

Aeterna Zentaris Inc.  
Form 20-F  
March 28, 2012  
Table of Contents

**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**
- x **Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the fiscal year ended December 31, 2011**  
**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.**

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

Quebec City, Quebec

Canada, G1P 4P5

(Address of Principal Executive Offices)

Dennis Turpin

Telephone: 418-652-8525

E-mail: dturpin@aezsinc.com

1405 du Parc-Technologique Blvd.

Quebec City, Quebec

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:

Title of Each Class	Name of Each Exchange on Which Registered
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: 104,762,096 common shares as at December 31, 2011.

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 International Accounting  Other

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

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

## **Table of Contents**

### **Basis of Presentation**

#### **General**

Except where the context otherwise requires, all references in this annual report on Form 20-F ( 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, 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 are presented as at December 31, 2011.

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 contains forward-looking statements made pursuant to the safe harbor provisions of the U.S. Securities Litigation Reform Act of 1995. Forward-looking statements involve known and unknown risks and uncertainties, which could cause the Company s actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue our research and development ( R&D ) projects, the successful and timely completion of clinical studies, the ability of the Company to take advantage of business opportunities in the pharmaceutical industry, uncertainties related to the regulatory process and general changes in economic conditions. Investors should consult the Company s quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Investors are cautioned not to rely on these forward-looking statements. The Company does not undertake to update these forward-looking statements and disclaim any obligation to update any such factors or to publicly announce the result of any revisions to any of the forwards-looking statements contained herein to reflect future results, events or developments except if required to do so by a governmental authority or applicable law.

**Table of Contents**

**TABLE OF CONTENTS**  
**GENERAL INFORMATION**

		<b>Page</b>
<b><u>PART I</u></b>		<b>1</b>
Item 1.	<u>Identity of Directors, Senior Management and Advisers</u>	1
	A. <u>Directors and senior management</u>	1
	B. <u>Advisors</u>	1
	C. <u>Auditors</u>	1
Item 2.	<u>Offer Statistics and Expected Timetable</u>	1
	A. <u>Offer statistics</u>	1
	B. <u>Method and expected timetable</u>	1
Item 3.	<u>Key Information</u>	1
	A. <u>Selected financial data</u>	1
	B. <u>Capitalization and indebtedness</u>	5
	C. <u>Reasons for the offer and use of proceeds</u>	5
	D. <u>Risk factors</u>	5
Item 4.	<u>Information on the Company</u>	21
	A. <u>History and development of the Company</u>	21
	B. <u>Business overview</u>	22
	C. <u>Organizational structure</u>	61
	D. <u>Property, plants and equipment</u>	61
Item 4A.	<u>Unresolved Staff Comments</u>	62
Item 5.	<u>Operating and Financial Review and Prospects</u>	62
Item 6.	<u>Directors, Senior Management and Employees</u>	93
	A. <u>Directors and senior management</u>	93
	B. <u>Compensation</u>	96
	C. <u>Board Practices</u>	113
	D. <u>Employees</u>	114
	E. <u>Share ownership</u>	114
Item 7.	<u>Major Shareholders and Related Party Transactions</u>	115
	A. <u>Major shareholders</u>	115
	B. <u>Related party transactions</u>	115
	C. <u>Interests of experts and counsel</u>	115
Item 8.	<u>Financial Information</u>	115
	A. <u>Consolidated statements and other financial information</u>	115
	B. <u>Significant changes</u>	115
Item 9.	<u>The Offering and Listing</u>	115
	A. <u>Offer and listing details</u>	115
	B. <u>Plan of distribution</u>	116
	C. <u>Markets</u>	116
	D. <u>Selling shareholders</u>	116
	E. <u>Dilution</u>	117
	F. <u>Expenses of the issuer</u>	117
Item 10.	<u>Additional Information</u>	117
	A. <u>Share capital</u>	117
	B. <u>Memorandum and articles of association</u>	117

**Table of Contents**

	C. <u>Material contracts</u>	127
	D. <u>Exchange controls</u>	129
	E. <u>Taxation</u>	130
	F. <u>Dividends and paying agents</u>	136
	G. <u>Statement by experts</u>	136
	H. <u>Documents on display</u>	136
	I. <u>Subsidiary information</u>	137
Item 11.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	137
Item 12.	<u>Description of Securities Other than Equity Securities</u>	139
	A. <u>Debt securities</u>	139
	B. <u>Warrants and rights</u>	139
	C. <u>Other securities</u>	139
	D. <u>American depository shares</u>	139
<b>PART II</b>		<b>140</b>
Item 13.	<u>Defaults, Dividend Arrearages and Delinquencies</u>	140
Item 14.	<u>Material Modification to the Rights of Security Holders and Use of Proceeds</u>	140
Item 15.	<u>Controls and Procedures</u>	140
Item 16A.	<u>Audit Committee Financial Expert</u>	141
Item 16B.	<u>Code of Ethics</u>	141
Item 16C.	<u>Principal Accountant Fees and Services</u>	141
	A. <u>Audit Fees</u>	141
	B. <u>Audit-related Fees</u>	142
	C. <u>Tax Fees</u>	142
	D. <u>All Other Fees</u>	142
	E. <u>Audit Committee Pre-Approval Policies and Procedures</u>	142
Item 16D.	<u>Exemptions from the Listing Standards for Audit Committees</u>	142
Item 16E.	<u>Purchases of Equity Securities by the Issuer and Affiliated Purchasers</u>	142
Item 16F.	<u>Changes in Registrant's Certifying Accountant</u>	142
Item 16G.	<u>Corporate Governance</u>	143
Item 16H.	<u>Mine Safety Disclosure</u>	143
<b>PART III</b>		<b>144</b>
Item 17.	<u>Financial Statements</u>	144
Item 18.	<u>Financial Statements</u>	144
Item 19.	<u>Exhibits</u>	205

**Table of Contents**

**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, 2011 and 2010, and the consolidated statement of financial position data as at December 31, 2011 and 2010, 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 operations data set forth in this Item 3.A with respect to the years ended December 31, 2009, 2008 and 2007, and the consolidated balance sheet data as at December 31, 2009, 2008 and 2007, have been derived from our previous consolidated financial statements not included herein, which were prepared in accordance with Canadian GAAP, except as otherwise described therein. 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, and Item 5. Operating and Financial Review and Prospects of this annual report.

**Table of Contents****Consolidated Statements of Comprehensive Loss***(in thousands of US dollars, except share and per share data)**Derived from financial statements prepared in accordance with IFRS*

	<b>Years ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>\$</b>	<b>\$</b>
<b>Revenues</b>		
Sales and royalties	31,306	24,857
License fees and other	4,747	2,846
	<b>36,053</b>	<b>27,703</b>
<b>Operating expenses</b>		
Cost of sales	27,560	18,700
Research and development costs, net of refundable tax credits and grants	24,517	21,257
Selling, general and administrative expenses	16,170	12,552
	<b>68,247</b>	<b>52,509</b>
<b>Loss from operations</b>	<b>(32,194)</b>	<b>(24,806)</b>
Finance income	6,239	1,800
Finance costs	(8)	(5,445)
<b>Net finance income (costs)</b>	<b>6,231</b>	<b>(3,645)</b>
Loss before income taxes	<b>(25,963)</b>	<b>(28,451)</b>
Income tax expense	<b>(1,104)</b>	<b>-</b>
<b>Net loss</b>	<b>(27,067)</b>	<b>(28,451)</b>
<b>Other comprehensive (loss) income:</b>		
Foreign currency translation adjustments	(789)	1,001
Actuarial gain (loss) on defined benefit plans	(1,335)	191
<b>Comprehensive loss</b>	<b>(29,191)</b>	<b>(27,259)</b>
<b>Net loss per share</b>		
Basic and diluted	<b>(0.29)</b>	<b>(0.38)</b>
<b>Weighted average number of shares outstanding</b>		
Basic and diluted	<b>94,507,988</b>	<b>75,659,410</b>



**Table of Contents****Consolidated Statements of Operations Data***(in thousands of US dollars, except share and per share data)**Derived from financial statements prepared in accordance with Canadian GAAP*

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Revenues</b>	63,237	38,478	42,068
<b>Operating expenses</b>			
Cost of sales, excluding depreciation and amortization	16,501	19,278	12,930
Research and development costs	44,217	57,448	39,248
Research and development tax credits and grants	(403)	(343)	(2,060)
Selling, general and administrative expenses	16,040	17,325	20,403
Depreciation and amortization			
Property, plant and equipment	3,285	1,515	1,562
Intangible assets	7,555	5,639	4,004
Impairment of long-lived assets held for sale			735
	87,195	100,862	76,822
<b>Loss from operations</b>	(23,958)	(62,384)	(34,754)
<b>Other income (expenses)</b>			
Interest income	349	868	1,904
Interest expense	(5)	(118)	(85)
Foreign exchange gain (loss)	(1,110)	3,071	(1,035)
Loss on disposal of long-lived assets held for sale		(35)	
Loss on disposal of equipment		(44)	(28)
	(766)	3,742	756
<b>Loss before income taxes from continuing operations</b>	(24,724)	(58,642)	(33,998)
<b>Income tax (expense) recovery</b>		(1,175)	1,961
<b>Net loss from continuing operations</b>	(24,724)	(59,817)	(32,037)
<b>Net loss from discontinued operations</b>			(259)
<b>Net loss for the year</b>	(24,724)	(59,817)	(32,296)
<b>Net loss per share from continuing operations</b>			
Basic and diluted	(0.43)	(1.12)	(0.61)

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

<b>Net loss per share</b>			
Basic and diluted	(0.43)	(1.12)	(0.61)
<b>Weighted average number of shares</b>			
Basic and diluted	56,864,484	53,187,470	53,182,803

**Table of Contents****Consolidated Statements of Operations Data***(in thousands of US dollars, except share and per share data)**Derived from reconciliation to US GAAP*

	<b>Years ended December 31,</b>		
	<b>2009*</b>	<b>2008*</b>	<b>2007*</b>
	\$	\$	\$
<b>Net loss for the year</b>	(16,794)	(56,070)	(37,428)
<b>Of which:</b>			
<b>Net loss from continuing operations</b>	(16,794)	(56,070)	(36,415)
<b>Net loss from discontinued operations</b>			(1,013)
<b>Net loss per share from continuing operations</b>			
Basic and diluted	(0.30)	(1.05)	(0.68)
<b>Net loss per share from discontinued operations</b>			
Basic and diluted			(0.02)
<b>Net loss per share</b>			
Basic and diluted	(0.30)	(1.05)	(0.70)
<b>Weighted average number of shares</b>			
Basic and diluted	56,864,484	53,187,470	53,182,803

**Consolidated Statement of Financial Position Data***(in thousands of US dollars)**Derived from financial statements prepared in accordance with IFRS for 2011 and 2010, and Canadian GAAP for 2009, 2008 and 2007*

	<b>As at December 31,</b>				
	<b>2011</b>	<b>2010</b>	<b>2009*</b>	<b>2008*</b>	<b>2007*</b>
	\$	\$	\$	\$	\$
Cash and cash equivalents	46,881	31,998	38,100	49,226	10,272
Short-term investments		1,934		493	31,115
Working capital	42,254	29,444	29,745	39,554	37,325
Restricted cash	806	827	878		
Total assets	75,369	61,448	86,262	108,342	123,363
Warrant liability short-term	42	955	*	*	*
Warrant liability long-term	9,162	13,412	*	*	*
Long-term payable	29	90	143	172	
Share capital	101,884	60,900	41,203	30,566	30,566
Shareholders' (deficiency) equity	(4,546)	(17,575)	9,226	21,475	88,591

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

\*We adopted IFRS in 2011 with a transition date of January 1, 2010. The selected financial information for the years ended December 31, 2009, 2008 and 2007 is derived from financial statements that were presented in accordance with Canadian GAAP and has not been restated in accordance with IFRS. Consequently, the selected financial information for the years ended December 31, 2009, 2008 and 2007 may not be comparable with the corresponding selected financial information for the years ended December 31, 2011 and 2010. Please refer to Critical Accounting Policies, Estimates and Judgments for the policy differences between Canadian GAAP and IFRS.

**Table of Contents****Consolidated Statement of Financial Position Data***(in thousands of US dollars)**Derived from financial statements prepared in accordance with IFRS for 2011 and 2010, and US GAAP for 2009, 2008 and 2007*

	<b>As at December 31,</b>				
	<b>2011</b>	<b>2010</b>	<b>2009*</b>	<b>2008*</b>	<b>2007*</b>
	\$	\$	\$	\$	\$
Cash and cash equivalents	46,881	31,998	38,100	49,226	10,272
Short-term investments		1,934		493	31,115
Working capital	42,254	29,444	29,745	39,554	37,325
Restricted cash	806	827	878		
Total assets	75,369	61,448	84,116	100,001	109,182
Warrant liability, short-term	42	955	*	*	*
Warrant liability, long-term	9,162	13,412	1,351	*	*
Long-term payable	29	90	143	172	
Share capital	101,884	60,900	33,226	22,589	22,589
Shareholders (deficiency) equity	(4,546)	(17,575)	5,729	13,134	74,410

\* We adopted IFRS in 2011 with a transition date of January 1, 2010. The selected financial information for the years ended December 31, 2009, 2008 and 2007 is derived from financial statements that were presented in accordance with Canadian GAAP and has not been restated in accordance with IFRS. Consequently, the selected financial information for the years ended December 31, 2009, 2008 and 2007 may not be comparable with the corresponding selected financial information for the years ended December 31, 2011 and 2010. Please refer to *Critical Accounting Policies, Estimates and Judgments* for the policy differences between Canadian GAAP and IFRS.

**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, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010, we had an accumulated deficit of \$189.0 million as at December 31, 2011. Our operating losses have adversely impacted, and will continue to adversely impact, our working capital, total assets and

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

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 ultimately do not generate sufficient revenue from commercialized products and achieve or maintain operating profitability, an investment in our securities could result in a significant or total loss.

---

**Table of Contents**

*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 securities.*

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. For example, our partner Keryx is conducting phase 3 trials of perifosine for the treatment of colorectal cancer and multiple myeloma. The enrollment of the trial in colorectal cancer has been completed and results of this trial are expected in the near future. If the results of this clinical trial are unfavorable, it would likely adversely affect our and our partners' perifosine development programs. In addition, unfavorable results in this trial could adversely affect our stock price. 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, we 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.

## **Table of Contents**

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 securities.

***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 at which 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 North America. 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.



---

## **Table of Contents**

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 continue to be subject to stringent ongoing government regulation for our products and, even if we obtain regulatory approvals, for our product candidates.***

The manufacture, marketing and sale of our products and product candidates are and will continue to be subject to strict and ongoing regulation, even if regulatory authorities approve our product candidates. 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 are and will continue to 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.

## **Table of Contents**

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. We cannot assure you 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 securities.

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

We will likely 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 otherwise described in this annual report, 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 would result in dilution to our shareholders. Moreover, the incurrence of indebtedness 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 and anticipated revenues, will be sufficient to fund our development programs, clinical trials and other operating expenses for more than 12 months following year-end. 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.

---

**Table of Contents**

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.

***A substantial portion of our future revenues may be dependent upon our agreements with Keryx Biopharmaceuticals, Inc. and Yakult Honsha Co. Ltd***

We currently expect that a substantial portion of our future revenues may be dependent upon our strategic partnerships with Keryx Biopharmaceuticals, Inc. ( Keryx ) for North America and Yakult Honsha Co. Ltd. ( Yakult ) for Japan. Under these strategic partnerships, Keryx and Yakult have significant development and commercialization responsibilities with respect to the development and sale of perifosine in their respective territories. If Keryx or Yakult were to terminate their agreements with us, fail to meet their obligations or otherwise decrease their level of efforts, allocation of resources or other commitments under their respective agreements, our future revenues and/or prospects could be negatively impacted and the development and commercialization of perifosine would be interrupted. In addition, if either Keryx or Yakult does not achieve some or any of their respective development, regulatory and commercial milestones or if they do not achieve certain net sales thresholds as set forth in the agreements, we will not fully realize the expected economic benefits of such agreements. Further, the achievement of certain of the milestones under these strategic partnership agreements will depend on factors that are outside of our control and most are not expected to be achieved for several years, if at all. Any failure to successfully maintain our strategic partnership agreements could materially and adversely affect our ability to generate revenues.

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

Although our audited consolidated financial statements as at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010 that management believed that the Company had, as at December 31, 2011, 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's assumptions will not change in our future financial statements.

Since our inception, we have incurred losses, accumulated deficits and negative cash flows from operations. We expect that this will continue throughout 2012.

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. If we do not raise additional capital, we do not expect our operations to generate sufficient cash flow to fund our obligations as they come due.

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 be material uncertainties related to certain adverse conditions and events that could cast significant doubt on our ability to remain a going concern.

## **Table of Contents**

### ***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 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 securities 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 Aeterna Zentaris, are uncertain and involve complex questions of law and fact for which

---

**Table of Contents**

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 licensors 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 licensors 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 patents, we 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 technology 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.

## **Table of Contents**

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 methods are found to infringe. Moreover, there may be published pending applications that do not currently include a claim covering our products or methods but which nonetheless provide support for a later drafted claim that, if issued, our products or methods 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 issue 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.

## **Table of Contents**

*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 securities.*

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 securities 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.



## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

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.

## **Table of Contents**

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 securities.

## **Table of Contents**

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, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010 included in this Annual Report on Form 20-F.

We have also entered into a variety of collaborative licensing 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 cetrotirelix, including Cetrotide®. 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 to our licensing partners who are responsible for marketing such 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.

## **Table of Contents**

***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 and, as such, we are subject to environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could incur significant fines or liabilities or suffer 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.

***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

---

**Table of Contents**

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.

*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 Material U.S. Federal Income Tax Considerations in this Annual Report on Form 20-F) that directly or indirectly hold common shares or warrants 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 percent of our gross income is passive income or (ii) at least 50 percent 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 2011 taxable year. However, 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. Thus no assurance can be provided that we will not be classified as a PFIC for the 2012 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 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. However, a mark-to-market election is not available in respect of a warrant.

Under recently enacted 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 ( IRS ) (on IRS Form 8621, which PFIC shareholders will be required to file with their income tax or information returns) relating to their ownership of our common shares. Pursuant to Notice 2011-55, the IRS has suspended this new

---

## **Table of Contents**

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 pre-existing 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 Material U.S. Federal Income Tax Considerations in this Annual Report on Form 20-F.

### ***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.

## **Risks Related to our Securities**

***Our share price is volatile, which may result from factors outside of our control. If our common shares were to be delisted from the NASDAQ Global Market ( NASDAQ ) or the 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.

During the year ended December 31, 2011, the closing price of our common shares ranged from \$1.43 to \$2.58 on NASDAQ and from C\$1.41 to C\$2.51 per share on TSX. 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 volumes 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;



**Table of Contents**

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 the market price of our common shares could increase the risk that securities class action litigation could be initiated against us. Litigation of this type 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 we are unsuccessful in maintaining NASDAQ's minimum bid price or other requirements in the future and are unable to subsequently regain compliance within the applicable grace period, our common shares will be subject to delisting. Should we receive a delisting notification, we may appeal to the Listing Qualifications Panel or apply to transfer the listing of our common shares to the NASDAQ Capital Market if we satisfy at such time all of the initial listing standards of the NASDAQ Capital Market, other than compliance with the minimum closing bid price requirement. If the application to the NASDAQ Capital Market were approved, then we would have an additional 180-day grace period in order to regain compliance with the minimum bid price requirement while listed on the NASDAQ Capital Market. There can be no assurance that we will meet the requirements for continued listing or whether an application to the NASDAQ Capital Market would be approved or that any appeal would be granted by the Listing Qualifications Panel.

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



---

**Table of Contents**

**Item 4. Information on the Company**

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

Aeterna Zentaris Inc. is a late-stage drug development company specialized in oncology and endocrine therapy.

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 December 30, 2002, we acquired Zentaris AG, a biopharmaceutical company based in Frankfurt, Germany. Zentaris was a spin-off of Degussa AG and Asta Medica GmbH, a former pharmaceutical company. With this acquisition, the Company changed its risk profile and inherited an extensive and robust product pipeline with capabilities from drug discovery to commercialization with a particular focus on endocrine therapy and oncology. As part of the acquisition, we also acquired a very experienced pharmaceutical team along with a network of strategic pharmaceutical partners. The total consideration paid for the acquisition of Zentaris was \$51.9 million, net of cash and cash equivalents acquired of \$2.3 million, of which an amount of \$26.7 million was paid in cash and the remaining amount of \$25.2 million as a balance of purchase price.

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* .

Throughout 2006, as part of a thorough, strategic planning process, our management and Board of Directors (the *Board* ) made the decision to spin off Atrium in two phases. On September 19, 2006, we initiated the first phase, a secondary offering in which we sold 3,485,000 Subordinate Voting Shares of Atrium at a price of CAN\$15.80 per share. This secondary offering closed on October 18, 2006, generating net proceeds of nearly \$45 million to Aeterna Zentaris. With this transaction closed, our remaining interest in Atrium was 11,052,996 Subordinate Voting Shares representing 36.1% of its issued and outstanding shares. Therefore, we no longer had a controlling interest in Atrium as at October 18, 2006.

The second phase was to distribute our remaining interest in Atrium to our shareholders concurrently with a reduction of the stated capital of our common shares.

On December 15, 2006, our shareholders approved a reduction of the stated capital of our common shares in an amount equal to the fair market value of our remaining interest in Atrium by way of a special distribution in kind to all our shareholders. This special distribution was completed on January 2, 2007. For each common share held as at the record date of December 29, 2006, our shareholders received 0.2078824 Subordinate Voting Shares of 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.

We currently have 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.

**Table of Contents**

From the formation of Atrium as our subsidiary in 1999 until the distribution of our remaining interest in Atrium on January 2, 2007, Atrium did not declare or pay any dividends to its shareholders. Since the disposition of our entire interest in Atrium, we have not had access to the liquidity or cash flows generated by Atrium.

Our current drug development strategy focuses mainly on our late-stage compounds perifosine and AEZS-108 (zoptarelin doxorubicin) in oncology, AEZS-130 (macimorelin) 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 a late-stage drug development company specialized in oncology and endocrine therapy.

Our pipeline encompasses compounds at all stages of development, from drug discovery through to marketed products. The highest development priorities in oncology are the completion of Phase 3 trials with perifosine in colorectal cancer (CRC) and in multiple myeloma (MM), as well as the further advancement of AEZS-108, for which we have successfully completed a Phase 2 trial in advanced endometrial and advanced ovarian cancer. We are planning for the initiation of a pivotal program with AEZS-108 in endometrial cancer and also a Phase 2 trial in triple-negative breast cancer. AEZS-108 is also in development in other cancer indications, including castration- and taxane-resistant prostate cancer, as well as refractory bladder cancer.

Our pipeline also encompasses other earlier-stage programs in oncology. AEZS-112, an oral anticancer agent which involves three mechanisms of action (tubulin, topoisomerase II and angiogenesis inhibition) has completed a Phase 1 trial in advanced solid tumors and lymphoma. Additionally, several novel targeted potential anti-cancer candidates such as AEZS-120, a live recombinant oral tumor vaccine candidate, as well as our phosphoinositide 3-kinase (PI3K)/Erk inhibitors AEZS-129, AEZS-131, AEZS-132 and their respective follow-up compounds are currently in preclinical development.

## **Table of Contents**

Our lead program in endocrinology, a Phase 3 trial under a Special Protocol Assessment ( SPA ) obtained from the FDA with AEZS-130 as an oral diagnostic test for adult growth hormone deficiency ( AGHD ), has been completed with positive results. We are planning to file an NDA for the registration of AEZS-130 in the United States, subject to a successful pre-NDA meeting with the FDA. Furthermore, AEZS-130 is in a Phase 2A trial for the treatment of cancer cachexia.

### Recent Developments

For a complete description of our recent corporate and pipeline developments, refer to Item 5. Operating and Financial Review and Prospects Highlights .

### **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 flagship product candidates in oncology and endocrinology. In addition, we also continue to advance certain other clinical and preclinical programs as described below, some of which are conducted through grants from various governmental agencies. Our vision is to become a fully-integrated specialty biopharmaceutical company.

**Table of Contents**

**Our product pipeline**

**Pipeline table**

**Status of our drug pipeline as at March 27, 2012**

<b>Discovery</b>	<b>Preclinical</b>	<b>Phase 1</b>	<b>Phase 2</b>	<b>Phase 3</b>	<b>Commercial</b>
~120,000	AEZS-120	AEZS-112	Perifosine	Perifosine	Cetrotide®
compound	Prostate cancer	(oncology)	Multiple cancers	Refractory	( <i>in vitro</i> fertilization)
library	vaccine			advanced	
	(oncology)		AEZS-108	colorectal cancer	
			Endometrial cancer	Multiple myeloma	
	AEZS-129, 131, 132		Triple-negative		
	and 136;		breast cancer	AEZS-130	
	Erk & PI3K		Ovarian cancer	Diagnostic in adult	
	inhibitors (oncology)		Castration-and	growth hormone	
			taxane-resistant -	deficiency (endocrinology)	
	AEZS-137		prostate cancer		
	(Disorazol Z)		Refractory bladder		
	(oncology)		cancer		
	AEZS-125 (LHRH-		Ozarelix		
	Disorazol Z)		Prostate cancer		
	(oncology)				
			AEZS-130		
			Therapeutic in		
			cancer cachexia		
<b>Partners</b>			Perifosine:	Perifosine:	Cetrotide®:
			<b>Keryx</b>	<b>Keryx</b>	<b>Merck Serono</b>

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

North America	North America	World except
<b>Handok</b>	<b>Handok</b>	Japan
Korea	Korea	<b>Nippon</b>
<b>Yakult</b>	<b>Yakult</b>	<b>Kayaku /</b>
Japan	Japan	<b>Shionogi</b>
<b>Hikma</b>	<b>Hikma</b>	Japan
Middle East/ North Africa	Middle East/ North Africa	

Ozarelix:

**Spectrum**

World (ex-Japan for  
oncology indications,  
ex-Korea and ex-other  
Asian countries for  
BPH indication)

**Handok**

Korea and other Asian  
countries for BPH  
indication

**Nippon Kayaku**

Japan for oncology  
indications

---

## **Table of Contents**

### ***Oncology***

Our highest priorities in oncology are with perifosine, to complete the two Phase 3 trials in CRC and in MM, and to continue our Phase 2 program in multiple cancers, as well as the further advancement of AEZS-108, for which we successfully completed Phase 2 trials in advanced endometrial and advanced ovarian cancer.

#### ***Perifosine***

Perifosine is a novel, oral anticancer treatment that inhibits Akt activation in the PI3K pathway. Perifosine, in combination with chemotherapeutic agents, is currently in Phase 3 studies for the treatment of metastatic colorectal cancer ( mCRC ), MM and in Phase 2 studies for the treatment of other cancers. We believe perifosine is the most advanced anticancer compound of its class in late-stage development. Perifosine as monotherapy is also being explored in chronic lymphocytic leukemia ( CLL ). The FDA has granted perifosine orphan-drug designation in MM and in neuroblastoma and Fast Track designations in both MM and refractory advanced CRC. Additionally, an agreement was reached with the FDA to conduct the Phase 3 trials in both of these indications under a SPA. Perifosine has also been granted Orphan Medicinal Product designation from the European Medicine Agency ( EMA ) in MM, and has received positive Scientific Advice from the EMA for both the MM and advanced CRC programs, with ongoing Phase 3 trials for these indications expected to be sufficient for registration in Europe. Perifosine rights have been licensed to Keryx for North America, to Yakult for Japan, to Handok Pharmaceuticals Co. Ltd. ( Handok ) for Korea and to Hikma Pharmaceuticals PLC ( Hikma ) for the Middle East and North Africa ( MENA ) region.

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

AEZS-108 represents a new targeting concept in oncology leading to personalized medicine using a cytotoxic peptide conjugate which is a hybrid molecule composed of a synthetic peptide carrier and doxorubicin. The design of AEZS-108 allows for the specific binding and selective uptake of the cytotoxic conjugate by luteinizing hormone-releasing hormone ( LHRH ) receptor-positive tumors. Phase 2 trials in advanced endometrial cancer and advanced ovarian cancer have been successfully completed. AEZS-108 is also in development in other cancer indications, including refractory bladder and castration-and taxane-resistant prostate cancer. A pivotal trial in endometrial cancer and also a Phase 2 trial in triple-negative breast cancer are expected to be initiated in 2012. We have obtained orphan-drug status for AEZS-108 in advanced ovarian cancer from the FDA and from the Committee for Orphan Medicinal Products ( COMP ) of the EMA. An IND in the United States is in place for the treatment of prostate, bladder and triple-negative breast cancer. We own the worldwide rights to AEZS-108 and 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, aside from Cetrotide®, we completed a Phase 3 trial with AEZS-130, which would be the first oral diagnostic test for AGHD.

#### ***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 after conclusion of a successful pre-NDA meeting with the FDA, we plan 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 agreed to allow for the initiation of a physician sponsored IND 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 which will be funding the study.

## **Table of Contents**

### ***Clinical and Preclinical Programs***

Additionally, we are advancing AEZS-112 in Phase 1, an oral anticancer agent which involves three mechanisms of action, (tubulin, topoisomerase II and angiogenesis inhibition), as well as several preclinical programs with targeted potential development candidates. Among the agents that we expect to reach the clinical development stage in the coming years are: AEZS-120 (oral prostate cancer vaccine), AEZS-129, AEZS-131 and AEZS-132 or their respective follow-up compounds (Erk and PI3K inhibitors).

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

## **1.0 ONCOLOGY**

### **1.1 SIGNAL TRANSDUCTION INHIBITORS**

#### **1.1.1 Perifosine**

Perifosine is a novel, oral anticancer treatment that inhibits Akt activation in the PI3K pathway.

Perifosine is an alkylphosphocholine compound with structural similarity to phospholipids, which are the main constituents of cellular membranes, and it is an active ingredient with antitumor capacities. In tumor cells, perifosine has demonstrated interactions with vital signal transduction mechanisms and induction of programmed cell death (apoptosis).

**Table of Contents**

Perifosine exerts a marked cytotoxic effect in animal and human tumor cell lines. The most sensitive cancer cell lines were larynx carcinoma, breast, small cell lung, prostate and colon. Based on the *in vitro* trials, the mode of action of perifosine appears to be fundamentally different from that of currently available cytotoxics.

Pharmacodynamic data have demonstrated that perifosine possesses antitumor activity, including tumor models that are resistant to currently available agents for cancer therapy. This activity is based on a direct and relatively specific action on tumors.

In preclinical and clinical Phase 1 trials (solid tumors), this orally administered agent has been found to have good tolerability.

Based on findings in various tumor models, the U.S. National Cancer Institute ( NCI ), along with our North American partner, Keryx, investigated additional dosage regimens of perifosine in oncology patients. A number of screening Phase 2 studies examined perifosine as a single agent or in combination in several tumor types. Encouraging results lead to further development in specific indications.

Perifosine, in combination with chemotherapeutic agents, is currently in Phase 3 studies for the treatment of CRC and MM, and in Phase 2 studies for the treatment of other cancers, and we believe is the most advanced anticancer compound of its class in late-stage development.

Perifosine as monotherapy is also being explored in CLL. The FDA has granted perifosine orphan-drug designation in MM and in neuroblastoma and Fast Track designations in both refractory advanced CRC and MM. Additionally, an agreement was reached with the FDA to conduct the Phase 3 trials in both of these indications under a SPA. Perifosine has also been granted Orphan Medicinal Product designation from the EMA in MM, and has received positive Scientific Advice from the EMA for both the advanced CRC and MM programs, with ongoing Phase 3 trials for these indications expected to be sufficient for registration in Europe. Perifosine rights have been licensed to Keryx for North America, to Handok for Korea, to Yakult for Japan and Hikma for the MENA region.

On July 12, 2011, the European Patent Office ( EPO ) granted a patent for the use of alkylphosphocholines, more specifically perifosine, in the preparation of a medicament for the treatment of benign and malignant tumours, prior to and/or during the treatment with approved antitumor antimetabolites such as 5-fluorouracil ( 5-FU ) and capecitabine. Filed on July 29, 2003, the patent (EP #1 545 553) entitled, *Use of Alkyl Phosphocholines in Combination with Anti-Tumours Medicaments*, became effective as of July 13, 2011, following its announcement in the European Patent Bulletin, and will expire on July 28, 2023.

1.1.1.1 Perifosine CRC

*Phase 2 trial perifosine + capecitabine*

On October 5, 2011, we announced that a manuscript, entitled *Randomized Placebo-Controlled Phase 2 Trials of Perifosine Plus Capecitabine as Second- or Third-Line Therapy in Patients with Metastatic Colorectal Cancer*, had been published in the October 3, 2011 online edition of the *Journal of Clinical Oncology* ( JCO ).

This randomized, double-blind, placebo-controlled study was conducted at 11 centers across the United States. Patients with 2<sup>nd</sup> or 3<sup>rd</sup> line mCRC were randomized to receive capecitabine (Xeloda®), an approved drug for mCRC, at a dose of 825 mg/m<sup>2</sup> BID (total daily dose of 1,650 mg/m<sup>2</sup>) on days 1 - 14 every 21 days, plus either perifosine or placebo at 50 daily. Treatment was continued until progression. The study enrolled a total of 38 patients, 34 of which were third-line or greater. Of the 38 patients enrolled, 35 were evaluable for response (20 patients on the perifosine + capecitabine arm and 15 patients on the placebo + capecitabine arm). Of the three patients on the placebo + capecitabine arm not evaluable for response, 2 patients were not evaluable due to toxicity (days 14, 46) and 1 patient was not evaluable due to a new malignancy on day 6. All patients in the perifosine + capecitabine arm were evaluable for response.



**Table of Contents**

The patients in the study were heavily pretreated, with the arms well-balanced in terms of prior treatment regimens. The median number of prior treatment regimens for all 38 patients was two (range 1-5), with prior treatment regimens as follows: 89% of the patients received FOLFIRI (irinotecan + 5-FU + leucovorin); 74% FOLFOX (oxaliplatin + 5-FU + leucovorin); 66% were previously treated with both FOLFIRI and FOLFOX; 79% received Avastin®; and 50% Erbitux®. Prior treatment with single agent capecitabine was excluded.

The primary endpoints of this study were to measure 1) time to progression ( TTP ), 2) overall response rate ( ORR ), defined as the percentage of patients achieving a complete response ( CR ) or partial response ( PR ) by Response Evaluation Criteria in Solid Tumors ( RECIST ), and 3) clinical benefit rate ( CBR ) defined as the percentage of patients on treatment for greater than three months with at least stable disease ( SD ). Safety of perifosine + capecitabine vs. placebo + capecitabine in this patient population was evaluated as a secondary endpoint.

Best response and median TTP of perifosine + capecitabine vs. placebo + capecitabine were as follows:

Group	N*	CR N (%)	PR N (%)	ORR N (%)	SD > 12 N (%)	CBR N (%)	Median TTP
Perifosine + capecitabine	20	1(5%)	3(15%)	4(20%)	11 weeks (55%)	15(75%)	27.5 weeks (95% CI**, 12.1 to 48.1)
Placebo + capecitabine	15	0	1 (7%)	1(7%)	5 weeks (33%)	6(40%)	10.1 weeks (95% CI, 6.6 to 13.0)

\* N = Number of patients

\*\* CI = Confidence interval

Perifosine + capecitabine more than doubled TTP vs. placebo + capecitabine with a statistically significant p-value <.001. In addition, perifosine + capecitabine more than doubled the ORR and almost doubled the CBR vs. placebo + capecitabine.

Although not a primary endpoint in the study, overall survival ( OS ) was analyzed with results as follows:

Group	Median OS
Perifosine + capecitabine	17.7 months (95% CI, 8.5 to 24.6)
Placebo + capecitabine	7.6 months (95% CI, 5.0 to 16.3)

Of notable interest were data showing a highly statistically significant benefit in median OS (more than doubling) and TTP for the subset of patients who were refractory to a 5-FU chemotherapy-based treatment regimen. 5-FU is a core component of the standard of care FOLFIRI and FOLFOX regimens, and capecitabine is a 5-FU pro-drug. These results are shown below:

Of notable interest were data showing a highly statistically significant benefit in median OS (more than doubling) and TTP for the subset of patients who were refractory to a 5-FU chemotherapy-based treatment regimen. 5-FU is a core component of the standard of care FOLFIRI and FOLFOX regimens, and capecitabine is a 5-FU pro-drug. These results are shown below:

Group	5-FU Ref* N (%)	> SD (min 12 weeks) N (%) p=0.066	Median TTP p<.001	Median OS p=0.0088
Perifosine + capecitabine	14(70%)	1 PR /8 SD (64%)	17.6 weeks (95% CI, 12 to 36)	15.1 months (95% CI, 7.2 to 22.3)

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

Capecitabine 11(73%) 0 PR /3 SD (27%) 9.0 weeks (95% CI, 6.6 to 11.0) 6.5 months (95% CI, 4.8 to 10.9)  
\* Ref= refractory

All 38 patients were evaluable for safety. The perifosine + capecitabine combination was well-tolerated with Grade 3 and Grade 4 adverse events of > 10% incidence for perifosine + capecitabine arm versus capecitabine arm as follows: anemia (15% vs. 0%), fatigue (0% vs. 11%), abdominal pain (5% vs. 11%) and hand-foot syndrome (30% vs. 0%). Of note, incidence of Grade 1 and Grade 2 hand-foot syndrome was similar in both the perifosine + capecitabine and capecitabine arms (25% vs. 22%, respectively). Hand-foot syndrome is a reported

---

## **Table of Contents**

adverse event with capecitabine monotherapy. Patients who remained on treatment longer in the Phase 2 study had a greater chance to develop hand-foot syndrome as illustrated by a median time to onset of Grade 3 and Grade 4 hand-foot syndrome in the perifosine + capecitabine arm of 19 weeks.

Based on the data, in which the combination of perifosine + capecitabine demonstrated statistical significance with respect to median OS and median time to tumor progression, the investigators concluded that the perifosine + capecitabine combination showed promising clinical activity compared to single-agent capecitabine, and that the difference in clinical outcome seen with the addition of perifosine was impressive.

### *Phase 3 trial and regulatory milestones*

On February 3, 2010, we announced that our partner Keryx had reached an agreement with the FDA on a SPA for the Phase 3 Xeloda® + Perifosine Evaluation in Colorectal Cancer Treatment ( X-PECT ) trial for perifosine in patients with refractory mCRC.

On April 5, 2010, our partner Keryx was granted Fast Track designation by the FDA for the Phase 3 X-PECT registration trial.

On April 8, 2010, we announced that our partner Keryx initiated a randomized (1:1), double-blind Phase 3 X-PECT trial comparing the efficacy and safety of perifosine + capecitabine (Xeloda®) vs. placebo + capecitabine in approximately 430 patients with refractory mCRC. Patients must have failed available therapy including 5-FU, oxaliplatin (Eloxatin®), irinotecan, bevacizumab (Avastin®) and, if K-Ras wild-type, failed therapy with prior cetuximab (Erbix®) or panitumumab (Vectibix®). For oxaliplatin-based therapy, failure of therapy also includes patients who discontinued due to toxicity. The primary endpoint is OS, with secondary endpoints including ORR (CR + PR), progression-free survival ( PFS ) and safety. Approximately 70 U.S. sites are participating in the study and un-blinding of the study will be triggered by 360 events of death. Dr. Johanna Bendell, Director of GI Oncology Research for the Sarah Cannon Research Institute, Nashville, Tennessee, leads the Phase 3 investigational team. Patient recruitment for this study was completed in July 2011.

On June 29, 2010, we announced that we had received positive Scientific Advice from the EMA regarding the Phase 3 X-PECT trial for the development of perifosine in refractory advanced CRC. The Scientific Advice from the EMA indicates that the ongoing study, in conjunction with safety data generated from other clinical studies with perifosine, is considered sufficient to provide all data necessary to support a marketing authorization of perifosine in advanced CRC. We do not intend to initiate any additional studies with perifosine for this indication. Therefore, for the development of perifosine in both MM and CRC, we believe that the planned North American clinical program, sponsored by our partner Keryx, is now sufficient for approval in Europe and in many countries in the rest of the world, where we hold rights for our compound.

On July 27, 2011, we announced completion of patient recruitment for the ongoing Phase 3 trial with perifosine in refractory advanced CRC, involving over 465 patients from 65 sites in the United States. This Phase 3 X-PECT trial is a randomized (1:1), double-blind trial comparing the efficacy and safety of perifosine + capecitabine vs. placebo + capecitabine. The primary endpoint is OS, with secondary endpoints including ORR (CR + PR), PFS and safety. Approximately 360 events of death will trigger the unblinding of the study.

On August 31, 2011, an independent Data Safety Monitoring Board ( DSMB ) completed an interim safety and futility analysis of the Phase 3 X-PECT study of perifosine in patients with refractory advanced CRC and recommended that the study continue to completion, as planned.

On January 3, 2012, we announced that our Japanese partner, Yakult, had initiated a Phase 1/2 trial in Japan to assess the safety and efficacy of perifosine in combination with a chemotherapeutic agent, capecitabine, in patients with refractory advanced CRC. The primary endpoint of the Phase 1 portion of the trial is the safety profile of perifosine in combination with capecitabine. The primary endpoint of the Phase 2 portion is efficacy (Disease Control Rate). The initiation of this trial on December 27, 2011 triggered a milestone receivable of \$2.6 million (according to the agreement signed in March 2011 for perifosine in Japan).

**Table of Contents**

*Competitors for Perifosine in CRC*

Products on the market:

Surgery is often the main treatment for early stage CRC. When CRC metastasizes (spreads to other parts of the body such as the liver), chemotherapy is commonly used. Treatment of patients with recurrent or advanced CRC depends on the location of the disease. Currently, there are seven approved drugs for patients with mCRC: 5-FU, capecitabine (Xeloda<sup>®</sup>), irinotecan (Camptosar<sup>®</sup>), oxaliplatin (Eloxatin<sup>®</sup>), bevacizumab (Avastin<sup>®</sup>), cetuximab (Erbix<sup>®</sup>), and panitumumab (Vectibix<sup>®</sup>). Depending on the stage of the cancer, two or more of these types of treatment may be combined at the same time, such as FOLFOX (5-FU; leucovorin; oxaliplatin) and FOLFIRI (5-FU; leucovorin; irinotecan), or used after one another. Bevacizumab, a vascular endothelial growth factor ( VEGF ) monoclonal antibody, is commonly administered with chemotherapy. Typically, patients who fail 5-FU, oxaliplatin, irinotecan, and bevacizumab-containing therapies, and who have wild-type KRAS status receive epidermal growth factor receptor ( EGFR ) monoclonal antibody therapy with either cetuximab or panitumumab. Once patients progress on these agents, there are no further standard treatment options.

Product / mode of action	Company	Sales
Avastin <sup>®</sup> (bevacizumab) / a humanized monoclonal antibody targeting vascular endothelial growth factor	Manufactured by Genentech/Roche	According to Decision Resources (Jan. 2012), a research and advisory firm focusing on pharmaceutical and healthcare issues ( Decision Resources (January 2012) ) the 2010 G7* sales were estimated to be \$2.3 billion
Oxaliplatin / platinum agent	Sanofi s Eloxatin/Eloxatine, Yakult Honsha s Elplat, generics	According to Decision Resources (January 2012), the 2010 G7* sales were estimated to be \$2.0 billion
Erbix <sup>®</sup> (cetuximab) / a chimeric monoclonal antibody that specifically blocks EGFR	Manufactured and distributed in North America: Bristol-Myers Squibb Co. and Eli Lilly and Co.	According to Decision Resources (January 2012), the 2010 G7* sales were estimated to be \$1.1 billion
Xeloda <sup>®</sup> (capecitabine) / oral fluoropyrimidine which generates fluorouracil preferentially in tumor tissues by enzymatic cascade	Distributed in the rest of the world by Merck KGaA. Manufactured by Roche	According to Decision Resources (January 2012), the 2010 G7* sales were estimated to be \$636 million
Vectibix <sup>®</sup> (panitumumab) / a recombinant, human IgG2 kappa monoclonal antibody that binds specifically to the human EGFR	Manufactured by Amgen	According to Decision Resources (January 2012), the 2010 G7* sales were estimated to be \$266.1 million

\* G7 = United States, France, Germany, Italy, Spain, UK and Japan.

**Table of Contents**

Products in Phase 3 development:

According to Decision Resources (January 2012), the most promising emerging therapies for CRC are the following: perifosine, regorafenib, aflibercept and ramucirumab.

Product / mode of action*	Company*	Development Status*
Regorafenib (BAY 73-4506) / oral multi-kinase inhibitor targeting angiogenic, stromal and oncogenic kinases	Bayer HealthCare Pharmaceuticals / Onyx Pharmaceuticals, Inc.	Phase 3 completed
Aflibercept (Zaltrap™) / intravenous angiogenesis inhibitor	Sanofi / Regeneron Pharmaceuticals	Regulatory applications for marketing approval submitted (FDA and EMA)
Ramucirumab (IMC-1121B) / intravenous fully human immunoglobulin G1 Mab targeted to VEGF-2	ImClone Systems (a subsidiary of Eli Lilly)	Phase 3

\* Source: Company's Website

Market Data - CRC

According to the American Cancer Society, CRC is the third most common cancer in both men and women in the United States. An estimated 103,170 cases of colon and 40,290 cases of rectal cancer are expected to occur in 2012 and nearly 51,690 people will die from the disease.

According to Decision Resources (January 2012), 368,000 patients will be diagnosed in Stage II-IV in the G7 market in 2014. In 2010, the total market for stage IV-second-line CRC treatments accounted for 25% of major-market sales (\$1.8 billion) and 5% (\$360 million) for the total market for the third-line CRC treatment.

**Treatable pool stage IV patient population\***

	3 <sup>rd</sup> line in 2014	2 <sup>nd</sup> line in 2014
<b>USA</b>	28,320	41,650
<b>EU-5</b>	48,070	74,480
<b>Japan</b>	19,750	35,270

\* According to Decision Resources (January 2012).

1.1.1.2 Perifosine - MM

*Phase 1/2 trial - Perifosine in combination with Revlimid® (lenalidomide) + dexamethasone*

In December 2008, our partner Keryx presented final results of the Phase 1 clinical trial in which patients with relapsed or refractory MM were administered a combination of perifosine + lenalidomide + dexamethasone. Four cohorts of 36 patients each were enrolled and perifosine dose was 50 or 100 mg (daily), lenalidomide dose was 15 or 25 mg for days 1 to 21 and dexamethasone dose was 20 mg (for days 1-4; 9-12; and 17-20 for 4 cycles, then 20 mg for days 1-4) in 28-day cycles. To limit dexamethasone-related toxicities, the protocol was amended to use weekly dexamethasone (40 mg), applying to cohorts 3, 4, and the maximal tolerated dose (MTD) cohort. Dose limiting toxicity (DLT) was defined as Grade 3 non-hematologic toxicity, Grade 4 neutropenia for 5 days and/or neutropenic fever, or platelets <25,000/mm<sup>3</sup> on >1 occasion

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

despite transfusion. Response was assessed by modified EBMT criteria. To be enrolled, patients had to have received at least one but no more than four prior therapies. Patients refractory to lenalidomide/dexamethasone were excluded. 32 patients (17 men and 15 women,

**Table of Contents**

median age 61 years old, range 37-80) were enrolled; 6 patients in cohort 1 (perifosine 50 mg, lenalidomide 15 mg, dexamethasone 20 mg); 6 patients in cohort 2 (perifosine 50 mg, lenalidomide 25 mg, dexamethasone 20 mg); 8 patients in cohort 3 (perifosine 100 mg, lenalidomide 15 mg, dexamethasone 40 mg/week); 6 patients in cohort 4 (perifosine 100 mg, lenalidomide 25 mg, dexamethasone 40 mg/week) and 6 patients at MTD (Cohort 4). Median prior lines of treatment was 2 (range 1-4). Prior therapy included dexamethasone (94%), thalidomide (83%), bortezomib (47%), and stem cell transplant (47%). 37% of patients had progressed on prior thalidomide/dexamethasone. Two patients did not complete one full cycle (non-compliance and adverse event not related to study drugs both in cohort 3) and were not included in the safety and efficacy analysis. Of the 30 patients evaluable for safety, the most common (310%) Grade 1 / 2 events included nausea (13%); diarrhea (17%); weight loss (17%); upper respiratory infection (23%); fatigue (30%); thrombocytopenia (20%); neutropenia (20%); hypophosphatemia (23%); increased creatinine (23%); anemia (36%); hypercalcemia (47%). Grade 3 / 4 adverse events 35% included neutropenia (20%); hypophosphatemia (17%); thrombocytopenia (13%); anemia (10%), fatigue (7%). There was one reported DLT in cohort 3 (nausea). Lenalidomide was reduced in 8 patients, perifosine reduced in 8 patients and dexamethasone reduced in 6 patients.

Patients have tolerated the treatment regimen of perifosine + lenalidomide + dexamethasone well with manageable toxicity, and with encouraging clinical activity demonstrated by an ORR (> PR) of 50%.

Updated results of this Phase 1 study were presented in February 2009 at the 12<sup>th</sup> International Multiple Myeloma Meeting by our partner Keryx. Results indicated that perifosine in combination with lenalidomide (Revlimid<sup>®</sup>) + dexamethasone continues to be well tolerated, with a median PFS in responding patients of 10.9 months. Median OS still was not reached and was at 17 months at time of analysis.

On December 6, 2010 at the American Society of Hematology s ( ASH <sup>™</sup> 52<sup>nd</sup> annual meeting in Orlando, Florida, we announced final positive results for this Phase 1 trial. The final data showed a 73% objective response rate (minimal response or better) with a 50% PR or better, a median PFS of 10.8 months, and a median duration for OS of 30.6 months. The myeloma investigators concluded that perifosine in combination with lenalidomide (Revlimid<sup>®</sup>) + dexamethasone was well tolerated even at the highest doses used, and demonstrated encouraging clinical activity and survival.

Best Response (N = 30 pts)	N (%)	Duration on Tx (months) Median (range)	<sup>3</sup> PR	<sup>3</sup> MR
Near complete response (nCR)	4(13%)	32+, 32+, 28, 6	50%	73%
Very good partial response (VGPR)	3(10%)	35, 7, 4		
Partial response (PR)	8(27%)	Median 5.5 (4 29)		
Minimal reponse (MR)	7(23%)	Median 12 (2 34)		

Stable disease (SD) 6(20%) Median 3 (2 30)

Progressive disease (PD) 2(7%) 9, 4 weeks

*Phase 1/2 trial Perifosine in combination with Velcade® (bortezomib) + dexamethasone*

Keryx presented preliminary results of a Phase 1/2 multicenter trial of perifosine + bortezomib (Velcade®) in patients with relapsed or relapsed/refractory MM who were previously relapsed from or refractory to bortezomib ± dexamethasone in December 2008 during the meeting of the ASH and in February 2009 at the 12<sup>th</sup> International Multiple Myeloma Meeting. Final results were presented during the ASH meeting in December 2009. The Phase 1 stage of the study enrolled a total of 18 patients in 4 cohorts of 3 patients each with dosing of perifosine



**Table of Contents**

50 mg or 100 mg (daily) and bortezomib 1.0 or 1.3 mg/m<sup>2</sup> (on day 1, 4, 8, 11) in 21-day cycles. The selected dose for Phase 2 was perifosine 50 mg once daily + bortezomib 1.3 mg/m<sup>2</sup> (on day 1, 4, 8, 11) in 21-day cycles, with a planned enrollment of 64 patients. Dexamethasone 20 mg (on day of and after each bortezomib dose) could be added in patients with PD. For the Phase 1 portion, DLT was defined as any Grade 3 non-hematologic toxicity, Grade 4 neutropenia for 5 day and/or neutropenic fever, or platelets <10,000/mm<sup>3</sup> on more than one occasion despite transfusion. Response was assessed by modified EBMT and Uniform criteria.

On October 13, 2011, we announced that the manuscript, entitled *Perifosine Plus Bortezomib and Dexamethasone in patients with Relapsed/Refractory Multiple Myeloma Previously Treated with Bortezomib: Results of a Multicenter Phase 1/2 Trial*, had been published in the October 10, 2011 online edition of the *Journal of Clinical Oncology* (JCO), in which Phase 1/2 combination activity of perifosine in the treatment of advanced MM patients was reported.

Eighty-four patients were enrolled in a combined Phase 1/2 study (18 patients in the Phase 1 component and 66 patients in the Phase 2 component), including 74 (88%) with relapsed/refractory MM. Sixty-one patients (73%) were bortezomib refractory and 43 (51%) were refractory to bortezomib with dexamethasone. The median number of prior treatments was five (range, one to 13 treatments). Prior therapies received at any time point included bortezomib (100%), with patients receiving a median of two (range, one to four) prior bortezomib-based regimens; dexamethasone (98%); lenalidomide (Revlimid<sup>®</sup>) (76%); thalidomide (Thalomid<sup>®</sup>) (75%); and prior stem cell transplant (58%).

Of the 73 evaluable patients, 53 patients (73%) were previously refractory to bortezomib (defined as progression on or within 60 days of treatment to a bortezomib-based regimen). Twenty evaluable patients (27%) were relapsed to a prior bortezomib-based regimen. Best response for all 73 evaluable patients was as follows:

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

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

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

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

Best response for each group was as follows:

Best Response	CR /nCR		PR		MR		ORR		SD	
Perifosine + bortezomib (N = 73)	2	3%	10	14%	6	8%	18	25%	19	26%
Dexamethasone added (N = 45)	1	2%	6	13%	10	22%	17	38%	14	31%

**Table of Contents**

Reported for the first time was median PFS and OS data for all evaluable patients, as follows:

<b>Evaluable Patients</b>	<b>Median PFS*</b>	<b>Median OS**</b>
---------------------------	--------------------	--------------------

All Evaluable Patients (N = 73)	6.4 months (95% CI, 5.3, 7.1)	25 months (95% CI, 16.3, 31.1)***
---------------------------------	-------------------------------	-----------------------------------

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

\*\* Kaplan Meier methodology was used to determine OS figures.

\*\*\* Results from the abstract *Perifosine Plus Bortezomid and Dexamethasone in Relapsed/Refractory Multiple Myeloma Patients Previously Treated with Bortezomib: Final Results of a Phase 1/2 Trial* (abstract # 815) were presented as an oral presentation at the ASH Annual Meeting and Exposition (Dec. 2011) in San Diego, California.

Of particular interest was the comparison of evaluable patients who were previously refractory and the patients who were relapsed to a bortezomib-based regimen. Median PFS and OS for bortezomib relapsed vs. refractory was as follows:

<b>Bortezomib Relapsed vs. Refractory</b>	<b>Median PFS*</b>	<b>Median OS**</b>
---	--------------------	--------------------

Bortezomib relapsed (N = 20)	8.8 months (95% CI, 6.3, 11.2)	30.4 months (95% CI, 17.8, NR)***
------------------------------	--------------------------------	-----------------------------------

Bortezomib refractory (N = 53)	5.7 months (95% CI, 4.3, 6.4)	22.5 months (95% CI, 14.2, 31.1)***
--------------------------------	-------------------------------	-------------------------------------

NR = Not Reached

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

\*\* Kaplan Meier methodology was used to determine OS figures.

\*\*\* Results from the abstract *Perifosine Plus Bortezomid and Dexamethasone in Relapsed/Refractory Multiple Myeloma Patients Previously Treated with Bortezomib: Final Results of a Phase 1/2 Trial* (abstract # 815) were presented as an oral presentation at the ASH Annual Meeting and Exposition (Dec. 2011) in San Diego, California.

No unexpected adverse events have been observed. Therapy was generally well-tolerated, and toxicities, including gastrointestinal side-effects and fatigue, proved manageable. No treatment-related mortality was seen. The investigators concluded the data reported for both safety and efficacy in this patient population were encouraging for the continued study of perifosine.

#### *Phase 3 trial and regulatory milestones*

In August 2009, we announced that our partner Keryx reported that it had reached an agreement with the FDA regarding an SPA on the design of a Phase 3 trial for perifosine, in relapsed or relapsed/refractory MM patients previously treated with bortezomib (Velcade®). The SPA provided agreement that the Phase 3 study design adequately addresses objectives in support of a regulatory submission.

In September 2009, we announced that our partner Keryx had received orphan-drug designation for perifosine from the FDA for the treatment of MM. 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 United States. 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.

On December 2, 2009, we announced that the FDA had granted Fast Track designation for perifosine for the treatment of relapsed/refractory MM. The Fast Track program of the FDA is designed to facilitate the development and expedite the review of new drugs that are intended to

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track designated drugs ordinarily qualify for priority review, thereby expediting the FDA review process.

On December 16, 2009, we announced that our partner Keryx initiated a Phase 3 trial for perifosine entitled, *A Phase 3 Randomized Study to Assess the Efficacy and Safety of Perifosine Added to the Combination of Bortezomib (Velcade®) and Dexamethasone in Multiple Myeloma Patients Previously Treated with Bortezomib*. The randomized (1:1), double-blind trial powered at 90%, will enroll approximately 400 patients with relapsed or

**Table of Contents**

relapsed/refractory MM (patients can be relapsed from and refractory to all non-bortezomib based therapies, however, patients can only be relapsed (progressed > 60 days after discontinuing therapy) from prior bortezomib-based therapies. Patients must have been previously treated with both bortezomib (Velcade®) and an immunomodulatory agent (Revlimid® or Thalidomid®) and previously treated with one to four prior lines of therapy. Enrolled patients are randomized to bortezomib (Velcade®) at 1.3 mg/m<sup>2</sup> days 1, 4, 8 and 11 every 21 days in combination with dexamethasone 20 mg on the day of and day after bortezomib (Velcade®) treatment, and either perifosine 50 mg daily or placebo. The primary endpoint is PFS and secondary endpoints include ORR, OS and safety. Approximately 265 events (defined as disease progression or death) will trigger the un-blinding of the data.

In March 2010, we announced that we had received a positive opinion for orphan medicinal product designation for perifosine from the COMP of the EMA, for the treatment of MM. Orphan medicinal product designation is granted by the European Commission, following a positive opinion from the COMP, to a medicinal product that is intended for the diagnosis, prevention or treatment of a life-threatening or a chronically debilitating condition affecting not more than five in 10,000 persons in the European Community when the application for designation is submitted.

Orphan medicinal product designation provides the sponsor with access to the Centralized Procedure for the application for marketing authorization, protocol assistance, up to a 100% reduction in fees related to a marketing authorization application, preauthorization inspection and post-authorization activities, and could provide ten years of market exclusivity in the EU, once approved for the treatment of MM.

On April 15, 2010, we received positive Scientific Advice (PSA) from the EMA for the Phase 3 registration trial with perifosine in MM, therefore indicating that the data from the ongoing trial are expected to be sufficient for product registration in Europe.

*Competitors for Perifosine in MM*

Products on the market

Major products available on the market for the treatment of MM are the following:

Product / mode of action*	Company*	Development Status*
Velcade® (bortezomib) / proteasome inhibitor	Takeda/Janssen-Cilag/Janssen	According to Decision Resources (January 2012), the 2010 G7** sales were estimated to be \$1.14 billion
Caelyx® /Doxil® (pegylated liposomal doxorubicin) / topoisomerase II inhibitor and DNA intercalating agent	Janssen (J&J): Doxil® / Merck & Co.: Caelyx	According to Decision Resources (January 2012), the 2010 G7** sales were estimated to be \$36.2 million
Thalomid® (thalidomide) / antiangiogenic compound	Celgene Corporation	According to Decision Resources (January 2012), the 2010 G7** sales were estimated to be \$383.9 million
Revlimid® (lenalidomide) / oral immunomodulatory drug	Celgene Corporation	According to Decision Resources (January 2012), the 2010 G7** sales were estimated to be \$1.94 billion

\* Source: Company's Website

\*\* G7 = United States, France, Germany, Italy, Spain, UK and Japan.

**Table of Contents**

Products in Phase 3 development:

Product / mode of action*	Company*	Development Status*
Carfilzomib / selective, irreversible proteasome inhibitors	Onyx Pharmaceuticals	- NDA submitted to the FDA
Pomalidomide / small-molecule, immunomodulatory drugs (angiogenesis, modulation of proinflammatory and regulatory cytokines, and immune stimulation of T cells and NK cells)	Celgene Corporation	- Phase 2 and Phase 3 - Phase 3
Panobinostat (LBH5893) / highly potent pan-deacetylase inhibitor targeting the epigenetic regulation of multiple oncogenic pathways	Novartis	- Phase 2 completed Phase 3
Zolinza (vorinostat MK0683) / oral histone deacetylase inhibitor	Merck	Phase 3 completed
Elotuzumab (HuLuc63) / humanized MAb	Bristol-Myers Squibb/Abbott	Phase 3

\* Source: Company's Website  
Market Data MM

MM is the second most common blood cancer in the United States and constitutes approximately 1% of all cancers (*source: NCI*).

According to Decision Resources Patient Data Base (March 2012), 49,840 patients will be diagnosed in the G7 market in 2014.

**Treatable pool relapsed/refractory patient population\***

	3 <sup>rd</sup> line in 2014	2 <sup>nd</sup> line in 2014
<b>USA</b>	10,080	14,830
<b>EU-5</b>	11,840	17,410
<b>Japan</b>	2,860	4,200

\* According to Decision Resources Patient Data Base (March 2012).

1.1.1.3 Perifosine Other indications

Perifosine is also studied in different indications including gliomas, RCC, sarcoma, Hodgkin's lymphoma (HL), neuroblastoma and other indications. As a monotherapy, perifosine is being explored in CLL.

On April 4, 2011, we announced that two posters on perifosine were presented at the 102<sup>nd</sup> annual meeting of the AACR at the Orange County Convention Center in Orlando, Florida. Perifosine demonstrated antitumor activity in several gastric cancer cell lines. Furthermore, perifosine enhanced the antitumor activity of 5-FU in parts of the cell lines, including 5-FU resistant cell lines. 5-FU is the active metabolite of the prodrug Xeloda, which is approved for the treatment of advanced gastric cancer in many countries including Japan.

---

## **Table of Contents**

Perifosine also markedly enhanced the antitumor activity of the cellular TRAIL based treatment and was able to overcome TRAIL resistance both *in vitro* and *in vivo*. The results are in line with other studies demonstrating the synergistic effects of perifosine with cytotoxic drugs, including bortezomib and 5-FU.

On December 12, 2011, we reported encouraging preclinical data for perifosine in HL. *In vitro* data from HL cell lines showed that perifosine combined with sorafenib induced increased apoptosis, while *in vivo* data for the same combination treatment for HL significantly increased survival in mice. Data were presented during the ASH Annual Meeting and Exposition, in San Diego, California.

The study was conducted to investigate, *in vitro* and *in vivo*, the activity and mechanism(s) of action of perifosine in combination with sorafenib by using three HL cell lines (HD-MyZ, L-540, HDLM-2). In the *in vitro* experiments perifosine/sorafenib treatment resulted in synergistic cell growth inhibition and cell death induction in HD-MyZ and L-540 cell lines, but not in the HDLM-2 cell line. Cell cycle arrest, down-modulating of the MAPK and PI3K/Akt pathways as well as caspase-independent cell death was observed, which was associated with severe mitochondrial dysfunction. Further, expression of genes involved in amino acid metabolism, cell cycle, DNA replication and cell death was shown to be modulated. In addition, overexpression of the tribbles homologue 3 [TRIB3] was observed.

*In vivo*, perifosine/sorafenib treatment significantly increased survival in the HD-MyZ model (45 vs. 81 days, as compared to controls), with 25% tumor-free mice at the end of the 200-day observation period. In the L-540 model, subcutaneous tumor volume was also reduced as compared to controls (by 42%), perifosine (by 35%) or sorafenib (by 46%) alone. In HD-MyZ and L-540 but not HDLM-2, the combined treatment induced an increase in tumor necrosis (2- to 8-fold, P £.0001) and in tumor apoptosis (2- to 2.5-fold, P £.0001). In 2 of 3 HL cell lines, perifosine/sorafenib combination treatment induced potent antitumor effects. A significant increase in mitochondrial injury and apoptosis and a marked reduction of cell viability were observed in the *in vitro* experiments. *In vivo* combination treatment increased survival and inhibited tumor growth.

On December 13, 2011, we reported encouraging clinical data for an ongoing Phase 2 clinical study in patients with refractory/relapsed HL during the ASH Annual Meeting and Exposition.

Preliminary response data showed that perifosine combined with sorafenib significantly increased median PFS in refractory/relapsed HL patients with high phosphorylation levels of Erk and Akt as compared to patients with low baseline phosphorylation levels of Erk and Akt.

The study evaluates phosphorylation levels of Erk (pErk) and Akt (pAkt) in circulating lymphocytes from patients enrolled in two consecutive Phase 2 trials evaluating activity and safety of sorafenib as a single agent or in combination with perifosine in relapsed/refractory HL patients. Four patients were treated with sorafenib alone at a dose level of 400 mg BID and twenty-one patients received a 4-week treatment with perifosine alone at a dose level of 50 mg BID, followed by a perifosine/sorafenib combination therapy with 50 mg BID and 400 mg BID, respectively. Circulating lymphocytes were evaluated for their phosphorylation levels of Erk and Akt, in order to assess predictive value of the phosphokinase levels for therapy responses.

Clinical response data showed that baseline pErk and pAkt levels were significantly higher in responsive patients, as compared to unresponsive patients. The pErk and pAkt levels measured after 60 days of therapy with perifosine combined with sorafenib were significantly reduced in responsive patients. The median baseline value of pErk and pAkt efficiently discriminated responsive and unresponsive patients which was associated with a significantly improved median PFS for patients with baseline pErk <sup>343%</sup> and/or pAkt <sup>>23%</sup>. Based on these data, the correlation of baseline pErk and pAkt levels with objective responses and time to tumor progression will need to be validated in prospective studies. In conclusion, refractory/relapsed HL patients with increased baseline levels of pErk and pAkt demonstrated increased PFS when treated with perifosine in combination with sorafenib.

### 1.1.1.4 Partners for perifosine

A CRADA was put in place with the National Institutes of Health/the NCI in May 2000.

## **Table of Contents**

A cooperation and license agreement was signed in September 2002 with Access Oncology, Inc. ( AOI ), for the use of perifosine as an anticancer agent covering the United States, Canada and Mexico. In January 2004, AOI was acquired by Keryx, which is pursuing the clinical development of perifosine under the same conditions as AOI. The agreement, in particular, provides us free access to all data from Keryx and its partners studies, as well as milestone payments and scale-up royalties (from high single to low double digit) to be paid to us on future net sales of perifosine in the United States, Canada and Mexico.

In April 2009 we entered into an agreement to out-license the rights of perifosine to Handok in South Korea.

On March 9, 2011, we announced that we had entered into an agreement with 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 up-front payment to us of 6 million (approximately \$8.4 million). Also per the agreement, we are entitled to receive in addition, up to a total of 44 million (approximately \$57.1 million) upon achieving certain pre-established milestones, including clinical and regulatory events in Japan. Furthermore, we will be supplying perifosine to Yakult on a cost-plus basis and we will be entitled to receive double-digit royalties on future net sales of perifosine in the Japanese market. Yakult will be responsible for the development, registration and commercialization of perifosine in Japan.

On November 23, 2011, we announced the signing of an exclusive commercialization and licensing agreement with Hikma for the registration and marketing of perifosine for the MENA region. Under the terms of the agreement, we received an upfront payment of \$0.2 million and are entitled to receive up to a total of \$1.8 million upon achieving certain pre-established milestones. Furthermore, we will be supplying perifosine to Hikma on a cost-plus basis and are entitled to receive double-digit royalties on future net sales of perifosine in the MENA region. Hikma will be responsible for the registration and commercialization of perifosine in the MENA region. We own rest of the world rights to perifosine.

### **1.1.2 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.

#### **1.1.2.1 AEZS-129**

On April 21, 2009, we presented two posters on AEZS-129, 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 inhibitor of PI3K. 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 4 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

**Table of Contents**

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 xenograft 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.

## 1.1.2.2 AEZS-131

On March 22, 2011, we presented preclinical results for AEZS-131 at the Informa Life Sciences Protein Kinases Congress in Berlin, Germany. AEZS-131 was established as a small molecular compound that inhibits Erk in the low nanomolar ( nM ) range and shows an excellent selectivity profile. Further characterization experiments revealed an ATP-competitive mode of action and the potent inhibition of the cellular downstream target Rsk1 in tumor cells. The frontrunner, AEZS-131, produces cell cycle arrest in G1 and results in growth inhibition of cancer cells. Furthermore, the potential of combination therapy of AEZS-131 with inhibitors of the PI3K pathway was addressed and the analysis of combination effects on tumor cell proliferation has been presented. These results support the evaluation of selective Erk inhibitors as antiproliferative agents either as monotherapy or in combination with inhibitors of the PI3K/Akt pathway.

On April 5, 2011, we announced results for AEZS-131 at the AACR s annual meeting. Results showed that AEZS-131 is an orally active small molecular compound that selectively inhibits Erk 1/2 with an IC50 of 4nM, blocks cellular Rsk-1 phosphorylation, modulates downstream cellular substrate activation, arrests tumor cells in G1 and inhibits the growth of multiple human tumor cell lines in the nM range. In *in vivo* pharmacokinetic studies, AEZS-131 showed a favorable PK profile. Antitumor activity was studied in *in vivo* mouse xenograft experiments utilizing the HCT 116 CRC model. AEZS-131 significantly inhibited tumor growth and was well tolerated at daily doses up to 120 mg/kg. Focus on inhibition of downstream kinase Erk 1/2 activity as a therapeutic target may be attractive because the pharmacologic inhibition of Erk 1/2 reverses Ras and Raf activation in cells which also demonstrate resistance to common Raf inhibitors, such as PLX-4720/4032.

On August 30, 2011, we presented preclinical data on AEZS-131 at the American Chemical Society National Meeting in Denver, Colorado. Data showed that the *in vitro* antiproliferative efficacy proved to be excellent in diverse human tumor cell lines and that GI<sub>50</sub> values in the low nM range were obtained. *In vivo* antitumor activity was studied in a mouse xenograft experiment utilizing the human HCT-116 colon cancer model. Up to 74% inhibition of tumor growth was achieved with daily oral doses of 30 – 120 mg/kg. Our medicinal chemistry programs are supported by X-ray crystallography and modeling towards the optimization of pyrido[2,3-b]pyrazines as novel series of kinase inhibitors.

On December 9, 2011, we announced positive preclinical data in triple-negative breast cancer ( TNBC ) for AEZS-131. Data showed that AEZS-131 selectively inhibits Erk at low nM concentrations and induces G1 arrest. Accordingly, the cytotoxic effect of AEZS-131 was most pronounced in TNBC cell lines with mutations in the MAPK pathway. Data were presented at the CTRC - AACR San Antonio Breast Cancer Symposium, in San Antonio, Texas. AEZS-131 was tested to check for selectivity, inhibition of Rsk-phosphorylation (cellular substrate of Erk), mode of action and cleavage of PARP. Cytotoxic efficacy was evaluated in a selection of TNBC cell lines, with or without mutations in the MAPK signal transduction pathway, by MTT assay. The study showed that AEZS-131 selectively inhibited Erk with an IC50<4nM. Phosphorylation of Rsk-1, the cellular substrate of Erk, was inhibited with an IC50 of 158 nM. AEZS-131 induced cell cycle arrest in G1 dose-dependently and cleavage of PARP. EC50 values were below 1µM for cell lines with mutations in the MAPK pathway. TNBC cell lines without mutations in the MAPK pathway were less responsive.

## 1.1.2.3 AEZS-132

On April 20, 2010, at the AACR s annual meeting we presented data on our dual Erk/PI3K inhibitors and on our selective Erk inhibitors. Data supported further evaluation of selective Erk inhibitors as antiproliferative agents, either as monotherapy or in combination with inhibitors of the PI3K/Akt pathway. Other data resulted in the identification of AEZS-132, a unique dual inhibitor of PI3K and Erk with a favourable pharmacology and ADMET profile, for further evaluation as an antitumor agent.



## **Table of Contents**

On November 17, 2010, at the EORTC-NCI-AACR meeting, we presented a poster on AEZS-132, the first-in-class dual PI3K/Erk inhibitor being selected as the optimized lead compound for further development. The compound is a unique orally active low molecular weight dual PI3K/Erk inhibitor derived from Aeterna Zentaris medicinal chemistry program. Due to its dual PI3K and Erk inhibition, a broad antitumor activity is expected in tumors with over-activation of both pathways. AEZS-132 demonstrated prolonged plasma exposure when given orally in mice. Significant tumor inhibition resulted from mouse xenograft models with human colon, endometrium and lung tumors.

On March 22, 2011, we presented preclinical results for AEZS-132 at the Informa Life Sciences Protein Kinases Congress in Berlin, Germany. AEZS-132 is a unique dual inhibitor of PI3K and Erk in the nM range and exerts high selectivity against other serine threonine and tyrosine kinases. AEZS-132 is also an ATP-competitive inhibitor, with a broad antiproliferative profile *in vitro*, a favorable safety profile and beneficial ADME properties. *In vivo* pharmacokinetic experiments showed plasma profiles expected to result in positive antitumor efficacy, and led to significant antitumor activity in mouse xenograft models, including HCT-116 (colon), A-549 (lung), and Hec1B (endometrium). Cellular inhibition of the downstream targets p-Akt and p-Rsk was confirmed within the *in vivo* tumor studies. In summary, we hope that AEZS-132, by targeting the PI3K and MAPK pathways, will be especially suited to treat tumors with over-activation of both pathways.

### 1.2 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.

## **Table of Contents**

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.

In preclinical studies conducted to date in several animal models of LHRH receptor-positive human cancer cell lines, AEZS-108 antitumor activity and tolerability were shown to be superior to that of doxorubicin. As would be expected, AEZS-108 was not active or was significantly less active than doxorubicin in LHRH receptor-negative cancer cell lines. On January 18, 2005, we announced the initiation of a company-sponsored Phase 1 dose-ranging study with the targeted anticancer agent AEZS-108.

In June 2006 and on November 27, 2006, we disclosed positive Phase 1 results regarding AEZS-108 in patients with gynaecological and breast cancers. Data showed the compound's good safety profile and established the maximum tolerated dose at 267 mg/m<sup>2</sup> which is equimolar to a doxorubicin dose of 77 mg/m<sup>2</sup>. Infusion was well tolerated at all dosages without supportive treatment. Pharmacokinetic analyses showed dose-dependent plasma levels of AEZS-108 and only minor release of doxorubicin. The Phase 1 open-label, multicenter, dose-escalation, safety and pharmacokinetic study conducted in Europe included 17 patients suffering from breast, endometrial and ovarian cancers with proven LHRH receptor status. Evidence of antitumor activity was found at 160 mg/m<sup>2</sup> and 267 mg/m<sup>2</sup> doses of AEZS-108, where 7 out of 13 patients showed signs of tumor response, including 3 patients with complete or partial responses. Recommended dose for Phase 2 trial was 267 mg/m<sup>2</sup> given once every three weeks (*source: Emons et al. Dose escalation and pharmacokinetic study of AEZS-108 (AN-152), an LHRH agonist linked to doxorubicin, in women with LHRH receptor-positive tumors. Gynecol Oncol. 2010 Dec;119(3):457-61*).

### **1.2.1 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 involved 82 patients with up to 41 patients with either 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 being 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 2 hours, every Day 1 of a 21-day (3-week) cycle. The proposed duration of the study treatment was 6 courses of 3-week cycles. The study was performed with 14 centers of the German Gynaecological Oncology Working Group, in cooperation with 3 clinical sites in Europe. The primary efficacy endpoint at the end of Stage II was defined as 5 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 a diagnosis of platinum-resistant 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 a diagnosis of disseminated endometrial cancer.

In November 2009, we announced preliminary positive efficacy data from this Phase 2 study in patients with platinum-resistant and taxane-pretreated ovarian cancer and in patients with advanced or recurrent endometrial cancer. Of the 42 patients with LHRH receptor-positive ovarian cancer and the 43 patients with LHRH receptor-positive endometrial cancer who entered study AGO-GYN, 5 completed their study treatment. A preliminary evaluation showed that both indications met the primary efficacy endpoint of 5 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 PFS and, ultimately, OS.

---

## **Table of Contents**

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) entitled *Phase 2 study of AEZS-108, a targeted cytotoxic LHRH analog, in patients with LHRH receptor-positive platinum resistant ovarian cancer*, details the use of AEZS-108 in women with histologically confirmed taxane-pretreated platinum-resistant/refractory LHRH receptor-positive advanced (FIGO III or IV) or recurrent ovarian cancer.

Forty-two patients with platinum-resistant ovarian cancer entered the study. Efficacy included PR in 5 patients (11.9%) and stable disease for more than 12 weeks in 11 patients (26.2%). Based on those data, a CBR of 38% can be estimated. Median TTP and OS were 3.5 months (104 days) and 15.6 months (475 days), respectively. OS compares 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 3 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 (2.4%) each of nausea, constipation, poor general condition, and an enzyme elevation. No cardiac toxicity was reported.

On September 14, 2011, we presented positive final Phase 2 efficacy and safety data for AEZS-108 in advanced endometrial cancer at the European Society of Gynecological Oncology in Milan, Italy. Data showed that AEZS-108, administered as a single agent at a dosage of 267 mg/m<sup>2</sup> every 3 weeks was active, well tolerated and that OS is 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 2 CR, 10 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 1 CR, 1 PR and 2 SDs in 8 of the patients with prior use of platinum/taxane regimens. Median TTP and OS were 7 months and 13.7 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 1 patient who had been treated only 3 weeks after a surgery. Good tolerability of AEZS-108 was also reflected by a low rate of severe non hematological 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.

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

At present, there is no 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 for treating advanced or recurrent endometrial cancer.

**Table of Contents**

Product / mode of action*	Company*	Development Status*
Ixabepilone / microtubule inhibitor	Bristol-Myers Squibb	Phase 3
Letrozole / non-steroidal aromatase inhibitor	Novartis	- Phase 2 completed
XL-147 (Exelixis) / potent and highly selective inhibitor of the class I PI3K family of lipid kinases which targets the PI3K/PTEN pathway	Sanofi	- Phase 3 (University of California, Davis) Phase 2
* Source: Company's Website and www.clinicaltrials.gov 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 47,130 new cases expected to occur in 2012. This disease primarily affects postmenopausal women at an average age of 60 years at diagnosis. In the United States, it is estimated that approximately 8,010 women will die of endometrial cancer in 2012.

According to Datamonitor Healthcare (March 2010), a research and advisory firm focusing on therapeutic, strategic and ehealth market analysis and competitive intelligence, the incidence of endometrial cancer in the seven major pharmaceutical markets was 92,180 patients and is forecasted to reach about 98,500 cases by 2019.

### 1.2.2 AEZS-108 Prostate and Bladder Cancer

In May 2009, we announced at the ASCO meeting the results supporting the evaluation of AEZS-108 in prostate cancer. Expression of LHRH receptors was determined using immunohistochemistry and the intensity was graded on a scale from zero to 3. The expression was analyzed in three cohorts of patients: (1) 47 men with localized prostate cancer treated with radical prostatectomy with no hormone therapy, (2) 61 men with localized prostate cancer treated with neoadjuvant LHRH agonists for varying duration prior to prostatectomy, and (3) 22 men with metastatic prostate cancer who received a palliative transurethral resection of the prostate after clinical progression. In the final cohort, 15 men were treated with castration and 7 were treated with LHRH agonists. 45 of 47 hormone naïve samples (95.7%) demonstrated LHRH receptor expression. Statistical analysis revealed a correlation between strong receptor expression and higher pathologic tumor stage as well as shorter OS. 60 of 61 samples treated with neoadjuvant LHRH agonist therapy (98.4%) demonstrated LHRH receptor expression. All 22 samples from patients with metastatic disease demonstrated LHRH receptor expression. The majority of these samples demonstrated moderate to strong intensity. LHRH receptors are expressed on prostate cancers cells of hormone naïve and castrated patients. The expression of these receptors appears to persist despite prolonged treatment with LHRH agonists. The new results show continued expression of LHRH receptors in prostate cancer specimens after prolonged use of LHRH agonists. These data provide further support to the investigation of the drug in hormone-refractory prostate cancer, a major genitourinary cancer indication in male patients.

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 12 patients; subsequently, a selected dose will be studied for its effect on PFS.

**Table of Contents**

On August 5, 2010, we announced that the 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 approximately \$1.5 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 both Phase 1/2 trials.

On September 26, 2011, we announced positive interim data for the Phase 1 portion of our 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: 3 patients each received AEZS-108 at the lower dose levels of 160 and 210 mg/m<sup>2</sup>, and 6 patients at 267 mg/m<sup>2</sup>. Data on 10 patients were presented as 2 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 and six Grade 3 toxicities. Signs of therapeutic activity included 5 patients with PSA regression. Three out of 4 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 internalization 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 positive updated results for the Phase 1 portion of our ongoing Phase 1/2 study in castration- and taxane-resistant prostate cancer ( CRPC ) with AEZS-108. This is a single-arm study with a Phase 1 lead-in portion (testing 3 dose levels) 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. Data were presented by Jacek Pinski, M.D., Ph.D., Associate Professor of Medicine at the Norris Comprehensive Cancer Center of the University of Southern California, during a poster session at the American Society of Clinical Oncology Genitourinary Cancers Symposium which is being held in San Francisco. Prior interim data on this study were presented at the European Society of Medical Oncology Congress in September 2011. The trial is being supported by a three-year US\$1.6 million grant from the National Institutes of Health to Dr. Pinski.

The results were based on 13 patients that were treated on 3 dose levels: 3 at 160 mg/m<sup>2</sup>, 3 at 210 mg/m<sup>2</sup>, and 7 at 267 mg/m<sup>2</sup>. Overall, AEZS-108 was well tolerated among this group of heavily pretreated older patients. To date, there have been 2 dose limiting toxicities; both were cases 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 has been 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 8 cycles (at 210 mg/m<sup>2</sup>) due to continued benefit. Among the 5 evaluable patients with measurable disease, 4 achieved stable disease. At the time of submission of the abstract, a decrease in PSA was noted in 6 patients. Six of 13 (46%) treated patients received at least 5 cycles of therapy with no evidence of disease progression at 12 weeks. Correlation studies on circulating tumor cells ( CTCs ) demonstrated the uptake of AEZS-108 into the targeted tumor. After completion of 3 additional patients at the 210 mg/m<sup>2</sup> dose level, the study is expected to be extended into the Phase 2 portion.

**1.2.3 AEZS-108 Triple-Negative Breast Cancer**

On October 25, 2011, we announced that the FDA had completed the review of the IND application filed by Alberto J. Montero M.D. of the Sylvester Comprehensive Cancer Center and concluded that Dr. Montero may proceed with 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. This open-label, randomized, two-arm, multicenter Phase 2 study will involve up to 74 patients who will be randomized in a 1:1 ratio into one of the two treatment arms: AEZS-108 (267 mg/m<sup>2</sup> every 21 days) [Arm A] or standard single agent cytotoxic chemotherapy [Arm B].

---

## **Table of Contents**

The primary study endpoint will be PFS. Secondary endpoints will include ORR and OS. The study will also evaluate AEZS-108's toxicity profile and the patients' quality of life relative to conventional cytotoxic chemotherapy used in the control arm of this study.

### **1.2.4 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. 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.

### **1.2.5 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*, possesses remarkable, non-specific cytotoxicity 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. AEZS-137 is thus a bacterially produced compound with cytotoxic activity in the sub-nanomolar range.

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. Data showed that AEZS-137 possesses outstanding 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 phase and subsequently induced apoptosis with remarkable potency, as shown by subnanomolar 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.

---

**Table of Contents**
**1.3 TUBULIN INHIBITORS / VASCULAR TARGETING AGENTS**
**1.3.1 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 cancer tubulin rather than bovine brain tubulin, it destroys the mitotic spindle of the cancer cells and it inhibits topoisomerase II activity. AEZS-112 arrests the cancer cells in the G2M phase at a nM concentration and induced apoptosis. AEZS-112 is not cross-resistant to cisplatin, vincristine and doxorubicine 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 is being 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 includes up to 50 patients with advanced solid tumors and lymphoma who have either failed standard therapy or for whom no standard therapy exists. Patients will receive a once-a-week oral administration of AEZS-112 for three consecutive weeks, followed by a one-week period without treatment. The cycles will be 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 is 13 mg/week, with doubling of doses in subsequent cohorts in the absence of significant toxicity. Primary endpoint of the Phase 1 trial focuses on determining the safety and tolerability of AEZS-112 as well as establishing the recommended Phase 2 dose and regimen. Secondary endpoints are 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 (12 men / 10 women) were studied on 7 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 3 doses taken 8 hours apart. Ultimately, 22 patients (12 men / 10 women) were studied on 5 dose levels ranging from 120 to 600 (= 200 x 3) mg/week. As at April 1, 2009, 62 treatment cycles were administered (mean 3.2/patient) and treatment was ongoing in 8 patients. SD for more than 12 weeks was observed in 16 patients; 4 more patients were ongoing at less than 12 weeks. Prolonged courses of SD ranging from 20 to 39+ weeks were observed in 9 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

---

## **Table of Contents**

the study, the split-dose scheme leads to a higher C<sub>max</sub> 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 are 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 12 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.

During the year 2011, we have developed a higher concentrated oral formulation of AEZS-112 in order to improve patient compliance. Clinical protocol is in preparation to continue to advance AEZS-112 with this new formulation.

### 1.4 IMMUNOTHERAPY / VACCINES

#### 1.4.1 AEZS-120

Cellular proteins expressed by oncogenes have been recognized as a major cause of tumor development. One of the central oncoproteins involved in cancer formation are the Raf proteins. Based on these proteins, new unique therapeutic strategies, new predictive animal models and new development products have been generated to efficiently combat cancer. These consist of virulence attenuated, genetically modified bacteria expressing tumor antigens, including oncoproteins or enzymes. Such bacteria are used for vaccination as well as tumor targeting and delivery of antitumoral compounds towards the tumor tissues. Therefore, this new vaccine approach exploits the ability of bacteria to induce potent immune responses as well as direct these responses against malignancies. The immunogenicity of the vaccine will be further enhanced by the capacity of bacteria to colonize tumor tissues. This property will be used to transport substances, e.g. proteins, into the tumor tissue, which are capable of converting non-toxic pro-drugs into active drugs. The use of bacterial carriers for therapeutic vaccination against tumors and the concept of bacterial tumor targeting will be further developed with the Julius-Maximilians-University of Würzburg, including the highly recognized researchers Prof. Dr. Ulf R. Rapp, who is a member of our Scientific Advisory Board, and Prof. Dr. Werner Goebel. Prof. Rapp is a known expert in the field of cell and tumor biology and Prof. Goebel is a pioneer in the field of vaccines based on recombinant bacteria.

The preclinical proof of principle has already been shown in a transgenic animal model and is supported by several patent applications filed in November 2006.

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

A grant application was filed in Germany and was approved in 2008 for a preclinical development program for AEZS-120 with our research collaborators, the Department of Medical Radiation Biology and Cell Research, and the Department of Microbiology of the University of Würzburg, Germany. In accordance with this grant, 50% of our preclinical development costs and 100% of those of our university partner will be reimbursed by the German Ministry of Science and Education.



## **Table of Contents**

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. Once this non-clinical program will have been completed and subject to a positive review by regulatory authorities, we aim to start Phase 1 clinical development in 2012. 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. As part of the collaboration, a melanoma vaccine based on the recombinant expression of a modified B-Raf protein has been generated.

## **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 the ghrelin receptor (GHSR-1a). It can be used in both endocrinology and in oncology indications. In endocrinology, we have completed a Phase 3 trial for its use as a simple 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, the FDA has allowed for the initiation of a physician sponsored IND 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.

In June 2006, Ardana presented results regarding AEZS-130 at the 2006 ENDO Convention. These results referred to the Phase 1 trial regarding the stimulating effects of AEZS-130 on growth hormone following both oral and intra-duodenal administration in healthy males. This study showed that AEZS-130 was well tolerated by the 36 volunteers enrolled and no adverse events were reported. Administration of AEZS-130 either orally or via intra-duodenal infusion results in increased levels of growth hormone in the blood. This stimulation of growth hormone appears to be selective as no other hormones/analytes that were measured (cortisol, ghrelin, prolactin, insulin, glucose and ACTH (adrenocorticotrophic hormone)) were affected in a dose-dependent or statistically significant way by administration of AEZS-130 either orally or via intra-duodenal infusion.

In May 2007, Ardana gained orphan drug designation for AEZS-130 as a diagnostic test for growth hormone deficiency in adults. The clinical development and toxicology programs for this indication were ongoing and Ardana announced the commencement in the United States of the planned pivotal registration study and the enrolment of the first patient in August 2007.

In June 2008, Ardana announced that the company stopped its operations and entered into voluntary administration. Consequently, the clinical study of AEZS-130 as a diagnostic test for AGHD was suspended.

In June 2009, we reported that, after having regained from Ardana in the prior year the worldwide rights to the growth hormone secretagogue, AEZS-130, we had entered into an agreement with the administrators of Ardana to acquire all Ardana assets relating to AEZS-130 for \$232,000. These assets include development data, inventory of compound, regulatory authorizations, including IND and orphan drug status as a diagnostic test granted in the United States, as well as a patent application protecting the use of AEZS-130 for the diagnostic of growth hormone secretion deficiency.

## **Table of Contents**

During the same month, the first clinical data relating to the use of AEZS-130 as a simple diagnostic test for AGHD were presented at the ENDO 2009 meeting by the main investigators Dr G. Merriam and Dr B.M.K. Biller. Data showed that in adult growth hormone deficient patients, the responses to the orally administered AEZS-130 compound were comparable to currently validated agents and clearly separated patients from normal control subjects.

In October 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 is 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 is not tested against a comparator drug, as Geref® has 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. In addition to the diagnostic indication, we believe that, based on the results of Phase 1 studies, AEZS-130 has potential applications for the treatment of cachexia, a condition frequently associated with severe chronic diseases such as cancer, chronic obstructive pulmonary disease and AIDS.

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 an 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 SPA agreement has resulted in a modification to the original study, but does not alter the basic study design so that the completed portion of the study will work with the new part of the study to provide one complete Phase 3 study.

### **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.

Each patient received two dosing regimens in random order, while fasting, at least 1 week apart. One regimen consisted of a 1 µg/kg (max. 100 µg) dose of GHRH (Geref Diagnostic®, Serono) with 30 g of ARG (ArGine®, Pfizer) administered intravenously over 30 minutes; the other regimen was a dose of 0.5 mg/kg body weight of AEZS-130 given in an oral solution of 0.5 mg/ml.

---

**Table of Contents**

**Completion of the study will be accomplished with the following revisions/additions to the current protocol:**

an additional 30 normal controls subjects will be enrolled to match the AGHD patients from the original cohort;

further, an additional 20 subjects will be enrolled 10 AGHD patients and 10 matched normal control subjects;

the above will bring the database to approximately 100 patients;

all subjects will receive a dose of 0.5 mg/kg body weight of AEZS-130; and

as a secondary endpoint, the protocol will require that at least 8 of the 10 newly enrolled AGHD patients be correctly classified by a pre-specified peak GH threshold level.

On July 26, 2011, we announced the completion of the Phase 3 study on 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. Results showed that AEZS-130 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, 8 of the 10 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. We are currently proceeding with further detailed analyses of the data and preparing for a pre-NDA meeting with the FDA in the upcoming months, which would be followed by the filing of a NDA for the registration of AEZS-130 in the United States.

On November 28, 2011, we announced that the FDA had completed the review of an IND application filed by 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 and concluded that Dr. Garcia may proceed with 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, initiated a 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 between the Company and 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 the ghrelin agonist, AEZS-130, in 18 to 26 patients with cancer-cachexia. AEZS-130 will be provided by Aeterna Zentaris. The study will involve 3 sequential groups receiving differing doses of AEZS-130. Each dose group will have 6 patients who will receive AEZS-130 and 2-4 patients who will receive placebo. After analysis of safety and efficacy at each dose level vs. placebo, a decision will be taken either to decrease or increase the dose. If there are major safety issues, the study will be stopped. For this study, adequate efficacy will be defined as a  $\geq 0.8$  kg of body weight gain or a  $\geq 50$  ng/mL increase in plasma IGF-1 levels. 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 1 week in view of developing a treatment for cachexia. The following parameters will be recorded to assess efficacy during the study: change of body weight, change of IGF-1 plasma levels, and change of quality of life score (Anderson Symptom Assessment Scale, FACIT-F). Other secondary objectives will include food intake, and changes in the following: appetite, muscle strength, energy expenditure, reward from food and functional brain connectivity.

## **Table of Contents**

### *Competitors for AEZS-130*

Competitors for AEZS-130 as a diagnostic test for AGHD are principally the diagnostic tests currently performed by endocrinologists.

Most commonly used diagnostics tests for GHD are:

measurement of blood levels of Insulin Growth Factor ( IGF )-1, which is often 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 monitoring 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 very 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.;

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's Website).

## 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 luteinising hormone releasing hormone (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.

---

**Table of Contents**

2.2.1.1 Cetorelix In Vitro Fertilization (COS/ART)

*Cetrotide®*

Cetorelix is the first LHRH antagonist which was approved for therapeutic use as part of fertilization programs in Europe and was launched on the market under the trade name Cetrotide® (cetorelix acetate) in 1999. In women who undergo controlled ovarian stimulation for recovery of oocytes for subsequent fertilization, Cetrotide® 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® 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®, permits the physician to interfere in the hormone regulation of the women undergoing treatment much more selectively and within a shorter time.

The effectiveness of Cetrotide® has been examined in five clinical trials (two Phase 2 and three Phase 3 trials). Two dose regimens were investigated in these trials: either a single dose per treatment cycle or multiple dosing. In the Phase 2 studies, a single dose of 3 mg was established as the minimal effective dose for the inhibition of premature LH surges with a protection period of at least four days. When Cetrotide® is administered in a multi-dose regimen, 0.25 mg was established as the minimal effective dose. The extent and duration of LH suppression was found to be dose-dependent. In the Phase 3 program, efficacy of the single 3 mg dose regimen and the multiple 0.25 mg dose regimen was established separately in two controlled studies utilizing active comparators. A third non-comparative study evaluated only the multiple 0.25 mg dose regimen of Cetrotide®. In the five Phase 2 and Phase 3 trials, 184 pregnancies were reported out of a total of 732 patients (including 21 pregnancies following the replacement of frozen-thawed embryos). In these studies, drug-related side effects were limited to a low incidence of injected site reactions; however, none of them was serious such as an allergic type of reaction or required withdrawal from treatment. In addition, no drug-related allergic reactions were reported from these clinical studies.

Cetrotide® is the only LHRH antagonist that is available in two dosing regimens. With an immediate onset of action, Cetrotide® 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). The treatment with Cetrotide® can be accomplished during a one-month cycle with a simplified, more convenient and shorter treatment requiring fewer injections than LHRH agonists.

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

*Partners for Cetrotide®*

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.

## **Table of Contents**

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 Cowen Healthcare Royalty Partners ( CHRP ) 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 CHRP in February 2011. Furthermore, under the terms of the agreement, we agreed to make a one-time cash payment to CHRP in an amount ranging from \$5 million up to a maximum of \$15 million in the event cetrorelix is approved for sale by the European regulatory authorities in an indication other than *in vitro* fertilization. The amount which would be due to CHRP will be higher the earlier the product receives European regulatory approval. Since cetrorelix development has been terminated, we do not expect to make this one-time cash payment to CHRP.

Cetrorelix 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 Pharmaceuticals, Inc. ( 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 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 of Spectrum's 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.

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

On January 27, 2010, Spectrum announced that it had terminated its development program with ozarelix in BPH. Consequently, an impairment loss of approximately \$1,422,000 was recorded as part of amortization expense, and all corresponding unamortized deferred revenues related to the use of ozarelix, totalling approximately \$1,606,000, were fully recognized in our consolidated statement of operations for the year ended December 31, 2009.

#### **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%.

## **Table of Contents**

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 ozarelix versus goserelin depot in men with prostate cancer (*source: 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 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.

---

**Table of Contents**

**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.



## **Table of Contents**

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.

---

## **Table of Contents**

### ***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 from 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. 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 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.



## **Table of Contents**

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.

### **Perifosine:**

U.S. patent 6,172,050 provides protection in the United States for the compound perifosine and other related alkyl phospholipid derivatives, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This U.S. patent expires in July 2013. A patent term extension of up to five years may be possible.

European patent 0 579 939 provides protection in European countries for the compound perifosine and other related alkyl phospholipid derivatives, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This European patent expires in June 2013. A patent term extension of up to five years by Supplementary Protection Certificates ( SPC ) may be possible.

Japanese patent 3 311 431 provides protection in Japan for the compound perifosine and other related alkyl phospholipid derivatives. This Japanese patent expires in July 2013. A patent term extension of up to five years may be possible.

Perifosine combined with antimetabolites:

U.S., European and Japanese patent applications have been filed, comprising the combination of perifosine with an antimetabolite for treating tumour diseases;

U.S. patent application 10/632,187, filed July 2003 and further continuation applications US 12/751,454, US 12/751,608 and US 12/798,267 are still pending. Granted patents will be expire in July 2023;

European patent 1 545 553 expires in July 2023;

Japanese patent application 2004-525354, filed July 2003 is still pending. Granted patent will expire in July 2023.

### **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.

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.



**Table of Contents**

**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.

**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.

**Table of Contents**

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>Perifosine</u></b>			
U.S. 6,172,050	Phospholipid derivatives	United States	2013-07-07
EP 0 579 939	Phospholipid derivatives	Germany, United Kingdom, France, Switzerland and others	2013-06-03
JP 3 311 431	Phospholipid derivatives	Japan	2013-07-08
EP 1 545 553	Alkylphosphocholines combined with antimetabolites	Europe	2023-07-28
<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-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
<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



Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

EP 1 309 585

Indole derivatives and their use as  
medicaments

Germany, United Kingdom,  
France, Switzerland and others

2021-07-26

60

**Table of Contents**

<b>Patent No.</b>	<b>Title</b>	<b>Country</b>	<b>Expiry Date</b>
<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

\* Including 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, 2011.

**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 27, 2012.

<b>Location</b>	<b>Use of space</b>	<b>Square Footage</b>	<b>Type of interest</b>
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

---

**Table of Contents**

**Item 4A. Unresolved Staff Comments**

None.

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

*Perifosine*

- § March 9, 2011: We announced that we had entered into an agreement with Yakult Honsha Co. Ltd. (Tokyo: 2267) ( Yakult ) for the development, manufacture and commercialization of perifosine in all human uses, excluding leishmaniasis, in Japan. Under the terms of the agreement, we received an initial \$8.4 million upfront payment and are entitled to receive additional payments of up to \$57.1 million upon achieving certain pre-established milestones including clinical and regulatory events in Japan. Furthermore, we will be supplying perifosine to Yakult on a cost-plus-basis and be entitled to receive double-digit royalties on future net sales of perifosine in Japan. Yakult will be responsible for the development, registration and commercialization of perifosine in Japan.
- § April 4, 2011: We announced that two posters on our lead anticancer agent, perifosine, had been presented at the 102<sup>nd</sup> annual meeting of the American Association for Cancer Research ( AACR ) held at the Orange County Convention Center in Orlando, Florida. The first poster demonstrated perifosine s antitumor activity in several gastric cancer cell lines. Furthermore, perifosine enhanced the antitumor activity of 5-fluorouracil ( 5-FU ) in parts of the cell lines - including 5-FU resistant cell lines. As for the second poster, perifosine markedly enhanced the antitumor activity of the cellular TRAIL based treatment and was able to overcome TRAIL resistance both *in vitro* and *in vivo*. The results are in line with other studies demonstrating the synergistic effects of perifosine with cytotoxic drugs, including bortezomib and 5-FU.
- § July 12, 2011: We announced that the European Patent Office had granted a patent for the use of alkylphosphocholines, more specifically perifosine, in combination with antitumor anti-metabolites, which include among others 5-FU and capecitabine in the preparation of a medicament for the treatment of benign and malignant tumors. This patent will expire on July 28, 2023.
- § July 27, 2011: We announced the completion of patient recruitment (over 465 patients) for the ongoing Phase 3 trial with perifosine in refractory advanced colorectal cancer ( CRC ).
- § August 31, 2011: We announced the completion of the pre-specified safety and futility interim analysis by the Data Safety Monitoring Board ( DSMB ) for the Phase 3 trial with perifosine in refractory advanced colorectal cancer. The DSMB recommended that the trial proceed as planned.
- § October 5, 2011: We announced that an article on perifosine had been published in the October 2011 online issue of the *Journal of Clinical Oncology* ( JCO ), in which positive Phase 2 results in metastatic colorectal cancer were reported.
- § October 13, 2011: We announced that an article on perifosine had been published in the October 2011 online issue of the JCO, in which positive Phase 1/2 results in multiple myeloma were reported.
- § November 23, 2011: We announced the signing of an exclusive commercialization and licensing agreement with Hikma Pharmaceuticals PLC ( Hikma ) (LSE: HIK) (NASDAQ Dubai: HIK) for the registration and marketing of perifosine for the Middle East and North Africa ( MENA ) region. Under the terms of the agreement, we received an upfront payment of \$0.2 million and are entitled to receive up to a total of \$1.8 million upon achieving certain pre-established milestones. Furthermore, we will be supplying perifosine to Hikma on a cost-plus-basis

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

and are entitled to receive double-digit royalties on future net sales of perifosine in the MENA region. Hikma will be responsible for the registration and commercialization of perifosine in the MENA territory.

**Table of Contents**

§ December 12, 2011: We announced encouraging preclinical data for perifosine in Hodgkin's lymphoma ( HL ). *In vitro* data from HL cell lines showed that perifosine combined with sorafenib induced increased apoptosis, while *in vivo* data for the same combination treatment for HL significantly increased survival in mice. Data were presented during the American Society of Hematology ( ASH ) Annual Meeting and Exposition held in San Diego, California.

§ December 13, 2011: We announced encouraging clinical data for an ongoing Phase 2 clinical study in patients with refractory/relapsed HL. Preliminary response data showed that perifosine combined with sorafenib significantly increased median progression free survival ( PFS ) in refractory/relapsed HL patients with high phosphorylation levels of Erk and Akt, as compared to patients with low baseline phosphorylation levels of Erk and Akt. Data were presented during the ASH Annual Meeting and Exposition held in San Diego, California.

§ On January 3, 2012: We announced that our Japanese partner, Yakult had initiated a Phase 1/2 trial in Japan to assess the safety and efficacy of perifosine, in combination with a chemotherapeutic agent, capecitabine, in patients with refractory advanced CRC. The initiation of this trial on December 27, 2011 triggered a milestone receivable of \$2.6 million.

***AEZS-108***

§ September 14, 2011: We presented positive final Phase 2 efficacy and safety data for AEZS-108 (zoptarelin doxorubicin) in advanced endometrial cancer at the 17<sup>th</sup> International Meeting of the European Society of Gynecological Oncology in Milan, Italy. Furthermore, a Parallel Scientific Advice process was granted by and initiated with the United States Food and Drug Administration (the FDA ) and the European Medicines Agency ( EMA ), with the aim of establishing a pivotal program in endometrial cancer.

§ September 26, 2011: We announced positive interim data for the Phase 1 portion of our Phase 1/2 trial with AEZS-108 in castration- and taxane-resistant prostate cancer ( CRPC ) at the European Society of Medical Oncology ( ESMO ) meeting in Stockholm, Sweden.

§ October 25, 2011: We announced that the FDA had agreed to allow for the initiation by Alberto J. Montero, M.D., of the Sylvester Comprehensive Cancer Center of an Investigational New Drug ( IND ) Phase 2 trial in triple-negative breast cancer ( TNBC ) with AEZS-108.

§ On January 5, 2012: We announced an agreement, dated December 19, 2011, with Ventana Medical Systems, Inc., a member of the Roche Group, to develop a companion diagnostic for the immunohistochemical determination of LHRH-receptor expression, for AEZS-108.

***AEZS-120***

§ July 20, 2011: We announced that we had reached a key milestone in the non-clinical development of AEZS-120, our oral prostate cancer vaccine candidate. The program encompassed the full development of a Good Manufacturing Practice ( GMP ) process as well as a safety and toxicology package.

---

**Table of Contents**

***AEZS-129***

§ 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 phosphoinositide 3-kinase s ( PI3K ) lacking activity against mTOR. Data suggest that AEZS-129 is a promising compound for clinical intervention of the PI3K/Akt pathway in human tumors.

***AEZS-130***

§ July 26, 2011: We announced the completion of the Phase 3 study for AEZS-130 (macimorelin) as a first oral diagnostic test for adult growth hormone deficiency ( AGHD ).

§ August 30, 2011: We reported favorable top-line results for the completed Phase 3 study for AEZS-130 as a first oral diagnostic test for AGHD. We also announced our intention to meet with the FDA for the future filing of a New Drug Application ( NDA ). The results showed that AEZS-130 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.

§ November 28, 2011: We announced that the FDA agreed to allow for the initiation by Jose M. Garcia, M.D., Ph.D., of Baylor College of Medicine and Michael E. DeBakey of Veterans Affairs Medical Center of an IND Phase 2A trial to assess the safety and efficacy of repeated doses of AEZS-130 in cancer-cachexia.

§ On March 8, 2012: We announced that the Michael E. DeBakey of Veterans Affairs Medical Center, in Houston, Texas, had initiated a Phase 2A trial with AEZS-130 in patients with cancer-cachexia.

***AEZS-131***

§ March 22, 2011: We presented preclinical results for AEZS-131 at the Informa Life Sciences Protein Kinases Congress in Berlin, Germany. AEZS-131 was established as a small molecular compound that inhibits Erk in the low nanomolar ( nM ) range and shows an excellent selectivity profile. Results support the evaluation of selective Erk inhibitors as antiproliferative agents either as monotherapy or in combination with inhibitors of the PI3K/Akt pathway.

§ April 5, 2011: We announced that a poster on our highly selective Erk 1/2 inhibitor anticancer compound, AEZS-131, had been presented at the 102<sup>nd</sup> annual meeting of the AACR. Results showed that AEZS-131 selectively inhibits Erk 1/2 with an IC<sub>50</sub> of 4nM, blocks cellular Rsk-1 phosphorylation, modulates downstream cellular substrate activation, arrests tumor cells in G1 and inhibits the growth of multiple human tumor cell lines in the nanomolar range. In *in vivo* pharmacokinetic studies, AEZS-131 showed a favorable PK profile.

§ August 30, 2011: We announced preclinical results demonstrating antitumor activity in different human tumor cell lines for AEZS-131 at the American Chemical Society National Meeting in Denver, Colorado.

§ December 9, 2011: We announced positive preclinical data in TNBC for AEZS-131 at the 34<sup>th</sup> Annual San Antonio Breast Cancer Symposium. Data showed that AEZS-131 selectively inhibits Erk at low nanomolar concentrations and induces G1 arrest. Accordingly, the cytotoxic effect of AEZS-131 was most pronounced in TNBC cell lines with mutations in the MAPK pathway.

***AEZS-132***

§ On March 22, 2011: We presented preclinical results for AEZS-132 at the Informa Life Sciences Protein Kinases Congress in Berlin, Germany. In summary, AEZS-132 is a unique dual kinase inhibitor targeting the PI3K and MAPK pathways, expected to be especially suited to treat tumors with over-activation of both pathways.

---

**Table of Contents**

***AEZS-137***

§ March 24, 2011: We announced that we had been awarded a grant of \$1.5 million from the German Ministry of Education and Research to develop, up to the clinical stage, cytotoxic conjugates of the proprietary cytotoxic compound AEZS-137 (disorazol Z) and peptides targeting G-protein coupled receptors, including luteinizing hormone releasing hormone ( LHRH ) receptors.

§ November 16, 2011: We announced the presentation of a poster on encouraging preclinical data for AEZS-137 at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, held at the Moscone Center West, in San Francisco. 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 phase and subsequently induced apoptosis with remarkable potency, as shown by subnanomolar EC50 values.

***Corporate Developments***

§ On February 22, 2011: We entered into an At-the-Market ( ATM ) sales agreement with MLV & Co. LLC (formerly McNicoll, Lewis & Vlaskovits LLC) ( MLV ), under which we were able to sell up to 12.5 million of our common shares through ATM issuances on the NASDAQ Global Market (the NASDAQ ) for aggregate gross proceeds not to exceed \$19.8 million. On April 29, 2011, we completed the drawdowns from this ATM, bringing the total aggregate gross proceeds to \$19.8 million.

§ On February 28, 2011: We announced that we had received a net sales royalty milestone of \$2.5 million from Cowen Healthcare Royalty Partners L.P. ( Cowen ). This milestone was payable pursuant to the sale, in December 2008, to Cowen of our rights to royalties on future net sales of Cetrotide®.

§ On June 29, 2011: We entered into an additional ATM Sales Agreement (the June ATM Sales Agreement ) with MLV, under which we could, at our discretion, from time to time during the 24-month term of the agreement, sell up to a maximum of 9.5 million of our common shares through ATM issuances on NASDAQ for aggregate gross proceeds not to exceed \$24.0 million. On December 7, 2011, we completed the drawdowns from this ATM, bringing the total aggregate gross proceeds to \$17.7 million.

***Subsequent to Year-End***

***At-The-Market issuance program***

§ On January 23, 2012, the Company, pursuant to its existing ATM sales agreement dated June 29, 2011, with MLV, was commencing a new ATM issuance program ( January 2012 ATM Sales Agreement ) under which it may, at its discretion, from time to time during the term of the sales agreement, sell up to a maximum of 10.4 million of its common shares through ATM issuances on NASDAQ up to an aggregate amount of \$16.0 million.

§ From January 23, 2012 through March 15, 2012, the Company issued a total of 3.6 million common shares under the January 2012 ATM Sales Agreement for aggregate gross proceeds of \$6.4 million, less cash transaction costs of \$0.2 million and previously deferred transaction costs of \$56,000.

***AEZS-108***

§ On February 3, 2012: We reported positive updated results for the Phase 1 portion of our ongoing Phase 1/2 study in CRPC with AEZS-108. Data, presented during a poster session at the American Society of Clinical Oncology Genitourinary Cancers Symposium in San Francisco, showed that AEZS-108 was well tolerated and demonstrated early evidence of antitumor activity in men with CRPC.





---

## **Table of Contents**

### **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, 2011. In this MD&A, Aeterna Zentaris, the Company, we, us, our and the Group refer to 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, 2011 and December 31, 2010 and for the years ended December 31, 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 US dollars, except for share, option and warrant data, per share and per warrant data and as otherwise noted.

### **Adoption of International Financial Reporting Standards ( IFRS )**

In 2008, the Canadian Accounting Standards Board confirmed that all publicly accountable enterprises must adopt IFRS in place of Canadian generally accepted accounting principles ( Canadian GAAP ) beginning on January 1, 2011 (for entities with a calendar year-end). As such, our consolidated financial statements as at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010 have been prepared in accordance with IFRS, as issued by the IASB, applicable to the preparation of annual financial statements.

Additionally, our consolidated statement of financial position as at January 1, 2010 and our comparative consolidated financial statements for 2010 have been adjusted to reflect our adoption of IFRS on a retrospective basis, effective on January 1, 2010 (the Transition Date ). Consequently, 2010 comparative financial information presented in this MD&A reflects the consistent, retrospective application of IFRS.

These updated figures were reflected in our first quarter report to shareholders.

Our transition to IFRS resulted in a decrease of shareholders' equity (deficiency) on the IFRS consolidated statement of financial position as at December 31, 2010 of approximately \$30.0 million and an increase in 2010 comprehensive loss of approximately \$4.1 million.

Our transition to IFRS also resulted in a decrease in shareholders' equity (deficiency) of \$20.1 million, a decrease in total assets of \$17.7 million and an increase in total liabilities of \$2.4 million, as at January 1, 2010. The decrease in shareholders' equity (deficiency) was primarily a result of the impairment of Cetrotide® asset, the derecognition of deferred transaction costs and the liability accounting for share purchase warrants.

A complete description of our transition to IFRS, including reconciliations of previously reported Canadian GAAP information, is provided in note 29 to our consolidated financial statements as at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010.

In this MD&A, we also include comparative financial information derived from our consolidated financial statements as at December 31, 2010 and 2009 and for each of the years then ended which, prior to January 1, 2011, were prepared in accordance with Canadian GAAP.

### **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, should, strive, target and will.

## **Table of Contents**

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 reasonably would 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&As, 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 a late-stage drug development company specializing in oncology and endocrine therapy. Our pipeline encompasses compounds at all stages of development, from drug discovery through to marketed products. The highest development priorities in oncology are the completion of Phase 3 trials with perifosine in colorectal cancer and in multiple myeloma, as well as the further advancement of AEZS-108, for which we have successfully completed a Phase 2 trial in advanced endometrial and advanced ovarian cancer. We are planning for the initiation of a pivotal program with AEZS-108 in endometrial cancer and also a Phase 2 trial in triple-negative breast cancer. AEZS-108 is also in development in other cancer indications, including castration- and taxane-resistant prostate cancer, as well as refractory bladder cancer.

Our pipeline also encompasses other earlier-stage programs in oncology. AEZS-112, an oral anticancer agent which involves three mechanisms of action (tubulin, topoisomerase II and angiogenesis inhibition) has completed a Phase 1 trial in advanced solid tumors and lymphoma. Additionally, several novel targeted potential anti-cancer candidates such as AEZS-120, a live recombinant oral tumor vaccine candidate, as well as our PI3K/Erk inhibitors AEZS-129, AEZS-131, AEZS-132 and their respective follow-up compounds are currently in preclinical development.

Our lead program in endocrinology, a Phase 3 trial under a Special Protocol Assessment ( SPA ) obtained from the FDA with AEZS-130 as an oral diagnostic test for AGHD, has been completed with positive results. We are planning to file an NDA for the registration of AEZS-130 in the United States, subject to a successful pre-NDA meeting with the FDA. Furthermore, AEZS-130 is in a Phase 2A trial for the treatment of cancer-cachexia.

**Table of Contents**

**Key Developments for the Year Ended December 31, 2011**

**Drug Development**

**Status of our drug pipeline as at March 27, 2012**

<b>Discovery</b>	<b>Preclinical</b>	<b>Phase 1</b>	<b>Phase 2</b>	<b>Phase 3</b>	<b>Commercial</b>
~120,000 compound library	AEZS-120  Prostate cancer vaccine (oncology)	AEZS-112  (oncology)	Perifosine  § Multiple cancers	Perifosine  § Refractory advanced colorectal cancer	Cetrotide®  ( <i>in vitro</i> fertilization)
	AEZS-129, 131, 132 and 136; Erk/PI3K inhibitors (oncology)		§ AEZS-108  § Endometrial cancer  § Triple-negative breast cancer	§ Multiple myeloma  AEZS-130	
	AEZS-137 (Disorazol Z) (oncology)		§ Ovarian cancer  § Castration- and taxane-resistant prostate cancer  § Refractory bladder cancer	§ Diagnostic in adult growth hormone deficiency (endocrinology)	
	AEZS-125 (LHRH-Disorazol Z) (oncology)		Ozarelix  § Prostate cancer		
			AEZS-130  § Therapeutic in cancer-cachexia		
<b>Partners</b>			Perifosine:  <b>Keryx</b>  North America  <b>Handok</b>  Korea  <b>Yakult</b>  Japan	Perifosine:  <b>Keryx</b>  North America  <b>Handok</b>  Korea  <b>Yakult</b>  Japan	Cetrotide®: <b>Merck Serono</b> (World except Japan)  <b>Nippon Kayaku / Shionogi</b>

**Hikma**

Middle East/North Africa

**Hikma**

Middle East/North  
Africa

Ozarelix:

**Spectrum**

World (ex-Japan for oncology indications, ex-Korea  
and ex-other Asian countries for BPH indication)

**Handok**

Korea and other Asian countries for BPH indication

**Nippon Kayaku**

Japan for oncology indications

---

**Table of Contents**

*Perifosine*

Perifosine is a novel, oral anticancer treatment that inhibits Akt activation in the PI3K pathway. Perifosine, in combination with chemotherapeutic agents, is currently in Phase 3 studies for the treatment of colorectal cancer and multiple myeloma, as well as in Phase 2 studies for the treatment of other cancers, and we believe is the most advanced anti-cancer compound of its class in late-stage development. The FDA has granted perifosine orphan-drug designation in multiple myeloma and in neuroblastoma and Fast Track designations in both refractory advanced colorectal cancer and multiple myeloma. Additionally, an agreement was reached with the FDA to conduct the Phase 3 trials in both of these indications under a SPA. Perifosine has also been granted Orphan Medicinal Product designation from the EMA in multiple myeloma, and based on discussions with the EMA, we believe the ongoing Phase 3 trials of perifosine in the colorectal cancer and multiple myeloma programs would be sufficient for registration in Europe for these indications, assuming positive data from the Phase 3 trials. Perifosine rights have been licensed to Keryx Biopharmaceuticals, Inc. ( Keryx ) for North America, to Handok Pharmaceuticals Co. Ltd. for Korea, to Yakult for Japan and to Hikma for the MENA region.

On March 8, 2011, we entered into an agreement with 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 us of 6.0 million (approximately \$8.4 million). Also per the agreement, we are entitled to receive in addition, up to a total of 44.0 million (approximately \$57.1 million) upon achieving certain pre-established milestones, including the occurrence of certain clinical and regulatory events in Japan. As at December 31, 2011, following the achievement of a milestone, we have revenue and trade receivables recorded for an additional amount of 2.0 million (approximately \$2.6 million) in connection with the agreement. Furthermore, we will be entitled to receive double-digit royalties on future net sales of perifosine in the Japanese market.

On November 23, 2011, we entered into an agreement with Hikma for the development, and commercialization of perifosine in all oncology uses. Under the terms of this agreement, Hikma made an initial, non-refundable gross upfront payment to us of \$0.2 million. Also per the agreement, we are entitled to receive up to a total of \$1.8 million upon achieving certain pre-established milestones, including the occurrence of certain regulatory events in certain countries in the MENA region. Furthermore, we will be entitled to receive double-digit royalties on future net sales of perifosine in the MENA market.

We have 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 the MENA region, which will facilitate the ultimate commercialization process within Japan and the MENA region. Additionally, we are contractually obligated to 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, we have agreed to supply perifosine, on a cost-plus basis, to Yakult and Hikma following regulatory approvals.

We have deferred the non-refundable license fees and we are amortizing the related payments as revenue on a straight-line basis over the duration of our continuing involvement, which approximates 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.

In determining the period over which license revenues are to be recognized, and in addition to due consideration of our continuing involvement, as discussed above, we considered the remaining expected life of applicable patents as the most reasonable basis for estimating the underlying product's life cycle. However, we 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 our continuing involvement and performance obligations or benefits expected to be derived by Yakult and Hikma.

---

## **Table of Contents**

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, we 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 agreements.

We were required to remit to the Japanese tax authorities \$0.8 million of the gross proceeds received from Yakult and will be required to remit approximately 0.2 million (approximately \$0.26 million) when the milestone receivable will be paid by Yakult. These amounts, which were withheld at source, were recognized as income tax expense in our consolidated statement of comprehensive loss.

On April 4, 2011, we announced that two posters on perifosine were presented at the 102<sup>nd</sup> annual meeting of the AACR at the Orange County Convention Center in Orlando, Florida. Perifosine demonstrated antitumor activity in several gastric cancer cell lines. Furthermore, perifosine enhanced the antitumor activity of 5-FU in parts of the cell lines, including 5-FU resistant cell lines. 5-FU is the active metabolite of the prodrug Xeloda, which is approved for the treatment of advanced gastric cancer in many countries including Japan.

Perifosine also markedly enhanced the antitumor activity of the cellular TRAIL based treatment and was able to overcome TRAIL resistance both *in vitro* and *in vivo*. The results are in line with other studies demonstrating the synergistic effects of perifosine with cytotoxic drugs, including bortezomib and 5-FU.

On July 12, 2011, we announced that the European Patent Office had granted a patent for the use of alkylphosphocholines, more specifically perifosine (octadecyl 1,1-dimethylpiperidino-4-yl phosphate), in the preparation of a medicament for the treatment of benign and malignant tumors, prior to and/or during the treatment with approved antitumor anti-metabolites such as 5-FU and capecitabine. Filed on July 29, 2003, the patent (EP #1 545 553), entitled *Use of Alkyl Phosphocholines in Combination with Anti-Tumour Medicaments*, became effective as of July 13, 2011 and will expire on July 28, 2023.

On July 27, 2011, we announced completion of patient recruitment for the ongoing Phase 3 trial with perifosine in refractory advanced colorectal cancer, involving over 465 patients from 65 sites in the United States. This Phase 3 X-PECT (Xeloda® + Perifosine Evaluation in Colorectal Cancer Treatment) trial is a randomized (1:1), double-blind trial comparing the efficacy and safety of perifosine + capecitabine vs. placebo + capecitabine. The primary endpoint is overall survival, with secondary endpoints including overall response rate (complete + partial responses), progression-free survival and safety. Approximately 360 events of death will trigger the unblinding of the study.

On August 31, 2011, we announced that the DSMB for the Phase 3 X-PECT study of perifosine in patients with refractory advanced colorectal cancer had completed a pre-specified interim analysis for safety and futility. The DSMB recommended that the Phase 3 study continue to completion, as planned.

On October 5, 2011, we announced that a manuscript, entitled *Randomized Placebo-Controlled Phase 2 Trial of Perifosine Plus Capecitabine as Second- or Third-Line Therapy in Patients with Metastatic Colorectal Cancer*, had been published in the October 3, 2011 online edition of the *Journal of Clinical Oncology* ( JCO ), in which Phase 2 activity of perifosine in the treatment of patients with refractory advanced CRC was reported. The publication highlighted the efficacy and safety data on the 38 CRC patients participating in this Phase 2, randomized, multicenter study, comparing perifosine plus capecitabine (P-CAP) to placebo plus capecitabine. Based on the data, in which the combination of P-CAP demonstrated statistical significance with respect to median overall survival and median time to tumor progression, the investigators concluded that the P-CAP combination showed promising clinical activity compared to single-agent capecitabine, and that the difference in clinical outcome seen with the addition of perifosine was impressive.

Efficacy data from this study had been previously presented in June 2010 at the 46<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology.

---

**Table of Contents**

On October 13, 2011, we announced that the manuscript, entitled *Perifosine Plus Bortezomib and Dexamethasone in patients with Relapsed/Refractory Multiple Myeloma Previously Treated with Bortezomib: Results of a Multicenter Phase 1/2 Trial*, had been published in the October 10, 2011 online edition of the JCO, in which Phase 1/2 combination activity of perifosine in the treatment of advanced multiple myeloma patients was reported. Results showed that the Overall Response Rate was 65% for bortezomib-relapsed patients and 32% for bortezomib-refractory patients. Median PFS was 6.4 months, with a median PFS of 8.8 months in the bortezomib-relapsed population. Therapy was generally well-tolerated, and toxicities, including gastrointestinal side-effects and fatigue, proved manageable. No treatment-related mortality was seen. The investigators concluded the data reported for both safety and efficacy in this patient population were encouraging for the continued study of perifosine. Data from this study had been previously presented at the 2009 ASH conference.

On December 12, 2011, we reported encouraging preclinical data for perifosine in HL. *In vitro* data from HL cell lines showed that perifosine combined with sorafenib induced increased apoptosis, while *in vivo* data for the same combination treatment for HL significantly increased survival in mice. Data were presented during the ASH Annual Meeting and Exposition, in San Diego, California.

The study was conducted to investigate, *in vitro* and *in vivo*, the activity and mechanism(s) of action of perifosine in combination with sorafenib by using three HL cell lines (HD-MyZ, L-540, HDLM-2). In the *in vitro* experiments perifosine/sorafenib treatment resulted in synergistic cell growth inhibition and cell death induction in HD-MyZ and L-540 cell lines, but not in the HDLM-2 cell line. Cell cycle arrest, down-modulating of the MAPK and PI3K/Akt pathways as well as caspase-independent cell death was observed, which was associated with severe mitochondrial dysfunction. Further, expression of genes involved in amino acid metabolism, cell cycle, DNA replication and cell death was shown to be modulated. In addition, overexpression of the tribbles homologue 3 [TRIB3] was observed.

*In vivo*, perifosine/sorafenib treatment significantly increased survival in the HD-MyZ model (45 vs. 81 days, as compared to controls), with 25% tumor-free mice at the end of the 200-day observation period. In the L-540 model, subcutaneous tumor volume was also reduced as compared to controls (by 42%), perifosine (by 35%) or sorafenib (by 46%) alone. In HD-MyZ and L-540 but not HDLM-2, the combined treatment induced an increase in tumor necrosis (2- to 8-fold, P £.0001) and in tumor apoptosis (2- to 2.5-fold, P £.0001). In 2 of 3 HL cell lines, perifosine/sorafenib combination treatment induced potent antitumor effects. Striking increase of mitochondrial injury and apoptosis, and marked reduction of cell viability was observed in the *in vitro* experiments. *In vivo* combination treatment increased survival and inhibited tumor growth.

On December 13, 2011, we reported encouraging clinical data for an ongoing Phase 2 clinical study in patients with refractory/relapsed HL. Preliminary response data showed that perifosine combined with sorafenib significantly increased median PFS in refractory/relapsed HL patients with high phosphorylation levels of Erk and Akt, as compared to patients with low baseline phosphorylation levels of Erk and Akt. Data were presented during the ASH Annual Meeting and Exposition, in San Diego, California.

The study evaluated phosphorylation levels of Erk (pErk) and Akt (pAkt) in circulating lymphocytes from patients enrolled in two consecutive Phase 2 trials evaluating activity and safety of sorafenib as a single agent or in combination with perifosine in relapsed/refractory HL patients. Four patients were treated with sorafenib alone at a dose level of 400mg BID and twenty-one patients received a 4-week treatment with perifosine alone at a dose level of 50mg BID, followed by a perifosine/sorafenib combination therapy with 50mg BID and 400mg BID, respectively. Circulating lymphocytes were evaluated for their phosphorylation levels of Erk and Akt, in order to assess predictive value of the phosphokinase levels for therapy responses.

Clinical response data showed that baseline pErk and pAkt levels were significantly higher in responsive patients, as compared to unresponsive patients. The pErk and pAkt levels measured after 60 days of therapy with perifosine combined with sorafenib were significantly reduced in responsive patients. The median baseline value of pErk and pAkt efficiently discriminated responsive and unresponsive patients which was associated with a significantly improved median PFS for patients with baseline pErk  $\geq 43\%$  and/or pAkt  $\geq 23\%$ . Based on these data, the correlation of baseline pErk and pAkt levels with objective responses and time to tumor progression will need to be validated in prospective studies.



---

## **Table of Contents**

On January 3, 2012, we announced that our Japanese partner, Yakult, had initiated a Phase 1/2 trial in Japan to assess the safety and efficacy of perifosine in combination with chemotherapeutic agent, capecitabine, in patients with refractory advanced CRC. The primary endpoint of the Phase 1 portion of the trial is the safety profile of perifosine in combination with capecitabine. The primary endpoint of the Phase 2 portion is efficacy (Disease Control Rate). This trial is sponsored by Yakult and its initiation on December 27, 2011 triggered a milestone payment which is payable in the first quarter of 2012 of approximately \$2 million from Yakult to Aeterna Zentaris under the agreement signed in March 2011 for perifosine in Japan described above.

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

On September 14, 2011, we presented positive final Phase 2 efficacy and safety data for AEZS-108 (zoletarelin doxorubicin) in advanced endometrial cancer at the European Society of Gynecological Oncology in Milan, Italy. Data showed that AEZS-108, administered as a single agent at a dosage of 267 mg/m<sup>2</sup> every 3 weeks was active, well tolerated and that overall survival is 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 Response Evaluation Criteria in Solid Tumors ( RECIST ). Secondary endpoints included safety, time-to-progression ( TTP ) and overall survival ( OS ).

In all, of 43 patients treated with AEZS-108, 39 were evaluable for efficacy. Efficacy confirmed by independent response review included 2 complete responses ( CR ), 10 partial responses ( PR ), and 17 patients with disease stabilization ( SD ). Based on those data, the estimated Overall Response Rate ( ORR = CR+PR) was 30.8% and the Clinical Benefit Rate ( CBR ) (CBR = CR+PR+SD) was 74.4%. Responses in patients previously treated with chemotherapy included 1 CR, 1 PR and 2 SDs in 8 of the patients with prior use of platinum/taxane regimens. Median TTP and OS were 7 months and 13.7 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 1 patient who had been treated only 3 weeks after a surgery. Good tolerability of AEZS-108 was also reflected by a low rate of severe non hematological 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 September 26, 2011, we announced positive interim data for the Phase 1 portion of our Phase 1/2 trial with AEZS-108 in castration- and taxane-resistant prostate cancer at the ESMO meeting in 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. Data showed that AEZS-108 was well tolerated at all dose levels and early evidence of antitumor activity was observed even at low dose level. 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. Furthermore, data from correlative studies demonstrated for the first time the internalization of AEZS-108 in circulating tumor cells of patients.

On October 25, 2011, we announced that the FDA had completed the review of the IND application filed by Alberto J. Montero, M.D., Assistant Professor, Department of Medicine, Division of Hematology/Oncology, Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine and concluded that Dr. Montero may proceed with 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. This will be an open-label, randomized, two-arm, multicenter Phase 2 study involving up to 74 patients. The primary study endpoint will be PFS. Secondary endpoints will also 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 used in the control arm of this study.

## **Table of Contents**

On January 5, 2012, we announced that we had entered into a collaboration agreement with Ventana Medical Systems, Inc., a member of the Roche Group, to develop a companion diagnostic for the immunohistochemical determination of LHRH-receptor expression, for AEZS-108. 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.

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

On July 20, 2011, we announced that we had successfully reached a key milestone in the non-clinical development of our live recombinant prostate cancer vaccine candidate, AEZS-120, for oral administration. The program 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, as previously agreed with the regulatory authorities. Subject to a positive review by the regulatory authorities, we aim to start Phase 1 clinical development in 2012. 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 the Company and \$870,000 for the university partner by the German Ministry of Education and Research (BMBF) for a period of three years. As part of the collaboration, a melanoma vaccine based on the recombinant expression of a modified B-Raf protein has been generated.

### ***AEZS-129***

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.

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

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

On August 30, 2011, we announced favorable top-line results of the completed Phase 3 study with AEZS-130 as the first oral diagnostic test for AGHD. The results showed that AEZS-130 reached its primary endpoint demonstrating >90% AUC of the ROC curve, which determines the level of specificity and sensitivity of the product.

The first part of the study, conducted by our former partner, Ardana, was a two-way crossover study involving 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. Each patient received two dosing regimens in random order, while fasting, at least 1 week apart. One regimen consisted of a 1 µg/kg (max. 100 µg) dose of GHRH (Geref Diagnostic®, Serono) with 30 g of ARG (Ar-Gine®, Pfizer) administered intravenously over 30 minutes; the other regimen was a dose of 0.5 mg/kg body weight of AEZS-130 given in an oral solution of 0.5 mg/ml. As a result of the SPA reached with the FDA in order to complete the trial, the second part of the study contained the following revisions/additions to the first protocol:

§ An additional 30 normal control subjects were to be enrolled to match the AGHD patients from the original cohort;

---

**Table of Contents**

§ Further, an additional 20 subjects were to be enrolled: 10 AGHD patients and 10 matched normal control subjects;

§ The above brought the database to ~100 subjects;

§ All subjects received a dose of 0.5 mg/kg body weight of AEZS-130;

§ As a secondary endpoint, the protocol required that at least 8 of the 10 newly enrolled AGHD patients be correctly classified by a pre-specified peak GH threshold level.

The parameters of the study were achieved as agreed to with the FDA under our SPA. Importantly, the primary efficacy parameters showed that the study achieved both specificity and sensitivity at a level of 90% or greater. In addition, 8 of the 10 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.

The Company is planning for the filing of an NDA for the registration of AEZS-130 in the United States as a diagnostic test for AGHD.

On November 28, 2011, we announced that the FDA had completed the review of an IND application filed by 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 the Michael E. DeBakey Veterans Affairs Medical Center, in Houston Texas and concluded that Dr. Garcia may proceed with the initiation of a Phase 2A trial to assess the safety and efficacy of repeated oral administration of AEZS-130 at different doses daily for 1 week in view of developing a treatment for 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 six months.

On March 8, 2012, we announced that the Michael E. DeBakey Veterans Affairs Medical Center, in Houston, Texas, initiated a 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 between the Michael E. DeBakey Veterans Affairs Medical Center, which is funding the study, and us. This is a double-blind, randomized, placebo-controlled Phase 2A trial to test the effects of different doses of the ghrelin agonist, AEZS-130, in 18 to 26 patients with cancer-cachexia. AEZS-130 will be provided by us. The study will involve 3 sequential groups receiving differing doses of AEZS-130. Each dose group will have 6 patients who will receive AEZS-130 and 2-4 patients who will receive a placebo. After analysis of safety and efficacy at each dose level vs. placebo, a decision will be taken either to decrease or increase the dose. If there are major safety issues, the study will be stopped. For this study, adequate efficacy will be defined as a  $\geq 0.8$  kg of body weight gain or a  $\geq 50$  ng/mL increase in plasma IGF-1 levels. 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 1 week in view of developing a treatment for cachexia. The following parameters will be recorded to assess efficacy during the study: change of body weight, change of IGF-1 plasma levels, and change of quality of life score (Anderson Symptom Assessment Scale, FACIT-F). Other secondary objectives will include food intake, and changes in the following: appetite, muscle strength, energy expenditure, reward from food and functional brain connectivity.

***AEZS-131***

On March 22, 2011, we presented preclinical results for AEZS-131 at the Informa Life Sciences Protein Kinases Congress in Berlin, Germany. AEZS-131 was established as a small molecular compound that inhibits Erk in the low nanomolar range and shows an excellent selectivity profile. Further characterization experiments revealed an ATP-competitive mode of action and the potent inhibition of the cellular downstream target Rsk1 in tumor cells. The frontrunner, AEZS-131, produces cell cycle arrest in G1 and results in growth inhibition of cancer cells. Furthermore, the potential of combination therapy of AEZS-131 with inhibitors of the PI3K pathway was

---

**Table of Contents**

addressed and the analysis of combination effects on tumor cell proliferation has been presented. These results support the evaluation of selective Erk inhibitors as antiproliferative agents either as monotherapy or in combination with inhibitors of the PI3K/Akt pathway.

On April 5, 2011, we announced that a poster on our highly selective Erk 1/2 inhibitor anticancer compound, AEZS-131, had been presented at the 102<sup>nd</sup> annual meeting of the AACR. Results showed that AEZS-131 selectively inhibits Erk 1/2 with an IC<sub>50</sub> of 4nM, blocks cellular Rsk-1 phosphorylation, modulates downstream cellular substrate activation, arrests tumor cells in G1 and inhibits the growth of multiple human tumor cell lines in the nanomolar range. In *in vivo* pharmacokinetic studies, AEZS-131 showed a favorable PK profile. Antitumor activity was studied in *in vivo* mouse xenograft experiments utilizing the HCT 116 colon cancer model. AEZS-131 significantly inhibited tumor growth and was well tolerated at daily doses up to 120 mg/kg. Focus on inhibition of downstream kinase Erk 1/2 activity as a therapeutic target may be attractive because the pharmacologic inhibition of Erk 1/2 reverses Ras and Raf activation in cells which also demonstrate resistance to common Raf inhibitors, such as PLX-4720/4032.

On August 30, 2011, we announced that a poster on our novel orally active anticancer Erk inhibitor, which includes AEZS-131, was presented at the American Chemical Society National Meeting in Denver, Colorado. The *in vitro* antiproliferative efficacy proved to be excellent in diverse human tumor cell lines. GI50 values in the low nanomolar range were obtained. *In vivo* antitumor activity was studied in a mouse xenograft experiment utilizing the human HCT-116 colon cancer model. Up to 74% inhibition of tumor growth was achieved with daily oral doses of 30 -120 mg/kg. Our medicinal chemistry programs are supported by X-ray crystallography and modeling towards the optimization of pyrido[2,3-b]pyrazines as novel series of kinase inhibitors.

On December 9, 2011, we announced positive preclinical data in TNBC for AEZS-131 at the 34<sup>th</sup> Annual San Antonio Breast Cancer Symposium. AEZS-131 was tested to check for selectivity, inhibition of Rsk-phosphorylation (cellular substrate of Erk), mode of action and cleavage of PARP. Cytotoxic efficacy was evaluated in a selection of TNBC cell lines, with or without mutations in the MAPK signal transduction pathway, by MTT assay. The study showed that AEZS-131 selectively inhibited ERK with an IC<sub>50</sub><4nM. Phosphorylation of Rsk-1 was inhibited with an IC<sub>50</sub> of 158 nM. AEZS-131 induced cell cycle arrest in G1 dose-dependently and cleavage of PARP. EC50 values were below 1µM for cell lines with mutations in the MAPK pathway. TNBC cell lines without mutations in the MAPK pathway were less responsive.

**AEZS-132**

On March 22, 2011, we presented preclinical results for AEZS-132 at the Informa Life Sciences Protein Kinases Congress in Berlin, Germany. AEZS-132 is a unique dual inhibitor of PI3K and Erk in the nanomolar range and exerts high selectivity against other serine threonine and tyrosine kinases. AEZS-132 is also an ATP-competitive inhibitor, with a broad antiproliferative profile *in vitro*, a favorable safety profile and beneficial ADME properties. *In vivo* pharmacokinetic experiments showed plasma profiles expected to result in positive antitumor efficacy, and led to significant antitumor activity in mouse xenograft models, including HCT-116 (colon), A-549 (lung), and Hec 1B (endometrium). Cellular inhibition of the downstream targets p-Akt and p-Rsk was confirmed within the *in vivo* tumor studies. In summary, AEZS-132 is a unique dual kinase inhibitor targeting the PI3K and MAPK pathways, expected to be especially suited to treat tumors with over-activation of both pathways.

**AEZS-137**

On March 24, 2011, we announced that we had been 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 (disorazol Z) 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 benefitting from this personalized medicine approach. The grant will be payable as a partial reimbursement of qualifying

---

## **Table of Contents**

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 \$0.7 million. Researchers from the department of Gynecology and Obstetrics at both the University of Göttingen and Würzburg, Germany, will also be part of the collaboration.

On November 16, 2011, we announced encouraging preclinical data for AEZS-137 from a poster presentation at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, in San Francisco. The poster showed that AEZS-137 possesses outstanding 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 phase and subsequently induced apoptosis with remarkable potency, as shown by subnanomolar EC50 values.

### ***Corporate Developments***

#### **At-the-Market Sales Agreement**

On February 22, 2011, we entered into an ATM sales agreement with MLV, under which we were able to sell up to 12.5 million of our common shares through ATM issuances on NASDAQ for aggregate gross proceeds not to exceed \$19.8 million. The ATM sales agreement 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. From February 20, 2011 and up to April 29, 2011, we issued a total of 10.0 million of our common shares for aggregate gross proceeds of \$19.8 million, less cash transaction costs of \$0.6 million and previously deferred transaction costs of \$0.2 million.

On June 29, 2011, we entered into a second ATM, the June ATM Sales Agreement with MLV, under which we could, at our discretion, from time to time during the 24-month term of the agreement, sell up to 9.5 million of our common shares through ATM issuances on NASDAQ for aggregate gross proceeds not to exceed \$24.0 million. The June ATM Sales Agreement, similar to the February ATM Sales Agreement, 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. From June 29, 2011 and up to December 7, 2011, under the June ATM agreement, we issued a total of 9.5 million of our common shares for aggregate gross proceeds of \$17.7 million, less cash transactions costs of \$0.6 million and previously deferred transaction costs of \$0.2 million.

Gross proceeds raised under both ATM sales agreements totalled \$37.5 million for the year ended December 31, 2011.

#### **Cowen Royalty Sales Milestone Payment**

On February 28, 2011, we announced that we had received a net sales milestone of \$2.5 million from Cowen Healthcare Royalty Partners, L.P. ( Cowen ). This milestone was payable pursuant to the previously announced sale to Cowen of Aeterna Zentaris' rights to royalties on future net sales of Cetrotide®, covered by the Company's license agreement with Merck Serono, and was contingent on 2010 net sales of Cetrotide® reaching a specified level.

### ***Subsequent to Year-End***

#### **At-The-Market Issuance Program**

On January 23, 2012, the Company, pursuant to its existing ATM sales agreement dated June 29, 2011, with MLV, was commencing a new ATM issuance program ( January 2012 ATM Sales Agreement ) under which it may, at its discretion, from time to time during the term of the sales agreement, sell up to a maximum of 10.4 million of its common shares through ATM issuances on NASDAQ up to an aggregate amount of \$16.0 million.

**Table of Contents**

From January 23, 2012 through March 15, 2012, the Company issued a total of 3.6 million common shares under the January 2012 ATM Sales Agreement for aggregate gross proceeds of \$6.4 million, less cash transaction costs of \$0.2 million and previously deferred transaction costs of \$56,000.

**AEZS-108**

On February 3, 2012, we reported positive updated results for the Phase 1 portion of our ongoing Phase 1/2 study in CRPC with AEZS-108. This is a single-arm study with a Phase 1 lead-in portion (testing 3 dose levels) 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. Data were presented by Jacek Pinski, M.D., Ph.D., Associate Professor of Medicine at the Norris Comprehensive Cancer Center of the University of Southern California, during a poster session at the American Society of Clinical Oncology Genitourinary Cancers Symposium in San Francisco. The trial is being supported by a three-year \$1.6 million grant from the National Institutes of Health to Dr. Pinski.

The results were based on 13 patients who have been treated on 3 dose levels: 3 at 160 mg/m<sup>2</sup>, 3 at 210 mg/m<sup>2</sup>, and 7 at 267 mg/m<sup>2</sup>. Overall, AEZS-108 has been well tolerated among this group of heavily pre-treated older patients. To date, there have been 2 dose limiting toxicities; both were cases 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 has been 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 8 cycles (at 210 mg/m<sup>2</sup>) due to continued benefit. Among the 5 evaluable patients with measurable disease, 4 achieved stable disease. At the time of submission of the abstract, a decrease in PSA was noted in 6 patients. Six of 13 (46%) treated patients have received at least 5 cycles of therapy with no evidence of disease progression at 12 weeks. Correlative studies on circulating tumor cells ( CTC ) have demonstrated the uptake of AEZS-108 into the targeted tumor. After completion of 3 additional patients at the 210 mg/m<sup>2</sup> dose level, the study is expected to be extended into the Phase 2 portion.

**Table of Contents****Consolidated Statements of Comprehensive Loss Information**

<i>(in thousands, except share and per share data)</i>	<b>Years ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009*</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Revenues</b>			
Sales and royalties	<b>31,306</b>	24,857	20,957
License fees and other	<b>4,747</b>	2,846	42,280
	<b>36,053</b>	27,703	63,237
<b>Operating expenses</b>			
Cost of sales	<b>27,560</b>	18,700	16,501
Research and development costs, net of refundable tax credits and grants	<b>24,517</b>	21,257	43,814
Selling, general and administrative expenses	<b>16,170</b>	12,552	16,040
Depreciation and amortization*	<b>*</b>	<b>*</b>	10,840
	<b>68,247</b>	52,509	87,195
<b>Loss from operations</b>	<b>(32,194)</b>	(24,806)	(23,958)
Finance income	<b>6,239</b>	1,800	349
Finance costs	<b>(8)</b>	(5,445)	(1,115)
<b>Net finance income (costs)</b>	<b>6,231</b>	(3,645)	(766)
Loss before income taxes	<b>(25,963)</b>	(28,451)	(24,724)
Income tax expense	<b>(1,104)</b>	-	-
<b>Net loss</b>	<b>(27,067)</b>	(28,451)	(24,724)
<b>Other comprehensive (loss) income:</b>			
Foreign currency translation adjustments	<b>(789)</b>	1,001	(1,335)
Actuarial gain (loss) on defined benefit plans	<b>(1,335)</b>	191	-
<b>Comprehensive loss</b>	<b>(29,191)</b>	(27,259)	(26,059)
<b>Net loss per share</b>			
Basic and diluted	<b>(0.29)</b>	(0.38)	(0.43)
<b>Weighted average number of shares outstanding</b>			
Basic and diluted	<b>94,507,988</b>	75,659,410	56,864,484

\* We adopted IFRS in 2011 with a transition date of January 1, 2010. The selected financial information for the years ended December 31, 2009, 2008 and 2007 is derived from financial statements that were presented in accordance with Canadian GAAP and has not been restated in accordance with IFRS. Consequently, the selected financial information for the years ended December 31, 2009, 2008 and 2007 may not be comparable with the corresponding selected financial information for the years ended December 31, 2011 and 2010. Please refer to Critical Accounting Policies, Estimates and Judgments for the policy differences between Canadian GAAP and IFRS.

## Table of Contents

### Revenues

**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 to Cowen Healthcare Royalty Partners L.P. 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 \$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 related to comparatively higher deliveries of Cetrotide® to Merck Serono.

Despite our original expectations for only slight sales volume increases for the year 2011, our sales and royalties were substantially higher than our original expectations due to an unforeseen increase in sales to Merck Serono.

Sales and royalties in 2012 are expected to stabilize, as compared to the amounts recorded in 2011, since we expect that the volume of Cetrotide® sales will stabilize in 2012.

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 of a milestone payment from Yakult with respect to the initiation of a Phase 1/2 trial with perifosine in CRC in Japan during the last quarter of the year 2011.

During 2012, we expect to provide more R&D services, compared to 2011, related to perifosine to our license partner for North America, Keryx. We expect the results of the ongoing Phase 3 trial of perifosine in CRC in the second quarter of 2012. If the data from the trial is positive, we expect to receive development and regulatory milestone payments from our various license partners. With these additional revenues, we expect that our license fees and other revenues will increase significantly in 2012, as compared to 2011.

### 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 88.03% for the year ended December 31, 2011, compared to 75.23% for the year ended December 31, 2010. Our lower 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



**Table of Contents**

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

<i>(in thousands)</i>	Years ended December 31,	
	2011	2010
	\$	\$
Employee compensation and fringe benefits	10,028	9,226
Third-party costs	10,244	8,138
Facilities rent and maintenance	1,835	1,773
Other costs*	2,793	2,807
R&D refundable tax credits and grants	(383)	(687)
	24,517	21,257

\* including depreciation and amortization charges.

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

<i>(in thousands, except percentages)</i>	Product	Status	Indication	Years ended December 31,			
				2011		2010	
				\$	%	\$	%
	Perifosine	Phases 2 and 3	Oncology	3,726	36.4	968	11.9
	AEZS-130	Phase 3	Endocrinology				
			(diagnosis of AGHD)	1,156	11.3	865	10.6
	Cetorelix	Phase 3*	BPH*	-	-	2,046	25.1
	AEZS-108	Phase 2	Oncology	1,652	16.1	2,089	25.7
	AEZS-112	Phase 1	Oncology	538	5.3	259	3.2
	AEZS-129, AEZS-131 and						
	AEZS-132; Erk/PI3K	Preclinical	Oncology	1,860	18.2	923	11.4
	Other		Oncology and				
			endocrinology	1,312	12.7	988	12.1
				10,244	100.0	8,138	100.0

\* Development activities terminated in the last quarter of 2009 and beginning of 2010.

We expect net R&D costs for 2012 to increase, compared to 2011, as we continue to focus on the development of perifosine and AEZS-108. In particular, we plan to pursue the ongoing Phase 3 study with perifosine in multiple myeloma, as well as initiate, with AEZS-108, a pivotal trial in endometrial cancer and support the ongoing Phase 1/2 studies in connection with triple-negative breast cancer and other indications.

We expect, excluding the impact of unforeseen foreign exchange rate fluctuations, that net R&D costs will total between \$30.0 million and \$32.0 million for the twelve-month period ending December 31, 2012, due to the additional expenses discussed above. 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. We also expect that many perifosine-related development activities will be sponsored by our North American license partner, Keryx, and Japanese partner, Yakult, and that we will continue to seek government grants for our earlier-stage projects.

**Selling, general and administrative ( 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.

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

During the year 2011, we recognized an impairment loss (\$1.1 million) following impairment testing that was performed on our 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.

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).

**Table of Contents**

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.

We expect that our SG&A expenses will slightly decrease in 2012, as compared to 2011, as costs return to more normalized operating levels, despite our expected inclusion of certain investments in perifosine's European pre-launch and marketing efforts.

**Net finance income (costs)**, comprised predominantly of net foreign exchange gains (losses), the change in fair value of our warrant liability and the gain on our short-term investment, 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 below.

<i>(in thousands)</i>	<b>Years ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>\$</b>	<b>\$</b>
<b>Finance income</b>		
Net gains due to changes in foreign currency exchange rates	<b>2,197</b>	932
Change in fair value of warrant liability	<b>2,533</b>	-
Interest income	<b>231</b>	181
Gain on held-for-trading financial instrument	<b>1,278</b>	687
	<b>6,239</b>	1,800
<b>Finance costs</b>		
Change in fair value of warrant liability	-	(5,437)
Unwinding of discount	<b>(8)</b>	(8)
	<b>(8)</b>	(5,445)
	<b>6,231</b>	(3,645)

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 \$0.81 as at January 4, 2010 to \$1.72 as at December 31, 2010, and \$1.54 as at December 31, 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 US dollar, as compared to an overall lower weakening of the euro against the US 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 US 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.

**Table of Contents**

It can be noted that the gains or losses resulting from the periodic mark-to-market valuation of our share purchase warrants did not result in any cash receipt or cash disbursement during the three-month or twelve-month periods ended December 31, 2011 and 2010.

**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 increase consists of foreign withholding taxes related to the Yakult upfront and milestone license fees revenues discussed above.

**Net loss** for the year ended December 31, 2011 was \$27.1 million, or \$0.29 per basic and diluted share, compared to \$28.5 million, or \$0.38 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®, 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**

The following is a summary of selected consolidated financial information derived from our unaudited interim period consolidated financial statements for each of the eight most recently completed quarters.

*(in thousands, except for per share data)*

	Quarters ended			
	December 31,	September 30,	June 30,	March 31,
	2011 \$	2011 \$	2011 \$	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 and diluted	(0.07)	0.01	(0.12)	(0.12)

	Quarters ended			
	December 31,	September 30,	June 30,	March 31,
	2010 \$	2010 \$	2010 \$	2010 \$
Revenues	9,971	5,726	5,584	6,422
Loss from operations	(4,003)	(5,456)	(7,950)	(7,397)
Net loss	(6,610)	(9,920)	(6,176)	(5,745)
Net loss per share* Basic and diluted	(0.08)	(0.12)	(0.08)	(0.09)

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

## **Table of Contents**

In the last eight quarters, revenues have increased, when compared quarter over quarter for each of the corresponding periods in 2011 vs. 2010, mainly due to the higher deliveries of Cetrotide® to Merck Serono, which increase have started in the fourth quarter of 2010, the recording of a contingent payment received from Cowen in the fourth quarter of 2010 as well as the recording of a milestone payment from Yakult in the fourth quarter of 2011.

In the last eight quarters, net (loss) income have been impacted by revenues, as mentioned above, by the increased level of net R&D costs in connection with the advancement of perifosine, AEZS-130 and Erk/PI3K compounds, by the recognition of impairment losses in the third and fourth quarters of 2011, by the initiation of pre-launch and marketing efforts related to the potential commercialization of perifosine in Europe in the third and fourth quarters of 2011, as well as by the foreign exchange gain or loss, the change in fair value of our warrant liability and the gain on our short-term investment.

### **Fourth Quarter 2011 Results**

#### **Revenues**

**Revenues** were \$12.6 million for the quarter ended December 31, 2011, compared to \$10.0 million for the same quarter in 2010. The increase in revenues is due primarily to comparative higher deliveries of Cetrotide® to Merck Serono (\$3.6 million) and to the recording of a milestone payment (\$2.6 million) from Yakult with respect to the initiation of a Phase 1/2 trial with perifosine in CRC in Japan, partly offset by the lower royalties in 2011 attributable to the contingent payment of \$2.5 million from Cowen recorded in December 2010.

#### **Operating expenses**

**Cost of sales** was \$8.1 million for the quarter ended December 31, 2011, compared to \$5.4 million for the same quarter in 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% for the quarter ended December 31, 2011, compared to 63% for the same period in 2010. Our lower margins are largely attributable to a lower contribution of royalties to total sales and royalties in 2011, as compared to 2010, as a result of a \$3.4 million royalty milestone payment recorded in 2010 from Cowen.

**R&D costs, net of refundable tax credits and grants** were \$7.8 million for the quarter ended December 31, 2011, compared to \$5.4 million for the same quarter in 2010. The comparative increase in R&D expenses primarily results from the increase in third-party costs incurred in connection with the advancement of perifosine, AEZS-108 and Erk/PI3K compounds (AEZS-129, AEZS-131, AEZS-132)-related activities.

**Selling, general and administrative ( SG&A ) expenses** were \$5.4 million for the quarter ended December 31, 2011, compared to \$3.2 million for the same quarter in 2010. The increase in SG&A expenses is mainly related to the recognition of 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), combined with the pre-launch and marketing efforts related to the potential commercialization of perifosine in Europe (\$0.5 million) and with the increase in foreign exchange loss (\$0.6 million).

**Table of Contents**

**Net finance income (costs)**, comprised predominantly of net foreign exchange gains, the change in fair value of our warrant liability and the gain on our short-term investment (2010 only), for the quarter ended December 31, 2011, totalled \$1.4 million, compared to (\$2.6 million) for the same period in 2010, as presented below.

	<b>Three months ended</b>	<b>Three months ended</b>
	<b>December 31,</b>	<b>December 31,</b>
<i>(in thousands)</i>	<b>2011</b>	<b>2010</b>
	<b>\$</b>	<b>\$</b>
<b>Finance income</b>		
Net gains due to changes in foreign currency exchange rates	<b>1,118</b>	276
Change in fair value of warrant liability	<b>221</b>	-
Interest income	<b>95</b>	70
Gain on held-for-trading financial instrument	<b>-</b>	687
	<b>1,434</b>	1,033
<b>Finance costs</b>		
Change in fair value of warrant liability	<b>-</b>	(3,638)
Unwinding of discount	<b>(2)</b>	(2)
	<b>(2)</b>	(3,640)
	<b>1,432</b>	(2,607)

**Net loss** amounted to \$7.5 million, or \$0.07 per basic and diluted share, for the quarter ended December 31, 2011, compared to \$6.6 million, or \$0.08 per basic and diluted share, for the same quarter in 2010. The increase in net loss is mainly attributable to the higher comparative R&D and SG&A expenses, partly offset by the significant increase in net finance income and by higher gross margin relating to sales of Cetrotide®.

Primarily, given the presence in our 2011 fourth quarter revenues of the \$2.6 million milestone receivable from Yakult with respect to the initiation of a Phase 1/2 trial with perifosine in CRC in Japan, and excluding any impact of foreign exchange gains or losses, as well as change in fair value of warrant liability, we expect that the net loss for the first quarter of 2012 will increase, as compared to the fourth quarter of 2011.

**Table of Contents****Consolidated Statement of Financial Position Information**

<i>(in thousands)</i>	<b>As at December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009*</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
Cash and cash equivalents	<b>46,881</b>	31,998	38,100
Short-term investment	-	1,934	-
Trade and other receivables and other current assets	<b>13,258</b>	9,877	10,913
Restricted cash	<b>806</b>	827	878
Property, plant and equipment, net	<b>2,512</b>	3,096	4,358
Other non-current assets	<b>11,912</b>	13,716	32,013
<b>Total assets</b>	<b>75,369</b>	61,448	86,262
Payables and other current liabilities	<b>17,784</b>	13,350	19,211
Long-term payable (current and non-current portions)	<b>88</b>	150	200
Warrant liability (current and non-current portions)	<b>9,204</b>	14,367	-
Non-financial non-current liabilities**	<b>52,839</b>	51,156	57,625
<b>Total liabilities</b>	<b>79,915</b>	79,023	77,036
<b>Shareholders (deficiency) equity</b>	<b>(4,546)</b>	(17,575)	9,226
<b>Total liabilities and shareholders (deficiency) equity</b>	<b>75,369</b>	61,448	86,262

\* We adopted IFRS in 2011 with a transition date of January 1, 2010. The selected financial information for the years ended December 31, 2009, 2008 and 2007 is derived from financial statements that were presented in accordance with Canadian GAAP and has not been restated in accordance with IFRS. Consequently, the selected financial information for the years ended December 31, 2009, 2008 and 2007 may not be comparable with the corresponding selected financial information for the years ended December 31, 2011 and 2010. Please refer to Critical Accounting Policies, Estimates and Judgments for the policy differences between Canadian GAAP and IFRS.

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

The increase in cash and cash equivalents as at December 31, 2011, as compared to December 31, 2010, is due to the receipt of net proceeds pursuant to drawdowns made in connection with the February and June ATM Sales Agreements, as discussed above, to the proceeds from the sale of our short-term investment, to the receipt of the upfront license payment in connection with our development, commercialization and licensing agreement entered into with Yakult, as noted above, as well as to the receipt of net proceeds from the exercise of share purchase warrants. These increases were partially offset by recurring disbursements and other variations in components of our working capital.

Trade and other receivables and other current assets increased from December 31, 2010 to December 31, 2011 mainly due to the increase in trade receivable in connection with the higher deliveries of Cetrotide<sup>®</sup> to Merck Serono for an amount of approximately \$2.9 million and due to the perifosine inventory to be sold to our partner Keryx for an amount of approximately \$0.7 million which in turn were partly offset by the impact of foreign exchange rate fluctuations.

Other non-current assets decreased from December 31, 2010 to December 31, 2011 primarily due to the net reduction in the carrying value of our identifiable intangible assets, which was negatively impacted by the impairment loss recognized on Cetrotide<sup>®</sup>, as discussed above.

Payables and other current liabilities increased from December 31, 2010 to December 31, 2011 mainly due to an increase of approximately \$2.4 million in trade accounts payable and accrued liabilities in connection with the higher deliveries of Cetrotide<sup>®</sup> and with the higher level of R&D expenses resulting from the advancement of perifosine, AEZS-130 and Erk/PI3K compounds, which includes an increase due to the perifosine R&D inventory received and payable for an amount of approximately \$1.3 million, to the increase in current portion of deferred revenues for an amount of \$1.3 million, and to the increase in accrued salaries for an amount of approximately \$0.5 million which in turn were partly offset by the impact of foreign exchange rate fluctuations.





**Table of Contents**

Our warrant liability was lower as at December 31, 2011, as compared to December 31, 2010, predominantly due to the change in fair value pursuant to the periodic mark-to-market revaluation of the underlying outstanding share purchase warrants, as well as following various warrant exercises during the twelve-month period ended December 31, 2011.

Non-financial liabilities were higher as at December 31, 2011, as compared to December 31, 2010, mainly as a result of the deferral of the upfront payment received in connection with our development, commercialization and licensing agreement entered into with Yakult, partially offset by the recurring amortization of deferred revenues.

The net decrease in shareholders' deficiency as at December 31, 2011, as compared to December 31, 2010, is predominantly attributable to an increase in share capital following the issuance of common shares pursuant to the aforementioned drawdowns made in connection with the February and June ATM Sales Agreements, partially offset by the increase in our deficit due to the net loss for the year ended December 31, 2011 and by the decrease in accumulated other comprehensive income, which in turn is comprised of cumulative translation adjustments.

**Financial Liabilities, Obligations and Commitments**

We have certain contractual leasing obligations and purchase obligation commitments. Purchase obligation commitments mainly include R&D services and manufacturing agreements related to the production of Cetrotide® and to other R&D programs. 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, as at December 31, 2011 are as follows:

<i>(in thousands)</i>	<b>Minimum lease payments \$</b>	<b>Minimum sub-lease payments \$</b>	<b>Utilities \$</b>
Less than 1 year	1,690	(226)	609
1 - 3 years	3,128	(451)	793
4 - 5 years	2,172	(451)	496
More than 5 years	373	(244)	-
<b>Total</b>	<b>7,363</b>	<b>(1,372)</b>	<b>1,898</b>

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

<i>(in thousands)</i>	<b>As at December 31, 2011 \$</b>
Less than 1 year	10,760
1 - 3 years	3,855
4 - 5 years	-
More than 5 years	-
<b>Total</b>	<b>14,615</b>

## **Table of Contents**

### **Outstanding Share Data**

As at March 27, 2012, there were 108,787,366 common shares issued and outstanding, as well as 7,497,634 stock options outstanding. Share purchase warrants outstanding as at March 27, 2012 represented a total of 8,752,868 equivalent common shares.

### **Capital Disclosures**

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

Historically, our priority has been to optimize our 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, however, we have raised additional capital via registered direct offerings and drawdowns related to the February and June ATM Sales Agreements, and we expect to continue to raise capital via drawdowns related to the January 2012 ATM Sales Agreement.

At December 31, 2011, cash and cash equivalents amounted to \$46.9 million. The Company believes that its cash position will be sufficient to finance its operations and capital needs for at least the next twelve months.

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 any other external source.

It is important to note that historical patterns of expenditures cannot be taken as an indication of future expenditures. The amount and timing of expenditures and availability of capital resources vary substantially from period to period, depending on the level of research and development activity being undertaken at any given time and on the availability of funding from investors and prospective commercial partners.

### **Liquidity, Cash Flows and Capital Resources**

Our operations and capital expenditures have been financed mainly through cash flows from operating activities and other non-dilutive activities, except for the registered direct offerings completed during the year ended December 31, 2010 and, more recently, the drawdowns related to our various ATM Sales Agreements, as discussed above.

Our cash and cash equivalents amounted to \$46.9 million as at December 31, 2011, as compared to \$32.0 million as at December 31, 2010. As at December 31, 2011, cash and cash equivalents, denominated in euro, amounted to 10.3 million.

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 twelve-month period following the balance sheet date of December 31, 2011.

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

The variations in our liquidity by activity are explained below.

## **Table of Contents**

### **Operating Activities**

Cash 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.

We expect net cash used in operating activities to increase during 2012, as compared to 2011, as we increase our investment in perifosine and in AEZS-108, as discussed above.

### **Financing Activities**

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 related to the February and June ATM Sales Agreements, discussed above, as well as to the increase in proceeds received following the exercise of share purchase warrants.

### **Investing Activities**

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 \$0.05 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**

As noted above, our consolidated financial statements as at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010 have been prepared in accordance with IFRS. Note 29 *Transition to IFRS* to our consolidated financial statements as at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010 discusses the impact of the transition to IFRS on our reported financial position, financial performance and cash flows, including the nature and effect of significant changes in accounting policies from those used in our previous Canadian GAAP consolidated financial statements as at December 31, 2010 and for the year then ended. Comparative figures for 2010 have been adjusted to give effect to these changes.

These consolidated financial statements were approved by our Board of Directors for issue on March 27, 2012.

Additionally, the preparation of consolidated financial statements in accordance with IFRS often requires management to make estimates about and apply assumptions or subjective judgment to future events and other matters that affect the reported amounts of our assets, liabilities, revenues, expenses and related disclosures. Assumptions, estimates and judgments are based on historical experience, expectations, current trends and other factors that management believes to be relevant at the time at which our 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.

Critical accounting estimates and judgments 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.

---

## **Table of Contents**

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

### **Accounting Standards 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. 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. We currently are evaluating any impact that this new guidance may have on our 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. We currently are evaluating any impact that this new guidance may have on our 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. We currently are evaluating any impact that this new guidance may have on our 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. We currently are evaluating any impact that this new guidance may have on our 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. We currently are evaluating any impact that this new guidance may have on our consolidated financial statements.

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. We currently are evaluating any impact that this new guidance may have on our consolidated financial statements.

## **Table of Contents**

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. We currently are evaluating any impact that this new guidance may have on our consolidated financial statements.

### **Outlook for 2012**

#### **Perifosine**

Our primary focus continues to be on the advancement of the ongoing Phase 3 registration studies in both refractory advanced colorectal cancer and multiple myeloma. We expect the results of the ongoing Phase 3 trial of perifosine in CRC in the second quarter of 2012.

We expect to continue to invest in the preparation of marketing and pre-launch activities of perifosine in Europe.

#### **AEZS-108**

We expect to initiate a multi-center pivotal study in endometrial cancer, as well as a multi-center Phase 2 study in triple-negative breast cancer. We also expect to pursue our Phase 1/2 studies in castration- and taxane-resistant prostate cancer with the University of Southern California, and in refractory bladder cancer with the University of Miami.

#### **AEZS-130**

Following the completion and positive Phase 3 results for AEZS-130 as a diagnostic for AGHD in the United States, we expect, after a successful receipt of pre-NDA meeting with the FDA, to file an NDA.

We also expect to pursue our ongoing Phase 2A study with AEZS-130 as a treatment for cancer-cachexia.

#### **Revenue Expectations**

Revenues are expected to increase in 2012, as compared to 2011, given our expectation for potential increased license fees revenues from our partners and despite the expected stabilization of our sales and royalties, as discussed above.

#### **Operating Expense Expectations**

During 2012, we expect to continue to focus our R&D efforts on our later-stage compounds, including perifosine and AEZS-108. With our focused strategy, and given our expectations related to R&D investments made on behalf of Keryx, we now expect our R&D expenses to total between \$30 million and \$32 million for the whole of 2012, as compared to \$24.5 million in 2011. However, certain perifosine-related R&D expenses will be reimbursed by our partner, Keryx.

We expect that our overall operating burn in 2012 will increase, as compared to 2011, due most notably to the receipt in 2011 of \$8.4 million in connection with our licensing agreement entered into with Yakult and our expected increase in R&D investments, as discussed above, partly offset by increased license fees from our partners.

**Table of Contents****Financial Risk Factors and Other Instruments****Fair Value**

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 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 our consolidated statements of comprehensive 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 \$1.43 to \$2.58 on NASDAQ during the year ended December 31, 2011.

Assuming the following variations of the market price of our common shares over a 12-month period:

Market price variations of -10% and +10%

If these variations were to occur, the impact on our net loss for warrant liability held at December 31, 2011 would be as follows:

<i>(in thousands)</i>	<b>Carrying amount \$</b>	<b>-10% \$</b>	<b>+10% \$</b>
Warrant liability*	9,204	1,155	(1,174)
<b>Total impact on net loss decrease/(increase)</b>		1,155	(1,174)

\* Includes current and non-current portions.

**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 US dollar exchange rates against the euro could have a potentially significant impact on our results of operations.

The following variations are reasonably possible over a 12-month period:

Foreign exchange rate variations of -5% (depreciation of the EUR) and +5% (appreciation of the EUR) against the US\$, from a year-end rate of EUR1 = US\$1.2972.

If these variations were to occur, the impact on the Company's net loss for each category of financial instruments held at December 31, 2011 would be as follows:

<i>(in thousands)</i>	<b>Carrying amount \$</b>	<b>Balances denominated in US\$</b>	
		<b>-5% \$</b>	<b>+5% \$</b>
Cash and cash equivalents	33,669	1,683	(1,683)
Warrant liability*	9,204	(460)	460

<b>Total impact on net loss</b>	<b>decrease/(increase)</b>	1,223	(1,223)
---------------------------------	----------------------------	-------	---------

\* Includes current and non-current portions.

## **Table of Contents**

For the year ended December 31, 2011, we were not a party to any forward-exchange contracts, and no forward-exchange contracts were outstanding as at March 27, 2012.

### **Liquidity Risk**

Liquidity risk is the risk that we will not be able to meet our financial obligations as they become due. As indicated in the Capital Disclosures section above, 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.

### **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 have a minimum rating of A3 .

As at December 31, 2011, trade accounts receivable for an amount of approximately \$7,415,000 were with two external customers or partners.

As at December 31, 2011, 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.

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

We did not enter into transactions with any related parties during the year ended December 31, 2011.

As at December 31, 2011, we did not have any interests in variable interest entities or any other off-balance sheet arrangements.



**Table of Contents****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 27, 2012.

<b>Name and Place of Residence</b>	<b>Position with Aeterna Zentaris</b>
Aubut, Marcel Quebec, Canada	Director
Blake, Paul Pennsylvania, United States	Senior Vice President and Chief Medical Officer
Dorais, José P. Quebec, Canada	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 New York, United States	Director
Pelliccione, Nicholas New York, United States	Senior Vice President, Regulatory Affairs and Quality Assurance
Seeber, Matthias Frankfurt, Germany	Senior Vice President, Administration and Legal Affairs
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.

---

**Table of Contents**

*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, Sodiq 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. 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 member 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 Pouliot 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, Biochem Pharma and St-Luc Hospital in Montreal. He is now a member of the Board of Alliance Films Inc., Investissement Québec and 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*.

*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 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.

*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

**Table of Contents**

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 Algorithmme Pharma Inc. and Insy's Therapeutics Inc., a Phoenix Arizona based specialty pharma Co. 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 Montréal) in 1966, he wrote the CICA exams the same year (Honors: Governor General's 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 Vice-chairman 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) and Hart Stores Inc. (TSXV). He is also a board member of various private companies and charities. Mr. Limoges became an FCA 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* since 2006, and holds an LL.B. (2004) degree from Université de Montréal.

*Michael Meyers, M.P.H.* 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, prior to his departure, 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.

---

**Table of Contents**

*Matthias Seeber* was appointed our Senior Vice President, Administration and Legal Affairs in December 2008. Mr. Seeber served as Managing Director of AEZS Germany since July 2003 up to his most recent appointment. Prior to that, he had assumed the position of Investor Relations Manager of Altana AG, following several years in the banking industry with Deka Investment Management and Dresdner Bank AG. Mr. Seeber is a member of the Deutsche Vereinigung für Finanzanalyse und Asset Management (DVFA/CEFA). He obtained his M.B.A. from George Mason University Graduate School of Business Administration in the United States.

*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 has been a member of the *Barreau du Québec* since 2000. 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, 2011: 1.000 = US\$1.3919 and CAN\$1.000 = US\$1.0111; for the financial year ended December 31, 2010: 1.000 = US\$1.326 and CAN\$1.000 = US\$0.970; and for the financial year ended December 31, 2009: 1.000 = US\$1.388 and CAN\$1.000 = US\$0.876.

**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 (the Governance Committee). The Governance Committee is composed of three (3) directors, each of whom is independent, namely Messrs. José P. Dorais (Chair), Juergen Ernst and Gérard Limoges. One of the members of the Governance Committee, Juergen Ernst, is 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, 2011.

**Table of Contents****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 ) as described in the table below.

Type of Compensation	Annual compensation for the year 2011 (in units of home country currency)
Chairman's Retainer	45,000
Vice Chairman's Retainer <sup>(1)</sup>	15,000
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
Governance Committee Chair Retainer	12,000
Governance Committee Member Retainer	2,000
Governance Committee Meeting Attendance Fees	1,000

(1) There is currently no Vice Chairman of the Board.

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. Therefore, he 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**

**Table of Contents**

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, 2011:

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
	(mm-dd-yyyy)	(#)	(CAN\$ or US\$)	(mm-dd-yyyy)	(CAN\$ or US\$)	(mm-dd-yyyy)	(#)
Aubut, Marcel	12-16-2002	15,000	CAN\$3.68	12-15-2012			
	12-11-2003	30,000	CAN\$1.74	12-10-2013			
	12-14-2004	15,000	CAN\$5.83	12-13-2014			
	12-13-2005	15,000	CAN\$3.53	12-12-2015			
	01-04-2007	5,000	CAN\$4.65	01-03-2017			
	12-11-2007	25,000	CAN\$1.82	12-10-2017			
	12-08-2008	15,000	CAN\$0.55	12-08-2018	CAN\$15,150		
	12-09-2009	20,000	CAN\$0.95	12-08-2019	CAN\$12,200		
	12-08-2010	30,000	CAN\$1.52	12-07-2020	CAN\$1,200		
	12-07-2011	50,000	US\$1.74	12-06-2021			
Dorais, José P.	12-08-2010	30,000	CAN\$1.52	12-07-2020	CAN\$1,200		
	12-07-2011	50,000	US\$1.74	12-06-2021			
Ernst, Juergen	02-25-2005	15,000	CAN\$5.09	02-24-2015			
	12-13-2005	15,000	CAN\$3.53	12-12-2015			
	01-04-2007	5,000	CAN\$4.65	01-03-2017			
	12-11-2007	25,000	CAN\$1.82	12-10-2017			
	11-14-2008	100,000	CAN\$0.65	11-13-2018	CAN\$91,000		
	12-08-2008	15,000	CAN\$0.55	12-08-2018	CAN\$15,150		
	12-09-2009	20,000	CAN\$0.95	12-08-2019	CAN\$12,200		
	12-08-2010	30,000	CAN\$1.52	12-07-2020	CAN\$1,200		
12-07-2011	50,000	US\$1.74	12-06-2021				
Lapalme, Pierre	12-09-2009	20,000	CAN\$0.95	12-08-2019	CAN\$12,200		
	12-08-2010	30,000	CAN\$1.52	12-07-2020	CAN\$1,200		
	12-07-2011	50,000	US\$1.74	12-06-2021			
Limoges, Gérard	12-14-2004	15,000	CAN\$5.83	12-13-2014			
	12-13-2005	15,000	CAN\$3.53	12-12-2015			
	01-04-2007	5,000	CAN\$4.65	01-03-2017			
	12-11-2007	25,000	CAN\$1.82	12-10-2017			
	12-08-2008	15,000	CAN\$0.55	12-08-2018	CAN\$15,150		
	12-09-2009	20,000	CAN\$0.95	12-08-2019	CAN\$12,200		
	12-08-2010	30,000	CAN\$1.52	12-07-2020	CAN\$1,200		
	12-07-2011	50,000	US\$1.74	12-06-2021			
Meyers, Michael	05-27-2011	20,000	US\$2.36	05-26-2021			
	12-07-2011	40,000	US\$1.74	12-06-2021			

(1) The number of securities underlying unexercised options represent all awards outstanding as at December 31, 2011.

(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 30, 2011) of CAN\$1.56 and US\$1.54, 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).



**Table of Contents****Total Compensation of Outside Directors**

The table below summarizes the total compensation earned by the Outside Directors during the financial year ended December 31, 2011 (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>	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)
Abut, Marcel	15,166	4,044		63,000				82,210
Dorais, José P. <sup>(4)</sup>	27,298	8,088		63,000			506	98,892
Ernst, Juergen	86,299	9,743		63,000			5,568	164,610
Lapalme, Pierre	19,210	9,099		63,000				91,309
Limoges, Gérard <sup>(5)</sup>	32,354	11,122		63,000				106,476
MacDonald, Pierre <sup>(6)</sup>	11,883	3,033					506	15,422
Meyers, Michael <sup>(7)</sup>	13,250	4,500		85,800			500	104,050

(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 at the date of grant (US\$1.74 for options granted on December 7, 2011 and US\$2.36 for options granted to Michael Meyers on May 27, 2011) multiplied by the Black-Scholes factor as at such date (72.41% for options granted on December 7, 2011 and 75.00% for options granted to Michael Meyers on May 27, 2011) 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) José P. Dorais was appointed Chairman of the Governance Committee on May 18, 2011.

(5) Gérard Limoges has been a member of the Governance Committee since May 18, 2011.

(6) Pierre MacDonald was a director of the Company from 2001 to May 18, 2011. He did not stand for re-election as director at the annual and special meeting of shareholders held on May 18, 2011 and therefore ceased to be a director as of such date.

(7) Michael Meyers was appointed director on March 22, 2011 and has been a member of the Audit Committee since May 18, 2011.

During the financial year ended December 31, 2011, the Company paid an aggregate amount of \$262,169 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 2011.

## 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 required to provide its shareholders with a fair return. However, the executive compensation program should not encourage senior executives in taking 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 the Company and each 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.

## **Table of Contents**

### **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 metrics. The variable compensation elements (annual bonuses and stock options) are designed to reward both short and long-term performance. For short-term performance, an annual bonus is awarded based on the 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 (for 2011, such operational and corporate goals are listed in the table below). While the Company's bonus payments are generally based on annual results, their value is generally capped and represents only a portion of each individual's overall total compensation opportunities. Finally, a significant portion of the compensation provided to the Company's executive officers is in the form of equity awards under the long-term incentive compensation plan that further align executives' interests 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 since grants under the long-term incentive compensation plan are 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 it may determine to be appropriate in the circumstances.

**Table of Contents**

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 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, based on the Governance Committee's recommendation, set goals for the Company at the end of 2010, 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, for many of which the Named Executive Officers are responsible.

In December 2011, the Governance Committee determined that the Company's executive officers met or exceeded each of the objectives set forth in the table below as follows:

<b>Objectives for 2011</b>	<b>Results for 2011</b>
<b>Clinical</b>	
Advancement of product pipeline	
Perifosine	Completed recruitment of metastatic colorectal Phase 3 study (468 patients)
	Supported Phase 3 study in MM by opening several centres outside North America
AEZS-130	Reported positive Phase 3 data as diagnostic in AGHD
AEZS-108	Reported positive final Phase 2 data in endometrial cancer
	Initiated Phase 1/2 study in refractory bladder cancer in the United States
<b>Regulatory</b>	
Optimize regulatory strategy with lead authorities	Obtained parallel scientific advice for a pivotal study for AEZS-108 in endometrial cancer by both the Food and Drug Administration (FDA) and the EMA
<b>Business Development/Alliance Management:</b>	
Expand partner portfolio for Perifosine in non-core territories	Signed license agreements with Yakult (for Japan) and Hikma (for MENA region)
Ensure steady supply of Cetrotide® to Merck Serono	Exceeded pre-defined threshold of Cetrotide® sales triggering further milestone payment by Cowen Healthcare Royalty Partners, L. P.

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

Manage alliances with existing drug development and commercialization partners actively

Continued to maintain excellent relations with alliance partners

***Financial***

Pursue dilutive and non-dilutive financing alternatives to ensure year-end 2011 cash and cash equivalents in excess of \$30 million

Completed two successful At-the-Market Financings (ATMs) generating proceeds in excess of \$36 million

Closed further licensing agreements generating significant upfront payments

Cash and cash equivalents as of December 31, 2011 totalled \$46.9 million

**Table of Contents**

***Investor Relations***

Expand North American research analyst coverage	Initiation of coverage by several North American institutions including, among others, Oppenheimer & Co Inc., JMP Securities and Needham & Company LLC.
---	---

Continue to present at strategic healthcare conferences	Presented at several strategic healthcare and partnership conferences and continued to build the Company's investor base
---	--

***Human Resources***

Maintain high level of motivation at all levels (and sites) of the Company	Executed effective HR policy comprising both monetary (compensation) and non-monetary (training, etc.) components to ensure both short- and long-term commitment of personnel while generally aligning employee's and shareholders' interests
--	---

Maintained HR-attrition policy while progressing development pipeline (active headcount virtually unchanged as compared to the prior year)

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.

**Table of Contents****Benchmarking**

In order to attain our objectives of providing market competitive compensation opportunities, our 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 of other companies that the Company competes for executive talent (the Reference Group). We did not, however, pay AON Consulting any fee or other remuneration in 2011. 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	27.70 <sup>(1)</sup>	57.02 <sup>(2)</sup>
<b>Market Capitalization</b>		
As at October 31, 2011	175.07	290.34
<b>Net Loss</b>		
Last fiscal year	23.22 <sup>(1)</sup>	19.82 <sup>(2)</sup>

(1) For the year ended December 31, 2010, as presented in our 2010 audited consolidated financial statements, which were presented in conformity with Canadian GAAP.

(2) The Reference Group for the financial year ended December 31, 2011 was selected in October 2011 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, 2011 was composed of the following companies: Acadia Pharmaceuticals Inc.; Acorda Therapeutics Inc.; Array Biopharma Inc.; BioSanté Pharmaceuticals, Inc.; Cell Therapeutics Inc.; Enzon Pharmaceuticals Inc.; Genomic Health Inc.; Ista Pharmaceuticals Inc.; Ligand Pharmaceuticals Inc.; Neurocrine Biosciences Inc.; Nps Pharmaceuticals Inc.; OncoGenex Pharmaceuticals Inc.; Onyx Pharmaceuticals, Inc.; Salix Pharmaceuticals Ltd; Savient Pharmaceuticals Inc.; and Xoma Ltd.

**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 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 our success and to ensure competitive compensation, in order that we may benefit from the expertise required to pursue our objectives.

Our 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 company 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.

Our current executive compensation program is comprised of the following four basic components:

- (i) base salary;
- (ii) non-equity incentives consisting of a cash bonus linked to both individual and corporate performance;
- (iii) long-term compensation consisting of our stock option plan established for the benefit of our directors, executive officers and employees (the Stock Option Plan ); and

---

**Table of Contents**

(iv) other elements of compensation consisting of benefits, perquisites and retirement benefits.

*Base Salary*

Salaries of our executive officers are established 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 our corporate objectives as well as the individual performance of the executive.

*Short-Term Non-Equity Incentive Compensation*

The short-term non-equity incentive compensation plan sets out the allocation of incentive awards based on the financial results and the advancement of the Company's product pipeline and 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, 2011, the Governance Committee recommended, and the Board approved, in the best interests of the Company, that, to the extent earned, a maximum of 70% of an executive officers' maximum bonus be paid in cash in respect of the year 2011 (paid in early 2012), while the remainder of any earned bonus be payable in the form of stock options (as had been done in 2010 as to 50% of any earned bonus and in 2009 as to 100% of any earned bonus), whereby US\$1.00 generally equals one stock option, as adjusted based on each senior executive's individual performance, such that, on a dollar-for-dollar basis, the US\$ amount of the non-cash bonus 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, in order to allow these grants to serve their purpose as partial replacement for annual cash bonuses. For the Company's European executives, the number of options was grossed-up by a multiple of 1.35 to reflect the then prevailing US\$ to exchange rate. See Summary of the Stock Option Plan below for more details on the Stock Option Plan.

In making decisions related to the short-term non-equity 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 2011, as described in Section Risk Assessment of Executive Compensation Program .

Mr. Turpin's 2011 goals were aligned with the Company's overall objectives, with an emphasis on supporting attainment of the financial objectives. Based upon results achieved, the Governance Committee determined that Mr. Turpin's individual performance exceeded expectations as follows: completed two successful At-the-Market Financings (ATMs) generating proceeds in excess of \$36 million as a consequence of which the Company completed 2011 with cash and cash equivalents exceeding significantly the budget amount, and contributed significantly to the achievement of the Company's various goals set in the area of Investor Relations. The Compensation Committee determined that Mr. Turpin's contributions to the achievement of the Company's goals merited a cash bonus in an amount of \$80,509 and an equity-based bonus in an amount of \$34,125 paid through the granting of 34,125 stock options based on 2011 performance.



---

**Table of Contents**

Mr. Seeber's 2011 goals were aligned with the Company's overall objectives, with an emphasis on the achievement of the Company's strategic milestones. Based upon results achieved, the Governance Committee determined that Mr. Seeber's individual performance contributed significantly to the achievement of the Company's various strategic milestones, including in respect of the various goals set in the areas of Business Development/Alliance Management and Human Resources. The Governance Committee determined that Mr. Seeber's contributions to the achievement of the Company's goals merited a cash bonus in an amount of \$82,818 and an equity-based bonus in an amount of \$34,425 paid through the granting of 34,425 stock options based on 2011 performance.

Dr. Blake's 2011 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. Based upon results achieved, the Governance Committee determined that Mr. Blake'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 lead authorities. The Governance Committee determined that Mr. Blake's contributions to the achievement of the Company's goals merited a cash bonus in an amount of \$89,670 and an equity-based bonus in an amount of \$38,430 paid through the granting of 38,430 stock options based on 2011 performance.

Mr. Pellicione's 2011 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. Based upon results achieved, the Governance Committee determined that Mr. Pellicione'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 lead authorities. The Governance Committee determined that Mr. Pellicione's contributions to the achievement of the Company's goals merited a cash bonus in an amount of \$77,739 and an equity-based bonus in an amount of \$33,316 paid through the granting of 33,316 stock options based on 2011 performance.

For the financial year ended December 31, 2011, cash bonuses paid to all of our executive officers under our short-term non-equity incentive compensation plan represented 70% of the target payout established by the Governance Committee under such plan. Similarly, stock options granted to our executive officers under the same short-term non-equity incentive compensation plan, in partial replacement of the remainder of any earned cash bonuses, represented 30% of the target payout 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 generally vest over a period of three years, with the first one-third to vest on the one-year anniversary of the date of grant; however, as mentioned in the section above, the vesting schedule for certain of the options granted to senior executives in the financial years ended December 2011, 2010 and 2009 was accelerated from three years to 18 months since the grants were intended to serve as a partial replacement for a certain portion of earned cash bonuses. Stock options are usually granted to executive officers in December of each year.

For the financial year ended December 31, 2011, the Governance Committee recommended, and the Board approved, in the best interests of the Company, that stock options be granted to executive officers under the long-term equity compensation plan, such stock options to vest according to the vesting schedule set forth in the Company's Stock Option Plan. The Governance Committee considered the performance of the Company and each executive in determining the appropriate level of equity incentive opportunity granted to each executive officer under the long-term equity compensation program in 2011. The Company and the Governance Committee believe that an equitable granting of stock options to senior executives is an important element of the Company's overall compensation philosophy with a view to ensuring that senior management works to ensure the long-term success and viability of the Company's business, particularly in light of the length of time required for a biopharmaceutical company such as Aeterna Zentaris to advance its product pipeline from pre-clinical to clinical through the commercialization stages of development.

**Table of Contents**

Based on the foregoing, the Governance Committee approved stock option awards as part of the long-term incentive compensation plan to each NEO on December 7, 2011 as follows:

<b>Named Executive Officer</b>	<b>Stock Options</b>	
	<b>Number granted</b>	<b>Exercise price</b>
Engel, Juergen	200,000	US\$1.74
Turpin, Dennis	70,000	US\$1.74
Seeber, Matthias	70,000	US\$1.74
Blake, Paul	70,000	US\$1.74
Pelliccione, Nicholas J.	70,000	US\$1.74

**Summary of the Stock Option Plan**

We established the Stock Option Plan in order to attract and retain directors, executive officers and employees, 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.

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).

## Table of Contents

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.

**Table of Contents**

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.

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 27, 2012, represented 12,401,760 common shares. There are currently 7,497,634 options outstanding under the Stock Option Plan representing approximately 6.9% of all issued and outstanding common shares. Under the Stock Option Plan, (i) 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, 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.

**Outstanding Option-Based Awards and Share-Based Awards**

The following table shows all awards outstanding to each of our Company's President and Chief Executive Officer, the Chief Financial Officer and our three (3) other most highly compensated executive officers of the Company during the most recently completed financial year (collectively, the Named Executive Officers) as at December 31, 2011:

Name	Issuance Date (mm-dd-yyyy)	Option-based Awards				Share-based Awards		
		Number of Securities Underlying Unexercised Options <sup>(1)</sup> (#)	Option Exercise Price (CAN\$ or US\$)	Option Expiration Date (mm-dd-yyyy)	Value of Unexercised In-the-money Options <sup>(2)</sup> (CAN\$ or US\$)	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 (\$)
Engel, Juergen	02-20-2003	60,000	CAN\$2.43	12-31-2012				

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

12-11-2003	60,000	CAN\$1.74	12-10-2013	
12-14-2004	100,000	CAN\$5.83	12-13-2014	
12-13-2005	50,000	CAN\$3.53	12-12-2015	
01-04-2007	50,000	CAN\$4.65	01-03-2017	
12-11-2007	50,000	CAN\$1.82	12-10-2017	
11-14-2008	200,000	CAN\$0.65	11-13-2018	CAN\$182,000
12-08-2008	75,000	CAN\$0.55	12-08-2018	CAN\$75,750

**Table of Contents**

Name	Issuance Date (mm-dd-yyyy)	Option-based Awards				Share-based Awards		
		Number of	Option	Option	Value of	Issuance	Number of	Market or
		Securities	Exercise	Expiration	Unexercised	Date	Shares or	Payout
		Underlying	Price	Date	In-the-money		Units of	Value of
		Unexercised		(mm-dd-yyyy)	Options <sup>(2)</sup>		shares that	Share-based
Options <sup>(1)</sup>					have Not	Awards that		
		(#)	(CAN\$ or US\$)		(CAN\$ or US\$)	Vested	have Not Vested	
						(#)	(\$)	
Turpin, Dennis	12-09-2009	165,000	CAN\$0.95	12-08-2019	CAN\$100,650			
	12-08-2010	222,750	CAN\$1.52	12-07-2020	CAN\$8,910			
	12-07-2011	267,000	US\$1.74	12-06-2021				
	11-01-2002	90,000	CAN\$0.94	10-31-2012	CAN\$55,800			
	12-16-2002	50,000	CAN\$3.68	12-15-2012				
	12-11-2003	60,000	CAN\$1.74	12-10-2013				
	12-14-2004	90,000	CAN\$5.83	12-13-2014				
	12-13-2005	50,000	CAN\$3.53	12-12-2015				
	01-04-2007	50,000	CAN\$4.65	01-03-2017				
	12-11-2007	50,000	CAN\$1.82	12-10-2017				
Blake, Paul	12-09-2009	115,000	CAN\$0.95	12-08-2019	CAN\$70,150			
	12-08-2010	56,850	CAN\$1.52	12-07-2020	CAN\$2,274			
	12-07-2011	104,125	US\$1.74	12-06-2021				
	07-27-2007	45,000	US\$3.05	07-26-2017				
	12-11-2007	50,000	US\$1.82	12-10-2017				
	12-08-2008	50,000	CAN\$0.55	12-08-2018	CAN\$50,500			
	12-09-2009	110,000	CAN\$0.95	12-08-2019	CAN\$67,100			
Seeber, Matthias	12-08-2010	64,050	CAN\$1.52	12-07-2020	CAN\$2,562			
	12-07-2011	108,430	US\$1.74	12-06-2021				
	02-20-2003	15,000	CAN\$2.43	12-31-2012				
	12-11-2003	45,000	CAN\$1.74	12-10-2013				
	12-14-2004	50,000	CAN\$5.83	12-13-2014				
	12-13-2005	40,000	CAN\$3.53	12-12-2015				
	01-04-2007	30,000	CAN\$4.65	01-03-2017				
	12-11-2007	25,000	CAN\$1.82	12-10-2017				
	12-08-2008	30,000	CAN\$0.55	12-08-2018	CAN\$30,300			
	12-09-2009	46,667	CAN\$0.95	12-08-2019	CAN\$28,467			
Pelliccione, Nicholas J.	12-08-2010	51,975	CAN\$1.52	12-07-2020	CAN\$2,079			
	12-07-2011	104,425	US\$1.74	12-06-2021				
	05-07-2007	25,000	US\$3.96	05-06-2017				
	12-11-2007	50,000	US\$1.82	12-10-2017				
	12-08-2008	20,000	CAN\$0.55	12-08-2018	CAN\$20,200			
	12-09-2009	60,000	CAN\$0.95	12-08-2019	CAN\$36,600			
	12-08-2010	50,000	CAN\$1.52	12-07-2020	CAN\$2,000			
12-07-2011	103,316	US\$1.74	12-06-2021					

(1) The number of securities underlying unexercised options represents all awards outstanding at December 31, 2011.

(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 30, 2011) of CAN\$1.56 and US\$1.54, respectively, and the exercise price of the options, multiplied by the number of unexercised options.

There are no vested share-based awards that have not yet been paid out or distributed.

**Table of Contents****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, 2011.

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	251,776		160,764
Turpin, Dennis	73,461		80,509
Seeber, Matthias	83,158		82,818
Blake, Paul	92,499		89,670
Pelliccione, Nicholas J.	52,840		77,739

(1) The amount 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.

**Other Forms of Compensation***Benefits and Perquisites*

Our 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*

One of our Named Executive Officers, namely 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 during the first five working years after initial participation in this plan and increase by 0.4% for each additional year of employment.

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 and/or children 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.



**Table of Contents**

**Defined Benefit Plans Table as at December 31, 2011**

Name	Number of years of credited service	Annual benefits payable		Accrued obligation at start of year	Compensatory change	Non- compensatory change	Accrued obligation at year end
		At year end	At age 65				
	(#)	(\$) <sup>(1)</sup>	(\$) <sup>(1)</sup>	(\$)	(\$) <sup>(1)</sup>	(\$)	(\$) <sup>(1)(2)</sup>
Engel, Juergen	34	202,755	202,755	3,323,028	549,986	(103,977)	3,569,399

(1) By way of exception to other currency conversions in this Circular, all amounts in the above table have been converted from euros to US\$ based on the exchange rate on December 31, 2011, which was 1.000 = US\$1.2972.

(2) The figure in the column Accrued obligation at year end was further reduced by an amount of \$199,638 representing mandatory pension payments made to Dr. Engel during 2011.

*Employer Contribution to Employees Retirement Plan*

In 2008, the Board approved a plan whereby we would contribute to our 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 employees under 50 years old. The plan also includes a contribution for employees over 50 years old up to a maximum of \$10,250 for Canadian employees and \$11,000 for those in the United States. Employees based in Frankfurt, Germany also benefit from certain employer contributions into the employees pension funds (DUPK/RUK). Our executive officers, including the Named Executive Officers, are eligible to participate in the aforementioned employer-contribution plans to the same extent and in the same manner as all of our other employees.

*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 the financial years ended December 31, 2011, 2010 and 2009.

**Table of Contents****SUMMARY COMPENSATION TABLE**

Name and principal position	Years	Salary	Share based awards	Option based awards <sup>(1)</sup>	Non-equity incentive		Pension Value	All other compensation <sup>(2)</sup>	Total compensation
					Annual incentive	Long-term incentive			
		(\$)	(\$)	(\$)	plan (\$)	plans (\$)	(\$)	(\$)	(\$)
Engel, Juergen	2011	505,260		336,420	160,764		590,136	214,212 <sup>(3)</sup>	1,806,792
	2010	419,348 <sup>(4)</sup>		265,763	109,395		34,605	68,593 <sup>(5)</sup>	897,704
President and CEO	2009	458,040		79,497			431,110	3,209 <sup>(6)</sup>	971,856
Turpin, Dennis	2011	332,434		131,198	80,509			5,056	549,197
	2010	309,978 <sup>(4)</sup>		67,828	55,169			7,518 <sup>(7)</sup>	440,493
Senior Vice President									
and CFO	2009	284,700		55,407					340,107
Seeber, Matthias	2011	342,512		131,576	82,818			56,966 <sup>(6)</sup>	613,872
	2010	288,162 <sup>(4)</sup>		62,011	51,051			38,217 <sup>(6)</sup>	439,441
Senior Vice President,									
Administration and									
Legal Affairs	2009	306,748		55,407				54,300 <sup>(6)</sup>	416,455
Blake, Paul	2011	370,223		136,622	89,670			11,000 <sup>(8)</sup>	607,515
	2010	359,876 <sup>(4)</sup>		76,418	64,050			11,000 <sup>(8)</sup>	511,344
Senior Vice President									
and Chief Medical									
Officer	2009	366,000		52,998				10,250 <sup>(8)</sup>	429,248
Pelliccione, Nicholas J.	2011	321,062		130,178	77,739			11,000 <sup>(8)</sup>	539,979
	2010	311,992 <sup>(4)</sup>		59,655	50,001			11,000 <sup>(8)</sup>	432,648
Senior Vice President Regulatory Affairs and Quality Assurance	2009	317,300		28,908				8,250 <sup>(8)</sup>	354,458

- (1) The value of the option-based awards represents the closing price of the common shares on NASDAQ at the date of grant (US\$1.74 for options granted on December 7, 2011, CAN\$1.52 equivalent to US\$1.47 for options granted on December 8, 2010, and CAN\$0.95 equivalent to US\$0.83 for options granted on December 9, 2009) multiplied by the Black-Scholes factor as at such date (72.414% for options granted on December 7, 2011, 80.921% for options granted on December 8, 2010, and 57.895% for options granted on December 9, 2009) 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, 2011. 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 (3) and note (5) below.
- (3) Represents mandatory pension payments made to Dr. Engel during 2011.
- (4) In 2010, the Named Executive Officers agreed to a voluntary reduction in salary between May 1, 2010 and August 31, 2010.
- (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 Pension Plan, above.
- (6) Represents DUPK/RUK (Germany) employer contributions to Dr. Engel's and Mr. Seeber's retirement savings plans.
- (7) Represents RRSF employer contribution to Mr. Turpin's retirement savings plan.
- (8) Represents 401(k) employer contributions to Messrs. Blake's and Pelliccione's retirement savings plans.

*Compensation of the Chief Executive Officer*

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

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 2011 was \$505,260, which places him approximately 1.03 times the 50<sup>th</sup> percentile in relation to the companies in the Reference Group.

---

## **Table of Contents**

Based upon the results attained versus established goals for fiscal 2011, as described in Section Short-Term Non-Equity Incentive Compensation the Governance Committee determined that the individual performance of Prof. Dr. Engel exceeded expectations in a number of key strategic areas, including in respect of the various goals set in the areas of Business Development and Investor Relations. See Section Risk Assessment of Executive Compensation Program above for more details on such goals.

Based on the foregoing, the Governance Committee recommended, and the Board approved, in the best interests of the Company given its financial situation, and in light of the Company's and the CEO's performance in 2011 as well as the fact that in the previous two years, the payment of cash bonuses was limited, that a maximum of 70% of the CEO's bonus under the short-term incentive plan be paid in cash in respect of the year 2011 (paid in early 2012), while the remainder of the bonus be payable in the form of stock options based on his individual performance. Thus, Prof. Dr. Engel received 70% of his target cash bonus for 2011, amounting to \$160,764, for his performance in the context of the Company's objectives and was awarded a grant of 67,000 stock options on December 7, 2011 (at an exercise price of US\$1.74) for his exceptional performance in leading the Company to attain its objectives in 2011. The terms of such stock options grant provide for accelerated vesting conditions, in order to allow these stock options to serve their purpose as a partial replacement for the remaining 30% of the CEO's 2011 bonus that would otherwise have been paid in cash. See Section Short-Term Non-Equity Incentive Compensation above for more details on such grants.

For the financial year ended December 31, 2011, the Governance Committee also recommended, and the Board approved, that 200,000 stock options be granted to the President and Chief Executive Officer under the long-term equity compensation plan, such stock options to vest in accordance with the vesting schedule set forth in the Company's Stock Option Plan. See Section Long-Term Equity Compensation Plan of Executive Officers Summary of the Stock Option Plan, for a complete description of our Stock Option Plan.

### ***C. Board Practices***

Our Articles provide that our Board shall be composed of a minimum of five and a maximum of fifteen 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.

**Table of Contents**

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 and Gérard Limoges.

**D. Employees**

As at March 1, 2012, we had a total of 89 Full Time Equivalent ( FTE ) (as compared to 87.8 at March 1, 2011 and 99 at March 1, 2010), of which 75.3 are based in Frankfurt, Germany, 5 in New Jersey, United States, and 8.7 in Quebec City, Canada. Of these, 53 are involved in discovery, preclinical, clinical and pharmaceutical development, 9 are involved in regulatory affairs, quality assurance and intellectual property, and 27 are involved in business operations, communications, finance, information technology, human resources, project management and legal affairs. We have agreements with all of our employees covering confidentiality and 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 March 27, 2012:

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	112,500	*	220,000	143,334
Paul Blake	70,350	*	427,480	297,700
José P. Dorais	0	*	80,000	10,000
Juergen Engel	117,779	*	1,299,750	958,500
Juergen Ernst	58,850	*	275,000	198,334
Pierre Lapalme	0	*	100,000	23,334
Gérard Limoges	9,000	*	175,000	98,334
Michael Meyers	0	*	60,000	0
Nicholas J. Pelliccione	27,750	*	308,316	188,334
Matthias Seeber	0	*	438,067	316,317
Dennis Turpin	21,250	*	715,975	592,900
<b>Total</b>	<b>417,479</b>	<b>0.38</b>	<b>4,099,588</b>	<b>2,827,087</b>

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

\* Less than 1%

(1) Based on 108,787,366 common shares outstanding as at March 27, 2012.

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

**Table of Contents**

**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 SEC and the Canadian securities regulatory authorities, as at March 27, 2012, there are no 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.

**United States Shareholders**

As at December 31, 2011, there were a total of 219 holders of record of our common shares, of which 9 were registered with addresses in the United States holding in the aggregate approximately 50.02% 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 a large portion 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 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.

**Item 9. The Offering and Listing**

**A. Offer and listing details**

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

**Table of Contents**

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
2011	2.58	1.43	2.51	1.41
2010	2.09	0.79	2.14	0.80
2009	2.83	0.46	3.11	0.57
2008	1.80	0.40	1.85	0.44
2007	4.36	1.46	5.10	1.47
<b>2009</b>				
Fourth quarter	1.25	0.80	1.40	0.83
Third quarter	2.83	0.89	3.11	0.97
Second quarter	2.35	0.89	2.63	1.06
First quarter	0.97	0.46	1.25	0.57
<b>2010</b>				
Fourth quarter	1.96	1.22	1.98	1.22
Third quarter	1.40	0.95	1.44	1.00
Second quarter	2.09	0.80	2.14	0.80
First quarter	0.93	0.79	0.99	0.81
<b>2011</b>				
Fourth quarter	1.78	1.43	1.80	1.47
Third quarter	2.35	1.43	2.26	1.41
Second quarter	2.58	1.82	2.51	1.75
First quarter	2.00	1.55	1.93	1.54
<b>Most recent 6 months</b>				
March 2012 <sup>(1)</sup>	2.15	1.69	2.13	1.67
February 2012	1.83	1.58	1.84	1.58
January 2012	1.71	1.56	1.78	1.58
December 2011	1.78	1.51	1.80	1.54
November 2011	1.76	1.46	1.80	1.50
October 2011	1.75	1.43	1.72	1.47
September 2011	1.99	1.48	1.98	1.54

(1) Up to and including March 26, 2012

**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.

## **Table of Contents**

### ***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 *Canada Business Corporations Act* (the CBCA ) and by its bylaws (the bylaws ). The Company s Restated Articles of Incorporation are on file with the Corporations Directorate of Industry Canada under Corporation Number 264271-9. The Restated Articles of Incorporation 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 of the Company have the right to inspect certain corporate records, including its Restated Articles of Incorporation 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 fifteen. 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. For as long as the Company is a company that publicly distributes its securities, at least two-thirds of its directors must not be officers or employees of the Company or its subsidiaries. None of the Restated Articles of Incorporation, the bylaws and the CBCA imposes any mandatory retirement requirements for directors.

---

**Table of Contents**

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 Restated Articles of Incorporation 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 Restated Articles of Incorporation 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 Restated Articles of Incorporation. However, the Company's bylaws and Restated Articles of Incorporation do not contain any restrictions on or variations of these borrowing powers.



---

## **Table of Contents**

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 Restated Articles of Incorporation 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 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 27, 2012, there were 108,787,366 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.

## **Table of Contents**

### **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**

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

The fundamental objectives of the Company's Shareholder Rights Plan (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.

## **Table of Contents**

### *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.

---

**Table of Contents**

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) 2 1/2% 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.



---

## **Table of Contents**

### *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 ).

## **Table of Contents**

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 (subject to the approval of the resolution by the shareholders at the Meeting and reconfirmation at the first annual meeting of shareholders of the Company following March 29, 2013 (being the third 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.

## **Table of Contents**

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

In order to change the rights of its shareholders, the Company would need to amend its Restated Articles of Incorporation 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 Restated Articles of Incorporation 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 exercises control or direction over directly or indirectly, 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.

**Table of Contents**

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 or holders 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 Restated Articles of Incorporation 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.

**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\$330 million (for 2012). 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

---

## **Table of Contents**

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\$330 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 grants of stock options which will be reviewed annually in accordance with our policies. 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 Messrs. Pelliccione and Seeber, 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 Named Executive Officer shall not, directly or indirectly, solicit any of our customers for the purpose or intent of selling them any products which are similar to or otherwise competing with our products; nor shall any Named Executive Officer induce, entice or otherwise attempt to directly or indirectly hire or engage any of our employees, for a period equal to one year following such executive's termination of employment with the Company.

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.

---

**Table of Contents**

The Change of Control Payments are as follows:

for Dr. Engel and Mr. Seeber, (i) the equivalent of 24 months of their then prevailing annual base salaries, (ii) an amount equivalent to twice 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 24 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;

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 Mr. 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.

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.

---

## **Table of Contents**

### **Other Material Contracts**

#### **Cetrotide®**

In November 2008, we signed a definitive agreement to sell to CHRP 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 CHRP (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 CHRP 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 CHRP in an amount ranging from \$5 million up to \$15 million.

#### **Perifosine**

We are party to a license and collaboration agreement with Keryx. Under the terms of this agreement, Keryx undertakes, at its own cost, all development activities necessary to obtain regulatory and marketing approvals of perifosine, a signal transduction inhibitor, for all uses in the United States, Canada and Mexico. The agreement provides for, among other things, the availability of data generated by both parties free of charge. In September 2002, we received an upfront payment of approximately \$0.5 million and are eligible to receive payments of up to an aggregate of \$18.3 million upon Keryx's successful achievement of clinical development and regulatory milestones, in addition to scale-up royalties (from high single to low double-digit) on future net sales in the United States, Canada and Mexico. The license and collaboration agreement terminates upon the later of the expiration of all underlying patent rights or ten years from the first commercial sale of perifosine in any of the covered territories. In addition, Keryx may, at its option, terminate the agreement with respect to a country in the covered territories or as to the entire agreement at any time by giving written notice to us. Upon such termination, the license shall terminate and Keryx shall pay us any accrued amounts payable under the agreement. The agreement may also be terminated for material breach by the other party and in the certain events of bankruptcy or insolvency of the other party.

On March 8, 2011, we entered into an agreement with Yakult for the development, manufacture and commercialization of perifosine in all human uses, excluding leishmaniasis, in Japan. Under the terms of this agreement, Yakult has made an initial non-refundable upfront payment to us of 6.0 million (approximately \$8.4 million). Also per the agreement, we will be entitled to receive up to a total of 44.0 million (approximately \$57.1 million) upon achieving certain pre-established milestones, including clinical and regulatory events in Japan. Furthermore, we will be entitled to receive double-digit royalties on future net sales of perifosine in the Japanese market. We have also agreed to supply perifosine to Yakult on a cost-plus-basis. In addition, under the agreement, we agreed to use commercially reasonable efforts to develop, manufacture and commercialize perifosine outside of Japan for specific indications, and Yakult is responsible for the development, registration and commercialization of perifosine in Japan. Either party may terminate the agreement for the material, uncured breach by the other party and in certain events of bankruptcy or insolvency of the other party.

#### ***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.



---

**Table of Contents**

***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 or a subsequent purchaser of such common shares 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.

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

---

**Table of Contents**

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.

---

**Table of Contents**

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. 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.

Material U.S. Federal Income Tax Considerations

The following discussion is a summary of 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 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 provisions of the Code) or to holders that may be subject to special rules under U.S. federal income tax law. 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 defined 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.

---

## **Table of Contents**

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. U.S. Holders should consult their tax advisors about the potential application of such laws and the application of the U.S. federal income tax rules summarized below to their particular situation. 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 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 if a valid election is in effect for it 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.

### ***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.

For taxable years beginning before January 1, 2013, dividends paid by the Company should be taxable to a non-corporate U.S. Holder at the special reduced rate normally applicable to long term capital gains, provided that certain conditions are satisfied. A U.S. Holder will not be able to claim the 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 percent 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 percent. 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.

---

**Table of Contents**

A U.S. Holder will generally be entitled, subject to certain limitations, 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. 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 foreign tax credit implications of the payment of Canadian taxes.

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 receives the dividend, regardless of whether such Canadian dollars are actually converted into U.S. dollars at that time. 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 or Other Taxable Disposition*

Subject to the PFIC rules discussed below, upon a sale 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 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. For taxable years beginning before January 1, 2013, the rates of taxation for long-term capital gains of non-corporate U.S. Holders are reduced compared to such rates thereafter provided that certain conditions are satisfied. 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.

The Company believes it was not a PFIC for the 2011 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 2012 taxable year and for any future taxable year.

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 class 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.

---

**Table of Contents**

U.S. Holders can avoid the interest charge described above by making a mark-to-market election with respect to the common shares, provided that common shares are marketable. The common shares will be marketable if they are regularly traded on a qualified exchange or other market. 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 and regularly traded on NASDAQ, which constitutes a qualified exchange. If the common shares 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 for prior taxable years. 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 for prior taxable years.

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 for any taxable year in which a U.S. Holder owns common shares but before a mark-to-market election is made, the interest charge rules described above will apply to any mark-to-market gain recognized in the year the election is made.

In some cases, a shareholder of a PFIC can avoid the interest charge and the other adverse PFIC consequences described above by making a qualified electing fund ( 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, 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.

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 a 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.

Under recently enacted 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 (on IRS Form 8621, which PFIC shareholders will be required to file with their income tax or information returns) relating to their ownership of common shares. Pursuant to Notice 2011-55, the IRS has suspended this new filing

---

**Table of Contents**

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 pre-existing 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).

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*

The proceeds of a sale or other disposition of common shares, as well as dividends paid or deemed paid with respect to common shares by a U.S. payor, 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 specified exceptions and future guidance, recently enacted U.S. tax legislation generally requires a U.S. Holder (that is an individual or, to the extent provided in future guidance, a domestic entity) to report 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) for taxable years beginning after March 18, 2010. 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

## **Table of Contents**

includes the Company's Management Information Circular for its annual meeting to be held on May 9, 2012 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, 2011 and our MD&A relating to these statements included elsewhere in this annual report. 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 .

Financial assets at FVTPL are comprised exclusively of the Company's short-term investment.

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, short-term investment, 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 have a minimum rating of A3 .

As at December 31, 2011, trade accounts receivable for an amount of approximately \$7,415,000 were with two external customers or partners.





**Table of Contents**

As at December 31, 2011, 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 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 our consolidated statements of comprehensive 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 \$1.43 to \$2.58 on NASDAQ and from C\$1.41 to C\$2.51 on the TSX during the twelve months ended December 31, 2011. Assuming the following variations of the market price of the Company's common shares over a 12-month period:

Market price variations of -10% and +10%

If these variations were to occur, the impact on the Company's net loss for warrant liability held at December 31, 2011 would be as follows:

	<b>Carrying amount</b>	<b>-10%</b>	<b>+10%</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
Warrant liability*	9,204	1,155	(1,174)
<b>Total impact on net loss decrease/(increase)</b>		1,155	(1,174)

\*Includes current and non-current portions.

*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 dollar exchange rates against the EUR could have a potentially significant impact on the Company's results of operations. The following variations are reasonably possible over a 12-month period:

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

Foreign exchange rate variation of -5% (depreciation of the EUR) and +5% (appreciation of the EUR) against the US\$, from a year-end rate of EUR1 = US\$1.2972.

**Table of Contents**

If these variations were to occur, the impact on the Company's net loss for each category of financial instruments held at December 31, 2011 would be as follows:

	Carrying amount \$	Balances denominated in US\$	
		-5% \$	+5% \$
Cash and cash equivalents	33,669	1,683	(1,683)
Warrant liability*	9,204	(460)	460
<b>Total impact on net loss decrease/(increase)</b>		1,223	(1,223)

\* Includes current and non-current portions.

**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.

---

**Table of Contents**

**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, 2011. 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, 2011.

**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, 2011.

**Attestation Report of the Independent Auditors**

The effectiveness of the Registrant's internal control over financial reporting as of December 31, 2011, has been audited by PricewaterhouseCoopers LLP, independent auditors, as stated in their report which is included under Item 18. Financial Statements .

---

**Table of Contents**

**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, 2011 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 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 Mr. 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 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, 2011 and 2010, the Registrant s principal accountant, PricewaterhouseCoopers LLP, billed \$650,460 and \$605,614, 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.

## **Table of Contents**

### ***B. Audit-related Fees***

During the financial years ended December 31, 2011 and 2010, the Registrant's principal accountant, PricewaterhouseCoopers LLP, billed \$76,822 and \$131,833, 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 expected adjustments related to the Registrant's transition to IFRS.

### ***C. Tax Fees***

During the financial years ended December 31, 2011 and 2010, the Registrant's principal accountant, PricewaterhouseCoopers LLP, billed \$50,282 and \$58,476, respectively, for services related to tax compliance, tax planning and tax advice.

### ***D. All Other Fees***

During the financial years ended December 31, 2011 and 2010, 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, 2011 and 2010, 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, 2011, 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.

**Table of Contents**

**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<sup>1</sup>/<sub>3</sub>% 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 is consistent with generally accepted business practices in Canada, the Registrant's country of domicile, and with the 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.



**Table of Contents**

**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 145 through 205.

144

**Table of Contents**

**Aeterna Zentaris Inc.**

Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended

December 31, 2011 and 2010

(in thousands of US dollars)

145

## **Table of Contents**

March 27, 2012

### **Independent Auditor's Report**

#### **To the Shareholders of Aeterna Zentaris Inc.**

We have completed integrated audits of Aeterna Zentaris Inc. and its subsidiaries' 2011 and 2010 consolidated financial statements and their internal control over financial reporting as at December 31, 2011. 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, 2011, December 31, 2010 and January 1, 2010 and the consolidated statement of comprehensive loss, changes in shareholders' equity and cash flows for the years ended December 31, 2011 and December 31, 2010, 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, 2011, December 31, 2010 and January 1, 2010 and its financial performance and its cash flows for the years ended December 31, 2011 and December 31, 2010 in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

#### **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, 2011, based on criteria established in *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

*PricewaterhouseCoopers LLP/s.r.l./s.e.n.c.r.l., Chartered Accountants*

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

*1250 René-Lévesque Boulevard West, Suite 2800, Montréal, Quebec, Canada H3B 2G4*

*T: +1 514 205 5000, F: +1 514 876 1502, [www.pwc.com/ca](http://www.pwc.com/ca)*

PwC refers to PricewaterhouseCoopers LLP, an Ontario limited liability partnership, which is a member firm of PricewaterhouseCoopers International Limited, each member firm of which is a separate legal entity.

---

## **Table of Contents**

### **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 appearing on Page 140 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 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, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by COSO.

Montréal, Québec, Canada

<sup>1</sup> Chartered accountant auditor permit No. 21323

**Table of Contents****Aeterna Zentaris Inc.**

## Consolidated Statements of Financial Position

(in thousands of US dollars)

	December 31, 2011 \$	December 31, 2010 \$	January 1, 2010 \$
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents (note 6)	46,881	31,998	38,100
Short-term investment (note 7)	-	1,934	-
Trade and other receivables (note 8)	8,325	5,421	3,549
Inventory (note 9)	3,456	3,311	4,415
Prepaid expenses and other current assets	1,477	1,145	2,407
	<b>60,139</b>	43,809	48,471
<b>Restricted cash (note 10)</b>	<b>806</b>	827	878
<b>Property, plant and equipment (note 11)</b>	<b>2,512</b>	3,096	4,358
<b>Other non-current assets</b>	<b>830</b>	803	528
<b>Identifiable intangible assets (note 12)</b>	<b>1,769</b>	3,299	4,127
<b>Goodwill (note 13)</b>	<b>9,313</b>	9,614	10,246
	<b>75,369</b>	61,448	68,608
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Payables and accrued liabilities (note 14)	12,257	10,260	11,845
Current portion of deferred revenues (note 5)	5,310	4,045	6,327
Income taxes (notes 5 and 22)	259	-	965
Current portion of long-term payable	59	60	57
	<b>17,885</b>	14,365	19,194
<b>Deferred revenues (note 5)</b>	<b>39,242</b>	39,052	45,919
<b>Warrant liability (note 15)</b>	<b>9,162</b>	13,412	1,664
<b>Long-term payable</b>	<b>29</b>	90	143
<b>Employee future benefits (note 19)</b>	<b>12,880</b>	11,533	12,021
<b>Provision and other non-current liabilities (note 16)</b>	<b>717</b>	571	507
	<b>79,915</b>	79,023	79,448
<b>SHAREHOLDERS DEFICIENCY</b>			
<b>Share capital (note 17)</b>	<b>101,884</b>	60,900	41,524
<b>Other capital</b>	<b>82,327</b>	81,091	79,943
<b>Deficit</b>	<b>(188,969)</b>	(160,567)	(132,307)
<b>Accumulated other comprehensive (loss) income</b>	<b>212</b>	1,001	-
	<b>(4,546)</b>	(17,575)	(10,840)
	<b>75,369</b>	61,448	68,608
Subsequent event (note 30)			

The accompanying notes are an integral part of these consolidated financial statements.

Approved by the Board of Directors

Juergen Ernst

Director

Gérard Limoges

Director

**Table of Contents****Aeterna Zentaris Inc.**

## Consolidated Statements of Changes in Shareholders' Deficiency

For the years ended December 31, 2011 and 2010

(in thousands of US dollars, except share data)

	Common shares				Accumulated other comprehensive income	
	(number of)*	Share capital	Other capital	Deficit	(loss)	Total
		\$	\$	\$	\$	\$
<b>Balance January 1, 2010</b>	<b>63,089,954</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	-	-	-	191	-	191
Comprehensive loss	-	-	-	(28,260)	1,001	(27,259)
Issuances pursuant to registered direct offerings, net of transaction costs (note 17)	19,917,075	18,391	-	-	-	18,391
Issuance pursuant to the exercise of warrants (note 15)	298,817	829	-	-	-	829
Issuance pursuant to the exercise of stock options (note 17)	124,068	156	(44)	-	-	112
Share-based compensation costs	-	-	1,192	-	-	1,192
<b>Balance December 31, 2010</b>	<b>83,429,914</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	-	-	-	(1,335)	-	(1,335)
Comprehensive loss	-	-	-	(28,402)	(789)	(29,191)
Share issuances in connection with At-the-Market drawdowns (note 17)	19,464,548	35,881	-	-	-	35,881
Share issuances pursuant to the exercise of warrants (note 15)	1,707,286	4,861	-	-	-	4,861
Share issuances pursuant to the exercise of stock options (note 17)	160,348	242	(97)	-	-	145
Share-based compensation costs	-	-	1,333	-	-	1,333
<b>Balance December 31, 2011</b>	<b>104,762,096</b>	<b>101,884</b>	<b>82,327</b>	<b>(188,969)</b>	<b>212</b>	<b>(4,546)</b>

\*Issued and paid in full

The accompanying notes are an integral part of these consolidated financial statements.





**Table of Contents****Aeterna Zentaris Inc.**

Consolidated Statements of Comprehensive Loss

For the years ended December 31, 2011 and 2010

(in thousands of US dollars, except share and per share data)

	Years ended December 31,	
	2011	2010
	\$	\$
<b>Revenues</b>		
Sales and royalties	31,306	24,857
License fees and other	4,747	2,846
	<b>36,053</b>	27,703
<b>Operating expenses (note 18)</b>		
Cost of sales	27,560	18,700
Research and development costs, net of refundable tax credits and grants	24,517	21,257
Selling, general and administrative expenses (notes 11 and 12)	16,170	12,552
	<b>68,247</b>	52,509
<b>Loss from operations</b>	<b>(32,194)</b>	(24,806)
Finance income (note 20)	6,239	1,800
Finance costs (note 20)	(8)	(5,445)
<b>Net finance income (costs)</b>	<b>6,231</b>	(3,645)
Loss before income taxes	(25,963)	(28,451)
Income tax expense (notes 5 and 22)	(1,104)	-
<b>Net loss</b>	<b>(27,067)</b>	(28,451)
<b>Other comprehensive (loss) income:</b>		
Foreign currency translation adjustments	(789)	1,001
Actuarial gain (loss) on defined benefit plans	(1,335)	191
<b>Comprehensive loss</b>	<b>(29,191)</b>	(27,259)

<b>Net loss per share (note 26)</b>		
Basic and diluted	(0.29)	(0.38)
<b>Weighted average number of shares outstanding (note 26)</b>		
Basic and diluted	94,507,988	75,659,410

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****Aeterna Zentaris Inc.**

## Consolidated Statements of Cash Flows

For the years ended December 31, 2011 and 2010

(in thousands of US dollars)

	Years ended December 31,	
	2011	2010
	\$	\$
<b>Cash flows from operating activities</b>		
Net loss	(27,067)	(28,451)
Items not affecting cash and cash equivalents		
Change in fair value of warrant liability (note 15)	(2,533)	5,437
Depreciation, amortization and impairment (notes 11 and 12)	2,876	1,573
Share-based compensation costs (note 17)	1,333	1,192
Non-cash consideration received in connection with an amended licensing agreement	-	(1,263)
Gain on held-for-trading financial instrument (note 7)	(1,278)	(687)
Employee future benefits (note 19)	492	249
Amortization of deferred revenues	(5,840)	(5,873)
Foreign exchange gain on items denominated in foreign currencies	(1,955)	(965)
(Gain) loss on disposal of property, plant and equipment	(26)	28
Amortization of prepaid and other non-cash items	4,207	4,587
Changes in operating assets and liabilities (note 21)	3,548	(7,539)
<b>Net cash used in operating activities</b>	<b>(26,243)</b>	<b>(31,712)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuances of common shares, net of cash transaction costs of \$1,204 in 2011 and \$1,506 in 2010 (note 17)	36,250	25,580
Proceeds from the exercise of share purchase warrants (note 15)	2,222	396
Proceeds from the exercise of stock options (note 17)	145	112
Repayment of long-term payable	(61)	(59)
<b>Net cash provided by financing activities</b>	<b>38,556</b>	<b>26,029</b>
<b>Cash flows from investing activities</b>		
Proceeds from the sale of short-term investment (note 7)	3,242	-
Purchase of identifiable intangible assets (note 12)	(69)	-
Purchases of property, plant and equipment (note 11)	(736)	(82)
Disposals of property, plant and equipment (note 11)	26	32
<b>Net cash provided by (used in) investing activities</b>	<b>2,463</b>	<b>(50)</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>107</b>	<b>(369)</b>
<b>Net change in cash and cash equivalents</b>	<b>14,883</b>	<b>(6,102)</b>
<b>Cash and cash equivalents Beginning of the year</b>	<b>31,998</b>	<b>38,100</b>

<b>Cash and cash equivalents</b>	<b>End of the year</b>	<b>46,881</b>	31,998
<b>Cash and cash equivalents components (note 6):</b>			
Cash		<b>15,112</b>	12,922
Cash equivalents		<b>31,769</b>	19,076
		<b>46,881</b>	31,998

The accompanying notes are an integral part of these consolidated financial statements.

---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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, reporting entity and basis of preparation**

**Summary of business**

Aeterna Zentaris Inc. ( Aeterna Zentaris or the Company ) is a late-stage 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 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.

The highest development priorities in oncology are the completion of Phase 3 trials with perifosine in colorectal cancer and in multiple myeloma as well as the further advancement of AEZS-108, for which the Company has successfully completed a Phase 2 trial in advanced endometrial and advanced ovarian cancer. The Company is currently planning for the initiation of a pivotal program with AEZS-108 in endometrial cancer. AEZS-108 is also in development in other cancer indications, including castration and taxane-resistant prostate cancer, refractory bladder cancer, as well as triple-negative breast cancer.

The Company's pipeline also encompasses other earlier-stage programs in oncology. AEZS-112, an oral anticancer agent which involves three mechanisms of action (tubulin, topoisomerase II and angiogenesis inhibition) has completed a Phase 1 trial in advanced solid tumors and lymphoma. Additionally, several targeted potential anti-cancer candidates such as AEZS-120, a live recombinant oral tumor vaccine candidate, as well as our PI3K/Erk inhibitors AEZS-129, AEZS-131, AEZS-132 and their respective follow-up compounds are currently in preclinical development.

The Company's lead program in endocrinology, a Phase 3 trial under a Special Protocol Assessment obtained from the FDA with AEZS-130 as an oral diagnostic test for Growth Hormone Deficiency in adults, has been completed with positive results. The Company expects to file a New Drug Application for the registration of AEZS-130 in the United States. Furthermore, AEZS-130 is in development for the treatment of cancer cachexia.

**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.



---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**Basis of preparation**

(a) Statement of compliance

The accompanying consolidated financial statements represent the first annual financial statements of the Company and its subsidiaries prepared in accordance with International Financial Reporting Standards ( IFRS ), as issued by the International Accounting Standards Board ( IASB ). The accompanying consolidated financial statements were also prepared in accordance with IFRS 1, *First-time Adoption of International Financial Accounting Standards* ( IFRS 1 ). The first date at which IFRS was applied was January 1, 2010 (the Transition Date ).

Prior to January 1, 2011, the Company s consolidated financial statements were prepared in accordance with Canadian generally accepted accounting principles ( GAAP ). In these consolidated financial statements, the term Canadian GAAP refers to Canadian GAAP as applicable prior to the adoption of IFRS.

Subject to certain transition exceptions and exemptions, discussed in note 29, the Company has consistently applied the same accounting policies in the preparation of its opening IFRS statement of financial position at January 1, 2010 throughout all periods presented, as if these policies had always been in effect. Note 29 discusses the impact of the transition to IFRS on the Company s reported financial position, financial performance and cash flows, including the nature and effect of significant changes in accounting policies from those used in the Company s consolidated financial statements for the year ended December 31, 2010 prepared in accordance with Canadian GAAP.

These consolidated financial statements were approved by the Company s Board of Directors for issue on March 27, 2012.

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 ).

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.

(b) Principles of consolidation

These consolidated financial statements include all entities in which the Company, directly or indirectly, holds more than 50% of the voting rights or over which it exercises control. Entities are included in the consolidation from the date that 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.



---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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) 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**

**Cash and cash equivalents**

Cash and cash equivalents consist of unrestricted cash on hand and balances with banks, as well as short-term 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.

**Short-term investment**

The Company's short-term investment represents shares of a publicly held company and is classified as held-for-trading and stated at fair 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.



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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:

	<b>Methods</b>	<b>Annual rates and period</b>
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 selling, general and administrative expenses, and research and development ( R&D ) on the statement of comprehensive income.

**Identifiable intangible assets**

Identifiable intangible assets with finite useful lives consist of in-process R&D, 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 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

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

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

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

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 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. 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.



---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 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.

*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.

Financial assets at FVTPL are comprised exclusively of the Company's short-term investment.

*Loans and receivables*

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

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.



**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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'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.

(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 rights 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*

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

Financial instruments classified as Other financial liabilities are measured initially at fair value and subsequently at amortized cost using the effective interest rate method.

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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) 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.

**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.



**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

*Royalty revenues*

The Company has deferred recognition of proceeds received in December 2008 from Cowen Healthcare Royalty Partners L.P. ( "Cowen" ) relating to the Company's rights to royalties on future sales of Cetrotide® 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®, a compound used for *in vitro* fertilization. Royalties on Merck Serono's net sales of Cetrotide®, formerly payable to the Company, are now payable directly to Cowen.

The Company recognized the proceeds received from Cowen 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 Cowen over the term of the underlying arrangement multiplied by the royalty payments due to Cowen 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.

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.



**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**Share-based compensation costs**

The Company operates an equity-settled share-based compensation plan under which the Company receives services from employees as consideration for equity instruments of the Company.

The Company accounts for all forms of employee 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.

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.

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**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 50% 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 often requires management to make estimates about and apply assumptions or subjective judgment to future events and other matters that affect the reported amounts of the Company's assets, liabilities, revenues, expenses and related disclosures. Assumptions, estimates and judgments 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.

Critical accounting estimates and judgments 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 judgments that the Company has made in the preparation of the consolidated financial statements.





**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

*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.

Management's assessments related to the recognition of revenues related to arrangements containing multiple elements are based on estimates and assumptions. 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 certain assumptions and estimates, including arrangement-specific cash flow projections (discounted using appropriate interest rates), the Company's continuing involvement in the arrangement, the benefits expected to be derived by the customer and expected patent lives. To the extent that any of the assumptions or estimates change, future operating results could be affected.

*Fair value of the short-term investment, warrant liability and stock options*

Determining the fair value of the short-term investment, 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 7, 15 and 17.

*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.

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.

---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

*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.

*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.

**4 Recent accounting pronouncements**

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.



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

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 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. 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 \$57,075,000) upon achieving certain pre-established milestones, including the occurrence of certain clinical and regulatory events in Japan. As at December 31, 2011, following the achievement of a milestone, the Company has revenue and trade receivables recorded for an additional amount of 2,000,000 (approximately \$2,594,000) in connection with the agreement. 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,

---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 will be entitled to receive up to a total of \$1,800,000 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.

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.

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 \$841,000 of the gross proceeds received from Yakult and will be required to remit 200,000 (approximately \$259,000) when the milestone receivable will be paid by Yakult. These amounts, which were (will be) 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*.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**6 Cash and cash equivalents**

	As at December 31, 2011 \$	As at December 31, 2010 \$	As at January 1, 2010 \$
Cash on hand and balances with banks	15,112	12,922	33,100
Short-term interest-bearing deposits	31,769	19,076	5,000
	<b>46,881</b>	<b>31,998</b>	<b>38,100</b>

**7 Short-term investment**

The short-term investment consisted of shares of a publicly held company. The underlying shares were sold in July 2011.

The change in the Company's short-term investment can be summarized as follows:

	Years ended December 31,	
	2011 \$	2010 \$
Balance at January 1	1,934	-
Addition of short-term investment	-	1,263
Change in fair value of shares	1,278	687
Change in value attributable to foreign exchange rate changes	30	(16)
Sale of short term investment	(3,242)	-

Balance at December 31 - 1,934

The fair value of the short-term investment as at December 31, 2010 was discounted via the application of the Black-Scholes pricing model with the following inputs and assumptions:

Number of shares	326,956
Market-value price per share	\$6.87
Expected dividend yield	0%
Expected volatility	36.2%
Risk-free annual interest rate	0.3%
Expected life (years)	0.34
Discount per share	\$0.98

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

The Black-Scholes valuation methodology uses Level 2 inputs in calculating fair value, as defined in IFRS 7, *Financial Instruments: Disclosures* ( IFRS 7 ), and as discussed in note 24.



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**8 Trade and other receivables**

	As at December 31, 2011 \$	As at December 31, 2010 \$	As at January 1, 2010 \$
Trade accounts receivable	7,716	4,555	2,444
Value added tax	439	595	729
Other	170	271	376
	<b>8,325</b>	<b>5,421</b>	<b>3,549</b>

**9 Inventory**

	As at December 31, 2011 \$	As at December 31, 2010 \$	As at January 1, 2010 \$
Raw materials	1,608	1,899	2,998
Work in progress	1,848	1,412	1,417
	<b>3,456</b>	<b>3,311</b>	<b>4,415</b>

**10 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 \$806,000 to a restricted cash account. The fixed amount, including any interest earned thereon, is restricted for as long as the underlying lease arrangement has not expired and therefore cannot be utilized for current purposes as at December 31, 2011.

**11 Property, plant and equipment**

Components of the Company's property, plant and equipment are summarized below.

	Equipment	Furniture and fixtures	Cost Computer equipment	Leasehold improvements	Total
--	-----------	---------------------------	-------------------------------	---------------------------	-------

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

	\$	\$	\$	\$	\$
At January 1, 2010	9,941	1,653	1,851	1,232	14,677
Additions	76	-	6	-	82
Disposals	(455)	-	(5)	-	(460)
Impact of foreign exchange rate changes	(623)	(102)	(114)	(76)	(915)
At December 31, 2010	8,939	1,551	1,738	1,156	13,384
Additions	684	-	46	6	736
Disposals	(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

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

	Accumulated depreciation				
	Furniture				Total
	Equipment	and fixtures	Computer equipment	Leasehold improvements	
	\$	\$	\$	\$	\$
At January 1, 2010	6,831	1,382	1,678	428	10,319
Disposals	(395)	-	(5)	-	(400)
Impairment loss	-	-	-	-	-
Recurring depreciation expense	736	54	102	113	1,005
Impact of foreign exchange rate changes	(423)	(84)	(103)	(26)	(636)
At December 31, 2010	6,749	1,352	1,672	515	10,288
Disposals	(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

	Carrying amount				
	Furniture				Total
	Equipment	and fixtures	Computer equipment	Leasehold improvements	
	\$	\$	\$	\$	\$
At January 1, 2010	3,110	271	173	804	4,358
At December 31, 2010	2,190	199	66	641	3,096
At December 31, 2011	2,071	24	60	357	2,512

Depreciation of \$918,000 (\$1,005,000 in 2010) is included in the statement of comprehensive loss: \$824,000 (\$902,000 in 2010) in R&D and \$94,000 (\$103,000 in 2010) 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 is included within general and administrative expenses in the accompanying consolidated statement of comprehensive loss.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**12 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, 2011			Year ended December 31, 2010		
	Cost \$	Accumulated amortization \$	Carrying value \$	Cost \$	Accumulated amortization \$	Carrying value \$
Balances At January 1	39,141	(35,842)	3,299	41,715	(37,588)	4,127
Additions	69	-	69	-	-	-
Impairment loss	-	(1,093)	(1,093)	-	-	-
Recurring amortization expense	-	(553)	(553)	-	(568)	(568)
Impact of foreign exchange rate changes	(1,228)	1,275	47	(2,574)	2,314	(260)
Balances At December 31	37,982	(36,213)	1,769	39,141	(35,842)	3,299

Amortization of \$553,000 (\$568,000 in 2010) is included in the statement of comprehensive loss: \$507,000 (\$481,000 in 2010) in R&D and \$46,000 (\$87,000 in 2010) in selling expenses.

During the year ended December 31, 2011, an impairment loss was recognized based on the results of impairment testing of the Company's 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.

Management determined that the recoverable amount of Cetrotide®, as at 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 is included within selling expenses in the accompanying consolidated statement of comprehensive loss.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**13 Goodwill**

Goodwill has been allocated to the only CGU of the Group.

The change in carrying value is as follows:

	Cost	Accumulated impairment loss	Carrying amount
	\$	\$	\$
Balance as at January 1, 2010	10,246	-	10,246
Impact of foreign exchange rate changes	(632)	-	(632)
Balance as at December 31, 2010	9,614	-	9,614
Impact of foreign exchange rate changes	(301)	-	(301)
Balance as at December 31, 2011	<b>9,313</b>	-	<b>9,313</b>

**14 Payables and accrued liabilities**

	As at December 31, 2011	As at December 31, 2010	As at January 1, 2010
	\$	\$	\$
Trade accounts payable	8,062	6,388	8,152
Salaries, employment taxes and benefits	1,958	1,427	587
Current portion of warrant liability	42	955	-
Accrued R&D costs	1,056	615	1,883
Accrued Cetrotide® services and deliveries	160	221	65
Other	979	654	1,158
	<b>12,257</b>	10,260	11,845



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**15 Warrant liability**

The change in the Company's warrant liability can be summarized as follows:

	Years ended December 31,	
	2011	2010
	\$	\$
Balance - Beginning of the year	14,367	1,664*
Share purchase warrants granted during the year (note 17)	-	7,341
Share purchase warrants exercised during the year	(2,638)	(429)
Change in fair value of share purchase warrants	(2,533)	5,437
Change in value attributable to foreign exchange rate changes	8	354
	9,204	14,367
Less: current portion	(42)	(955)
	9,162	13,412
Balance - End of the year	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,			
	2011		2010	
	Number	Weighted average exercise price (US\$)	Number	Weighted average exercise price (US\$)
Balance - Beginning of the year	12,923,390	1.53	4,110,603	1.70
Granted	-	-	9,111,604	1.44
Exercised	(1,707,286)	1.30	(298,817)	1.32
Expired	(2,148,936)	2.10	-	-

Balance - End of the year	9,067,168	1.44	12,923,390	1.53
---------------------------	-----------	------	------------	------



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 following table summarizes the share purchase warrants outstanding and exercisable as at December 31, 2011:

Exercise price (US\$)	Warrants outstanding and currently exercisable		
	Number	Weighted average remaining contractual life (years)	Total intrinsic value
1.25	733,334	2.81	213
1.37	3,496,879	3.47	586
1.50	4,572,777	3.72	183
1.72	264,178	3.46	-
	9,067,168	3.54	982

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, 2011.

	October 2009		April 2010	June 2010	
	Investor Warrants	October 2009 Compensation Warrants	Investor Warrants	Investor Warrants	June 2010 Compensation Warrants
Number of equivalent shares	733,334	128,333	4,444,444	3,496,879	264,178
Market-value per share price	1.54	1.54	1.54	1.54	1.54
Exercise price	1.25	1.50	1.50	1.37	1.72
Risk-free annual interest rate	(a) 0.34%	0.12%	0.55%	0.47%	0.47%
Expected volatility	(b) 95.18%	56.85%	99.25%	98.95%	99.13%
Expected life (years)	(c) 2.81	0.81	3.80	3.47	3.46
Expected dividend yield	(d) 0.0%	0.0%	0.0%	0.0%	0.0%

- (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 24.



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**16 Provision and other non-current liabilities**

	As at December 31, 2011	As at December 31, 2010	As at January 1, 2010
	\$	\$	\$
Onerous lease provision (see below)	619	441	491
Other	187	183	66
	<b>806</b>	624	557
Current	89	53	50
Non-current	717	571	507
	<b>806</b>	624	557

**Onerous lease provision\***

	Year ended December 31, 2011
	\$
Balance at January 1, 2011	441
Additional provision recognised	189
Utilization of provision	(62)
Effect of change in the discount rate	43
Unwinding of discount	8
Balance at December 31, 2011	619
Current portion	(89)
Non-current portion at December 31, 2011	530

- \* 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 six years. On December 1<sup>st</sup> 2011, following the relocation of one of the Company's offices, the lease arrangement became fully onerous. As such, an additional provision was recognised.

## **17 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 issued in connection with At-the-Market ( ATM ) drawdowns**

#### *February ATM Sales Agreement*

On February 22, 2011, the Company entered into an ATM sales agreement (the February ATM Sales Agreement ), under which the Company was able, at its discretion and from time to time during the 24-month term of the agreement, to sell up to 12,500,000 of its common shares through ATM issuances on the Nasdaq Stock Market for aggregate gross proceeds not to exceed \$19,750,831. The February ATM Sales Agreement 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.

---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 issued a total of 9,964,548 common shares under the February ATM Sales Agreement for aggregate gross proceeds of \$19,749,945, less cash transaction costs of \$592,498 and previously deferred transaction costs of \$207,000.

*June ATM Sales Agreement*

On June 29, 2011, the Company entered into an additional ATM sales agreement (the *June ATM Sales Agreement*), under which the Company was able, at its discretion, from time to time during the 24-month term of the agreement, sell up to 9,500,000 of its common shares through ATM issuances on the Nasdaq Stock Market for aggregate gross proceeds not to exceed \$24,000,000. The June ATM Sales Agreement 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.

The Company issued a total of 9,500,000 common shares under the June ATM Sales Agreement for aggregate gross proceeds of \$17,705,416, less cash transaction costs of \$612,357 and previously deferred transaction costs of \$162,407.

**Common shares issued in connection with registered direct offerings**

*April 20, 2010 registered direct offering*

On April 20, 2010, the Company completed a registered direct offering of 11,111,111 units, with each unit consisting of one common share and a warrant to purchase 0.40 of a common share, at a price of \$1.35 per unit (the *April 2010 Offering*). Total proceeds raised upon completion of the April 2010 Offering amounted to \$15,000,000, less cash transaction costs of approximately \$1,315,000. The securities described above were offered by the Company pursuant to a shelf prospectus dated March 12, 2010 and a prospectus supplement dated April 15, 2010.

The Company granted warrants (the *April 2010 Investor Warrants*) to the investors who participated in the April 2010 Offering. Each April 2010 Investor Warrant entitles the holder to purchase 0.40 of a common share at an exercise price of \$1.50 per share. The April 2010 Investor Warrants are exercisable between October 20, 2010 and October 20, 2015, and, upon complete exercise, would result in the issuance of an aggregate of 4,444,444 common shares.

The Company estimated the fair value attributable to the April 2010 Investor Warrants of \$3,639,815 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 2.56%, expected volatility of 87.3%, an expected term of 5 years, a dividend yield of 0.0% and an issue-date market share price of \$1.24.

*June 21, 2010 registered direct offering*

On June 21, 2010, the Company completed a registered direct offering of 8,805,964 units, with each unit consisting of one common share and a warrant to purchase 0.50 of a common share, at a price of \$1.3725 per unit (the *June 2010 Offering*). Total proceeds raised upon completion of the June 2010 Offering amounted to \$12,086,186, less cash transaction costs of approximately \$783,000. The securities described above were offered by the Company pursuant to a shelf prospectus dated March 12, 2010 and a prospectus supplement dated June 15, 2010.

---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 granted warrants (the June 2010 Investor Warrants ) to the investors who participated in the June 2010 Offering. Each June 2010 Investor Warrant entitles the holder to purchase a common share at an exercise price of \$1.3725 per share. The June 2010 Investor Warrants are exercisable between June 21, 2010 and June 21, 2015, and, upon complete exercise, would result in the issuance of an aggregate of 4,402,982 common shares.

The Company estimated the fair value attributable to the June 2010 Investor Warrants of \$3,502,572 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 2.05%, expected volatility of 89.3%, an expected term of 5 years, a dividend yield of 0.0% and an issue-date market share price of \$1.18.

The Company also granted warrants (the June 2010 Compensation Warrants ) to the sole placement agent (and to certain of its designated representatives) engaged in connection with the June 2010 Offering. Each June 2010 Compensation Warrant entitles the holder to purchase a common share at an exercise price of \$1.7156 per share. The June 2010 Compensation Warrants are exercisable between June 15, 2010 and June 15, 2015, and, upon complete exercise, would result in the issuance of 264,178 common shares.

The Company estimated the fair value attributable to the June 2010 Compensation Warrants of \$198,609 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 2.04%, expected volatility of 89.4%, an expected term of 5 years, a dividend yield of 0.0% and an issue-date market share price of \$1.18. The initial fair value of the June 2010 Compensation Warrants has been accounted for as additional transaction costs, since the instruments were granted to the sole placement agent as part of the terms of the underlying engagement and in recognition of the efforts made in connection with the June 2010 Offering.

**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. 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.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**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.

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, 524,468 of the options granted in 2011 and 883,525 of the options granted in 2010 vest over a period of 18 months.

The following table summarizes the activity under the Company's stock option plan.

	Years ended December 31,							
	2011		2010		2010		2010	
	Canadian Dollar Options		US Dollar Options		Canadian Dollar Options		US Dollar Options	
	Number	Weighted average exercise price (CAN\$)	Number	Weighted average exercise price (US\$)	Number	Weighted average exercise price (CAN\$)	Number	Weighted average exercise price (US\$)
Balance - Beginning of the year	6,558,679	2.55	293,334	2.83	5,920,588	2.72	293,334	2.83
Granted	15,000	1.93	1,434,468	1.75	1,088,525	1.51	-	-
Exercised	(160,348)	0.89	-	-	(124,068)	0.90	-	-
Forfeited	(46,666)	1.54	-	-	(74,699)	0.95	-	-
Expired	(178,333)	6.18	-	-	(251,667)	3.22	-	-
Balance - End of the year	6,188,332	2.50	1,727,802	1.93	6,558,679	2.55	293,334	2.83

Exercise price (CAN\$)	Number	CAN\$ options outstanding as at December 31, 2011		Total intrinsic value
		Weighted average remaining contractual life (years)	Weighted average exercise price (CAN\$)	

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

(CAN\$)

0.55 to 0.95	1,776,974	7.55	0.82	1,319
0.96 to 1.56	1,048,525	8.14	1.50	63
1.57 to 1.82	944,500	3.05	1.77	-
1.83 to 3.54	797,500	2.34	3.21	-
3.55 to 4.92	775,333	1.98	4.08	-
4.93 to 8.88	845,500	2.07	5.96	-
	6,188,332	4.85	2.50	1,382



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

CAN\$ options exercisable as at December 31, 2011				Total
Exercise price		Weighted average remaining	Weighted average exercise price	intrinsic value
(CAN\$)	Number	contractual life (years)	(CAN\$)	(CAN\$)
0.55 to 0.95	1,723,646	7.54	0.81	1,287
0.96 to 1.56	692,353	7.73	1.49	48
1.57 to 1.82	944,500	3.05	1.77	-
1.83 to 3.54	782,500	2.20	3.23	-
3.55 to 4.92	775,333	1.98	4.08	-
4.93 to 8.88	845,500	2.07	5.96	-
	5,763,832	4.55	2.57	1,335

US\$ options outstanding as at December 31, 2011				Total
Exercise price		Weighted average remaining	Weighted average exercise price	intrinsic value
(US\$)	Number	contractual life (years)	(US\$)	(US\$)
1.74 to 1.78	1,414,468	9.93	1.74	-
1.79 to 1.87	115,000	5.94	1.82	-
1.88 to 3.96	198,334	5.74	3.37	-
	1,727,802	9.19	1.93	-

US\$ options exercisable as at December 31, 2011				Total
Exercise price	Number	Weighted average remaining	Weighted average exercise price	intrinsic value
(US\$)				

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

		<b>contractual life</b>	<b>(US\$)</b>	<b>value</b>
		<b>(years)</b>		<b>(US\$)</b>
1.79 to 1.87	115,000	5.94	1.82	-
1.88 to 3.96	178,334	5.33	3.48	-
	293,334	5.57	2.83	-

As at December 31, 2011, the total compensation cost related to unvested Canadian Dollar stock options not yet recognized amounted to \$146,641 (\$1,014,958 in 2010). This amount is expected to be recognized over a weighted average period of 0.98 year (1.02 years in 2010).

As at December 31, 2011, the total compensation cost related to unvested US Dollar stock options not yet recognized amounted to \$1,322,752 (\$0 in 2010). This amount is expected to be recognized over a weighted average period of 1.48 years.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 settles stock options exercised through the issuance of common shares from treasury.

**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.

		Years ended December 31,	
		2011	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\$1.40	CAN\$1.09

- (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.

		Year ended
		December 31, 2011
Expected dividend yield	(a)	0.0%
Expected volatility	(b)	81.6%
Risk-free annual interest rate	(c)	1.4%
Expected life (years)	(d)	6.82

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

Weighted average grant date fair value

**US\$1.27**

- (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 24.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**18 Operating expenses**

Components of the Company's operating expenses include the following:

	<b>Years ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>\$</b>	<b>\$</b>
Subcontractor fees	25,667	15,907
Raw material purchases	2,154	1,897
Change in inventory	(261)	896
Cost of sales	27,560	18,700
Salaries, employment taxes and short-term benefits	13,029	11,885
Post-employment benefits	864	665
Termination benefits	182	45
Share-based compensation costs	1,333	1,192
<b>Total employee benefits expenses</b>	<b>15,408</b>	<b>13,787</b>
Goods and services <sup>(1)</sup>	20,334	17,316
Lease payments <sup>(2)</sup> , net of sublease payments of \$179,000	2,153	1,825
Refundable tax credits and grants	(383)	(687)
Depreciation and amortization	1,471	1,573
Impairment losses	1,405	-
Operating foreign exchange (gains) loss	299	(5)
<b>Total operating expenses</b>	<b>68,247</b>	<b>52,509</b>

(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 16), except for the unwinding of discount.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**19 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.

The following table provides a reconciliation of the changes in the aforementioned plans' accrued benefit obligations:

	Pension benefit plans		Other benefit plans	
	2011	2010	2011	2010
	\$	\$	\$	\$
Obligation Beginning of year	10,492	10,767	1,041	1,254
Current service cost	185	217	206	254
Interest cost	555	546	54	63
Actuarial (gain) loss	1,335	(191)	46	(370)
Benefits paid	(354)	(173)	(196)	(86)
Effect of foreign currency exchange rate changes	(444)	(674)	(40)	(74)
Obligation End of year	11,769	10,492	1,111	1,041
Amount recognized				
In comprehensive loss	(740)	(763)	(306)	53
In other comprehensive (loss) income	(1,335)	191	-	-

The cumulative amount of actuarial losses recognized in other comprehensive (loss) income as at December 31, 2011 is approximately \$1,144,000 (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:

	Pension benefit plans		Other benefit plans	
Actuarial assumptions	2011	2010	2011	2010

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

	%	%	%	%
Discount rate	4.20	5.10	4.20	5.10
Pension benefits increase	2.00	2.00	2.00	2.00
Rate of compensation increase	2.75 to 3.75	2.75 to 3.75	2.75	2.75

The last actuarial reports give effect to the pension and post-employment benefit obligations as at December 31, 2011. The next actuarial reports are planned for December 31, 2012.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

In accordance with the assumptions used as at December 31, 2011, the future benefits expected to be paid can be presented as follows:

	\$
2012	680
2013	745
2014	702
2015	692
2016	644
2017 through 2020	3,148
	6,611

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 \$312,984 for the year ended December 31, 2011 (\$257,260 for 2010).

**20 Finance income and finance costs**

Components of the Company's finance income and finance costs can be summarized as follows:

	Years ended December 31,	
	2011	2010
	\$	\$
<b>Finance income</b>		
Net gains due to changes in foreign currency exchange rates	2,197	932
Net change in fair value of warrant liability	2,533	-
Interest income	231	181
Gain on held-for-trading financial instrument	1,278	687
	6,239	1,800
<b>Finance costs</b>		
Net change in fair value of warrant liability	-	(5,437)
Unwinding of discount	(8)	(8)
	(8)	(5,445)
	6,231	(3,645)





**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**21 Supplemental disclosure of cash flow information**

	Years ended December 31,	
	2011	2010
	\$	\$
<b>Changes in operating assets and liabilities</b>		
Trade and other receivables	(3,332)	(2,029)
Inventory	(261)	896
Prepaid expenses and other current assets	(4,068)	(3,344)
Other non-current assets	(456)	(315)
Payables and accrued liabilities	2,970	(1,956)
Provision and other non-current liabilities	(24)	109
Deferred revenues	8,614	-
Income taxes	105	(900)
	<b>3,548</b>	<b>(7,539)</b>

During the year ended December 31, 2011, the Company paid approximately \$841,000 in income taxes, as discussed in note 5.

**22 Income taxes**

	Years ended December 31,	
	2011	2010
	\$	\$
Current:	(1,104)	-
Deferred:		
Origination and reversal of temporary differences	9,017	7,632
Change in enacted tax rates	(104)	(272)
Adjustments in respect of prior years	3,428	(176)
Change in unrecognized tax assets	(12,341)	(7,184)
	-	-
Income tax expense	(1,104)	-

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 reconciliation of the combined Canadian federal and Quebec provincial income tax rate to the income tax expense is provided below:

	<b>Years ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Combined Canadian federal and provincial statutory income tax rate	<b>28.4%</b>	29.9%
	<b>Years ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>\$</b>	<b>\$</b>
Income tax recovery based on statutory income tax rate	<b>7,290</b>	8,500
Change in unrecognized tax assets	<b>(12,341)</b>	(7,184)
Permanent difference attributable to the use of local currency for tax reporting	<b>378</b>	1,232
Permanent difference attributable to net change in fair value of warrant liability	<b>661</b>	(1,761)
Stock-based compensation costs	<b>(441)</b>	(357)
Difference in statutory income tax rate of foreign subsidiaries	<b>893</b>	391
Permanent difference attributable to unrealized foreign exchange gain/loss	<b>(32)</b>	(159)
Change in enacted rates used	<b>(104)</b>	(272)
Expiry of loss carryforwards	<b>-</b>	(164)
Foreign withholding tax	<b>(1,104)</b>	-
Adjustments in respect of prior years	<b>3,428</b>	(176)
Other	<b>268</b>	(50)
	<b>(1,104)</b>	-

The decrease in the applicable tax rates is mainly due to the reduction of the federal income tax rate in 2011 from 18% to 16.5%.

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).

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 2011, an amount of \$12,341,000 would have been credited to the income statement, \$425,000 to other comprehensive income and \$334,000 to equity. The remaining variation in unrecognized tax assets of \$2,610,000 is due to exchange rate differences.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

*Loss before income taxes*

Loss before income taxes is attributable to the Company's tax jurisdictions as follows:

	Years ended December 31,	
	2011	2010
	\$	\$
Germany	(25,246)	(19,763)
Canada	(290)	(8,664)
United States	(427)	(24)
	(25,963)	(28,451)

Significant components of deferred tax assets and liabilities:

	As at	As at	As at
	December 31, 2011	December 31, 2010	January 1, 2010
	\$	\$	\$
Deferred tax assets			
Long-term:			
Operating losses carried forward	224	1,531	1,383
Research and development costs	-	169	226
	224	1,700	1,609
Deferred tax liabilities			
Deferred revenues	-	1,083	1,089
Property, plant and equipment	197	243	262
Warrant liability	-	169	188
Other	27	205	70
	224	1,700	1,609
<b>Deferred tax assets (liabilities), net</b>	-	-	-

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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, 2011	As at December 31, 2010	As at January 1, 2010
	\$	\$	\$
Deferred tax assets			
Inventory	740	352	262
Deferred revenues	507	65	713
Other	-	9	108
	<b>1,247</b>	426	1,083
Long term:			
Operating losses carried forward	38,665	33,745	26,078
Intangible assets	13,170	14,394	16,448
Research and development costs	12,310	10,934	10,257
Unused tax credits	10,667	7,158	6,738
Employee future benefits	1,534	1,233	1,136
Property, plant and equipment	1,301	1,237	702
Share issue expenses	813	715	374
Deferred revenues	589	-	-
Onerous lease provision	186	151	174
Other	139	138	1
	<b>79,374</b>	69,705	61,908
<b>Unrecognized deferred tax assets</b>	<b>80,621</b>	70,131	62,991

As at December 31, 2011, 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	4,719                      -

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

2028	10,962	10,079
2029	6,520	6,496
2030	5,586	5,666
2031	2,606	2,606
	30,393	24,747

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 \$10,667,000 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 \$106,521,789 in Germany, for which there is no expiry date and to \$791,333 in the United States, which expire as follows:

	<b>United States</b>
	<b>\$</b>
2027	17
2028	596
2029	178
	791

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.

**23 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.

The Company's priority is to optimize its liquidity needs 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, however, the Company has raised additional capital via registered direct offerings and drawdowns related to the Company's ATM sales agreement, as discussed in notes 17 and 30.

At December 31, 2011, cash and cash equivalents amounted to US\$46,881,000. The Company believes that its cash position will be sufficient to finance its operations and capital needs for at least, but not limited to the next twelve months.

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.





**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 Financial instruments and financial risk management**

Financial assets (liabilities) as at December 31, 2011, December 31, 2010 and January 1, 2010 are presented below.

<b>December 31, 2011</b>	<b>Loans and receivables \$</b>	<b>Financial liabilities at FVTPL \$</b>	<b>Other financial liabilities \$</b>	<b>Total \$</b>
Cash and cash equivalents	46,881	-	-	46,881
Trade and other receivables (note 8)	8,325	-	-	8,325
Restricted cash (note 10)	806	-	-	806
Payables and accrued liabilities (note 14)	-	-	(12,126)	(12,126)
Long-term payable*	-	-	(88)	(88)
Warrant liability (note 15)*	-	(9,204)	-	(9,204)
Other non-current liabilities (note 16)	-	-	(187)	(187)
	56,012	(9,204)	(12,401)	34,407

\* Includes current and non-current portions.

<b>December 31, 2010</b>	<b>Financial asset at FVTPL \$</b>	<b>Loans and receivables \$</b>	<b>Financial liabilities at FVTPL \$</b>	<b>Other financial liabilities \$</b>	<b>Total \$</b>
Cash and cash equivalents	-	31,998	-	-	31,998
Short-term investment (note 7)	1,934	-	-	-	1,934
Trade and other receivables (note 8)	-	5,421	-	-	5,421
Restricted cash (note 10)	-	827	-	-	827
Payables and accrued liabilities (note 14)	-	-	-	(9,305)	(9,305)
Long-term payable*	-	-	-	(150)	(150)
Warrant liability (note 15)*	-	-	(14,367)	-	(14,367)
Other non-current liabilities (note 16)	-	-	-	(183)	(183)
	1,934	38,246	(14,367)	(9,638)	16,175

\*Includes current and non-current portions.



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

January 1, 2010	Loans and receivables \$	Financial liabilities at FVTPL \$	Other financial liabilities \$	Total \$
Cash and cash equivalents	38,100	-	-	38,100
Trade and other receivables (note 8)	3,549	-	-	3,549
Restricted cash (note 10)	878	-	-	878
Payables and accrued liabilities (note 14)	-	-	(11,845)	(11,845)
Long-term payable*	-	-	(200)	(200)
Warrant liability (note 15)	-	(1,664)	-	(1,664)
Other non-current liabilities (note 16)	-	-	(66)	(66)
	42,527	(1,664)	(12,111)	28,752

\*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).

The carrying values of the Company's cash and cash equivalents, trade and other receivables, restricted cash, payables, provisions, accrued liabilities, long-term payable and other long-term 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.

---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

(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 8) and to restricted cash (note 10). 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 have a minimum rating of A3.

As at December 31, 2011, trade accounts receivable for an amount of approximately \$7,415,000 were with Company 1 and Company 3 (note 28).

As at December 31, 2011, 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.

(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 23), 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.

(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 loss, has been and may continue in future periods to be materially affected most notably by changes in the Company's common share price, which on the Nasdaq market, has ranged from \$1.43 to \$2.58 during the year ended December 31, 2011. Assuming the following variations of the market price of the Company's common shares over a 12-month period:

Market price variations of -10% and +10%

190

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

If these variations were to occur, the impact on the Company's net loss for warrant liability held at December 31, 2011 would be as follows:

	<b>Carrying amount</b>	<b>-10%</b>	<b>+10%</b>
	\$	\$	\$
Warrant liability*	9,204	1,155	(1,174)
<b>Total impact on net loss decrease/(increase)</b>		1,155	(1,174)

\*Includes current and non-current portions.

*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 dollar exchange rates against the EUR could have a potentially significant impact on the Company's results of operations. The following variations are reasonably possible over a 12-month period:

Foreign exchange rate variations of -5% (depreciation of the EUR) and +5% (appreciation of the EUR) against the US\$, from a year-end rate of EUR1 = US\$1.2972.

If these variations were to occur, the impact on the Company's net loss for each category of financial instruments held at December 31, 2011 would be as follows:

	<b>Balances denominated in US\$</b>		
	<b>Carrying amount</b>	<b>-5%</b>	<b>+5%</b>
	\$	\$	\$
Cash and cash equivalents	33,669	1,683	(1,683)

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

Warrant liability*	9,204	(460)	460
<b>Total impact on net loss decrease/(increase)</b>		<b>1,223</b>	<b>(1,223)</b>

\*Includes current and non-current portions.

**25 Commitments, contingencies and guarantee**

The Company is committed to various operating leases for its premises plus service and manufacturing contracts.



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

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, 2011 are as follows:

	Minimum lease payments	Minimum sub-lease payments	Utilities
	\$	\$	\$
Less than 1 year	1,690	(226)	609
1 - 3 years	3,128	(451)	793
4 - 5 years	2,172	(451)	496
More than 5 years	373	(244)	-
<b>Total</b>	<b>7,363</b>	<b>(1,372)</b>	<b>1,898</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:

	December 31, 2011
	\$
Less than 1 year	10,760
1 - 3 years	3,855
4 - 5 years	-
More than 5 years	-
<b>Total</b>	<b>14,615</b>

**Contingencies**

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

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, 2011 or 2010, nor are there any known disputes pending against the Company that could significantly impact the Company's consolidated financial statements.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 Net loss per share**

The following table sets forth pertinent data relating to the computation of basic and diluted net loss per share attributable to common shareholders.

	<b>Years ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>\$</b>	<b>\$</b>
<b>Net loss</b>	<b>(27,067)</b>	<b>(28,451)</b>
<b>Basic weighted average number of shares outstanding</b>	<b>94,507,988</b>	<b>75,659,410</b>
Dilutive effect of stock options	<b>1,143,749</b>	<b>326,478</b>
Dilutive effect of share purchase warrants	<b>1,697,418</b>	<b>-</b>
<b>Diluted weighted average number of shares outstanding</b>	<b>97,349,155</b>	<b>75,985,888</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	<b>3,681,864</b>	<b>4,999,656</b>
Warrants (number of equivalent shares)	<b>-</b>	<b>12,923,390</b>

For the years ended December 31, 2011 and 2010, the diluted net loss per share was the same as the basic net loss 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 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 ATM drawdowns and registered direct offerings, which resulted in the issuance of a total of 19,464,548 and 19,917,075 common shares (see note 17) during the years ended December 31, 2011 and 2010, respectively. See also note 30.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**27 Compensation of key management**

Compensation awarded to key management\* included:

	2011	2010
	\$	\$
Salaries and short-term employee benefits	2,886	2,524
Post-employment benefits	684	114
Termination benefits	-	-
Share-based compensation cost	936	554
	<b>4,506</b>	<b>3,192</b>

\* Key management includes the Company's directors and members of the Executive Committee.

**28 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,	
	2011	2010
	\$	\$
United States	5,492	9,902
Switzerland	24,977	15,907
Japan	5,472	1,684
Other	112	210
	<b>36,053</b>	<b>27,703</b>

Revenues have been allocated to geographic regions based on the country of residence of the Company's external customers or partners.



**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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, 2011 \$	As at December 31, 2010 \$	As at January 1, 2010 \$
Germany	13,557	15,579	18,109
United States	-	381	551
Canada	36	49	71
	<b>13,593</b>	16,009	18,731

\* 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 two years are as follows:

	Years ended December 31,	
	2011 \$	2010 \$
Company 1	24,977	15,907
Company 2	4,556	7,990
Company 3	3,657	-

**29 Transition to IFRS**

The accompanying consolidated financial statements were prepared as described in note 1 and reflect the relevant provisions of IFRS 1. IFRS 1 is based on the principle that the adoption of IFRS should be applied retrospectively. Retrospective application necessitates that comparative financial information be provided, and, as a result, the first date at which the Company has applied IFRS was January 1, 2010. However, IFRS 1 offers certain optional exemptions and mandatory exceptions to the retrospective application of IFRS to first-time preparers of IFRS financial statements. Those exemptions and exceptions, which are relevant to the Company, are discussed in turn below.

**Optional IFRS exemptions***Business combinations*

## Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

IFRS 1 allows first-time preparers to elect not to restate any business combinations that have occurred prior to the Transition Date in accordance with IFRS 3, *Business Combinations* (as revised in 2008) ( IFRS 3 ). Retrospective application would require that all business combinations that occurred prior to an entity's date of transition to IFRS be restated, and any goodwill arising on such business combinations would be adjusted from its carrying value as determined under Canadian GAAP.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 elected to apply this exemption and has not restated any prior business combinations. Consequently, IFRS 3 is applicable only to business combinations occurring after the Transition Date. There have been no business combinations since the Transition Date, and, as a result, the Company will apply the provisions of IFRS 3 to future transactions, if any.

*Currency translation differences*

Full retrospective application of IFRS would require an entity to determine the cumulative foreign currency translation differences, as per the provisions of IAS 21, *The Effects of Changes in Foreign Exchange Rates*, from the date that a subsidiary or an equity-method investee was acquired. IFRS 1 permits a first-time adopter to reset any cumulative translation differences that existed at the date of transition to IFRS to zero. The Company has elected to reset its cumulative translation adjustment balance to zero on January 1, 2010, with a corresponding adjustment to the Company's Transition Date deficit.

**Mandatory IFRS exception***Accounting estimates*

IFRS 1 requires that estimates under IFRS at the date of transition should be consistent with estimates made for the same date under previous GAAP, after applying any adjustments to reflect differences in accounting policies, unless there is objective evidence that those estimates were made in error. As such, a first-time adopter cannot use hindsight in order to create or revise any accounting estimates. Estimates previously made by the Company under Canadian GAAP have not been revised, except where necessary to reflect any differences in accounting policies.

**Reconciliation of Canadian GAAP to IFRS**

IFRS 1 requires a first-time adopter of IFRS to reconcile shareholders' equity (deficiency), comprehensive income (loss) and cash flows for prior periods beginning on the date of transition to IFRS. The Company's first-time adoption of IFRS did not have any impact on previously reported cash flows from operating activities, financing activities or investing activities. Reconciliations of shareholders' equity (deficiency) as at January 1, 2010 and December 31, 2010 and comprehensive loss for the year December 31, 2010 are provided below.

<b>Reconciliation of shareholders</b>	<b>As at</b>	<b>As at</b>
	<b>December 31,</b>	<b>January 1,</b>
<b>equity (deficiency)</b>	<b>2010</b>	<b>2010</b>
	<b>\$</b>	<b>\$</b>
Shareholders' equity under Canadian GAAP	12,439	9,226
IFRS adjustments attributable to:		
Impairment of Cetrotide® asset	(a) (11,179)	(12,907)
Derecognition of deferred transaction costs	(b) (3,947)	(4,747)
Liability accounting for share purchase warrants	(c) (14,367)	(1,664)
Onerous lease provision	(d) (312)	(367)



Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

Termination benefit adjustment	(e)	(209)	(381)
Shareholders' deficiency under IFRS		(17,575)	(10,840)

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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>Year ended December 31, 2010 \$</b>
<b>Reconciliation of comprehensive loss</b>	
Comprehensive loss under Canadian GAAP	(23,169)
IFRS adjustments attributable to:	
Impairment of Cetrotide® asset	(a) 924
Derecognition of deferred transaction costs	(b) 504
Liability accounting for share purchase warrants	(c) (6,368)
Onerous lease provision	(d) 52
Termination benefit adjustment	(e) 152
Share-based compensation	(f) (306)
Foreign currency translation adjustments to shareholders' deficiency	952
Comprehensive loss under IFRS	(27,259)

**Explanatory notes**

In addition to the IFRS 1 exemptions discussed above, the following section discusses the changes in accounting policies that resulted in the adjustments shown in the preceding reconciliations.

## (a) Impairment of assets

Under Canadian GAAP, property, plant and equipment and intangible assets with finite lives were reviewed for impairment whenever events or circumstances indicated that the carrying values of those assets may not be recoverable. Impairments were deemed to exist when the carrying value of the asset or asset group was greater than the undiscounted future cash flows expected to be provided by the asset or asset group. The amount of impairment loss, if any, was equivalent to the excess of the asset's or asset group's carrying value over fair value, which in turn was determined based upon discounted cash flows or appraised values, depending on the nature of assets.

Under IFRS, once an indication of impairment is identified, similar to Canadian GAAP, an entity is required to make a formal estimate of recoverable amount. However, unlike Canadian GAAP, the carrying amount of an asset that is subject to impairment testing under IFRS is compared to the higher of fair value less costs to sell or value in use. Where the recoverable amount of an asset subject to impairment testing is compared to the asset's value in use, any future cash flows expected to be provided by the asset are discounted, unlike Canadian GAAP.

As a result of the change in measurement methodology, the Company recognized an additional impairment charge, amounting to \$12,907,000 as of the Transition Date related to the intangible asset, Cetrotide®, since the carrying amount of that asset exceeded its recoverable amount. The Company has adjusted related amortization charges in the Company's comparative consolidated statement of comprehensive loss for the year ended December 31, 2010.

---

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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) Deferred transaction costs

Under Canadian GAAP, transaction costs incurred in connection with the Company's December 2008 sale to Cowen of the Company's rights to royalties on future sales of Cetrotide<sup>®</sup> were capitalized as deferred charges and were being amortized based on the units-of-revenue method and over the same period in which the related deferred revenues were recognized as royalty revenues.

Under IFRS, the related transaction costs have been charged to expense as incurred.

As a result, the Company has derecognized the remaining unamortized portion of the deferred transaction costs, amounting to \$4,747,000, as of the Transition Date and has reversed any related amortization expense in the Company's comparative consolidated statements of comprehensive loss for the year ended December 31, 2010.

(c) Accounting for share purchase warrants

Under Canadian GAAP, the Company had classified and was accounting for all of its outstanding common share purchase warrants as equity, on the basis that the warrants did not embody a contractual obligation on the Company to deliver cash or another financial asset to the holder of those warrants. All share purchase warrants issued in connection with the Company's registered direct offerings contain a written put option, arising upon the occurrence of a Fundamental Transaction, as defined in all outstanding warrants and including a change in control. The exercise of the put options was not considered to be probable at any reporting date under Canadian GAAP.

Under IFRS, financial instruments that have terms whereby the issuer of the instrument does or could in the future not have the unconditional right to avoid delivering cash must be classified as a liability and measured at FVTPL. Additionally, IFRS requires that any transaction costs on financial instruments carried at FVTPL be expensed immediately, and not included in the initial measurement of the instrument.

As a result of the presence of the aforementioned put options, and despite the fact that the repurchase feature is conditional on a defined contingency, the share purchase warrants are required to be classified as a liability under IFRS, since such a contingency ultimately could result in the transfer of assets by the Company. As a result, all share purchase warrants are classified as a liability and are measured at fair value, or \$1,664,000 as of the Transition Date, and any periodic changes in fair value are recognized as gains or losses through profit or loss. Transaction costs related to the FVTPL instruments were expensed under IFRS.

(d) Onerous lease provision

Under Canadian GAAP, there is no single standard that provides guidance related to the identification or accounting for provisions, nor are provisions specifically defined. Additionally, onerous contracts are not specifically referred to under Canadian GAAP. Implicit references to onerous arrangements are derived from broader principles underlying the definition of a contingency or liability and are oftentimes limited in practice to an entity's exit or restructuring activities.

Under IFRS, accounting for onerous contracts, defined as contracts in which the unavoidable costs of meeting the obligations under the contract exceed the economic benefits expected to be received under it, is explicitly prescribed. Furthermore, the Company is required to determine, at each reporting date, whether any onerous contracts exist, and, if the Company has a contract that is deemed to be onerous, the present obligation under that contract must be recognized and measured as a provision.



**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 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 determined that it had a lease arrangement that was partially onerous as of the Transition Date, and as a result, a provision of \$367,000 was recognized at that date.

(e) Employee benefits

*Actuarial gains and losses*

Under Canadian GAAP, all actuarial gains and losses arising in the calculation of the Company's defined benefit obligation have been recorded in profit or loss as incurred.

Under IFRS, actuarial gains and losses may be recognized, as incurred, in other comprehensive income or loss, provided that the Company does so for all of its defined benefit plans and all of its actuarial gains and losses.

Management has chosen to recognize actuarial gains and losses as incurred directly in other comprehensive loss beginning on the Transition Date. As a result, the Company adjusted its employee benefit expenses to remove the net actuarial gains, amounting to \$191,000 for the year ended December 31, 2010. Instead, net actuarial gains has been recorded directly in other comprehensive loss, net of tax, in the deficit in the consolidated statement of financial position as at December 31, 2010, without recycling to the consolidated statement of comprehensive loss in subsequent periods.

*Termination benefits*

Certain Group employees in Germany are eligible to participate in a partial retirement program, which is composed of a full-time service period and an inactive period, where the employee receives 50% of his or her salary for each year as well as an annual bonus during the entire partial retirement period.

Under Canadian GAAP, the annual bonus to be paid in the inactive period is recognized as expense on a pro rata basis over the full-time service period.

Under IFRS, the entire bonus element of the partial retirement arrangement is recognized as an expense immediately when the related partial retirement agreement is established.

As a result, the Company has recognized an additional liability, amounting to \$381,000, to reflect the aggregate bonus element of the partial retirement arrangement as of the Transition Date.

(f) Share-based payments

Under Canadian GAAP, for share-based awards with graded vesting, the Company recognizes the fair value of the award (all tranches) on a straight-line basis over the underlying vesting period. Additionally, forfeitures of awards are not estimated at the date of grant and therefore are not included in the calculation of the grant-date fair value. Instead, all forfeitures of awards are recognized as they occur.



**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

Under IFRS, each tranche of a share-based award with graded vesting is treated as a separate award, and the resulting compensation expense is recognized for each tranche over its distinct vesting period. Furthermore, expected forfeitures of awards are required to be estimated at the date of grant and therefore are factored into the determination of fair value.

The Company has adjusted its periodic share-based compensation expense for underlying awards in order to reflect the change in policy related to graded vesting and estimated expected forfeitures. These adjustments have resulted in an increase in share-based compensation costs of \$306,000 for the year ended December 31, 2010.

**Reconciliations of consolidated financial statements**

Presented below are reconciliations of the Company's consolidated financial statements previously prepared under Canadian GAAP to the consolidated financial statements prepared in accordance with IFRS.

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**Reconciliation of Consolidated Statement of Financial Position as at December 31, 2010**

Canadian GAAP accounts	Canadian GAAP balances \$	IFRS adjustments \$	IFRS reclassifications \$	IFRS balances \$	IFRS accounts
<b>ASSETS</b>					<b>ASSETS</b>
<b>Current assets</b>					<b>Current assets</b>
Cash and cash equivalents	31,998	-	-	31,998	Cash and cash equivalents
Short-term investment	1,934	-	-	1,934	Short-term investment
Accounts receivable					
Trade	4,555	-	866	5,421	Trade and other receivables
Other	748	-	(748)	-	
Income taxes	118	-	(118)	-	
Inventory	3,311	-	-	3,311	Inventory
Prepaid expenses and other current assets	1,511	(366)	-	1,145	Prepaid expenses and other current assets
	44,175	(366)	-	43,809	
<b>Restricted cash</b>	827	-	-	827	<b>Restricted cash</b>
<b>Property, plant and equipment</b>	3,096	-	-	3,096	<b>Property, plant and equipment</b>
<b>Deferred charges and other long-term assets</b>	4,384	(3,581)	-	803	<b>Deferred charges and other non-current assets</b>
<b>Intangible assets</b>	14,478	(11,179)	-	3,299	<b>Identifiable intangible assets</b>
<b>Goodwill</b>	9,614	-	-	9,614	<b>Goodwill</b>
	76,574	(15,126)	-	61,448	
<b>LIABILITIES</b>					<b>LIABILITIES</b>
<b>Current liabilities</b>					<b>Current liabilities</b>
Accounts payable and accrued liabilities	9,382	878	-	10,260	Payables and accrued liabilities
Deferred revenues	4,045	-	-	4,045	Current portion of deferred revenues
Current portion of long-term payable	60	-	-	60	Current portion of long-term payable
	13,487	878	-	14,365	
<b>Deferred revenues</b>	39,052	-	-	39,052	<b>Deferred revenues</b>
	-	13,412	-	13,412	<b>Warrant liability</b>



Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

<b>Long-term payable</b>	90	-	-	90	<b>Long-term payable</b>
<b>Employee future benefits</b>	11,324	209	-	11,533	<b>Employee future benefits</b>
<b>Other long-term liability</b>	182	389	-	571	<b>Provision and other non-current liabilities</b>
	64,135	14,888	-	79,023	
<b>SHAREHOLDERS EQUITY</b>					<b>SHAREHOLDERS DEFICIENCY</b>
<b>Share capital</b>	60,149	751	-	60,900	<b>Share capital</b>
<b>Warrants</b>	9,493	(9,493)	-	-	
<b>Other capital</b>	80,785	306	-	81,091	<b>Other capital</b>
<b>Deficit</b>	(150,756)	(9,811)	-	(160,567)	<b>Deficit</b>
<b>Accumulated other comprehensive income</b>	12,768	(11,767)	-	1,001	<b>Accumulated other comprehensive income</b>
	12,439	(30,014)	-	(17,575)	
	76,574	(15,126)	-	61,448	

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**Reconciliation of Consolidated Statement of Comprehensive Loss for the year ended December 31, 2010**

Canadian GAAP accounts	Canadian GAAP balances \$	IFRS adjustments \$	IFRS reclassifications \$	IFRS balances \$	IFRS accounts
<b>Revenues</b>					<b>Revenues</b>
Sales and royalties	24,857	-	-	24,857	Sales and royalties
License fees and other	2,846	-	-	2,846	License fees and other
	27,703	-	-	27,703	
<b>Operating expenses</b>					<b>Operating expenses</b>
Cost of sales, excluding depreciation and amortization	18,700	-	-	18,700	Cost of sales
Research and development costs, net of tax credits and grants	19,859	1,398	-	21,257	Research and development costs, net of refundable tax credits and grants
Selling, general and administrative expenses	11,875	682	(5)	12,552	Selling, general and administrative expenses
Depreciation and amortization					
Property, plant and equipment	1,005	(1,005)	-	-	
Intangible assets	1,492	(1,492)	-	-	
	52,931	(417)	(5)	52,509	
<b>Loss from operations</b>	(25,228)	417	5	(24,806)	<b>Loss from operations</b>
<b>Other income</b>					
Unrealized gain on held-for-trading financial instrument	687	-	(687)	-	
Interest income	181	-	4,860	5,041	Finance income
Foreign exchange gain	1,170	1,091	(2,261)	-	
Loss on disposal of equipment	(28)	-	28	-	Finance costs
	-	(6,741)	(1,945)	(8,686)	Net finance income (costs)
	2,010	(5,650)	(5)	(3,645)	
<b>Net loss</b>	(23,218)	(5,233)		(28,451)	<b>Net loss</b>

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

Other comprehensive income:					Other comprehensive income:				
Foreign currency translation adjustments					Foreign currency translation adjustments				
	49	952	-	1,001					
	-	191	-	191					Actuarial gain on defined benefit plans, net of tax
<b>Comprehensive loss</b>	(23,169)	(4,090)	-	(27,259)	<b>Comprehensive loss</b>				
<b>Net loss per share</b>					<b>Net loss per share</b>				
Basic and diluted					Basic and diluted				
	(0.31)	(0.07)	-	(0.38)					
<b>Weighted average number of shares</b>					<b>Weighted average number of shares</b>				
Basic and diluted					Basic and diluted				
	75,659,410	-	-	75,659,410					

**Table of Contents****Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**Reconciliation of Consolidated Statement of Financial Position as at January 1, 2010**

Canadian GAAP accounts	Canadian GAAP balances \$	IFRS adjustments \$	IFRS reclassifications \$	IFRS balances \$	IFRS accounts
<b>ASSETS</b>					<b>ASSETS</b>
<b>Current assets</b>					<b>Current assets</b>
Cash and cash equivalents	38,100	-	-	38,100	Cash and cash equivalents
Accounts receivable					
Trade	2,444	-	1,105	3,549	Trade and other receivables
Other	992	-	(992)	-	
Income taxes	113	-	(113)	-	
Inventory	4,415	-	-	4,415	Inventory
Prepaid expenses and other current assets	2,949	(542)	-	2,407	Prepaid expenses and other current assets
	49,013	(542)	-	48,471	
<b>Restricted cash</b>	878	-	-	878	<b>Restricted cash</b>
<b>Property, plant and equipment</b>	4,358	-	-	4,358	<b>Property, plant and equipment</b>
<b>Deferred charges and other long-term assets</b>	4,733	(4,205)	-	528	<b>Deferred charges and other non-current assets</b>
<b>Intangible assets</b>	17,034	(12,907)	-	4,127	<b>Identifiable intangible assets</b>
<b>Goodwill</b>	10,246	-	-	10,246	<b>Goodwill</b>
	86,262	(17,654)	-	68,608	
<b>LIABILITIES</b>					<b>LIABILITIES</b>
<b>Current liabilities</b>					<b>Current liabilities</b>
Accounts payable and accrued liabilities	11,919	(74)	-	11,845	Payables and accrued liabilities
Deferred revenues	6,327	-	-	6,327	Current portion of deferred revenues
Income taxes	965	-	-	965	Income taxes
Current portion of long-term payable	57	-	-	57	Current portion of long-term payable
	19,268	(74)	-	19,194	
<b>Deferred revenues</b>	45,919	-	-	45,919	<b>Deferred revenues</b>

Edgar Filing: Aeterna Zentaris Inc. - Form 20-F

	-	1,664	-	1,664	<b>Warrant liability</b>
<b>Long-term payable</b>	143	-	-	143	<b>Long-term payable</b>
<b>Employee future benefits</b>	11,640	381	-	12,021	<b>Employee future benefits</b>
<b>Other long-term liability</b>	66	441	-	507	<b>Provision and other non-current liability</b>
	77,036	2,412	-	79,448	
					<b>SHAREHOLDERS</b>
<b>SHAREHOLDERS EQUITY</b>					<b>DEFICIENCY</b>
<b>Share capital</b>	41,203	321	-	41,524	<b>Share capital</b>
<b>Warrants</b>	2,899	(2,899)	-	-	
<b>Other capital</b>	79,943	-	-	79,943	<b>Other capital</b>
<b>Deficit</b>	(127,538)	(4,769)	-	(132,307)	<b>Deficit</b>
<b>Accumulated other comprehensive income</b>	12,719	(12,719)	-	-	
	9,226	(20,066)	-	(10,840)	
	86,262	(17,654)	-	68,608	

**Table of Contents**

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

As at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and 2010

(tabular amounts in thousands of US dollars, except share/option/warrant and per share/option/warrant data and as otherwise noted)

**30 Subsequent events**

On January 23, 2012, the Company, pursuant to its existing ATM sales agreement dated June 29, 2011, with MLV, was commencing a new ATM issuance program ( January 2012 ATM Sales Agreement ) under which it may, at its discretion, from time to time during the term of the sales agreement, sell up to a maximum of 10,400,000 of its common shares through ATM issuances on the NASDAQ up to an aggregate amount of \$16,000,000.

From January 23, 2012 through March 15, 2012, the Company issued a total of 3,565,470 common shares under the January 2012 ATM Sales Agreement for aggregate gross proceeds of \$6,397,045, less cash transaction costs of \$191,911 and previously deferred transaction costs of \$56,000.

**Table of Contents**

**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 By-Law One adopted by the Registrant's Board of Directors on March 22, 2011 (incorporated by reference to Exhibit 1.2 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)
- 2 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 Stock Option Plan of the Registrant (incorporated by reference to Exhibit 4.1 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)
- 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 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)
- 4.12 License and Cooperation Agreement for Perifosine by and between Zentaris AG and AOI Pharma, Inc. dated September 18, 2002 (incorporated by reference to Exhibit 99.1 to the Registrant's report on Form 6-K furnished to the Commission on March 30, 2010)

---

**Table of Contents**

- 4.13 Addendum agreement to License and Cooperation Agreement for Perifosine by and between Zentaris AG and AOI Pharma, Inc. dated December 3, 2003 (incorporated by reference to Exhibit 99.2 to the Registrant's report on Form 6-K furnished to the Commission on March 30, 2010)
- 4.14 First Amendment to License and Cooperation Agreement for perifosine by and between Aeterna Zentaris GmbH and AOI Pharma Inc., dated November 29, 2007 (incorporated by reference to Exhibit 99.3 to the Registrant's report on Form 6-K furnished to the Commission on March 30, 2010)
- 4.15 Development, Commercialization and Licensing Agreement for perifosine by and between Aeterna Zentaris GmbH and Yakult Honsha Co., Ltd dated March 8, 2011 (incorporated by reference to Exhibit 99.1 to the Registrant's report on Form 6-K furnished to the Commission on March 31, 2011)
- 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.

Confidential treatment has been requested for certain portions of this exhibit, which portions have been omitted and filed separately with the U.S. Securities and Exchange Commission.



**Table of Contents**

**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, CA  
Senior Vice President and Chief Financial Officer

**Date: March 27, 2012**