, was recorded as additional depreciation expense, which in turn was included within general and administrative expenses in the accompanying consolidated statement of comprehensive loss.

## 11 Identifiable intangible assets

Identifiable intangible assets with finite useful lives consist entirely of in-process R&D costs, patents and trademarks. The changes in the carrying value of the Company's identifiable intangible assets with finite useful lives are summarized below.

	Year ended December 31, 2012			Year ended December 31, 2011		
	Cost	Accumulated amortization	Carrying value	Cost	Accumulated amortization	Carrying value
	\$	\$	\$	\$	\$	\$
Balances - At January 1	37,982	(36,213)	1,769	39,141	(35,842)	3,299
Additions	—	—	—	69	—	69
Retirement	(431)	431	—	—	—	—
Impairment loss	—	(184)	(184)	—	(1,093)	(1,093)
Recurring amortization expense	—	(472)	(472)	—	(553)	(553)
Impact of foreign exchange rate changes	621	(606)	15	(1,228)	1,275	47
Balances - At December 31	38,172	(37,044)	1,128	37,982	(36,213)	1,769

Amortization of \$472,000 (\$553,000 in 2011) is included in the statement of comprehensive loss: \$472,000 (\$507,000 in 2011) in R&D and nil (\$46,000 in 2011) in selling expenses.

During the year ended December 31, 2012, an impairment loss was recognized based on the results of impairment testing of the Company's patents and trademarks. The impairment loss was recognized predominantly to take into account the retirement of certain patents and trademarks. Following management's analyses, which demonstrated that the remaining carrying value of these assets was no longer recoverable, an impairment charge of approximately \$184,000, was recorded as additional amortization expense, which in turn is included within R&D expenses in the accompanying consolidated statement of comprehensive loss.

During the year ended December 31, 2011, an impairment loss was recognized based on the results of impairment testing of the Company's Cetrotide<sup>®</sup> asset. The impairment loss was recognized predominantly to take into account management's lower trend estimates related to the commercialization of Cetrotide<sup>®</sup>, due to changes in the competitive environment in the Japanese market. Management determined that the recoverable amount of Cetrotide<sup>®</sup>, as at

# Aeterna Zentaris Inc.

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September 30, 2011, was equivalent to the asset's value in use, as defined by IAS 36, *Impairment of Assets*. Value in use was determined by applying a discount rate of 20%-a pre-tax rate that reflects both current market assessments of the time value of money and the risks specific to the asset for which the future cash flow estimates have not been adjusted-to the estimated future cash flows deemed to be attributable to the use of Cetrotide®. Management has projected cash flows over a period of 11 years, which is until the end of the expected life of Cetrotide® and has used an average growth rate of 1.7 % for the years 1 to 6 and an average growth rate of -9.7% for the years 7 to 11 to extrapolate cash flow projections. More specifically, the discount rate represents an estimate of a reasonable return that would be expected by an investor in an arm's length monetization transaction in respect of future Cetrotide®-derived cash flows. Following management's analyses, which demonstrated that the remaining carrying value of Cetrotide® was no longer recoverable, an impairment charge of approximately \$1,093,000, was recorded during the year ended December 31, 2011 as additional amortization expense, which in turn was included within selling expenses in the accompanying consolidated statement of comprehensive loss.

### 12 Goodwill

Goodwill has been allocated to the only CGU of the Group.

The change in carrying value is as follows:

	<b>Cost</b>	<b>Accumulated impairment loss</b>	<b>Carrying amount</b>
	\$	\$	\$
Balance as at January 1, 2011	9,614	—	9,614
Impact of foreign exchange rate changes	(301)	—	(301)
Balance as at December 31, 2011	9,313	—	9,313
Impact of foreign exchange rate changes	153	—	153
Balance as at December 31, 2012	<b>9,466</b>	—	<b>9,466</b>

### 13 Payables and accrued liabilities

	<b>As at December 31,</b>	
	<b>2012</b>	<b>2011</b>
	\$	\$
Trade accounts payable	<b>6,671</b>	8,062
Salaries, employment taxes and benefits	<b>707</b>	1,958
Current portion of warrant liability	—	42
Accrued R&D costs	<b>1,530</b>	1,056
Accrued Cetrotide® services and deliveries	<b>434</b>	160
Other accrued liabilities	<b>1,098</b>	979
	<b>10,440</b>	12,257

# Aeterna Zentaris Inc.

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(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

### 14 Warrant liability

The change in the Company's warrant liability can be summarized as follows:

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
Balance – Beginning of the year	9,204	14,367	1,664 *
Share purchase warrants granted during the year (note 16)	4,100	—	7,341
Share purchase warrants exercised during the year	(382)	(2,638)	(429)
Change in fair value of share purchase warrants	(6,746)	(2,533)	5,437
Change in value attributable to foreign exchange rate changes	—	8	354
	6,176	9,204	14,367
Less: current portion	—	(42)	(955)
Balance – End of the year	6,176	9,162	13,412

\* Includes current portion of \$0 and non-current portion of \$1,664.

A summary of the activity related to the Company's share purchase warrants is provided below.

	Years ended December 31,					
	2012		2011		2010	
	Number	Weighted average exercise price (US\$)	Number	Weighted average exercise price (US\$)	Number	Weighted average exercise price (US\$)
Balance – Beginning of the year	1,511,179	8.62	2,153,872	9.17	685,088	10.21
Granted	2,970,000	3.45	—	—	1,518,587	8.67
Exercised	(52,383)	8.24	(284,545)	7.81	(49,803)	7.95
Expired	(21,386)	9.00	(358,148)	12.59	—	—
Balance – End of the year	4,407,410	5.14	1,511,179	8.62	2,153,872	9.17

The following table summarizes the share purchase warrants outstanding and exercisable as at December 31, 2012:

Exercise price (US\$)	Warrants outstanding and currently exercisable		
	Number	Weighted average remaining contractual life (years)	Total intrinsic value
3.45	2,970,000	4.80	—
7.50	122,221	1.81	—
8.24	530,424	2.47	—
9.00	740,737	2.80	—
10.29	44,028	2.46	—
	4,407,410	4.07	—

## Aeterna Zentaris Inc.

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(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

The table presented below shows the inputs and assumptions applied to the Black-Scholes option pricing model in order to determine the fair value of warrants outstanding as at December 31, 2012.

	October 2009 Investor Warrants	April 2010 Investor Warrants	June 2010 Investor Warrants	June 2010 Compensation Warrants	October 2012 Investor Warrants
Number of equivalent shares	122,221	740,737	530,424	44,028	2,970,000
Market-value per share price	2.38	2.38	2.38	2.38	2.38
Exercise price	7.50	9.00	8.24	10.29	3.45
Risk-free annual interest rate	(a) 0.23%	0.34%	0.30%	0.30%	0.68%
Expected volatility	(b) 109.43%	101.04%	98.31%	98.46%	108.66%
Expected life (years)	(c) 1.81	2.80	2.47	2.46	4.80
Expected dividend yield	(d) 0.00%	0.00%	0.00%	0.00%	0.00%

(a) Based on United States Treasury Government Bond interest rates with a term that is consistent with the expected life of the warrants.

(b) Based on the historical volatility of the Company's stock price over the most recent period consistent with the expected life of the warrants, as well as on future expectations.

(c) Based upon time to expiry from the reporting period date.

(d) The Company has not paid dividends nor intends to pay dividends in the foreseeable future.

The Black-Scholes valuation methodology uses "Level 2" inputs in calculating fair value, as defined in IFRS 7 and as discussed in note 23 – Financial instruments and financial risk management.

#### 15 Provision and other non-current liabilities

	As at December 31,	
	2012	2011
	\$	\$
Onerous lease provision (see below)	436	530
Other	149	187
	<u>585</u>	<u>717</u>

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## Notes to Consolidated Financial Statements

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### Onerous lease provision\*

	Year ended December 31, 2012
	\$
Balance at January 1, 2012	619
Additional provision recognized	—
Utilization of provision	(92)
Effect of change in the discount rate	—
Unwinding of discount	3
Balance at December 31, 2012	530
Current portion	(94)
Non-current portion at December 31, 2012	436

\* The provision for onerous lease contract represents the present value of the future lease payments that the Company is presently obligated to make under non-cancellable onerous operating lease contract, less revenue expected to be earned on the lease, including estimated future sub-lease revenue. The estimate may vary as a result of changes in the utilisation of the leased premises and sub-lease arrangement. The unexpired term of the lease is five years.

## 16 Share capital

The Company has authorized an unlimited number of common shares (being voting and participating shares) with no par value, as well as an unlimited number of preferred, first and second ranking shares, issuable in series, with rights and privileges specific to each class, with no par value.

### Share consolidation

On October 2, 2012, the Company completed a share consolidation of its issued and outstanding common shares on a 6-to-1 basis. Therefore, the 112,375,726 common shares issued and outstanding immediately prior to the Share Consolidation were consolidated into 18,729,288 common shares. The Company's outstanding stock options and share purchase warrants were adjusted on the same basis with proportionate adjustments being made to each stock option and share purchase warrant exercise price.

All shares, options and share purchase warrants as well as per share, option and share purchase warrant information has been retroactively adjusted to reflect and give effect to the Share Consolidation as if it occurred at the beginning of the period presented.

### Common shares issued in connection with "At-the-Market" ("ATM") drawdowns

#### January 2012 ATM Program

On January 23, 2012, the Company entered into an ATM sales agreement (the "January 2012 ATM Program"), under which the Company was able, at its discretion and from time to time, to sell up to 1,733,333 of its common shares through ATM issuances on the NASDAQ for aggregate gross proceeds not to exceed \$16,000,000. The January 2012 ATM Program provided that common shares were to be sold at market prices prevailing at the time of sale and, as a result, prices may have varied.

Between January 23, 2012 and December 31, 2012, the Company issued a total of 1,190,973 common shares under the January 2012 ATM Program for aggregate gross proceeds of \$8,783,947, less cash transaction costs of \$263,518 and previously deferred transaction costs of \$139,089.

# Aeterna Zentaris Inc.

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### Common shares issued in connection with a public offering

#### *Public offering*

On October 17, 2012, the Company completed a public offering (the "Offering") of 6,600,000 units, at a purchase price of \$2.50 per unit, with each unit consisting of one common share and 0.45 of a warrant to purchase a common share. The related warrants (the "October 2012 Investor Warrants") represent the right to acquire an aggregate of 2,970,000 common shares, as discussed below.

Total cash proceeds raised through the Offering amounted to \$16,500,000, less cash transaction costs of approximately \$1,403,000 and previously deferred transaction costs of \$102,000. The securities were offered by the Company pursuant to a shelf prospectus dated June 8, 2012 and a prospectus supplement dated October 12, 2012.

The Company granted the October 2012 Investor Warrants to the investors who participated in the Offering at an exercise price of \$3.45 per share. The Investor Warrants are exercisable at any time during their five-year term and, upon complete exercise, would result in the issuance of an aggregate of 2,970,000 common shares that would generate additional proceeds of \$10,246,500.

The Company estimated the fair value attributable to the 2,970,000 October 2012 Investor Warrants as of the date of grant by applying the Black-Scholes pricing model, to which the following additional assumptions were applied: a risk-free annual interest rate of 0.66%, an expected volatility of 106.87%, an expected life of 5 years and a dividend yield of 0.0%. As a result, the fair value of the share purchase warrants was estimated at \$4,100,000 using an iteration process for determining the fair value of the units' components.

As such, the total gross proceeds of the Offering were allocated as follows: \$4,100,000 was allocated to Warrant liability and the balance of \$12,400,000, representing \$1.88 per common share, was allocated to Share capital. Transaction costs were allocated to the liability and equity units' components in proportion to the allocation of proceeds. As such, an amount of \$370,000 (note 17 – Operating expenses) was allocated to the share purchase warrants and immediately recognized in general and administrative expenses in the statement of comprehensive loss and an amount of \$1,135,000 was allocated to the common shares and deducted from Share capital.

### Shareholder rights plan

Effective March 29, 2010, the Company adopted a shareholder rights plan (the "Rights Plan"). The Rights Plan was approved by the Board of Directors on March 22, 2010 and ratified on May 13, 2010 by the Company's shareholders. Under the terms of the Rights Plan, its continued existence must be reconfirmed by the Company's shareholders at the Company's annual meeting of shareholders to be held on May 8, 2013 (the "Meeting"). If not reconfirmed, the Rights Plan and the rights issued thereunder will terminate at the close of the Meeting, unless earlier terminated. The rights issued to the shareholders under the Rights Plan will be exercisable, under certain conditions, only when a person or entity, including related parties, acquires or announces his/her or its intention to acquire more than twenty (20) percent of the outstanding common shares of the Company (as such shares may be redesignated or reclassified) without complying with the "permitted bid" provisions of the Rights Plan or without approval of the Company's Board of Directors. Should such an acquisition occur, each right would, upon exercise, entitle a holder, other than the person pursuing the acquisition together with any related parties, to purchase common shares of the Company at a fifty (50) percent discount to the market price of the Company's shares at that time.

### Stock options

In December 1995, the Company's Board of Directors adopted a stock option plan (the "Stock Option Plan") for its directors, senior executives, employees and other collaborators who provide services to the Company. The total number of common shares that may be issued under the Stock Option Plan cannot exceed 11.4% of the total number of issued and outstanding common shares at any given time.

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Options granted under the Stock Option Plan expire after a maximum period of ten years following the date of grant. Options granted under the Stock Option Plan generally vest over a three-year period. However, 778,780 of the options granted in 2012 and 87,411 of the options granted in 2011 vest over a period of 18 months. Furthermore, 191,666 of the options granted in 2012 vested over certain other periods\*.

The following table summarizes the activity under the Company's stock option plan.

	Years ended December 31,					
	2012		2011		2010	
	Canadian Dollar Options		Canadian Dollar Options		Canadian Dollar Options	
	Number	Weighted average exercise price (CANS)	Number	Weighted average exercise price (CANS)	Number	Weighted average exercise price (CANS)
Balance – Beginning of the year	1,031,328	14.99	1,093,047	15.32	986,700	16.31
Granted	—	—	2,500	11.58	181,416	9.04
Exercised	(25,582)	8.51	(26,724)	5.33	(20,678)	5.40
Forfeited	(57,437)	15.07	(7,777)	9.24	(12,450)	5.70
Expired	(220,434)	23.22	(29,718)	37.08	(41,941)	19.32
Balance – End of the year	727,875	12.71	1,031,328	14.99	1,093,047	15.32

	Years ended December 31,					
	2012		2011		2010	
	US Dollar Options		US Dollar Options		US Dollar Options	
	Number	Weighted average exercise price (US\$)	Number	Weighted average exercise price (US\$)	Number	Weighted average exercise price (US\$)
Balance – Beginning of the year	287,950	11.59	48,886	16.98	48,886	16.98
Granted	1,060,445 *	2.4	239,064	10.49	—	—
Exercised	—	—	—	—	—	—
Forfeited	(19,903)	10.44	—	—	—	—
Balance – End of the year	1,328,492	4.27	287,950	11.59	48,886	16.98

\* During the period, under the Company's stock option plan and in addition to the stock options granted to employees, the Company granted 125,000 stock options to a financial advisor and 66,666 stock options to an investor relations advisor. The 125,000 stock options will vest upon the achievement of a certain strategic alliance transaction and will expire ten years after the grant date. Among the 66,666 stock options, 33,333 vested upon signature of the service agreement and the remainder vested 90 days later. These 66,666 stock options will expire five years after the grant date.



**Aeterna Zentaris Inc.**

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**CAN\$ options outstanding as at December 31, 2012**

<b>Exercise price (CAN\$)</b>	<b>Number</b>	<b>Weighted average remaining contractual life (years)</b>	<b>Weighted average exercise price (CAN\$)</b>	<b>Total intrinsic value (CAN\$)</b>
3.30 to 4.80	101,722	5.89	3.59	—
4.81 to 7.02	170,395	6.93	5.70	—
7.03 to 9.78	164,088	7.09	8.99	—
9.79 to 21.21	165,739	2.85	13.63	—
21.22 to 53.28	125,931	2.49	33.22	—
	727,875	5.13	12.71	—

**CAN\$ options exercisable as at December 31, 2012**

<b>Exercise price (CAN\$)</b>	<b>Number</b>	<b>Weighted average remaining contractual life (years)</b>	<b>Weighted average exercise price (CAN\$)</b>	<b>Total intrinsic value (CAN\$)</b>
3.30 to 4.80	101,722	5.89	3.59	—
4.81 to 7.02	170,395	6.93	5.70	—
7.03 to 9.78	154,092	7.03	8.99	—
9.79 to 21.21	164,073	2.79	13.65	—
21.22 to 53.28	125,931	2.49	33.22	—
	716,213	5.08	12.77	—

**US\$ options outstanding as at December 31, 2012**

<b>Exercise price (US\$)</b>	<b>Number</b>	<b>Weighted average remaining contractual life (years)</b>	<b>Weighted average exercise price (US\$)</b>	<b>Total intrinsic value (US\$)</b>
2.17 to 2.39	786,280	9.93	2.17	165,119
2.40 to 2.92	141,666	9.43	2.66	—
2.93 to 10.17	132,499	7.01	3.49	—
10.18 to 10.68	215,828	8.93	10.44	—
10.69 to 23.76	52,219	4.81	16.80	—
	1,328,492	9.22	4.27	165,119

## Aeterna Zentaris Inc.

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US\$ options exercisable as at December 31, 2012				
Exercise price (US\$)	Number	Weighted average remaining contractual life (years)	Weighted average exercise price (US\$)	Total intrinsic value (US\$)
2.40 to 2.92	16,666	9.44	2.62	—
2.93 to 10.17	67,500	4.75	3.26	—
10.18 to 10.68	98,354	8.93	10.44	—
10.69 to 23.76	49,997	4.65	16.92	—
	232,517	6.83	9.19	—

As at December 31, 2012, the total compensation cost related to unvested Canadian Dollar stock options not yet recognized amounted to \$22,766 (\$146,641 in 2011). This amount is expected to be recognized over a weighted average period of 1.03 year (0.98 year in 2011).

As at December 31, 2012, the total compensation cost related to unvested US Dollar stock options not yet recognized amounted to \$1,660,787 (\$1,322,752 in 2011). This amount is expected to be recognized over a weighted average period of 1.00 year (1.48 year in 2011).

The Company settles stock options exercised through the issuance of common shares from treasury.

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#### Fair value input assumptions for Canadian Dollar Options granted

The table below shows the assumptions, or weighted average parameters, applied to the Black-Scholes option pricing model in order to determine stock-based compensation costs over the life of the awards.

		Year ended December 31, 2011	Year ended December 31, 2010
Expected dividend yield	(a)	0.0%	0.0%
Expected volatility	(b)	81.0%	84.5%
Risk-free annual interest rate	(c)	1.8%	2.6%
Expected life (years)	(d)	6.82	6.07
Weighted average grant date fair value		CAN\$8.43	CAN\$6.54

(a) The Company has not paid dividends nor intends to pay dividends in the foreseeable future.

(b) Based on the historical volatility of the Company's stock price over the most recent period consistent with the expected life of the stock options, as well as on future expectations.

(c) Based on Canadian Government Bond interest rates with a term that is consistent with the expected life of the stock options.

(d) Based upon historical data related to the exercise of stock options, on post-vesting employment terminations and on future expectations related to exercise behaviour.

#### Fair value input assumptions for US Dollar Options granted

The table below shows the assumptions, or weighted average parameters, applied to the Black-Scholes option pricing model in order to determine stock-based compensation costs over the life of the awards.

		Years ended December 31,	
		2012	2011
Expected dividend yield	(a)	0.0%	0.0%
Expected volatility	(b)	95.4%	81.6%
Risk-free annual interest rate	(c)	0.98%	1.4%
Expected life (years)	(d)	6.77	6.82
Weighted average grant date fair value		US\$1.93	US\$7.63

(a) The Company has not paid dividends nor intends to pay dividends in the foreseeable future.

(b) Based on the historical volatility of the Company's stock price over the most recent period consistent with the expected life of the stock options, as well as on future expectations.

(c) Based on United States Treasury Government Bond interest rates with a term that is consistent with the expected life of the stock options.

(d) Based upon historical data related to the exercise of stock options, on post-vesting employment terminations and on future expectations related to exercise behaviour.

The Black-Scholes pricing models referred above use "Level 2" inputs in calculating fair value, as defined by IFRS 7, and as discussed in note 23 – Financial instruments and financial risk management.

## Aeterna Zentaris Inc.

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#### 17 Operating expenses

Components of the Company's operating expenses include the following:

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
Subcontractor fees	25,515	25,667	15,907
Raw material purchases	1,780	2,154	1,897
Change in inventory	(560)	(261)	896
Depreciation of equipment	85	—	—
Cost of sales	26,820	27,560	18,700
Salaries, employment taxes and short-term benefits	11,158	13,029	11,885
Post-employment benefits	701	864	665
Termination benefits	189	182	45
Share-based compensation costs	1,455	1,333	1,192
Total employee benefits expenses	13,503	15,408	13,787
Goods and services <sup>(1)</sup>	17,229	20,334	17,316
Lease payments <sup>(2)</sup> , net of sublease payments of \$226,000 in 2012 and \$179,000 in 2011 and 2010	1,751	2,153	1,825
Refundable tax credits and grants	(868)	(383)	(687)
Share-based compensation costs related to collaborators	342	—	—
Transaction costs related to share purchase warrants	370	—	—
Depreciation and amortization	1,135	1,471	1,573
Impairment losses	184	1,405	—
Operating foreign exchange (gains) loss	203	299	(5)
Total operating expenses	60,669	68,247	52,509

(1) Goods and services include third-party R&D costs, laboratory supplies, royalty expenses, professional fees, marketing services, insurance as well as travel expenses.

(2) Lease expense also includes changes in the onerous lease provision (note 15 – Provision and other non-current liabilities), except for the unwinding of discount.

#### 18 Employee future benefits

The Company's subsidiary in Germany provides unfunded defined benefit pension plans and unfunded post-employment benefit plans for some groups of employees. Provisions for pension obligations are established for benefits payable in the form of retirement, disability and surviving dependent pensions.

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(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

The following table provides a reconciliation of the changes in the aforementioned plans' accrued benefit obligations:

	Pension benefit plans			Other benefit plans		
	2012	2011	2010	2012	2011	2010
	\$	\$	\$	\$	\$	\$
Obligation - Beginning of year	11,769	10,492	10,767	1,111	1,041	1,254
Current service cost	139	185	217	134	206	254
Interest cost	491	555	546	46	54	63
Actuarial (gain) loss	3,705	1,335	(191)	79	46	(370)
Benefits paid	(337)	(354)	(173)	(219)	(196)	(86)
Effect of foreign currency exchange rate changes	295	(444)	(674)	18	(40)	(74)
Obligation - End of year	16,062	11,769	10,492	1,169	1,111	1,041
Amount recognized						
In comprehensive loss	(630)	(740)	(763)	(259)	(306)	53
In other comprehensive (loss) income	(3,705)	(1,335)	191	—	—	—

The cumulative amount of actuarial losses recognized in other comprehensive (loss) income as at December 31, 2012 is approximately \$4,849,000 (cumulative actuarial losses of approximately \$1,144,000 as at December 31, 2011 and cumulative actuarial gain of approximately \$191,000 as at December 31, 2010).

The significant actuarial assumptions adopted to determine the Company's accrued benefit obligations are as follows:

Actuarial assumptions	Pension benefit plans			Other benefit plans		
	2012	2011	2010	2012	2011	2010
	%	%	%	%	%	%
Discount rate	2.60	4.20	5.10	2.60	4.20	5.10
Pension benefits increase	2.00	2.00	2.00	2.00	2.00	2.00
Rate of compensation increase	2.75 to 3.75	2.75 to 3.75	2.75 to 3.75	2.75	2.75	2.75

The last actuarial reports give effect to the pension and post-employment benefit obligations as at December 31, 2012. The next actuarial reports are planned for December 31, 2013.

The calculation of the Pension benefit plans obligation is sensitive to the discount rate assumption set out above. From December 31, 2010 to December 31, 2012, management determined that the discount rate assumption should be decreased as a result of changes in the European economic environment.

As the European economic environment continue to evolve, an increase of 0.25% in discount rate shown above is considered reasonably possible in the next financial year. The effect of this change would be a decrease in the pension benefit plans obligation of approximately \$1,125,000.

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In accordance with the assumptions used as at December 31, 2012, future benefits expected to be paid are as follows:

	\$
2013	485
2014	520
2015	555
2016	566
2017	585
2018 through 2021	3,254
	<u>5,965</u>

Cash required in the next year to fund the plans will approximate the amount of expected benefits.

Total expenses for the Company's defined contribution plan in its German subsidiary amounted to approximately \$331,287 for the year ended December 31, 2012 (\$312,984 for 2011 and \$257,260 for 2010).

## 19 Finance income and finance costs

Components of the Company's finance income and finance costs can be summarized as follows:

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
<b>Finance income</b>			
Net gains due to changes in foreign currency exchange rates	—	2,197	932
Change in fair value of warrant liability	6,746	2,533	—
Interest income	228	223	173
Gain on held-for-trading financial instrument	—	1,278	687
	<u>6,974</u>	<u>6,231</u>	<u>1,792</u>
<b>Finance costs</b>			
Net losses due to changes in foreign currency exchange rates	(382)	—	—
Change in fair value of warrant liability	—	—	(5,437)
	<u>(382)</u>	<u>—</u>	<u>(5,437)</u>
	<u>6,592</u>	<u>6,231</u>	<u>(3,645)</u>

## Aeterna Zentaris Inc.

### Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

#### 20 Supplemental disclosure of cash flow information

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
<b>Changes in operating assets and liabilities</b>			
Trade and other receivables	383	(3,332)	(2,029)
Inventory	(560)	(261)	896
Prepaid expenses and other current assets	(4,914)	(4,068)	(3,344)
Other non-current assets	(364)	(456)	(315)
Payables and accrued liabilities	(1,836)	2,970	(1,956)
Provision and other non-current liabilities	(49)	(24)	109
Deferred revenues	—	8,614	—
Income taxes	(254)	105	(900)
	<u>(7,594)</u>	<u>3,548</u>	<u>(7,539)</u>

During the year ended December 31, 2012, the Company paid approximately \$259,000 in income taxes (\$841,000 in 2011) in the form of foreign jurisdiction withholding tax on payments received pursuant to the licensing agreement.

#### 21 Income taxes

Significant components of current and deferred income tax expense:

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
Current:	—	(1,104)	—
Deferred:			
Origination and reversal of temporary differences	7,282	9,017	7,632
Change in enacted tax rates	—	(104)	(272)
Adjustments in respect of prior years	44	3,428	(176)
Change in unrecognized tax assets	(7,326)	(12,341)	(7,184)
Income tax expense	<u>—</u>	<u>(1,104)</u>	<u>—</u>

The reconciliation of the combined Canadian federal and Quebec provincial income tax rate to the income tax expense is provided below:

	Years ended December 31,		
	2012	2011	2010
Combined Canadian federal and provincial statutory income tax rate	<u>26.9%</u>	<u>28.4%</u>	<u>29.9%</u>

## Aeterna Zentaris Inc.

### Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
Income tax recovery based on statutory income tax rate	5,494	7,290	8,500
Change in unrecognized tax assets	(7,326)	(12,341)	(7,184)
Permanent difference attributable to the use of local currency for tax reporting	14	378	1,232
Permanent difference attributable to net change in fair value of warrant liability	1,182	661	(1,761)
Stock-based compensation costs	(421)	(441)	(357)
Difference in statutory income tax rate of foreign subsidiaries	997	893	391
Permanent difference attributable to unrealized foreign exchange gain/loss	(22)	(32)	(159)
Change in enacted rates used	—	(104)	(272)
Expiry of loss carryforwards	—	—	(164)
Foreign withholding tax	—	(1,104)	—
Adjustments in respect of prior years	44	3,428	(176)
Other	38	268	(50)
	—	(1,104)	—

The decrease in the applicable tax rates is mainly due to the reduction of the federal income tax rate from 18.0% to 16.5% to 15.0% for 2010, 2011 and 2012 respectively.

Income tax expense of \$1,104,000 for the year ended December 31, 2011 represents current taxation in the form of foreign jurisdiction tax withholdings on payments pursuant to a licensing agreement (note 5 – Development, commercialization and license agreement).

Deferred income tax assets are recognized to the extent that the realization of the related tax benefit through reversal of temporary differences and future taxable profits is probable. If income tax assets had been booked in 2012, an amount of \$7,326,000 would have been credited to the income statement, \$1,183,000 to other comprehensive income and \$408,000 to equity. The remaining variation in unrecognized tax assets of \$1,706,000 is due to exchange rate differences.

#### Loss before income taxes

Loss before income taxes is attributable to the Company's tax jurisdictions as follows:

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
Germany	(20,957)	(25,246)	(19,763)
Canada	322	(290)	(8,664)
United States	224	(427)	(24)
	(20,411)	(25,963)	(28,451)



**Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

Significant components of deferred tax assets and liabilities:

	As at December 31,	
	2012	2011
	\$	\$
Deferred tax assets		
Long-term:		
Operating losses carried forward	840	224
	840	224
Deferred tax liabilities		
Property, plant and equipment	160	197
Warrant liability	626	—
Other	54	27
	840	224
<b>Deferred tax assets (liabilities), net</b>	<b>—</b>	<b>—</b>

**Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

Significant components of unrecognized deferred tax assets are as follows:

	As at December 31,	
	2012	2011
	\$	\$
Deferred tax assets		
Inventory	9	740
Deferred revenues	464	507
	<u>473</u>	<u>1,247</u>
Long term:		
Operating losses carried forward	49,453	38,665
Intangible assets	12,271	13,170
Research and development costs	12,642	12,310
Unused tax credits	10,904	10,667
Employee future benefits	2,772	1,534
Property, plant and equipment	1,376	1,301
Share issue expenses	867	813
Deferred revenues	182	589
Onerous lease provision	159	186
Other	145	139
	<u>90,771</u>	<u>79,374</u>
Unrecognized deferred tax assets	<u>91,244</u>	<u>80,621</u>

As at December 31, 2012, amounts and expiry dates of tax attributes to be deferred for which no deferred tax asset was recognized were as follow:

	Canada	
	Federal	Provincial
	\$	\$
2015	2,495	—
2028	11,205	8,446
2029	6,665	6,640
2030	5,710	5,689
2031	2,664	2,642
2032	6,153	6,153
	<u>34,892</u>	<u>29,570</u>

# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

The Company has estimated non-refundable research and development tax credits of approximately \$10,904,000 which can be carried forward to reduce Canadian federal income taxes payable and which expire at dates ranging from 2018 to 2030. Furthermore, the Company has unrecognized tax assets in respect of operating losses in Germany and in the United States. The losses amount to \$129,333,000 in Germany, for which there is no expiry date and to \$735,000 in the United States, which expire as follows:

	<u>United States</u>
	<u>\$</u>
2028	557
2029	178
	<u>735</u>

The operating loss carryforwards and the tax credits claimed are subject to review, and potential adjustment, by tax authorities.

Other deductible temporary differences for which tax assets have not been booked are not subject to a time limit, except for share issue expenses which are amortizable over 5 years.

## 22 Capital disclosures

The Company's objective in managing capital, primarily composed of shareholders' deficiency and cash and cash equivalents, is to ensure sufficient liquidity to fund R&D activities, general and administrative expenses, working capital and capital expenditures.

In the past, the Company has had access to liquidity by non-dilutive sources, including the sale of non-core assets, investment tax credits and grants, interest income, licensing and related services and royalties. More recently, the Company has raised capital via public equity offerings and drawdowns under various ATM sales programs, as discussed in note 16 – Share capital.

At December 31, 2012, the Company's working capital amounted to \$42,925,000, including cash and cash equivalents of \$39,521,000. The accumulated deficit at the same date was \$213,086,000. Based on the Company's assessment, which took into account current cash levels, as well as its strategic plan and corresponding budgets and forecasts, the Company believes that it has sufficient liquidity and financial resources to fund planned expenditures and other working capital needs for at least, but not limited to, the 12-month period following the statement of financial position date of December 31, 2012. See note 23 – Financial instruments and financial risk management – Liquidity risk.

The capital management objective of the Company remains the same as that of previous periods. The policy on dividends is to retain cash to keep funds available to finance the activities required to advance the Company's product development pipeline.

The Company is not subject to any capital requirements imposed by any regulators or by any other external source.

# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

### 23 Financial instruments and financial risk management

Financial assets (liabilities) as at December 31, 2012 and December 31, 2011 are presented below.

December 31, 2012	Loans and receivables	Financial liabilities at FVTPL	Other financial liabilities	Total
	\$	\$	\$	\$
Cash and cash equivalents (note 6)	39,521	—	—	39,521
Trade and other receivables (note 7)	7,993	—	—	7,993
Restricted cash (note 9)	826	—	—	826
Payables and accrued liabilities (note 13)	—	—	(10,346)	(10,346)
Long-term payable*	—	—	(30)	(30)
Warrant liability (note 14)*	—	(6,176)	—	(6,176)
Other non-current liabilities (note 15)	—	—	(149)	(149)
	48,340	(6,176)	(10,525)	31,639

\* Includes current and non-current portions.

December 31, 2011	Loans and receivables	Financial liabilities at FVTPL	Other financial liabilities	Total
	\$	\$	\$	\$
Cash and cash equivalents (note 6)	46,881	—	—	46,881
Trade and other receivables (note 7)	8,325	—	—	8,325
Restricted cash (note 9)	806	—	—	806
Payables and accrued liabilities (note 13)	—	—	(12,126)	(12,126)
Long-term payable*	—	—	(88)	(88)
Warrant liability (note 14)*	—	(9,204)	—	(9,204)
Other non-current liabilities (note 15)	—	—	(187)	(187)
	56,012	(9,204)	(12,401)	34,407

\* Includes current and non-current portions.

#### Fair value

The Black-Scholes valuation methodology uses "Level 2" inputs in calculating fair value, as defined in IFRS 7, which establishes a hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The input levels discussed in IFRS 7 are:

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs other than quoted prices included within Level 1 that are observable for an asset or liability, either directly (i.e. prices) or indirectly (i.e. derived from prices).
- Level 3 – Inputs for an asset or liability that are not based on observable market data (unobservable inputs).

# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

The carrying values of the Company's cash and cash equivalents, trade and other receivables, restricted cash, payables and accrued liabilities, long-term payable and other non-current liabilities approximate their fair values due to their short-term maturities or to the prevailing interest rates of the related instruments, which are comparable to those of the market.

### Financial risk factors

The following provides disclosures relating to the nature and extent of the Company's exposure to risks arising from financial instruments, including credit risk, liquidity risk and market risk (share price risk and currency risk), and how the Company manages those risks.

#### (a) Credit risk

Credit risk is the risk of an unexpected loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. The Company regularly monitors credit risk exposure and takes steps to mitigate the likelihood of this exposure resulting in losses. The Company's exposure to credit risk currently relates to cash and cash equivalents (note 6), to trade and other receivables (note 7) and to restricted cash (note 9). The Company invests its available cash in amounts that are readily convertible to known amounts of cash and deposits its cash balances with financial institutions that are rated the equivalent of "A3" and above. This information is supplied by independent rating agencies where available and, if not available, the Company uses publicly available financial information to ensure it invests its cash in creditworthy and reputable financial institutions.

As at December 31, 2012, trade accounts receivable for an amount of approximately \$7,306,000 were with Company 1 (note 27 – Segment information) and another customer.

As at December 31, 2012, no trade accounts receivable were past due or impaired.

Generally, the Company does not require collateral or other security from customers for trade accounts receivable; however, credit is extended following an evaluation of creditworthiness. In addition, the Company performs ongoing credit reviews of all of its customers and establishes an allowance for doubtful accounts when accounts are determined to be uncollectible.

The maximum exposure to credit risk approximates the amount recognized on the statement of financial position.

#### (b) Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they become due. As indicated in the capital disclosures section (note 22), the Company manages this risk through the management of its capital structure. It also manages liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors reviews and approves the Company's operating and capital budgets, as well as any material transactions out of the ordinary course of business. The Company has adopted an investment policy in respect of the safety and preservation of its capital to ensure the Company's liquidity needs are met. The instruments are selected with regard to the expected timing of expenditures and prevailing interest rates.

Management of the Company believes that it has sufficient funds to pay its ongoing general and administrative expenses, to pursue its R&D activities and to meet its liabilities, obligations and existing commitments for the ensuing twelve months as they fall due. In assessing whether the going concern assumption is appropriate, management takes into account all available information about the future, which is at least, but not limited to, twelve months from the end of the reporting period. The Company expects to continue to incur operating losses and may require significant capital to fulfill its future obligations. See note 22 – Capital disclosure. The Company's ability to continue future operations beyond December 31, 2013 and fund its activities is dependent on management's ability to secure additional financings which may be completed in a number of ways including but not limited to licensing deals, partnerships and share issuance. Management will pursue such additional sources of financing when required, and while management has been successful in securing financing in the past, there can be no assurance it will be able to do so in the future or that these sources of funding or initiatives will be available for the Company or that they will be available on terms which are acceptable to the Company.

# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

### (c) Market risk

#### Share price risk

The change in fair value of the Company's warrant liability, which is measured at FVTPL, results from the periodic "mark-to-market" revaluation, via the application of the Black-Scholes option pricing model, of currently outstanding share purchase warrants. The Black-Scholes valuation is impacted, among other inputs, by the market price of the Company's common shares. As a result, the change in fair value of the warrant liability, which is reported as finance income (costs) in the accompanying consolidated statements of comprehensive income (loss), has been and may continue in future periods to be materially affected most notably by changes in the Company's common share price closing, which on the NASDAQ, has ranged from \$1.87 to \$12.90 during the year ended December 31, 2012.

If variations in the market price of our common shares of -10% and +10% were to occur, the impact on the Company's net (loss) income for warrant liability held at December 31, 2012 would be as follows:

	Carrying amount	-10%	+10%
	\$	\$	\$
Warrant liability	6,176	768	(783)
<b>Total impact on net loss – decrease / (increase)</b>		<b>768</b>	<b>(783)</b>

#### Foreign currency risk

Since the Company operates internationally, it is exposed to currency risks as a result of potential exchange rate fluctuations related to non-intragroup transactions. In particular, fluctuations in the US and CA dollar exchange rates against the EUR could have a potentially significant impact on the Company's results of operations.

If foreign exchange rate variations of -5% (depreciation of the EUR) and +5% (appreciation of the EUR) against the US\$ and the CA\$, from period-end rates of EUR1 = US\$1.3185 and of EUR1=CA\$1.3118 were to occur, the impact on the Company's net (loss) income for each category of financial instruments held at December 31, 2012 would be as follows:

	Carrying amount	Balances denominated in US\$	
		-5%	+5%
	\$	\$	\$
Cash and cash equivalents	24,551	1,228	(1,228)
Warrant liability	6,176	(309)	309
<b>Total impact on net loss – decrease / (increase)</b>		<b>919</b>	<b>(919)</b>

	Carrying amount	Balances denominated in CA\$	
		-5%	+5%
	\$	\$	\$
Cash and cash equivalents	7,064	353	(353)
<b>Total impact on net loss – decrease / (increase)</b>		<b>353</b>	<b>(353)</b>

## Aeterna Zentaris Inc.

### Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

#### 24 Commitments, contingencies and guarantee

The Company is committed to various operating leases for its premises plus service and manufacturing contracts.

Future minimum lease payments and future minimum sublease payments expected to be received under non-cancellable operating leases (subleases), as well as future payments in connection with utility service agreements, as at December 31, 2012 are as follows:

	<u>Minimum lease payments</u>	<u>Minimum sub-lease payments</u>	<u>Utilities</u>
	\$	\$	\$
Less than 1 year	1,669	(226)	610
1 - 3 years	3,215	(451)	861
4 - 5 years	997	(451)	105
More than 5 years	29	(19)	—
<b>Total</b>	<b>5,910</b>	<b>(1,147)</b>	<b>1,576</b>

The Company has a leasing arrangement in Germany under which it rents laboratory, storage and office space. The original term of the lease, ten years (or March 2016), is automatically renewable for two further five-year periods if not terminated otherwise by the Company within 12 months prior to original expiry. Under the terms of the arrangement, the minimum lease payment may be increased or lowered proportionally to the fluctuation in consumer price index for Germany if that change is more than 5% on an accumulated basis. The terms of the lease arrangement for the ten years following automatic renewal are the same as per the original agreement.

In October 2007, the Company entered into a \$100,000 letter of credit agreement in favour of its landlord in the United States with respect to the Company's long-term lease obligation. In August 2009 and November 2011, the amount of the letter of credit was reduced to \$75,000 and \$50,000, respectively, as per the original landlord-tenant agreement, and is payable to the landlord in the event that the Company fails to perform any of its obligations under the related lease agreement.

Service and manufacturing commitments given, which consist of R&D service agreements and manufacturing agreements for Cetrotide<sup>®</sup>, are as follows:

	<u>December 31, 2012</u>
	\$
Less than 1 year	10,123
1 - 3 years	6,693
4 - 5 years	—
More than 5 years	—
<b>Total</b>	<b>16,816</b>

#### Contingencies

In the normal course of operations, the Company may become involved in various claims and legal proceedings related to, for example, contract terminations, employee-related and other matters. No contingent liabilities have been accrued as at December 31, 2012 or 2011.

# Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

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(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

### Class Action Lawsuit

On December 21, 2012, a second amended securities class action ("SASCA") was filed against the Company and certain of its senior officers in the purported class action lawsuit initially filed in June 2012 in the United States District Court, Southern District of New York. On February 1, 2013, the Company filed a motion to dismiss the SASCA complaint. This lawsuit, alleging failures to disclose certain information under U.S. federal securities laws, is being prosecuted by a lead plaintiff on behalf of shareholders who acquired the Company's common shares between June 1, 2009 and April 1, 2012 and does not claim a specified amount of damages.

The Company has not recorded any liability related to these matters. The Company's directors' and officers' insurance policy provides for reimbursement of costs and expenses incurred in connection with this lawsuit, including legal and professional fees, as well as potential damages awarded, if any, subject to certain policy restrictions, limits and deductibles. The Company continues to believe that there is no basis for the lawsuit and it intends to defend itself vigorously. However, no assurance can be given with respect to the ultimate outcome of such proceedings, and the amount of any damages awarded in such lawsuit could be substantial.

## 25 Net loss per share

The following table sets forth pertinent data relating to the computation of basic and diluted net income (loss) per share attributable to common shareholders.

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
<b>Net loss</b>	<b>(20,412)</b>	<b>(27,067)</b>	<b>(28,451)</b>
<b>Basic weighted average number of shares outstanding</b>	<b>19,775,073</b>	<b>15,751,331</b>	<b>12,609,902</b>
Dilutive effect of stock options	31,614	190,625	54,413
Dilutive effect of share purchase warrants	—	282,903	—
<b>Diluted weighted average number of shares outstanding</b>	<b>19,806,687</b>	<b>16,224,859</b>	<b>12,664,315</b>
<b>Items excluded from the calculation of diluted net loss per share because the exercise price was greater than the average market price of the common shares or due to their anti-dilutive effect</b>			
Stock options	1,183,388	613,644	833,276
Warrants (number of equivalent shares)	1,803,730	—	2,153,898

For the years ended December 31, 2012, 2011 and 2010, the diluted net (loss) income per share was the same as the basic net (loss) income per share, since the effect of the assumed exercise of stock options and warrants to purchase common shares is anti-dilutive. Accordingly, the diluted net income (loss) per share for these periods was calculated using the basic weighted average number of shares outstanding.

The weighted average number of shares is influenced most notably by share issuances made in connection with financing activities, such as public equity offerings and ATM drawdowns, which resulted in the issuance of a total of 7,790,973 (see note 16 – Share capital), 3,244,094 and 3,319,513 common shares during the years ended December 31, 2012, 2011 and 2010, respectively.



## Aeterna Zentaris Inc.

### Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

#### 26 Compensation of key management

Compensation awarded to key management\* included:

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
Salaries and short-term employee benefits	2,354	2,886	2,524
Post-employment benefits	957	684	114
Termination benefits	—	—	—
Share-based compensation cost	941	936	554
	<u>4,252</u>	<u>4,506</u>	<u>3,192</u>

\* Key management includes the Company's directors and members of the Executive Committee.

Executive Officers Employment Agreements provides that, if the Company terminates their employment without cause or due to a change of control, they are entitled to termination benefits of the equivalent of between 12 and 24 months of their then applicable base salary, an amount equivalent to between 100% and 200% of their annual bonus received (or their eligible bonus, in case of change of control) for the most recently completed year and an amount equivalent to between 12 and 18 months of the cost of the other benefits to which they are entitled.

#### 27 Segment information

The Company operates in a single operating segment, being the biopharmaceutical segment.

##### Geographical information

The Company is domiciled in Canada and derives all its revenues from its operating subsidiaries domiciled in Germany.

Revenues by geographical area are detailed as follows:

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
United States	5,158	5,492	9,902
Switzerland	24,406	24,977	15,907
Japan	4,062	5,472	1,684
Other	39	112	210
	<u>33,665</u>	<u>36,053</u>	<u>27,703</u>

Revenues have been allocated to geographic regions based on the country of residence of the Company's external customers or partners.

## Aeterna Zentaris Inc.

### Notes to Consolidated Financial Statements

As at December 31, 2012 and December 31, 2011 and for the years ended December 31, 2012, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

Non-current assets\* by geographical area are detailed as follows:

	As at December 31,	
	2012	2011
	\$	\$
Germany	12,713	13,557
United States	2	—
Canada	26	36
	<u>12,741</u>	<u>13,593</u>

\* Non-current assets exclude financial instruments and other non-current assets.

Companies information about major customers representing 10% or more of the Company's revenues in any of the last three years are as follows:

	Years ended December 31,		
	2012	2011	2010
	\$	\$	\$
Company 1	24,406	24,977	15,907
Company 2	4,175	4,556	7,990
Company 3	1,040	3,657	—

## 28 Subsequent events

### *Perifosine*

On March 11, 2013, following a preplanned safety and efficacy first interim analysis performed by an independent Data Safety Monitoring Board ("DSMB"), and following its recommendation, the Company decided to discontinue its Phase 3 trial of perifosine in multiple myeloma. As at March 21, 2013, the Company is evaluating any impact that this event may have on the Company's consolidated financial statements and, since all necessary information is not yet available, it is not possible as of the date hereof to make an estimate of the financial impact of this event.

Depending on the Company's definitive evaluation and conclusions with respect to the financial impact of the aforementioned perifosine-related event, there may be a significant impact on the duration of the Company's continuing involvement and performance obligations with regard to its licensing and partnering arrangements for perifosine (note 5 – Development, commercialization and license agreement), which would in turn affect or reduce the amortization period over which license revenues are to be recognized. As at December 31, 2012, perifosine-related deferred revenues represented an amount of approximately \$6,100,000 and had a remaining estimated amortization period of 5.8 years.

## Item 19. Exhibits

### Exhibit Index

- 1.1 Restated Certificate of Incorporation and Restated Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 99.2 to the Registrant's report on Form 6-K furnished to the Commission on May 25, 2011)
- 1.2 Certificate of Amendment and Articles of Amendment of the Registrant (incorporated by reference to Exhibit 99.2 to the Registrant's report on Form 6-K furnished to the Commission on October 3, 2012)
- 1.3 Amended and Restated By-Law One adopted by the Registrant's Board of Directors on March 21, 2013
- 2.1 Amended and Restated Shareholder Rights Plan Agreement between the Registrant and Computershare Trust Company of Canada dated as at March 29, 2010 (incorporated by reference to Exhibit 99.1 to the Registrant's report on Form 6-K furnished to the Commission on March 29, 2010)
- 4.1 Amended and Restated Stock Option Plan of the Registrant
- 4.2 Employment Agreement dated July 18, 2007 between Paul Blake, M.D. and the Registrant (incorporated by reference to Exhibit 4.2 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2007 filed with the Commission on March 28, 2008)
- 4.3 Service Contract dated December 5, 2007 between Aeterna Zentaris GmbH and Prof. Juergen Engel, Ph.D. Consent of the Registrant's Independent Registered Public Accounting Firm (incorporated by reference to Exhibit 4.3 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2007 filed with the Commission on March 28, 2008)
- 4.4 Amendment #1 to Service Contract dated September 1, 2008 between Aeterna Zentaris GmbH and Prof. Juergen Engel, Ph.D. (incorporated by reference to Exhibit 4.4 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2008 filed with the Commission on March 30, 2009)
- 4.5 Amendment #2 to Service Contract dated August 30, 2010 between Aeterna Zentaris GmbH and Prof. Juergen Engel, Ph.D. (incorporated by reference to Exhibit 4.5 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2010 filed with the Commission on March 31, 2011)
- 4.6 Employment Agreement dated September 1, 2008 between the Registrant and Prof. Juergen Engel, Ph.D. (incorporated by reference to Exhibit 4.5 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2008 filed with the Commission on March 30, 2009)
- 4.7 Employment Agreement dated May 7, 2007 between the Registrant and Nicholas J. Pelliccione (incorporated by reference to Exhibit 4.7 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2007 filed with the Commission on March 28, 2008)
- 4.8 Service Contract dated May 18, 2006 among Aeterna Zentaris GmbH, the Registrant and Matthias Seeber (incorporated by reference to Exhibit 4.7 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2008 filed with the Commission on March 30, 2009)
- 4.9 Amendment #1 to Service Contract dated December 9, 2008 among Aeterna Zentaris GmbH, the Registrant and Matthias Seeber (incorporated by reference to Exhibit 4.8 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2008 filed with the Commission on March 30, 2009)
- 4.10 Amendment to Amended Employment Agreement dated as at June 20, 2007 among the Registrant, Aeterna Zentaris, Inc. and Dennis Turpin (incorporated by reference to Exhibit 4.8 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2007 filed with the Commission on March 28, 2008)
- 4.11† Purchase Agreement by and among Aeterna Zentaris IVF GmbH, Aeterna Zentaris GmbH, the Registrant and Healthcare Royalty Partners L.P. (formerly Cowen Healthcare Royalty Partners L.P.) dated November 11, 2008 (incorporated by reference to the Registrant's report on Form 6-K furnished to the Commission on November 24, 2008)
- 8.1 Subsidiaries of the Registrant
- 11.1 Code of Ethical Conduct of the Registrant (incorporated by reference to Exhibit 11.1 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2008 filed with the Commission on March 30, 2009)
- 11.2 Audit Committee Charter of the Registrant (incorporated by reference to Exhibit 11.2 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2010 filed with the Commission on March 31, 2011)
- 12.1 Certification of the Principal Executive Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002
- 12.2 Certification of the Principal Financial Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002
- 13.1 Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 13.2 Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 15.1 Consent of the Independent Auditors

† Confidential treatment has been granted for certain portions of this exhibit, which portions have been omitted and filed separately with the U.S. Securities and Exchange Commission.

## SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

AETERNA ZENTARIS INC.

/s/ Dennis Turpin

Dennis Turpin, CPA, CA  
Senior Vice President and Chief Financial  
Officer

**Date: March 21, 2013**

AETERNA ZENTARIS INC.

(the "Corporation")

AMENDED AND RESTATED BY-LAW ONE

MEETINGS OF SHAREHOLDERS AND DIRECTORS, COMMITTEES AND OTHER MATTERS

ARTICLE I. MEETINGS OF SHAREHOLDERS.

- 1.1 Place, Time and Notice. Meetings of shareholders of the Corporation shall be held at the registered office of the Corporation or at such other place and at such time as the Board of Directors, the Chief Executive Officer or the President may determine, from time to time.
- 1.2 Electronic Meetings. If the directors of the Corporation call a meeting of shareholders pursuant to the laws governing the Corporation, those directors may determine that the meeting shall be held in accordance with the regulations, if any, governing the Corporation entirely by means of telephonic, electronic or other communication facility that permits all participants to communicate adequately with each other during the meeting.
- 1.3 Chairman. Subject to the provisions of any resolution of the Board of Directors, the Chairman of the Board or, in his absence or inability or refusal or failure to act, a Vice or Deputy Chairman of the Board or, in his absence or inability or refusal or failure to act, the President or, in his absence or inability or refusal or failure to act, the Vice-President or, if there be more than one Vice-President, that one of them who may have been designated for the purpose by the Board of Directors, shall preside at all meetings of shareholders. All of the foregoing officers may attend such meetings but no Vice-President shall act as chairman if the Board of Directors shall have determined that he shall not so act. If all of the foregoing officers be absent or unable or refuse or fail to act, the persons present may choose a chairman.

The chairman of any meeting of shareholders shall conduct the procedure thereat in all respects and his decision on all matters, including, but without in any way limiting the generality of the foregoing, any question regarding the validity or invalidity of any proxy, shall be conclusive and binding upon the shareholders. A declaration by the chairman at any meeting that a resolution has been carried or carried unanimously or carried by any particular majority or lost or not carried by a particular majority shall be conclusive evidence of such fact.

The chairman of any meeting of shareholders may, in his discretion, order a ballot. Moreover, any shareholder or its representative, where the shareholder is a body corporate or an association, or his proxyholder, either before or after any vote by show of hands, may require a ballot on any question at any time before the termination of the meeting. A demand for a ballot may be withdrawn.

If at any meeting a ballot is to be taken, it shall be taken in such manner and either at once or after adjournment as the chairman directs. The result of a ballot shall be deemed to be a resolution of the meeting at which the ballot was taken whether or not a vote on a show of hands had previously been taken on the same question.

The chairman of any meeting of shareholders may appoint up to two (2) persons, who may but need not be directors, officers, employees or shareholders of the Corporation, to act as scrutineers at such meeting.

- 1.4 Quorum. The holder or holders of not less than ten (10) per cent of the outstanding shares of the Corporation carrying voting rights at the meeting, present in person or represented by proxy or by an authorized representative, shall constitute a quorum.

The quorum at any reconvened meeting of shareholders so adjourned is fixed at one (1) shareholder present or represented in accordance with this By-Law. The reconvened meeting may then proceed to examine and dispose of the business for which it was called.

- 1.5 Voting Rights. At all meetings of shareholders, every shareholder entitled to vote thereat, whether present in person or by proxyholder, or, in the case of a body corporate or association by a duly authorized representative, shall be entitled to one (1) vote for each voting share; if, however, in virtue of the law or the articles of the Corporation another scale of voting rights is fixed with respect to a particular matter or to another class of shares, such scale of voting shall be adopted.
- 1.6 Particulars of Proxies. The directors may also permit particulars of proxies for use at or in connection with any such meeting which have been deposited with the Corporation or its agent at a place other than the place of such meeting to be cabled, telecopied or telegraphed to the secretary of the Corporation prior to such meeting. In such event, such proxies, if otherwise in order, shall be valid and any votes cast in accordance therewith shall be counted.
- 1.7 Nominations of Directors. Subject only to the Canada Business Corporations Act (the "Act") and the articles of the Corporation (the "Articles"), only persons who are nominated in accordance with the following procedures shall be eligible for election as directors of the Corporation. Nominations of persons for election to the board of directors of the Corporation (the "Board") may be made at any annual meeting of shareholders, or at any special meeting of shareholders if one of the purposes for which the special meeting was called was the election of directors:
- a. by or at the direction of the Board, including pursuant to a notice of meeting;
  - b. by or at the direction or request of one or more shareholders pursuant to a proposal made in accordance with the provisions of the Act, or a requisition of the shareholders made in accordance with the provisions of the Act; or
  - c. by any person (a "Nominating Shareholder"): (A) who, at the close of business on the date of the giving of the notice provided for below in this Section 1.7 and on the record date for notice of such meeting, is entered in the securities register as a holder of one or more shares carrying the right to vote at such meeting or who beneficially owns shares that are entitled to be voted at such meeting; and (B) who complies with the notice procedures set forth below in this Section 1.7.

In addition to any other applicable requirements, for a nomination to be made by a Nominating Shareholder, the Nominating Shareholder must have given timely notice thereof in proper written form to the Secretary of the Corporation at the principal executive offices of the Corporation.

To be timely, a Nominating Shareholder's notice to the Secretary of the Corporation must be made:

- a. in the case of an annual meeting of shareholders, not less than 30 nor more than 65 days prior to the date of the annual meeting of shareholders; provided, however, that in the event that the annual meeting of shareholders is to be held on a date that is less than 50 days after the date on which the first public announcement (the "Notice Date") of the date of the annual meeting was made, notice by the Nominating Shareholder may be made not later than the close of business on the tenth (10th) day following the Notice Date; and
- b. in the case of a special meeting (which is not also an annual meeting) of shareholders called for the purpose of electing directors (whether or not called for other purposes), not later than the close of business on the fifteenth (15th) day following the day on which the first public announcement of the date of the special meeting of shareholders was made.
- c. In no event shall any adjournment or postponement of a meeting of shareholders or the announcement thereof commence a new time period for the giving of a Nominating Shareholder's notice as described above.

To be in proper written form, a Nominating Shareholder's notice to the Secretary of the Corporation must set forth:

- a. as to each person whom the Nominating Shareholder proposes to nominate for election as a director: (A) the name, age, business address and residential address of the person; (B) the principal occupation or employment of the person; (C) the class or series and number of shares in the capital of the Corporation which are controlled or which are owned beneficially or of record by the person as of the record date for the meeting of shareholders (if such date shall then have been made publicly available and shall have occurred) and as of the date of such notice; and (D) any other information relating to the person that would

be required to be disclosed in a dissident's proxy circular in connection with solicitations of proxies for election of directors pursuant to the Act and Applicable Securities Laws (as defined below); and

- b. as to the Nominating Shareholder giving the notice, any proxy, contract, arrangement, understanding or relationship pursuant to which such Nominating Shareholder has a right to vote any shares of the Corporation and any other information relating to such Nominating Shareholder that would be required to be made in a dissident's proxy circular in connection with solicitations of proxies for election of directors pursuant to the Act and Applicable Securities Laws (as defined below).

The Corporation may require any proposed nominee to furnish such other information as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve as an independent director of the Corporation or that could be material to a reasonable shareholder's understanding of the independence, or lack thereof, of such proposed nominee.

No person shall be eligible for election as a director of the Corporation unless nominated in accordance with the provisions of this Section 1.7; provided, however, that nothing in this Section 1.7 shall be deemed to preclude discussion by a shareholder (as distinct from the nomination of directors) at a meeting of shareholders of any matter in respect of which it would have been entitled to submit a proposal pursuant to the provisions of the Act. The Chairman of the meeting shall have the power and duty to determine whether a nomination was made in accordance with the procedures set forth in the foregoing provisions and, if any proposed nomination is not in compliance with such foregoing provisions, to declare that such defective nomination shall be disregarded.

For purposes of this Section 1.7:

- a. "**public announcement**" shall mean disclosure in a press release reported by a national news service in Canada, or in a document publicly filed by the Corporation under its profile on the System of Electronic Document Analysis and Retrieval at [www.sedar.com](http://www.sedar.com); and
- b. "**Applicable Securities Laws**" means the applicable securities legislation of each relevant province of Canada, as amended from time to time, the rules, regulations and forms made or promulgated under any such statute and the published national instruments, multilateral instruments, policies, bulletins and notices of the securities commission and similar regulatory authority of each province of Canada.

Notwithstanding any other provision of this Section 1.7, notice given to the Secretary of the Corporation pursuant to this Section 1.7 may only be given by personal delivery, facsimile transmission or by email (to the Secretary of the Corporation), and shall be deemed to have been given and made only at the time it is served by personal delivery, email or sent by facsimile transmission (provided that receipt of confirmation of such transmission has been received) to the Secretary at the address of the principal executive offices of the Corporation; provided that if such delivery or electronic communication is made on a day which is a not a business day or later than 5:00 p.m. (Québec time) on a day which is a business day, then such delivery or electronic communication shall be deemed to have been made on the subsequent day that is a business day.

Notwithstanding the foregoing, the Board may, in its sole discretion, waive any requirement in this Section 1.7.

## **ARTICLE 2. MEETINGS OF DIRECTORS.**

- 2.1 Place, Time and Notice. Immediately after the annual meeting of shareholders in each year, a meeting of such of the newly elected directors as are then present may be held, provided that they shall constitute a quorum, without notice, for the appointment of officers of the Corporation and the transaction of such other business as may come before the meeting.

Subject to the provisions of any resolution of the Board of Directors, meetings of the Board of Directors may be called at any time by the Chairman of the Board or a Vice or Deputy Chairman of the Board or the President or any Vice-President who is a director or any two directors and notice of the time and place for holding any meeting of the Board of Directors shall be given at least twelve (12) hours prior to the time fixed for the meeting. Any meeting so called may be held at the registered office of the Corporation or any other place which shall have been fixed by the Board of Directors.

The Board of Directors may also from time to time provide for the holding of regular meetings of the Board of Directors at such place, within or outside of Canada, with or without notice, as may be determined by resolution.

- 2.2 Chairman. Subject to the provisions of any resolution of the Board of Directors, the Chairman of the Board or, in his absence or inability or refusal or failure to act, any Vice or Deputy Chairman of the Board or, in his absence or inability or refusal or failure to act, the President or, in his absence or inability or refusal or failure to act, the

Vice-President or, if there be more than one Vice-President, that one of them who may have been designated for the purpose by the Board of Directors, shall preside at all meetings of the Board of Directors; provided that neither the President nor any Vice-President shall so act unless he is a director. If all of the foregoing officers be absent or unable or refuse or fail to act, the directors present may choose a chairman from among their number. The chairman at any meeting of directors may vote as a director.

- 2.3 Quorum. Except where the Corporation has only one director, the Board of Directors may, from time to time, fix by resolution the quorum for meetings of the Board of Directors but until otherwise fixed a majority of directors in office, from time to time, shall constitute a quorum.

### **ARTICLE 3. COMMITTEES**

- 3.1 Election. The Board of Directors may, from time to time, appoint from their number committees of directors, however designated, containing such proportion of Canadian residents as may be required by law.
- 3.2 Chairman, Quorum and Procedure. Any committee of directors shall have the power to appoint a chairman and a vice or deputy chairman, to fix its quorum, which quorum shall consist of not less than a majority of its members, and to determine its procedure.
- 3.3 Secretary. The secretary of the Corporation shall act as secretary of each committee of directors unless some other secretary be appointed by the committee.
- 3.4 Powers. The Board of Directors may delegate to any such committee of directors any of the powers of the board except those which by law a committee of directors has no authority to exercise.
- 3.5 Proceedings open to the Board. All proceedings of committees of directors shall be open to the examination of the Board of Directors of the Corporation and shall be reported to the board of directors if and when the Board of Directors so directs.
- 3.6 Meetings. Meetings of committees of directors may be held at the registered office of the Corporation or at such other place within or outside of Canada as a committee may from time to time determine. Meetings of a committee may be called by or by the order of the president, the chairman of the committee, the vice-chairman or any two (2) members thereof.
- 3.7 Remuneration. The members of a committee of directors shall be entitled to receive such remuneration for their services as members of the committee as the directors may from time to time determine.
- 3.8 Removal and Replacement. The directors may from time to time remove any member of a committee of directors from office.

The directors may also from time to time fill any vacancy which may occur in the membership of a committee.

### **ARTICLE 4. OTHER MATTERS**

- 4.1 Indemnification. The Corporation shall, to the full extent provided by law, indemnify a director or officer of the Corporation, a former director or officer of the Corporation or another individual who acts or acted at the Corporation's request as a director or officer, or an individual acting in a similar capacity, of another entity, against all costs, charges and expenses, including an amount paid to settle an action or satisfy a judgment, reasonably incurred by the individual in respect of any civil, criminal, administrative, investigative or other proceeding in which the individual is involved because of that association with the corporation or other entity.



**AMENDED AND RESTATED STOCK OPTION PLAN OF  
AETERNA ZENTARIS INC.**

**1. Purpose of the Plan**

- 1.1 The purpose of the stock option plan for directors, officers, employees and suppliers of ongoing services (the "Plan") of Aeterna Zentaris Inc. (the "Corporation") is to secure for the Corporation and its shareholders the benefit of an incentive interest in share ownership by directors, officers and employees of the Corporation and its Subsidiaries, as the case may be, and by certain designated suppliers of ongoing services.

**2. Administration**

- 2.1 The Plan shall be administered by the Corporation's Board of Directors (the "Board") or the Corporate Governance, Nominating and Human Resources Committee, as the same may be constituted from time to time (the "Committee"). The Board or the Committee shall have full and complete latitude to interpret the Plan and to establish the rules and regulations applying to it and to make all other determinations it deems necessary or useful for the administration of the Plan, provided that such interpretations, rules, regulations and determinations shall be consistent with the relevant policy statements of the competent securities authorities and the rules of the stock exchanges on which the securities of the Corporation are listed.

**3. Shares Subject to the Plan**

- 3.1 The shares issuable further to the exercise of options granted under the Plan are the Common Shares of the Corporation (the "Shares"). The total number of Shares that may be issued under the Plan shall not exceed eleven point four percent (11.4%) of the total number of issued and outstanding Shares at any given time. No Optionee (as defined hereinbelow) shall hold options to purchase more than five percent (5%) of the number of Shares issued and outstanding from time to time.
- 3.2 In addition: (i) the number of securities issuable to "insiders" (as such term is defined in the TSX Company Manual) of the Corporation, at any time, under all security-based compensation arrangements of the Corporation, cannot exceed ten percent (10%) of its issued and outstanding securities; and (ii) the number of securities issued to insiders of the Corporation, within any one-year period, under all security-based compensation arrangements of the Corporation, cannot exceed ten percent (10%) of its issued and outstanding securities.
- 3.3 In addition: (i) the aggregate fair value of options granted under all security-based compensation arrangements of the Corporation to any one non-employee director of the Corporation entitled to receive a benefit under the Plan, within any one-year period, cannot exceed US\$100,000 valued on a Black-Scholes basis and as determined by the Committee; and (ii) the aggregate number of securities issuable to all non-employee directors of the Corporation entitled to receive a benefit under the Plan, within any one-year period, under all security-based compensation arrangements of the Corporation, cannot exceed one percent (1%) of its issued and outstanding securities.
- 3.4 All options that are exercised, or that expire or are cancelled without being exercised, shall become available to be granted (or "reloaded") under the terms of the Plan upon such exercise, cancellation or expiration, as the case may be.

**4. Grant of Options**

- 4.1 The Board or the Committee shall from to time designate the directors (non-employee directors in the case of directors of the Corporation), officers or employees of the Corporation or any of its Subsidiaries, as the case may be, or suppliers of ongoing services to whom options shall be granted (an "Optionee") and the number of Shares covered by each of such options. For the purposes of the Plan, "Subsidiaries" shall mean any legal entity of which the Corporation holds or is the beneficiary, at any time, directly or indirectly, otherwise than as security only, of securities conferring over fifty percent (50%) of the votes enabling it to elect the majority of the directors of such entity as well as any current or future Subsidiary of such legal entity. Any Optionee may hold more than one option. The granting of each option shall be

evidenced by a letter from the Corporation addressed to the Optionee setting forth the number of Shares covered by such option, the subscription price, the terms and conditions of exercise of the option and the option period.

4.2 Subject to the provisions of Section 3, the non-employee directors of the Corporation are eligible to receive grants of up to 60,000 options per year. These options shall be vested over a period of three (3) years in equal thirds with the first third becoming vested on the first anniversary of the grant date, the second third becoming vested on the second anniversary of the grant date and the final third becoming vested on the third anniversary of the grant date. The specific number of options to be granted to non-employee directors in accordance with the foregoing shall be determined by the Board upon recommendation of the Committee.

## 5. Exercise Price

5.1 The exercise price of an option shall be established by the Board or the Committee at the time of the grant and this price shall not be less than the greater of the closing prices of the Shares on the Toronto Stock Exchange and the Nasdaq National Market on the last trading day preceding the date of grant of the option (the "Grant Date"). If either of these exchanges is closed or if the Shares did not trade on one of the two exchanges on the last trading day preceding the Grant Date, the exercise price shall be the closing price of the Shares at the open exchange ("Exercise Price").

The closing price of the Shares shall be converted into Canadian dollars, when this conversion is required, at the noon buying rate of the Bank of Canada on the last trading day preceding the Grant Date established in the previous paragraph.

## 6. Option Period

6.1 Subject to the provisions of Section 6.2, each option granted under the Plan shall be exercisable during a period established by the Board or the Committee (the "Option Period"). The Option Period shall commence no earlier than the Grant Date and shall terminate no later than ten years after such date (the "Outside Expiry Date").

6.2 Notwithstanding the provisions of Section 6.1, an option shall not be exercisable by an Optionee from and after each and every one of the following dates (an "Early Expiry Date"), unless the Board or the Committee decides otherwise:

6.2.1 (i) in the case where the Optionee is an officer or an employee, the date on which the Optionee resigns or voluntarily leaves his employment with the Corporation or one of its Subsidiaries, as the case may be, or the date on which the employment of the Optionee with the Corporation or one of its Subsidiaries is terminated for just cause, as the case may be, including, without limiting the scope of the foregoing, in the event of a breach of his obligations to the Corporation, or (ii) in the case where the Optionee is a director of the Corporation or one of its Subsidiaries, as the case may be, but is not employed by either the Corporation or one of its Subsidiaries, the date on which such Optionee ceases to be a member of the relevant Board of Directors for any reason other than death;

6.2.2 (i) in the case where the Optionee is an officer or employee, six (6) months following the date on which the Optionee's employment with the Corporation or any of its Subsidiaries, as the case may be, is terminated by reason of death or (ii) in the case where the Optionee is a director of the Corporation or any of its Subsidiaries, as the case may be, but is not employed by either the Corporation or any of its Subsidiaries, six (6) months following the date on which such Optionee ceases to be a member of the relevant Board of Directors by reason of death;

6.2.3 in the case where the Optionee is an officer or employee, thirty (30) days following the date on which the Optionee's employment with the Corporation or any of its Subsidiaries, as the case may be, is terminated for any cause or reason other than those mentioned in paragraphs 6.2.1 and 6.2.2 including, without limiting the scope of the foregoing, disability, long-term illness, retirement or early retirement; or

6.2.4 in the case where the Optionee is a supplier of ongoing services, thirty (30) days following the date on which the Optionee ceases to act as a supplier of ongoing services to the Corporation or any of its Subsidiaries, as the case may be, for any cause or reason.

6.3 Subject to Section 6.4 hereof, all rights conferred by an option under the Plan that shall not have been exercised by either an Early Expiry Date or the Outside Expiry Date shall be forfeited and cancelled.

6.4 If an Early Expiry Date or the Outside Expiry Date applicable to any option granted under the Plan falls within a blackout period imposed by the Corporation under the Corporation's trading restrictions and blackout periods policy (as such policy may be amended from time to time by the Corporation), or within seven (7) business days immediately following such a blackout period, then the applicable Early Expiry Date or the Outside Expiry Date, as the case may be, will be

automatically extended to the date which is seven (7) business days after the last day of the blackout period. The seven (7) business day extension period established in this paragraph is a fixed period which is not subject to Board discretion.

## **7. Exercise of Options**

7.1 Subject to the provisions of Section 6, an option may be exercised in whole, at any time, or in part, from time to time, during the Option Period, but in all cases in accordance with the exercise schedule established by the Board or the Committee and applicable at the time of the grant.

7.2 An option may be exercised by written notice to the Secretary of the Corporation. Such notice shall set forth the number of options exercised and the number of underlying Shares subscribed for pursuant to such exercise and the address to which the certificate evidencing such Shares is to be delivered. Such notice shall also be accompanied by a certified cheque made payable to the Corporation in the amount of the Exercise Price. The Corporation shall cause a certificate for the number of Shares specified in the notice to be issued in the name of the Optionee and delivered to the address specified in the notice no later than ten (10) business days following the receipt of such notice and cheque.

## **8. No Assignment**

8.1 No option or interest therein shall be assignable by the Optionee other than by will or in accordance with the applicable laws of estates and succession.

## **9. Not a Shareholder**

9.1 An Optionee shall have no rights as a shareholder of the Corporation with respect to any Shares covered by his/her option until he/she shall have become the holder of record of such Shares.

## **10. Offer for Shares of the Corporation**

10.1 In the event that, at any time, an offer to purchase is made to all holders of Shares, notice of such offer shall be given by the Corporation to each Optionee and all unexercised options will become exercisable immediately at the Exercise Price, but only to the extent necessary to enable an Optionee to tender his/her Shares in response to the offer should the Optionee so desire.

## **11. Modification of the Plan**

Board, shareholder and requisite regulatory approvals shall be required for any of the following amendments to be made to the Plan:

11.1 any amendment to Section 3.2 that would have the effect of permitting, without having to obtain shareholder approval on a "disinterested vote" at a duly convened shareholders' meeting, the grant of any option(s) under this Plan otherwise prohibited by Section 3.2;

11.2 any amendment to the number of securities issuable under the Plan (except for any adjustment described in paragraph 12.1.4 hereof);

11.3 any amendment which would permit any option granted under the Plan to be transferable or assignable other than by will or in accordance with the applicable laws of estates and succession;

11.4 the addition of a cashless exercise feature, payable in cash or securities, which does not provide for a full deduction of the number of underlying securities from the Plan reserve;

11.5 the addition of a deferred or restricted share unit or any other provision which results in employees receiving securities while no cash consideration is received by the Corporation;

11.6 with respect to any Optionee (whether or not such Optionee is an "insider" of the Corporation),

(i) any reduction in the exercise price of any option after the option has been granted, or

(ii) any cancellation of an option and the re-grant of that option under different terms, or

(iii) any extension to the term of an option beyond the Outside Expiry Date (except for extensions made pursuant to Section 6.4),

except in respect of any adjustment described in paragraph 12.1.4 hereof;

- 11.7 any amendment to the method of determining the exercise price of an option granted pursuant to the Plan;
- 11.8 the addition of any form of financial assistance or any amendment to a financial assistance provision which is more favourable to employees;
- 11.9 any amendment to Section 3.3 that would have the effect of removing or increasing the limitations on the aggregate number of securities issuable to, and/or the aggregate fair value of options granted or that may be granted to, non-employee directors within any one-year period (except for any adjustment described in paragraph 12.1.4 hereof); and
- 11.10 any amendment to this Section 11.

## 12. Amendments and Termination

- 12.1 The Board may, subject to receipt of requisite regulatory approval, where required, in its sole discretion, make all other amendments to the plan that are not contemplated in Section 11 above including, without limitation, the following:
  - 12.1.1 amendments of a "housekeeping" or clerical nature or to clarify the Plan's provisions;
  - 12.1.2 amendments regarding any vesting period of an option;
  - 12.1.3 amendments regarding the extension of an option beyond an Early Expiry Date in respect of any Optionee;
  - 12.1.4 adjustments to the number of issuable Shares underlying, or the exercise price of, outstanding options resulting from a split or a consolidation of the Shares, a reclassification, the payment of a stock dividend, the payment of a special cash or non-cash distribution to the Corporation's shareholders on a *pro rata* basis provided such distribution is approved by the Corporation's shareholders in accordance with applicable law, a recapitalization, a reorganization or any other event which necessitates an equitable adjustment to the outstanding options in proportion with corresponding adjustments made to all outstanding Shares;
  - 12.1.5 discontinuing or terminating the Plan; and
  - 12.1.6 any other amendment which does not require shareholder approval under Section 11 hereof.
- 12.2 Notwithstanding Section 12.1 above, the Corporation shall not contravene any requirements, rules, laws and regulations of the TSX or of any regulatory authorities.
- 12.3 Notwithstanding any provisions to the contrary, any amendment to or termination of the Plan shall in no way amend or otherwise affect the conditions of the options already granted under the Plan to the extent that such options have not then been exercised, unless the rights of the optionholder have already expired or have already been fully exercised or unless the optionholder affected by such change has already agreed to it.

## 13. Miscellaneous Provisions

- 13.1 The Corporation's obligations under the terms of the Plan are subject to all applicable laws, regulations or rules of any governmental agency or other competent authority in respect of the issuance or distribution of securities and to the rules of any stock exchange on which the Shares are listed. Each Optionee shall agree to comply with such laws, regulations and rules and to provide to the Corporation any information or undertaking required to comply with such laws, regulations and rules.
- 13.2 The participation in the Plan of a director, an officer or an employee of the Corporation or any of its Subsidiaries shall be entirely optional and shall not be interpreted as conferring upon a director, an officer or an employee of the Corporation or any of its Subsidiaries any right or privilege whatsoever, except for the rights and privileges set out expressly in the Plan. Neither the Plan nor any act that is done under the terms of the Plan shall be interpreted as restricting the right of the Corporation or any of its Subsidiaries to terminate the employment of an officer or employee at any time. Any notice of dismissal given to an officer or employee at the time his/her employment is terminated, or any payment in the place and stead of such notice, or any combination of the two, shall not have the effect of extending the duration of the employment for purposes of the Plan.
- 13.3 No director, officer or employee of the Corporation or any of its Subsidiaries shall acquire the automatic right to be granted one or more options under the terms of the Plan by reason of any previous grant of options under the terms of the Plan.

- 13.4 The Plan does not provide for any guarantee in respect of any loss or profit which may result from fluctuations in the price of the Shares.
- 13.5 The Corporation and its Subsidiaries shall assume no responsibility as regards the tax consequences that participation in the Plan will have for a director, an officer or an employee of, or supplier of ongoing services to, the Corporation or any of its Subsidiaries, and such persons are urged to consult their own tax advisors in such regard.
- 13.6 The Plan and any option granted under the terms of the Plan shall be governed and interpreted according to the laws of the Province of Quebec and the laws of Canada applicable thereto.
- 13.7 Once approved by the Corporation's shareholders, the Plan will modify and restate the stock option plan adopted by the Corporation on November 7, 1995 as amended. This Plan confers no other advantage upon the beneficiaries of the stock option plan.

**STOCK OPTION PLAN**  
**OF AETERNA ZENTARIS INC.**  
**SUBSCRIPTION FORM**

(Date)

Aeterna Zentaris Inc.  
1405 du Parc-Technologique Blvd.  
Québec, Québec  
G1P 4P5

Attention of the Secretary

I, the undersigned, , hereby exercise options and subscribe for Common Shares of Aeterna Zentaris Inc. (the "Corporation") pursuant to the exercise of such options under the terms of the Stock Option Plan of the Corporation, out of the Common Shares available for purchase by the undersigned, and I enclose herewith my certified cheque (or money order) made payable to the order of Aeterna Zentaris Inc., in the amount of dollars in payment of the said subscription.

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(Signature)

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(Full Address)

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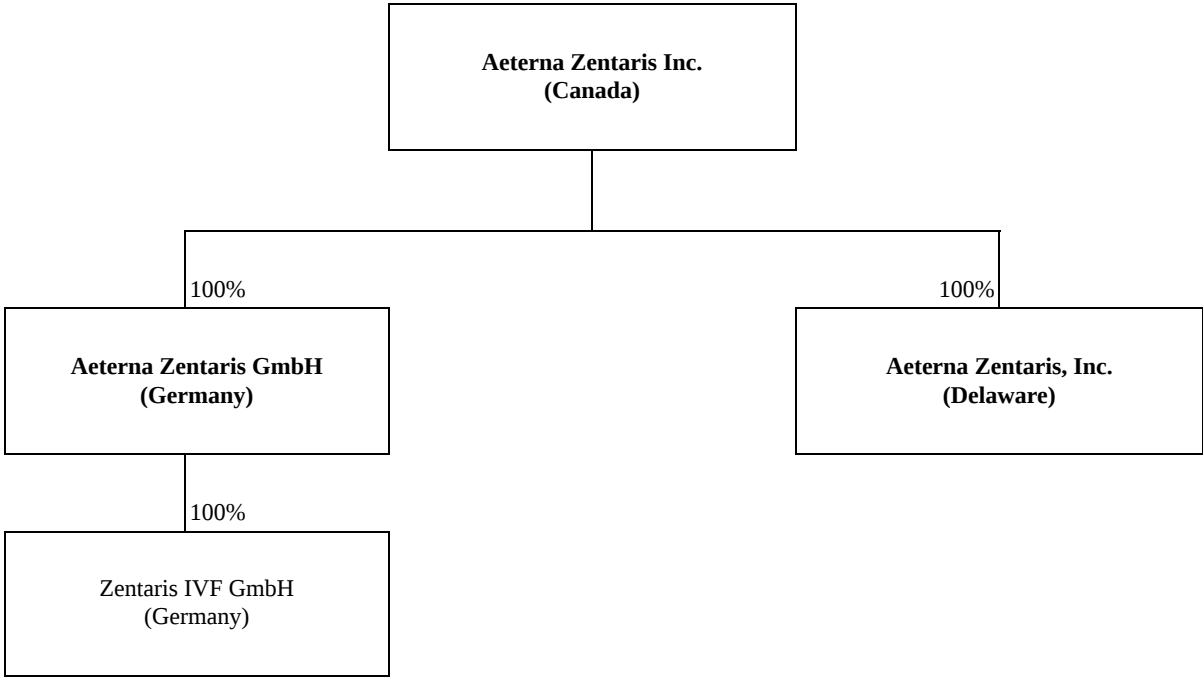
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(Telephone)

The French version of this Schedule shall prevail.

**SUBSIDIARIES OF THE REGISTRANT**

**AETERNA ZENTARIS INC.**



*Certification of the Principal Executive Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002***Certification**

I, Prof. Dr. Juergen Engel, certify that:

1. I have reviewed this annual report on Form 20-F of Aeterna Zentaris Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as at, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as at the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

**Date: March 21, 2013**

/s/ Juergen Engel

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Prof. Dr. Juergen Engel  
President and Chief Executive Officer  
(principal executive officer)



*Certification of the Principal Financial Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002***Certification**

I, Dennis Turpin, certify that:

1. I have reviewed this annual report on Form 20-F of Aeterna Zentaris Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as at, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as at the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

**Date: March 21, 2013**

/s/ Dennis Turpin

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Dennis Turpin

Senior Vice President and Chief Financial Officer

(principal financial officer)

*Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*

**CERTIFICATION PURSUANT TO**

**18 U.S.C. SECTION 1350,**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of Aeterna Zentaris Inc. (the "Company") on Form 20-F for the year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Juergen Engel, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**Dated: March 21, 2013**

/s/ Juergen Engel

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Prof. Dr. Juergen Engel

President and Chief Executive Officer

*Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

**CERTIFICATION PURSUANT TO**

**18 U.S.C. SECTION 1350,**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of Aeterna Zentaris Inc. (the "Company") on Form 20-F for the year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dennis Turpin, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**Dated: March 21, 2013**

/s/ Dennis Turpin

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Dennis Turpin

Senior Vice President and Chief Financial Officer

**CONSENT OF INDEPENDENT AUDITOR**

We hereby consent to the incorporation by reference in the Registration Statements on Form F-10/A (No. 333-181714) of Aeterna Zentaris Inc. of our report dated March 21, 2013 relating to the consolidated financial statements and effectiveness of internal control over financial reporting, which appears in Aeterna Zentaris Inc.'s Annual Report on Form 20-F.

*PricewaterhouseCoopers LLP*

**Chartered Professional Accountants**

Montreal, Quebec  
March 21, 2013