

Aeterna Zentaris Inc.  
Form 20-F  
March 30, 2009  
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**
- Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the fiscal year ended December 31, 2008**
- 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

**ÆTERNA 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.**  
**Québec, Quebec**  
**Canada, G1P 4P5**

**Dennis Turpin**

**Telephone: (418)-652-8525**

**E-mail: dturpin@aezsinc.com**

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

| <b>Title of Each Class</b> | <b>Name of Each Exchange on Which Registered</b> |
|----------------------------|--|
| Common Shares              | NASDAQ Global Market<br>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 of the close of the period covered by the annual report: 53,187,470 common shares as of December 31, 2008.

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in a definitive proxy or information statements incorporated by reference in Part III of this Form 20-F or any amendment to this Form 20-F.

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 checkmark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP  International Financial Reporting Standards as issued by the International Accounting Standards Board  Other

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 and references to CAN\$ are to Canadian dollars. Unless otherwise indicated, the statistical and financial data contained in this annual report are presented as at December 31, 2008.

**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 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 we disclaim any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments except if we are requested 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>Advisers</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>                            | 4           |
| C. <u>Reasons for the offer and use of proceeds</u>                  | 4           |
| D. <u>Risk factors</u>   | 4           |
| Item 4. <u>Information on the Company</u>                            | 15          |
| A. <u>History and development of the Company</u>                     | 15          |
| B. <u>Business overview</u>  | 17          |
| C. <u>Organizational structure</u>                                   | 41          |
| D. <u>Property, plants and equipment</u>                             | 42          |
| Item 4A. <u>Unresolved Staff Comments</u>                            | 42          |
| Item 5. <u>Operating and Financial Review and Prospects</u>          | 42          |
| Item 6. <u>Directors, Senior Management and Employees</u>            | 75          |
| A. <u>Directors and senior management</u>                            | 75          |
| B. <u>Compensation</u>   | 78          |
| C. <u>Board practices</u>  | 91          |
| D. <u>Employees</u>  | 92          |
| E. <u>Share ownership</u>  | 93          |
| Item 7. <u>Major Shareholders and Related Party Transactions</u>     | 93          |
| A. <u>Major shareholders</u>   | 93          |
| B. <u>Related party transactions</u>                                 | 94          |
| C. <u>Interests of experts and counsel</u>                           | 94          |
| Item 8. <u>Financial Information</u>                                 | 94          |
| A. <u>Consolidated statements and other financial information</u>    | 94          |
| B. <u>Significant changes</u>  | 95          |
| Item 9. <u>The Offering and Listing</u>                              | 95          |
| A. <u>Offer and listing details</u>                                  | 95          |
| B. <u>Plan of distribution</u>                                       | 95          |
| C. <u>Markets</u>  | 95          |
| D. <u>Selling shareholders</u>                                       | 95          |
| E. <u>Dilution</u>   | 96          |
| F. <u>Expenses of the issuer</u>                                     | 96          |
| Item 10. <u>Additional Information</u>                               | 96          |
| A. <u>Share capital</u>  | 96          |
| B. <u>Memorandum and articles of association</u>                     | 96          |
| C. <u>Material contracts</u>   | 104         |

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

|           |                                    |     |
|-----------|------------------------------------|-----|
| <u>D.</u> | <u>Exchange controls</u>           | 105 |
| <u>E.</u> | <u>Taxation</u>                    | 105 |
| <u>F.</u> | <u>Dividends and paying agents</u> | 110 |
| <u>G.</u> | <u>Statement by experts</u>        | 110 |

---

Table of Contents

|                        |           |  |            |
|------------------------|-----------|--|------------|
|                        | <u>H.</u> | <u>Documents on display</u>  | 110        |
|                        | <u>I.</u> | <u>Subsidiary information</u>  | 111        |
| <u>Item 11.</u>        |           | <u>Quantitative and Qualitative Disclosures About Market Risk</u>                  | 111        |
| <u>Item 12.</u>        |           | <u>Description of Securities Other than Equity Securities</u>                      | 111        |
|                        | <u>A.</u> | <u>Debt securities</u>   | 111        |
|                        | <u>B.</u> | <u>Warrants and rights</u>   | 111        |
|                        | <u>C.</u> | <u>Other securities</u>  | 111        |
|                        | <u>D.</u> | <u>American depositary shares</u>  | 111        |
| <b><u>PART II</u></b>  |           |  | <b>111</b> |
| <u>Item 13.</u>        |           | <u>Defaults, Dividend Arrearages and Delinquencies</u>                             | 111        |
| <u>Item 14.</u>        |           | <u>Material Modification to the Rights of Security Holders and Use of Proceeds</u> | 111        |
| <u>Item 15.</u>        |           | <u>Controls and Procedures</u>   | 112        |
| <u>Item 16.</u>        |           | <u>[Reserved]</u>  | 113        |
| <u>Item 16A.</u>       |           | <u>Audit Committee Financial Expert</u>  | 113        |
| <u>Item 16B.</u>       |           | <u>Code of Ethics</u>  | 113        |
| <u>Item 16C.</u>       |           | <u>Principal Accountant Fees and Services</u>                                      | 113        |
|                        | <u>A.</u> | <u>Audit Fees</u>  | 113        |
|                        | <u>B.</u> | <u>Audit-related Fees</u>  | 114        |
|                        | <u>C.</u> | <u>Tax Fees</u>  | 114        |
|                        | <u>D.</u> | <u>All Other Fees</u>  | 114        |
|                        | <u>E.</u> | <u>Audit Committee Pre-Approval Policies and Procedures</u>                        | 114        |
| <u>Item 16D.</u>       |           | <u>Exemptions from the Listing Standards for Audit Committees</u>                  | 114        |
| <u>Item 16E.</u>       |           | <u>Purchases of Equity Securities by the Issuer and Affiliated Purchasers</u>      | 114        |
| <u>Item 16F.</u>       |           | <u>Changes in Registrant's Certifying Accountant</u>                               | 114        |
| <u>Item 16G.</u>       |           | <u>Corporate Governance</u>  | 114        |
| <b><u>PART III</u></b> |           |  | <b>115</b> |
| <u>Item 17.</u>        |           | <u>Financial Statements</u>  | 115        |
| <u>Item 18.</u>        |           | <u>Financial Statements</u>  | 115        |
| <u>Item 19.</u>        |           | <u>Exhibits</u>  | 174        |

**Table of Contents**

**PART I**

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

***A. Directors and senior management***

Not applicable.

***B. Advisers***

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 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 Earnings Data:***Amounts under Canadian GAAP**(in thousands of US dollars, except share and per share data)*

|  | Years Ended December 31, |          |          |          |          |
|--|--------------------------|----------|----------|----------|----------|
|  | 2008                     | 2007     | 2006     | 2005     | 2004     |
|  | \$                       | \$       | \$       | \$       | \$       |
| <b>Revenues</b>  | 38,478                   | 42,068   | 38,799   | 44,813   | 42,972   |
| <b>Operating expenses</b>                                  |                          |          |          |          |          |
| Cost of sales  | 19,278                   | 12,930   | 11,270   | 8,250    | 7,992    |
| Selling, general and administrative                        | 17,325                   | 20,403   | 16,478   | 14,403   | 13,137   |
| Research and development costs                             | 57,448                   | 39,248   | 27,422   | 25,544   | 23,431   |
| Research and development tax credits and grants            | (343)                    | (2,060)  | (1,564)  | (317)    | (845)    |
| Depreciation and amortization                              |                          |          |          |          |          |
| Property, plant and equipment                              | 1,515                    | 1,562    | 2,816    | 1,665    | 1,958    |
| Intangible assets  | 5,639                    | 4,004    | 6,148    | 4,279    | 4,178    |
| Impairment of long-lived asset held for sale               |                          | 735      |          |          |          |
|  | 100,862                  | 76,822   | 62,570   | 53,824   | 49,851   |
| <b>Loss from operations</b>                                | (62,384)                 | (34,754) | (23,771) | (9,011)  | (6,879)  |
| <b>Other income (expenses)</b>                             |                          |          |          |          |          |
| <b>Interest income</b>                                     | 868                      | 1,904    | 1,441    | 1,235    | 1,286    |
| Interest expense   |                          |          |          |          |          |
| Long-term debt and convertible term loans                  |                          | (85)     | (1,270)  | (6,979)  | (4,150)  |
| Other  | (118)                    |          | (163)    | (31)     | (69)     |
| Foreign exchange (loss) gain                               | 3,071                    | (1,035)  | 319      | (87)     | (491)    |
| Loss on disposal of long-lived assets held for sale        | (35)                     |          |          |          |          |
| Loss on disposal of equipment                              | (44)                     | (28)     |          |          |          |
| Gain on disposal of a long-term investment                 |                          |          | 409      |          |          |
|  | 3,742                    | 756      | 736      | (5,862)  | (3,424)  |
| <b>Share in the results of an affiliated company</b>       |                          |          | 1,575    |          |          |
| <b>Loss before income taxes from continuing operations</b> | (58,642)                 | (33,998) | (21,460) | (14,873) | (10,303) |
| <b>Income tax (expense) recovery</b>                       | (1,175)                  | 1,961    | 29,037   | (609)    | (273)    |
| <b>Net (loss) earnings from continuing operations</b>      | (59,817)                 | (32,037) | 7,577    | (15,482) | (10,576) |
|  |                          | (259)    | 25,813   | 26,053   | 6,151    |

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

**Net (loss) earnings from discontinued operations**

|   |          |          |        |        |         |
|---|----------|----------|--------|--------|---------|
| <b>Net (loss) earnings for the year</b> | (59,817) | (32,296) | 33,390 | 10,571 | (4,425) |
|---|----------|----------|--------|--------|---------|

**Net (loss) earnings per share from continuing operations**

|         |        |        |      |        |        |
|---------|--------|--------|------|--------|--------|
| Basic   | (1.12) | (0.61) | 0.14 | (0.34) | (0.23) |
| Diluted | (1.12) | (0.61) | 0.14 | (0.34) | (0.23) |

**Net (loss) earnings per share from discontinued operations**

|         |  |  |      |      |      |
|---------|--|--|------|------|------|
| Basic   |  |  | 0.50 | 0.57 | 0.13 |
| Diluted |  |  | 0.48 | 0.57 | 0.13 |

**Net (loss) earnings per share**

|         |        |        |      |      |        |
|---------|--------|--------|------|------|--------|
| Basic   | (1.12) | (0.61) | 0.64 | 0.23 | (0.10) |
| Diluted | (1.12) | (0.61) | 0.62 | 0.23 | (0.10) |

**Weighted average number of shares**

|         |            |            |            |            |            |
|---------|------------|------------|------------|------------|------------|
| Basic   | 53,187,470 | 53,182,803 | 52,099,290 | 46,139,814 | 45,569,176 |
| Diluted | 53,187,470 | 53,182,803 | 52,549,260 | 46,139,814 | 45,569,176 |

Table of Contents*Amounts under U.S. GAAP*

|   | Years ended December 31, |            |            |            |            |
|---|--------------------------|------------|------------|------------|------------|
|   | 2008                     | 2007       | 2006       | 2005       | 2004       |
|   | \$                       | \$         | \$         | \$         | \$         |
| <b>Net (loss) earnings for the year</b>                           | (56,070)                 | (37,428)   | 34,262     | 15,970     | (2,082)    |
| <b>Out of which:</b>  |                          |            |            |            |            |
| <b>Net (loss) earnings from:</b>                                  |                          |            |            |            |            |
| <b>continuing operations</b>                                      | (56,070)                 | (36,415)   | 8,449      | (10,083)   | (8,158)    |
| <b>discontinued operations</b>                                    |                          | (1,013)    | 25,813     | 26,053     | 6,076      |
| <b>Net (loss) earnings per share from continuing operations</b>   |                          |            |            |            |            |
| Basic   | (1.05)                   | (0.68)     | 0.16       | (0.22)     | (0.18)     |
| Diluted   | (1.05)                   | (0.68)     | 0.16       | (0.22)     | (0.18)     |
| <b>Net (loss) earnings per share from discontinued operations</b> |                          |            |            |            |            |
| Basic   |                          | (0.02)     | 0.50       | 0.56       | 0.13       |
| Diluted   |                          | (0.02)     | 0.49       | 0.56       | 0.13       |
| <b>Net (loss) earnings per share</b>                              |                          |            |            |            |            |
| Basic   | (1.05)                   | (0.70)     | 0.66       | 0.34       | (0.05)     |
| Diluted   | (1.05)                   | (0.70)     | 0.65       | 0.34       | (0.05)     |
| <b>Weighted average number of shares</b>                          |                          |            |            |            |            |
| Basic   | 53,187,470               | 53,182,803 | 52,099,290 | 46,139,814 | 45,569,176 |
| Diluted   | 53,187,470               | 53,182,803 | 52,549,260 | 46,139,814 | 45,569,176 |

**Consolidated Balance Sheet Data:***Amounts under Canadian GAAP*

|                            | As at December 31, |         |         |         |         |
|----------------------------|--------------------|---------|---------|---------|---------|
|                            | 2008               | 2007    | 2006    | 2005    | 2004    |
|                            | \$                 | \$      | \$      | \$      | \$      |
| Cash and cash equivalents  | 49,226             | 10,272  | 8,939   | 12,234  | 13,568  |
| Short-term investments     | 493                | 31,115  | 51,550  | 22,370  | 22,477  |
| Working capital            | 39,554             | 37,325  | 85,413  | 99,502  | 60,291  |
| Total assets               | 108,342            | 123,363 | 223,491 | 419,785 | 290,539 |
| Long-term debt and payable | 172                |         | 687     | 29,866  | 17,398  |
| Share capital              | 30,566             | 30,566  | 168,466 | 130,344 | 127,585 |
| Shareholder s equity       | 21,475             | 88,591  | 178,879 | 109,531 | 100,076 |

*Amounts under U.S. GAAP*

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

|                            | 2008    | 2007    | As at December 31,<br>2006 | 2005    | 2004    |
|----------------------------|---------|---------|----------------------------|---------|---------|
|                            | \$      | \$      | \$                         | \$      | \$      |
| Cash and cash equivalents  | 49,226  | 10,272  | 8,939                      | 12,234  | 13,568  |
| Short-term investments     | 493     | 31,115  | 51,550                     | 22,370  | 22,477  |
| Working capital            | 39,554  | 37,325  | 85,413                     | 99,502  | 60,291  |
| Total assets               | 100,001 | 109,182 | 209,143                    | 404,587 | 271,440 |
| Long-term debt and payable | 172     |         | 687                        | 30,858  | 19,986  |
| Share capital              | 22,589  | 22,589  | 160,489                    | 129,750 | 126,991 |
| Shareholder s equity       | 13,134  | 74,410  | 169,704                    | 99,797  | 86,659  |

**Table of Contents**

***B. Capitalization and indebtedness***

Not applicable.

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

Not applicable.

***D. Risk factors***

**Risks related 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 of December 31, 2008, we had an accumulated deficit of \$102.8 million. Our operating losses have adversely impacted, and will continue to adversely impact, our working capital, total assets and shareholders' equity. 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 research and development ( R&D ) and clinical study programs and our sales and marketing activities and seek regulatory approval for our product candidates. Even if we succeed in developing new commercial products, we expect to incur additional operating losses for at least the next several years. If we do not ultimately generate sufficient revenue from commercialized products and achieve or maintain operating profitability, an investment in our securities could result in a significant or total loss.

*We do not have the required regulatory approvals to market certain of our product candidates, and we do not know if we will ever receive such approvals.*

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

With the exception of Cetrotide® (cetorelix) for the treatment of infertility, 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. Preparing, submitting and advancing applications for regulatory approval is complex, expensive and time-consuming and entails significant uncertainty. Even if a product candidate is approved by the Food and Drug Administration ( 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.

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 our share price.*

We will only receive regulatory approval for a product candidate if we can demonstrate in carefully designed and conducted clinical trials that the product candidate is both safe and effective. We do not know whether our pending or any future clinical trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products. Unfavorable data from those studies could result in the withdrawal of marketing approval for approved products or an extension of the review period for developmental products. Clinical trials are inherently lengthy, complex, expensive and uncertain processes. 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.

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 Contract Research Organizations ( 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 our share price.

*If we encounter difficulties enrolling patients in our clinical trials, our trials could be delayed or otherwise adversely affected.*

Clinical trials for our product candidates require that we or third parties identify and enroll a specific number of patients. We or such third parties may not be able to enroll a sufficient number of patients to complete our clinical trials in a timely manner. Patient enrollment is a function of many factors including:

- design of the protocol;
- the size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the drug under study and of the control drug, if any;
- availability of competing therapies already approved;
- number of competing clinical trials ongoing in the same indication;
- efforts to facilitate timely enrollment in clinical trials;

Table of Contents

- patient referral practices of physicians; and
- availability of clinical trial sites.

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.

***Even if we obtain regulatory approvals for our product candidates, we will be subject to stringent ongoing government regulation.***

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

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

If we, or any future marketing collaborators or contract manufacturers, fail to comply with applicable regulatory requirements, we may be subject to sanctions including fines, product recalls or seizures and related publicity requirements, injunctions, total or partial suspension of production, civil penalties, suspension or withdrawals of previously granted regulatory approvals, warning or untitled letters, refusal to approve pending applications for marketing approval of new products or of supplements to approved applications, import or export bans or restrictions, and criminal prosecution and penalties. Any of these penalties could delay or prevent the promotion, marketing or sale of our products.

***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 our share price.

***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, our share price 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.

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

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.

Table of Contents

***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 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 also may 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 (the USPTO) to determine priority of invention in the

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

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

Table of Contents

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.

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 any of our trademarks or will not request reconsideration of one of our trademarks at some time in

Table of Contents

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.

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

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

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

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

- the duration and results of our clinical trials for cetorelix, ozarelix and perifosine, as well as other product candidates going forward;
- unexpected delays or developments in seeking regulatory approvals;
- the time and cost in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- other unexpected developments encountered in implementing our business development and commercialization strategies;
- the outcome of litigation, if any; and

- further arrangements, if any, with collaborators.

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

*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 our share price.*

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;

Table of Contents

- 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, our share price could fluctuate significantly or decline.

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

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

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

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

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

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

We may not realize the contemplated benefits of such agreements nor can we be certain that any of these parties will fulfill their obligations in a manner which maximizes our revenue. These arrangements may also require us to transfer certain material rights or issue our equity or voting 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;

Table of Contents

- 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 our share price.

We have entered into important strategic partnership agreements relating to cetorelix, ozarelix and perifosine for various indications. Detailed information on our research and collaboration agreements is available in Notes 26 and 27 to our annual audited consolidated financial statements as of and for the year ended December 31, 2008 included elsewhere in this annual report.

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.

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

In particular, we have entered into an agreement with Tulane University ( Tulane ), which provides for the payment by us of single-digit royalties on future worldwide net sales for all indications, except in the BPH indication, where it provides the payment of low single-digit royalties. Tulane is also entitled to receive a low double-digit royalty on any lump sum, periodic or other cash payments received by us from sub-licensees (see Note 27 to our annual audited consolidated financial statements as of and for year ended December 31, 2008 included elsewhere in this annual report).

*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 cGCP guidelines and the investigational plan and protocols contained in an Investigational New Drug application ( IND ), 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.

Table of Contents

***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.

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

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

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

Our manufacturing experience to date with respect to our product candidates consists of producing drug substance for clinical studies. To be successful, these product candidates have to be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. Our strategic partners' current manufacturing facilities have the capacity to produce projected product requirements for the foreseeable future, but we will need to increase capacity if sales continue to grow. Our strategic partners may not be able to expand capacity or to produce additional product requirements on favorable terms. Moreover, delays associated with securing additional manufacturing capacity may reduce our revenues and adversely affect our business and financial position. There can be no assurance that we will be able to meet increased demand over time.

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

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

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



*consequences.*

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

Table of Contents

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

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

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

Our operations are in many instances conducted in currencies other than the U.S. dollar (principally Euros), and fluctuations in the value of foreign currencies could cause us to incur currency exchange losses. We do not currently employ a hedging strategy against exchange rate risk. We cannot say 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.

***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 shares**

***Our share price is volatile, which may result from factors outside of our control. If we experience low trading volume or if our securities are delisted from the TSX or NASDAQ, you may have difficulty selling your shares.***

During 2008, the closing price of our shares ranged from CAN\$0.44 to CAN\$1.85 per share on the Toronto Stock Exchange ( TSX ), and from \$0.40 to \$1.80 on the NASDAQ Global Market ( NASDAQ ). Our share price may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. The biopharmaceutical sector in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of shares and trading volume of companies in the biopharmaceutical industry can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, operating performance. Our share price and trading volume may fluctuate based on a number of factors including, but not limited to:

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

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

Table of Contents

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

In the past, following periods of large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company. 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 shares on the TSX and NASDAQ. 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. During the latter half of 2008 and for part of 2009, our shares have closed below the \$1.00 per share minimum for several consecutive days on the NASDAQ. If the closing bid price falls below the \$1.00 minimum for more than 30 consecutive trading days, we would have 180 days to satisfy the \$1.00 minimum bid price, which must be maintained for a period of at least ten trading days in order to regain compliance. If our shares continue to close below \$1.00 per share during the initial 180 day period following a notice of noncompliance from NASDAQ, we could transfer from the NASDAQ Global Market to the NASDAQ Capital Market. Transferring from the NASDAQ Global Market to the NASDAQ Capital Market would provide us with an additional 180-day calendar day compliance period to regain compliance with the NASDAQ minimum bid price rule. On October 24, 2008, we announced that we had received a notification from NASDAQ regarding the failure by us to comply with NASDAQ's minimum bid price requirements. Although NASDAQ has temporarily suspended enforcement of its minimum bid price requirements, such requirements will be reinstated on April 19, 2009, or pending approval by the Securities and Exchange Commission of NASDAQ's proposed rule change, July 19, 2009. If we fail to meet any of NASDAQ's continued listing requirements and NASDAQ attempts to enforce compliance with its rules, our common shares may be delisted from NASDAQ. If our shares were delisted from TSX or NASDAQ, you may have difficulty in disposing of your shares.

***Our largest shareholders have influence over our business and corporate matters, including those requiring shareholder approval. This could delay or prevent a change in control. Sales of common shares by such shareholders could have an impact on our share price.***

Our two largest shareholders, which held 18.33% and 16.57% of our outstanding shares as of December 31, 2008, have influence over our business and corporate matters, including those requiring shareholder approval. This could delay or prevent a change in control. Sales of common shares by such shareholders could have an impact on our share price.

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

**Item 4. Information on the Company**

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

Æterna Zentaris Inc. is a global biopharmaceutical company focused on endocrine therapy and oncology with expertise in drug discovery, development and commercialization.

We were incorporated on September 12, 1990 under the laws of Canada. Our registered office is located at 1405 du Parc-Technologique Blvd., Québec, 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 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 inherited a very experienced pharmaceutical team along with a network of strategic pharmaceutical partners. The total consideration paid

Table of Contents

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 cash and the remaining amount of \$25.2 million as 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. Aeterna Zentaris 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 to sell 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 of 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 of 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.

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



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, nor will we in ensuing years. During the last three years, we have advanced our product development pipeline with a specific focus on our lead product candidates cetrotelix and AEZS-108 along with our partnered late-stage programs, ozarelix and perifosine, as well as our targeted earlier-stage programs, as depicted in the chart reproduced under the heading, *Our Product Pipeline* on page 21.

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

**B. Business overview**

Recent Developments

*Corporate Transactions*

***Sale of Impavido®***

On March 1, 2008, we entered into a definitive purchase and sales agreement with respect to all rights related to the manufacturing, production, distribution, marketing, sale and/or use of Impavido® (miltefosine) with Paladin Labs Inc. for an aggregate cash purchase price of approximately \$9.2 million. The transaction closed on March 31, 2008.

***Sale of building and land***

On June 26, 2008, we sold our Québec building and land for a gross amount of \$7.1 million that was paid entirely in cash. The net proceeds received amounted to \$6.5 million, resulting in an additional loss on sale of \$0.8 million. In connection with this sale, we entered into a long-term lease agreement with the principal tenant of the building.

***Sale of Cetrotide® royalty stream***

In November 2008, we entered into a purchase and sales agreement (the *Monetization Agreement*) with Cowen Healthcare Royalty Partners L.P. ( *CHRP* ) relating to our rights to royalties on future sales of Cetrotide® covered by our license agreement with Merck-Serono.



In connection with the transactions contemplated by the Monetization Agreement, which was effective on October 1, 2008 and closed in December 2008, we received \$52.5 million from CHRP, less transaction costs of \$1.0 million that had been advanced by CHRP to certain third-party firms and institutions on our behalf, resulting in net proceeds of \$51.5 million. Under the terms of the Monetization Agreement, we are entitled to receive an additional payment of \$2.5 million contingent on 2010 net sales of Cetrotide® reaching a specified level.

Under the terms of the Monetization Agreement, if cetorelix, the active substance in Cetrotide®, 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 \$5.0 million up to a maximum of \$15.0 million. The amount which may be due to CHRP will be higher in proportion to the timing of the product's receiving European regulatory approval; that is, the earlier the product receives regulatory approval, the higher the amount payable to CHRP will be.

*Partnership for cetorelix in BPH*

On March 5, 2009, we entered into a development, commercialization and license agreement with sanofi-aventis for the development, registration and marketing of cetorelix in BPH for the US market. Under the terms of the agreement, sanofi-aventis made an initial upfront payment to us of \$30.0 million, and we will be entitled to receive a total of \$135.0 million in payments upon achieving certain pre-established regulatory and commercial milestones. Furthermore, we will be entitled to receive escalating double-digit royalties on future net sales of cetorelix for BPH in the United States, while retaining the option to co-promote the product in that territory.

Table of Contents

***Changes to our Management Team and Board of Directors***

On April 11, 2008, Juergen Ernst, Chairman of the Board of Aeterna Zentaris at the time, was, appointed our interim President and Chief Executive Officer following the resignation of the former President and Chief Executive Officer.

On September 1, 2008, Prof. Juergen Engel, Ph.D., who was Executive Vice President and Chief Scientific Officer of Aeterna Zentaris at the time, was appointed our President and Chief Executive Officer. He succeeded Juergen Ernst, who became Executive Chairman of the Board, also as of September 1, 2008.

In December 2008, Matthias Seeber was appointed our Senior Vice President, Administration and Legal Affairs.

***Pipeline developments***

*Cetorelix:*

On March 22, 2007, our partner Shionogi announced positive results for a Phase 2a Japanese trial that was initiated in 2005. This trial was designed to evaluate primarily pharmacokinetics and safety (systemic and local tolerability) in Japanese subjects, whereas evaluation of efficacy was only exploratory. A total of 50 patients were included in five dosing groups corresponding to single administration of 30 mg, 60 mg or 90 mg of cetorelix and multiple administration of 60 mg and 90 mg, three times eight weeks apart. The observation period was up to 32 weeks in the multiple administration dosing groups. The Japanese patients responded to cetorelix with a transient reduction of testosterone concentration in blood, which did not reach or remain at the castration level. Intramuscular ( IM ) injection of cetorelix pamoate was safe and well tolerated at all dosages tested. None of the dosage regimens tested caused a suppression of prostate specific antigen ( PSA ) levels. Results also showed that the bioavailability of cetorelix in Japanese patients is similar to what is observed in non-Japanese patients. The sizes per dosage group were too small to evaluate efficacy trends for statistical significance. On the basis of this study, Shionogi initiated a 300-patient Phase 2b study to assess primarily the efficacy of cetorelix in BPH in Japanese patients with a different treatment regimen than the one used in Europe and North America. Phase 2b results were subsequently announced by Shionogi in November 2008. Results indicated an improvement of the International Prostate Symptom Score ( IPSS ) in the treatment group in a dose-dependent manner, although it was not statistically significant compared to the placebo group due to a high placebo response. A statistically significant reduction of prostate volume was observed between treatment and placebo groups. Shionogi also announced that a new Japanese study including higher dose divided into two doses with a two-week interval, according to the regimen used in our Phase 3 program, was in preparation.

In April 2008, we reported completion of patient recruitment for the first efficacy study of our Phase 3 program in BPH with cetorelix. This one year placebo-controlled study, involving 667 patients located mainly in North America, is assessing an intermittent dosage regimen of cetorelix as a potential safe and tolerable treatment providing prolonged improvement in BPH-related signs and symptoms. Results of this trial are expected in the third quarter of 2009.

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

In July 2008, we signed a license and cooperation agreement for the commercialization of cetorelix in BPH with Handok Pharmaceuticals Co., Ltd. ( Handok ) for the Korean market.

In October 2008, we reported the completion of patient recruitment for the second efficacy trial of the Phase 3 program with cetorelix in BPH. This trial, during which dosing had commenced in March 2008, has a similar design to the first efficacy trial and involves 420 patients located in Europe. Results of this trial are expected in the fourth quarter of 2009.

In December 2008, we reported completion of patient recruitment for the safety trial of the Phase 3 program with cetorelix in BPH. Results of this study, involving 529 patients located in North America, as well as those of a QTc study, are expected by the end of 2009.

On March 5, 2009, we entered into a development, commercialization and license agreement with sanofi-aventis for the development, registration and marketing of cetorelix in BPH for the US market. Under the terms of the agreement, sanofi-aventis made an initial upfront payment to us of \$30.0 million, and we will be entitled to receive a total of \$135.0 million in payments upon achieving certain pre-established regulatory and commercial milestones. Furthermore, we will be entitled to receive escalating double-digit royalties on future net sales of cetorelix for BPH in the United States, while retaining the option to co-promote the product in that territory. Sanofi-aventis may perform future Phase 3b and 4 clinical trials, while we will have access to all corresponding data for other territories.

Table of Contents

*AEZS-108:*

In February 2008, we reported that a first group of patients had been treated with our cytotoxic conjugate compound linked to doxorubicin, AEZS-108, for a European open-label, non-comparative multi-center Phase 2 trial in advanced ovarian and endometrial cancers.

In October 2008, we announced that we had entered the second stage of patient recruitment for our Phase 2 trial in ovarian cancer, after first stage data had shown two partial responses. In November 2008, we reported that we had entered the second stage of patient recruitment for our Phase 2 trial in endometrial cancer with AEZS-108. The decision to enter the second stage of patient recruitment was made following recent first stage data reporting one complete response and two partial responses among 14 patients with a diagnosis of disseminated endometrial cancer. The open-label, non-comparative multi-center Phase 2 program will treat up to 82 women with LHRH-receptor positive ovarian and endometrial cancerous tumors. The trial is being conducted in 15 centers in Europe. We expect to disclose Phase 2 results in the fourth quarter of 2009.

*Ozarelix:*

Our partner, Spectrum Pharmaceuticals, Inc. ( Spectrum ) released the results of a North American Phase 2 trial with ozarelix, a fourth generation LHRH antagonist in BPH. Spectrum indicated that ozarelix demonstrated sufficient clinical activity to justify its continued development. In early 2009, Spectrum initiated a North American multi-center, randomized, double-blind, placebo-controlled study in lower urinary tract symptoms due to BPH that will involve over 800 patients.

During the third quarter of 2008, we signed an agreement with Handok for the commercialization of ozarelix in BPH for the Korean and other Asian markets.

*Perifosine:*

Perifosine, the first-in-class AKT inhibitor in multiple Phase 2 studies, is being developed as an orally active radio-enhancer and anti-cancer agent.

We are currently conducting a randomized, double-blind, placebo-controlled European multi-center Phase 2 trial with perifosine (an oral signal transduction inhibitor), combined with radiotherapy in 160 patients with inoperable Stage III non-small cell lung cancer to prove its activity as radio-enhancer. We expect to disclose results related to this trial in the second quarter of 2009.

During 2008, our partner, Keryx Biopharmaceuticals, Inc. ( Keryx ), continued the development of perifosine with multiple Phase 1 and Phase 2 studies in North America in various cancers. Keryx has announced that it intends to move perifosine into Phase 3 in at least one indication in North America in 2009.

*AEZS-112:*

AEZS-112 is currently in a Phase 1 trial in patients with solid tumors and lymphoma. We are sponsoring and conducting this open-label, dose-escalation, multi-center, intermittent treatment trial in the United States. The trial will include up to 50 patients who have either failed standard therapy or for whom no alternative therapy exists. The primary endpoints of the trial will focus on determining the safety and tolerability of AEZS-112 as well as establishing the recommended Phase 2 dose and regimen. We expect progression of this trial in 2009 to identify maximum tolerated dose of AEZS-112. We also expect to report first results at the Annual meeting of the American Association for Cancer Research (AACR) in Denver in late April 2009.

AEZS-112 is the first anti-cancer drug in development involving three mechanisms of action such as tubulin and topoisomerase II inhibition. AEZS-112 expresses different actions, such as pro-apoptotic and antiangiogenic properties.

*AEZS-130:*

During the third quarter of 2008, we recovered worldwide rights from Ardana Bioscience Ltd. ( Ardana ) for the Growth Hormone Secretagogue compound, AEZS-130. We are currently evaluating future development options for the use of this compound in growth hormone deficiencies.

Table of Contents

**Our business strategy**

Our strategy is to advance our product development pipeline with a clear focus on our flagship product candidate, cetrotorelix for the BPH indication, and AEZS-108, our lead program in oncology for the treatment of endometrial and ovarian cancer.

Our foremost priority is cetrotorelix for the BPH indication. Based on various third-party sources, BPH affects more than 20 million men in the United States alone and represents a market of approximately \$3 billion in the 7 major markets. Additionally, it is estimated that approximately 5.6 million men will be treated in the United States for Lower Urinary Tract Symptoms ( LUTS ) associated with BPH. The prevalence of BPH in the United States is expected to increase to 26.8 million in 2020, and the LUTS treated population to approximately 8 million men in 2020. The potential for base case peak annual sales of cetrotorelix is over \$500 million in the United States market alone. We intend to continue to diligently advance the cetrotorelix Phase 3 program with the objective of filing a New Drug Application ( NDA ). We also have the intent to file in Europe a Marketing Authorization Application ( MAA ).

Our lead oncology product candidate, AEZS-108, currently in Phase 2 clinical trials, is our second priority. AEZS-108 is currently dosing patients with advanced endometrial and ovarian cancer in a multi-center trial in Europe with the expectation of reporting results from this trial in the fourth quarter of 2009.

We intend to continue developing our earlier-stage high-potential product candidate, AEZS-112, currently in Phase 1 clinical trial in patients with solid tumors and lymphoma.

Additionally, we are advancing several preclinical programs with targeted potential development candidates. Among the targets for which we expect to propose clinical development candidates in the coming years are: ghrelin receptor ligands, PI3K/Erk inhibitors, LHRH peptidomimetics and erucylphosphocholine derivatives.

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

We are currently in a phase in which our products and product candidates are being further developed or marketed jointly with strategic partners. We expect we will continue to engage strategic partnerships in the future as we move to realize our vision of becoming a fully integrated specialty biopharmaceutical company.

Table of Contents

**Our product pipeline**

**Pipeline table**

**Status of our drug pipeline as at March 20, 2009**

| Discovery                   | Preclinical  | Phase 1   | Phase 2  | Phase 3  | Commercial   |
|-----------------------------|--|---|--|--|--|
| 120,000<br>compound library | AEZS-115<br><br>Non-peptide<br>luteinizing<br>hormone-releasing<br>hormone ( LHRH )<br>antagonists<br>(endometriosis &<br>urology) | AEZS-112<br>(oncology)<br><br>AEZS-130<br>(endocrinology) | AEZS-108<br>(endometrial and<br>ovarian cancers)<br><br>Cetrorelix<br>(endometriosis)<br><br>(BPH in Japan)<br><br>Ozarelix<br>(BPH, prostate<br>cancer)<br><br>Perifosine<br>(multiple cancers) | Cetrorelix<br>(BPH)  | Cetrotide®<br>( <i>in vitro</i><br>fertilization)      |
|                             | AEZS-120<br>(oncology vaccine)   |   |  |  |  |
|                             | AEZS-126<br>Erk & PI3K<br>Inhibitors (oncology)  |   |  |  |  |
|                             | AEZS-127   |   |  |  |  |
|                             | ErPC<br>(oncology)   |   |  |  |  |
|                             | Ghrelin receptor<br>ligands<br>(endocrinology)   |   |  |  |  |
| <b>Partners</b>             |  |   | Cetrorelix:<br><br><b>Shionogi in Japan</b>  | Cetrorelix (BPH):<br><br><b>sanofi-aventis in<br/>the United</b> | Cetrotide®:<br><b>Merck Serono</b><br>(World ex-Japan) |

|  | States                 | Shionogi and Nippon Kayaku (Japan) |
|--|------------------------|------------------------------------|
| Ozarelix:<br><b>Spectrum</b> in North America and India,<br><b>Nippon Kayaku</b> in Japan (oncology) | <b>Handok</b> in Korea |                                    |
| Ozarelix (BPH):  |                        |                                    |
| <b>Handok</b> in Korea, Indonesia, Malaysia, the Philippines and Singapore                           |                        |                                    |
| Perifosine:  |                        |                                    |
| <b>Keryx</b> in North America  |                        |                                    |



Table of Contents

**LHRH ANTAGONISTS**

**Cetorelix**

Cetorelix 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, cetorelix 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.

*The mode of action of cetorelix and the distinction between LHRH antagonists and LHRH agonists*

LHRH is released by the hypothalamus in the brain and controls the production of sex hormones (i.e. testosterone in the testes and estrogen and progesterone in ovaries) via the activation of LHRH receptors located on the pituitary gland (hypophysis).

When using LHRH agonists, the LHRH receptors on the pituitary gland are stimulated leading to an initial increased secretion of the hormones luteinizing hormone ( LH ) and follicle stimulating hormone ( FSH ), which in turn regulates the formation of testosterone and estrogen. The increase or surge of hormonal levels induces a flare-up effect that can last up to three weeks until the pituitary markedly decreases the release of LH and FSH by desensitization and depletion of LHRH receptors (i.e. down-regulation) resulting in a considerable drop in testosterone and estrogen levels. Though the initial flare-up effect is limited in time, it can sometimes cause, depending on the nature and stage of the particular disorder, considerable additional symptoms or even life-threatening complications, which in turn require additional therapeutic intervention. By simultaneous administration of anti-androgens, the flare-up effect can be attenuated. However, this additional treatment also bears the risk of certain side effects, e.g. disturbances of the function of the stomach, intestines and liver.

During full hormone suppression, LHRH agonists reduce the male sex hormones to ranges below castration level. In women, the hormone levels are far below the ranges observed after the end of the climacteric. Treatment with an LHRH agonist, therefore, is regularly associated with side effects such as hot flashes, depression, muscle weakness, loss of libido and, particularly in women, osteoporosis and ovarian cysts. At the end of treatment, it takes several weeks for the hormone function to return to normal ranges. At the same time, an excessive rebound effect can lead to renewed deterioration of the symptoms.

We believe that cetrorelix, an LHRH antagonist, because of its different mode of action, can avoid the side effects associated with the administration of LHRH agonists. Since LHRH antagonists have a rapid onset of action, the treatment time to response with cetrorelix can be much shorter than with agonists. Moreover, in various clinical studies, the effect of cetrorelix therapy lasted much longer than that of hormone suppression, which consequently confirms the new therapeutic principle of intermittent treatment. Periods with moderate and well-tolerated hormonal suppression can be followed by intervals without treatment during which side effects are avoided and quality of life is restored. Since there is no necessity for long-term

Table of Contents

therapy and the overall treatment time is much shorter, the risk of side effects is also reduced. In particular, we also believe that the risk of developing osteoporosis in patients taking the cetrorelix therapy regimen is diminished.

Cetrorelix might therefore be useful in a variety of malignant and non-malignant indications in which a suppression of the pituitary-gonadal axis is desired. The degree of suppression of gonadotrophins and sex steroids required is dependent on the clinical circumstances and disease treated. For example, in patients undergoing controlled ovarian stimulation for assisted reproductive techniques, endogenous gonadotrophin secretion has to be controlled, whereas development of the follicle must not be adversely affected.

*Cetrorelix in in vitro fertilization (COS/ART)*

Cetrorelix 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® (cetrorelix 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 our LHRH antagonist, 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 cetrorelix acetate by Merck Serono in the United States and Europe. Approval for Cetrotide® in Japan was gained in April 2006. 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 December 2008, we sold our royalties on future sales of Cetrotide® covered by our license agreement with Merck Serono for \$52.5 million to CHRP less transaction costs of \$1.0 million resulting in initial net proceeds to us of \$51.5 million. In addition, contingent on 2010 net sales of Cetrotide® reaching a specified level, we may receive an additional payment of \$2.5 million from CHRP. 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 cetrotide is approved for sale by the European regulatory authorities in an indication other than *in vitro* fertilization. The amount which would be due to CHRP will be higher the earlier the product receives European regulatory approval.

*Clinical development overview of cetrotide in BPH, endometriosis and uterine myoma*

*Cetrotide in BPH*

BPH is a hormone-driven enlargement of the male prostate gland. The prostate is located directly at the vesicle outlet in the male surrounding the first part of the urethra. The enlargement puts pressure on the urethra, causing difficulty in urinating. BPH is classified into three stages according to symptoms: 1) the irritant phase, where the patient suffers dysuria (pain when urinating) and nocturia (the urge to urinate during the night); 2) residual urine occurring in the bladder thus increasing problems during urinating; and 3) overflow of the bladder. These can result in formation of bladder stones, congestion of urine and engorged kidneys which can in turn lead to life-threatening kidney damage.

Because LHRH agonists decrease testosterone to castration levels, treatment of BPH with LHRH agonists is not convenient and therefore not the best approach. Drug therapy with plant-based drugs, alpha-blockers or alpha-reductase inhibitors ( 5-ARIs ) is possible but the plant-based drugs and alpha-blockers cannot delay further prostate growth, they merely improve the symptoms in 50% of patients. Treatment with alpha-reductase inhibitors decreases the size of the prostate; however, this form of therapy is successful only in patients with a greatly increased prostate volume and only after a treatment period of at least six months. In contrast, clinical studies suggest that cetrotide improves the symptoms of BPH and reduces the size of the prostate after a short treatment period without chemical castration. The effects are independent of the prostate volume and are maintained for a long period following treatment withdrawal.

BPH clinical trials

In October 2004, cetrotide completed an extensive program of seven Phase 2 trials in urology, a significant part of which was sponsored by our partner at the time, Solvay. All Phase 2 studies performed so far in patients with symptomatic BPH revealed that cetrotide is therapeutically active in this indication as demonstrated by an improvement in symptoms as assessed primarily by the IPSS as well as an increase in urinary peak flow rate and a reduction in prostate volume.

On January 30, 2006, we announced that we had regained our worldwide rights (ex-Japan) from our partner Solvay to develop and potentially market cetrotide in BPH. The ongoing development of cetrotide in endometriosis was pursued by Solvay until we regained the rights for that indication in May 2007.

Our Phase 3 program began in January 2007. The Phase 3 program consists of two placebo-controlled efficacy studies, an open label safety study and a Thorough QT/QTc Study consistent with the ICH E14 Guideline.

The two placebo-controlled studies each compare two intermittently administered dose regimes with placebo in patients with BPH who are then assessed one year after beginning therapy. The primary end-point in each trial is the change in IPSS between the beginning of treatment to the end of follow-up after 52 weeks. The IPSS has been used successfully as the primary endpoint in a number of other drug development programs for BPH. Some of the other measures that are evaluated in these studies include urine flow, general aspects of safety and quality of life issues, which are particularly relevant to males aged 50 and over who suffer from BPH. On April 15, 2008, we announced completion of recruitment of 670 patients for the first efficacy trial conducted mainly in North America. Recruitment for the second study conducted in Europe was opened in March 2008 and was closed with 420 patients enrolled on October 1, 2008.

The third study in the Phase 3 program is an open-label study of the dose regime we are planning to market and includes approximately 500 patients. It is more focused on aspects of general safety, quality of life and tolerability of cetrorelix, although the effects of cetrorelix on the patients' symptoms are also being evaluated. First patient dosing was announced on May 14, 2008 and we announced completion of recruitment of 527 patients on December 11, 2008. The final component of the Phase 3 program, the Thorough QT/QTc Study, is being designed with input from the FDA in order to ensure that we meet the regulatory guidance on this topic for novel drugs under development.

Table of Contents

On March 22, 2007, our partner Shionogi announced positive results for a Phase 2a Japanese trial that was initiated in 2005. This trial was designed to evaluate primarily pharmacokinetics and safety (systemic and local tolerability) in Japanese subjects, whereas evaluation of efficacy was only exploratory. A total of 50 patients were included in five dosing groups corresponding to single administration of 30 mg, 60 mg or 90 mg cetorelix and multiple administration of 60 mg and 90 mg, three times eight weeks apart. The observation period was up to 32 weeks in the multiple administration dosing groups. The Japanese patients responded to cetorelix with a transient reduction of testosterone concentration in blood, which did not reach or remain at the castration level. IM injection of cetorelix pamoate was safe and well tolerated at all dosages tested. None of the dosage regimens tested caused a suppression of PSA levels. Results also showed that the bioavailability of cetorelix in Japanese patients is similar to what is observed in non-Japanese patients. The sizes per dosage group were too small to evaluate efficacy trends for statistical significance. On the basis of this study, Shionogi initiated a 300-patient Phase 2b study to assess primarily the efficacy of cetorelix in BPH in Japanese patients with a different treatment regimen than the one used in Europe and North America. Phase 2b results were announced by Shionogi in November 2008. Results indicated an improvement of IPSS in the treatment group in a dose-dependent manner, although it was not statistically significant compared to the placebo group due to a high placebo response. A statistically significant reduction of prostate volume was observed between treatment and placebo groups. Shionogi also announced that a new Japanese study including higher dose divided into two doses with two-week interval, according to the regimen used in our Phase 3 program, was in preparation.

In May 2008, we presented results for the cetorelix mode of action in BPH. In this study, we investigated the presence and characteristics of LHRH receptors in 35 specimens of human BPH tissues. Results showed that the expression of mRNA for LHRH receptors was detected in 33 of 35 (94%) BPH specimens. LHRH antagonist cetorelix showed high affinity binding to LHRH receptors expressed in BPH tissues. The LHRH receptor epitope identified by the monoclonal antibody was present in the basal cell layer of normal and hyperplastic prostate glands in all cases. The expression of specific receptor proteins for LHRH in human BPH provides a rationale for improvement in methods of therapy for clinical BPH. The demonstration of the high incidence of LHRH receptors in human BPH tissues suggests the possibility of rapid and long lasting improvement of symptoms in BPH patients treated with cetorelix.

In connection with our strategic review, we announced on October 2, 2007 that we had decided to seek a commercialization partner for cetorelix in the BPH indication and, subject to favorable Phase 3 clinical results and regulatory approval, we expect to launch cetorelix in this indication in the second half of 2011.

Regarding the potential market of cetorelix in BPH, based on various third-party sources, such as BPH, Urologic Diseases in America 2004; NIH Publication 04-5512:43-67; The American Journal of Managed Care, the prevalence of BPH in 2007 in the United States is estimated to be 20 million individuals as defined by International Prostate Symptom Score (IPSS) >7. Additionally, it is estimated that approximately 12.2 million men have been diagnosed and 5.6 million men treated for BPH. As population demographics shift toward an elderly population, BPH treated population in the United States is expected to grow by 41% between 2007 and 2025, exceeding 8 million. The potential for base case peak annual sales of cetorelix is over \$500 million in the United States market alone.

*Cetorelix in endometriosis*

Endometriosis is the estrogen-driven displacement of endometrium-like tissue (tissue from the mucous membranes of the uterus) to other organs outside the womb. In the abdomen, the tissue can spread to the fallopian tubes, the ovaries, the bladder, the small and large intestines, the stomach, the lungs or the legs. Estrogen-dependent diseases often regress when estrogen production is reduced (endometriosis, and the pelvic pain associated with it, improves when estrogen production is reduced). Excessive and prolonged reduction of estrogen production, however, is typically associated with adverse side effects, such as vasomotor symptoms and bone loss.

A similar, very low estrogen level can be induced by oophorectomy (surgical removal of the ovaries) and by chronic LHRH agonist treatment. In both cases, estrogen replacement treatment is necessary to reduce the hypo-estrogenic effects (e.g. bone loss, climacteric symptoms) associated with these therapeutic approaches. Administration of LHRH agonists can initially lead to a deterioration of symptoms due initially to the flare-up effect, then, due to the complete suppression of estrogen below castration level values for many months. These symptoms can further deteriorate upon withdrawal of hormonal replacement. The longer the treatment period with traditional LHRH agonists is, the higher the risk of developing osteoporosis. Its use is therefore restricted to six months and can be extended only if estrogens and progesterones are administered concomitantly.



Table of Contents

We believe that the side effects could be avoided with our LHRH antagonist cetrorelix due to the absence of flare-up effects and to the possibility of controlling estrogen levels at values comparable to the ones observed at the beginning of the regular monthly cycle. Since the controlled hormone withdrawal is achieved in a very short period of time, complaints from monthly bleeding are reduced while inflammatory *foci* of endometriosis are depleted of their basis. Therefore, we believe that treatment time can be reduced. Initial experiences show that the effect of therapy persists for many months. Since the effect of cetrorelix starts within a short period of time and the risk of developing osteoporosis is low, we believe that cetrorelix therapy can be repeated in several cycles.

Endometriosis clinical trials

In earlier Phase 2 clinical trials, cetrorelix was given at a rate of 3 mg per week over a period of eight weeks. All patients were free of pain during the course of treatment. A second laparoscopy (direct visualization of the peritoneal cavity, ovaries, outside of the tubes and uterus) was performed after eight weeks and an improvement of the disease was shown in 60% of the cases. The efficacy was comparable to agonists but with the benefit of an almost complete absence of side effects. Cetrorelix allowed targeted control of the hormone level to show rapid effects, while avoiding the problems of menopause and risks (e.g. osteoporosis) associated with an otherwise complete and long-term withdrawal of hormones. We believe that the rapid onset of action would be ideal for intermittent therapies, allowing for treatment-free intervals with re-dosing at the time when the therapeutic effect starts to fade.

On April 29, 2004, we announced the results of Phase 2 placebo-controlled studies demonstrating that cetrorelix use was associated with a rapid and durable therapeutic response, namely improvement of endometriosis-related symptoms, such as pelvic pain, extending up to several months following only two IM injections of cetrorelix with a one-month interval.

On March 16, 2005, we announced that our worldwide (ex-Japan) exclusive development and marketing partner, Solvay, initiated a full development program for the potential treatment of endometriosis with cetrorelix. On May 8, 2007, we and Solvay announced the termination of the license and cooperation agreement for cetrorelix for all remaining indications, including endometriosis, effective on that date, as a result of which we regained exclusive worldwide (ex-Japan) rights for cetrorelix in all indications without any financial compensation payable to Solvay. The move by Solvay out of the women's health field resulted from a change in their strategic focus to newly defined therapeutic areas following the acquisition of the Fournier group in France.

In connection with our strategic review, we announced on October 2, 2007 that, after optimization of formulation and trial design, we planned to move into Phase 2b with cetrorelix in the endometriosis indication. The decision to proceed with development was made based on the proven safety and efficacy of Cetrotide®, the overall database from preclinical and clinical studies in endometriosis and the large unmet medical needs and commercial opportunity in the area of endometriosis. In 2008, we performed a technical review of cetrorelix in endometriosis with the support of medical experts in this field. On that basis, we are now evaluating different options to resume the development of the program.

*Cetrorelix in uterine myoma*

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

As part of the seven Phase 2 programs, cetrorelix was also evaluated for the indication of uterine myoma. A uterus myoma is a benign tumor of the uterine muscles. If the entire uterine wall is penetrated by myoma, one refers to uterus myomatosis. Depending upon the length and the direction, it is either referred to as a subserous myoma, which is located below the peritoneal covering of the uterus and grows towards the intestinal cavity, or a submucous myoma, which is located below the mucous membrane and grows into the uterine cavity. The most frequent form, however, is the intramural myoma bound in the muscular layer of the uterus. Intramural myoma leads to pain in the lower abdomen and in some cases to prolonged or severe monthly bleeding outside the normal cycle. This can cause severe blood loss leading to anemia. Infertility and pregnancy problems such as miscarriage or premature delivery are also frequent consequences. When the myoma puts pressure on the intestine or the bladder, the result can be constipation, bladder pain or a desire to urinate. If the myoma exerts pressure on nerves leaving the spinal cord, the result can be back and neuralgic pain in the legs.

Table of Contents

Uterine myoma clinical trials

On April 29, 2004, we disclosed positive Phase 2 results from a double-blind, placebo-controlled, multi-center trial evaluating the subcutaneous formulation of cetrorelix, administered weekly for four weeks, as a pre-surgical treatment to 109 women with uterine myomas. In addition to evaluating the safety and tolerability of different doses of the new formulation, the trial also evaluated whether cetrorelix use could lead to the reduction of myoma and uterine volumes within a shorter treatment period than that normally required for LHRH agonists. Data from this trial demonstrated that cetrorelix use led to a reduction of myoma and uterine volumes after a one-month treatment period, which is significantly shorter than the two- to six-month treatment period typically required for LHRH agonists. The best response rate was obtained at a dose of 10 mg of cetrorelix per week. Cetrorelix use did not lead to castration-like symptoms. We have not yet pursued the development of cetrorelix for this indication.

***Partners for cetrorelix***

We previously licensed cetrorelix to Solvay worldwide (ex-Japan) for all indications with the exception of IVF/COS/ART, which rights belong to Merck Serono and Japanese rights are held by Shionogi. In the BPH indication, for which we regained exclusive worldwide (ex-Japan) rights, Japanese rights are held by Shionogi. On May 8, 2007, we and Solvay announced the termination of the license and cooperation agreement for cetrorelix for all remaining indications, including endometriosis, effective on that date, as a result of which we regained exclusive worldwide (ex-Japan) rights for cetrorelix in all indications without any financial compensation payable to Solvay.

On March 22, 2007, we announced that Nippon Kayaku had terminated its development agreement pertaining to cetrorelix pamoate to focus solely in oncology.

We signed a license and cooperation agreement for the commercialization of cetrorelix (BPH indication) with Handok for the Korean market during the third quarter of 2008.

On March 5, 2009, we entered into a development, commercialization and license agreement with sanofi-aventis for the development, registration and marketing of cetrorelix in BPH for the US market. Under the terms of the agreement, sanofi-aventis made an initial upfront payment to us of \$30.0 million, and we will be entitled to receive a total of \$135.0 million in payments upon achieving certain pre-established regulatory and commercial milestones. Furthermore, we will be entitled to receive escalating double-digit royalties on future net sales of cetrorelix for BPH in the United States, while retaining the option to co-promote the product in that territory. Sanofi-aventis may perform future Phase 3b and Phase 4 clinical trials, while we will have access to all corresponding data for other territories.

***Competition for cetrorelix***

The market leaders in the indication of BPH are Pfizer, Astellas/Boehringer Ingelheim, sanofi-aventis and Abbott with alpha-blockers and Merck and GlaxoSmithKline with alpha-reductase inhibitors. Rapaflo™ (Silodosin), a selective alpha-blocker developed by Watson

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

Pharmaceutical (North America), Recordati S.p.A. (Europe and the Middle East), Kissei Pharmaceutical (Japan) and Daiichi Pharmaceutical (China) for the treatment of BPH was approved by the FDA in October 2008, while Recordati announced in November 2008 the filing of a MAA in Europe. Silodosin was launched in 2006 in Japan for the treatment of dysuria associated with BPH as Urief® 2mg and 4mg capsules by Kissei Pharmaceutical and Daiichi Pharmaceutical.

Worldwide, there are four LHRH agonists for the treatment of endometriosis, including those of TAP Pharmaceutical Products (Abbott and Takeda), Astra Zeneca, Pfizer and sanofi-aventis.

Concerning the class of LHRH antagonists, the compound degarelix from Ferring Pharmaceuticals obtained, in December 2008, a marketing approval from the regulatory agencies in the United States and the European Union for the treatment of advanced prostate cancer. Although the indication is different from the one targeted by cetrorelix, this is an important recognition of the class of LHRH antagonists with a third approved class member after cetrorelix and ganirelix. In particular, all studies of degarelix have found the drug to be well tolerated with no evidence of systemic allergic reactions.

### **Ozarelix**

Ozarelix is a modified LHRH antagonist which is a linear decapeptide sequence. Ozarelix is a fourth-generation LHRH antagonist aiming at extended suppression of testosterone levels that does not require a sophisticated depot formulation for

Table of Contents

long-lasting activity. The aim of this project is to identify an active substance with superior properties for the development of longer-acting formulations that we believe are particularly suitable for tumor therapy.

Single doses of ozarelix depot were tested in healthy male volunteers. Ozarelix was well tolerated and produced a dose-dependent suppression of testosterone. An immediate decrease in testosterone plasma levels was observed in all dose groups reaching levels below 1 ng/ml within the first 12 hours after application. Duration of suppression was dose-dependent and at the highest dose of 60 mg caused testosterone suppression for one month.

On August 12, 2004, we entered into a licensing and collaboration agreement with Spectrum for ozarelix and its potential to treat hormone-dependent cancers as well as benign proliferative disorders, such as BPH and endometriosis. Under the terms of the agreement, we granted an exclusive license to Spectrum to develop and commercialize ozarelix 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.

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

***BPH clinical trials***

In October 2006, we announced positive and highly statistically significant Phase 2 results for ozarelix in BPH. The multi-center double-blind, randomized, placebo-controlled dose-ranging Phase 2 trial included 144 patients who received different IM dosage regimens of ozarelix, or a placebo, to assess its safety and efficacy. Ozarelix was administered on day 1 or days 1 and 15. The primary efficacy endpoint of improving clinical symptoms of BPH at week 12, as measured by significant changes in IPSS, was achieved at all dosage regimens. However, the best results in terms of the most important decrease of the IPSS score were obtained with a dose of 15 mg administered on days 1 and 15. The observed mean decrease of the IPSS score at week 12 was minus 8.6 (-8.6), it peaked at minus 9.4 (-9.4) at week 20 and was still at minus 8.7 (-8.7) as of week 28. Testosterone suppression levels were maintained above castration levels at all times. Secondary efficacy parameters such as uroflow, residual urinary volume, quality of life and circulating testosterone levels were also measured and showed good results. The outcome of the trial demonstrated an excellent safety profile with ozarelix as patients had no serious side effects. The erectile function was also not affected at any dose regimens.

On January 3, 2007, Spectrum announced the FDA's acceptance of an IND for ozarelix in BPH. Spectrum initiated a Phase 2b study in January 2007. Dr. Claus Roehrborn from the UT Southwestern Medical Center in Dallas, Department of Urology, served as the lead investigator. The Phase 2b study was a randomized placebo-controlled trial of ozarelix and involved approximately 70 patients. Patients were dosed with 15 mg of ozarelix (administered IM) or placebo on days 1 and 15 and were followed for nine months. The primary endpoint for the study was the improvement in lower urinary tract symptoms (LUTS) secondary to BPH as measured by the IPSS score for ozarelix 15 mg compared to placebo at 12 weeks. Secondary endpoints included measurements in peak urine flow (Qmax), erectile function, quality of life measures as well as safety and tolerability. The study further assessed the safety and efficacy of this dosing regimen at time points up to 24 weeks and the durability of the IPSS response up to 36 weeks.

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

On May 23, 2007 and September 5, 2007, Spectrum disclosed detailed Phase 2 results for ozarelix in BPH at two medical conferences. Results indicate that ozarelix was well tolerated and demonstrated statistically significant as well as clinically meaningful efficacy in the treatment of LUTS secondary to BPH. The effect developed rapidly, with noticeable activity at four weeks from starting treatment, were maximal at 12-16 weeks, and persisted for the six-month observation period. At week 12, all ozarelix-treated groups showed improvement with the greatest improvement in the 15mg + 15mg group. Change from baseline in IPSS score was 8.6 ( $p < 0.001$ ); change from baseline in urine flow was 4.7 ( $p = 0.002$ ); testosterone levels declined transiently and returned to baseline in most patients by four weeks and in all patients by six weeks following dosing. Results also showed no statistically significant impact on quality of life or erectile function. Serious adverse events were reported in four patients on ozarelix (myocardial infarction, pneumonitis, hypotension, renal colic) but were not considered treatment-related. No systemic allergic reactions were seen and the injections were well tolerated.

Complete results of the 9-month Phase 2b trial were released by Spectrum on April 22, 2008. A total of 76 patients were enrolled in the trial to meet the target of 68 evaluable patients. Two patients withdrew consent prior to randomization, resulting in an Intent-to-Treat population (ITT) of 74 patients, of which 57 completed all study visits. Spectrum's monitoring of the conduct of the study revealed major protocol violations at four of the 15 sites. Violations included: inaccurate diagnosis, concomitant use of other drugs effective in BPH, and patient participation in multiple trials at the same time. One of these sites was closed early due to irregularities in data collection and was reported to the FDA. Because of these major

Table of Contents

protocol violations, an analysis excluding these four sites was performed. All 44 patients at the other 11 sites met protocol inclusion criteria and were included in a per-protocol population analysis. Because randomization was within site, balance between treatment groups was maintained. In the ITT population, ozarelix demonstrated a numerical improvement in peak urine flow (2.5mL/sec) compared to placebo (1.3mL/sec) at 12 weeks, but did not reach statistical significance ( $p=0.41$ ). The improvement in IPSS at 12 weeks was 4.4 in placebo group and 2.9 in the ozarelix group and did not reach statistical significance ( $p=0.37$ ). In the per-protocol analysis, ozarelix demonstrated a clinically meaningful improvement in IPSS of 6.0 compared to 3.0 for placebo. This improvement in IPSS was observed as early as 8 weeks, approached statistical significance ( $p=0.09$ ) and the effect was observed out to 36 weeks. Ozarelix demonstrated a numerical improvement in peak urine flow (1.6mL/sec) as early as four weeks, compared to no change in placebo (0.0mL/sec), ( $p=0.14$ ), although this difference was not consistently seen at later time points. In both the ITT and the per-protocol populations, ozarelix was well tolerated, allergic reactions were not seen, and there was no reported adverse effect on erectile function as measured by the International Index of Erectile Function (IIEF-EF). Based on these results, Spectrum initiated in September 2008 the recruitment of 860 patients for a new BPH study, as mentioned on the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website.

***Prostate cancer clinical trials***

In August 2006, we announced positive Phase 2 result 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%. Following these results, we, in collaboration with Spectrum, initiated an additional Phase 2 study in European centers to verify and optimize the findings derived from the cohort of patients having received 130 mg of ozarelix per cycle.

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.

**Non-peptide LHRH antagonists**

As outlined above, the LHRH receptor plays an important role in a number of benign and malignant tumors. Our drug discovery unit searches for small, non-peptide molecules which have the same effect on the receptor. Their advantage lies in the potential for oral administration.

AEZS-115 is a new orally bioavailable LHRH antagonist with LHRH-receptor binding affinity in the nanomolar range which is developed for hormone therapy of endocrinological disorder and of benign and malignant tumors. The compound demonstrates excellent selectivity to LHRH-receptor and has advanced to a preclinical stage where the *in vivo* activity has been confirmed. Major advantages are the dose-dependent reduction of sexual hormones without flare-up effect whereas no decrease down to castration level is necessary and therefore side effects are reduced.

In January 2006, we regained the exclusive worldwide rights to develop and commercialize AEZS-115 from Solvay. Attractive *in vivo* activity of this orally available peptidomimetic LHRH-antagonist was demonstrated with a single, oral administration (20mg/kg) in rats which led to efficient and revocable suppression of plasma testosterone levels for up to 12 hours. Furthermore, a repeat of the dosing of AEZS-115 increased the suppression time without accumulation in the plasma.

In 2007, an oral formulation was selected and pharmacokinetic data were obtained.

First preclinical results were presented at the 2008 San Antonio Breast Cancer Symposium on December 12, 2008 and showed substantial anti-tumor activity of AEZS-115 in human ovarian and breast cancer cell lines, as evidenced by exposure of human cell lines SKOV3, Ovarcar 3 (human ovarian cancer cell lines) and MDA-MB 468 (human breast cancer cell line) to increasing concentrations of AEZS-115, peptidic GnRH-antagonist cetrorelix and GnRH-agonist Triptorelin (1, 10, and 100  $\mu$ M) for 48 days. The number of viable cells was determined by crystal violet staining as well as by ATP-dependent luminometric assays. Results showed that both GnRH-antagonists dose-dependently inhibited growth of all three cell lines,



Table of Contents

while GnRH-agonist Triptorelin showed marginal growth inhibition. Cell growth was inhibited by 40-60% following exposure to a concentration of 10  $\mu$ M of AEZS-115 and by 60-80% when cells were exposed to 100  $\mu$ M. Inhibition with cetorelix at 100  $\mu$ M ranged from 20-40%, while only minor effects on cell growth were seen at 10 $\mu$ M. Optimization is ongoing.

**SIGNAL TRANSDUCTION INHIBITORS**

**Perifosine**

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 anti-tumor capacities. In tumor cells, perifosine has demonstrated interactions with vital signal transduction mechanisms and induction of programmed cell death (apoptosis).

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 anti-tumor activity, including

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

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. Five Phase 1 trials have been conducted on perifosine, including one trial of perifosine in combination with radiotherapy.

Based on findings in various tumor models, the U.S. National Cancer Institute, 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, the first-in-class AKT inhibitor in multiple Phase 2 studies, is being developed as an orally active radio-enhancer and anti-cancer agent.

Table of Contents

***Perifosine Radio-enhancer***

A proof-of-concept Phase 1 study of perifosine in combination with radiotherapy conducted by the National Cancer Institute of the Netherlands was completed in 2004. Results from this trial were presented at ASCO 2004. A total of 21 radiotherapy-naïve patients, of whom 17 had advanced non-small cell lung cancer (NSCLC) and 14 had become refractory to prior chemotherapy, received oral perifosine doses ranging from 50 mg to 200 mg/day concurrently with standard doses of radiotherapy. The trial data demonstrated an acceptable safety and tolerability profile, with 150 mg/day established as the dose recommended for use in subsequent clinical trials. Also demonstrated was preliminary evidence of anti-tumor activity at all dosage levels, including complete or partial responses (complete disappearance and decreased tumor size, respectively), or stable disease, with a median follow-up for responders of eight months. Importantly, in the cohort of 10 patients who were treated with 150 mg/day, the established dose recommended for use in subsequent clinical trials, there were three complete responses, three partial responses and four patients with stable disease.

On September 22, 2005, we announced the initiation of a multi-center Phase 2 randomized, double-blind, placebo-controlled trial with perifosine in combination with radiotherapy for NSCLC. Patients received perifosine 150 mg daily for five to six weeks and are followed for at least 12 months. The primary endpoint of this trial is the extent and duration of local control, i.e. the absence of tumor recurrence or progression in the area that has been irradiated. The trial is being conducted in collaboration with the Netherlands Cancer Institute. The lead investigator is Marcel Verheij, M.D., Ph.D., of the Department of Radiation Oncology / Division of Cellular Biochemistry, at the Netherlands Cancer Institute in Amsterdam. We announced completion of recruitment of 160 patients with inoperable Stage III NSCLC on November 14, 2007. As the patients are followed for a one-year period after receiving treatment, we expect to announce top-line results in early 2009.

***Perifosine Anti-cancer agent***

Perifosine Multiple myeloma ( MM )

In June and December 2007, Keryx announced preliminary positive Phase 1 and Phase 2 data on perifosine in patients with relapsed/refractory MM. Data demonstrated clinical activity of perifosine in combination with bortezomib and dexamethasone, and with lenalidomide plus dexamethasone.

In December 2008, 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 and dexamethasone. Four cohorts of  $\geq 6$  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, followed by 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 (G) 3 non-hematologic toxicity, G4 neutropenia for 5 days and/or neutropenic fever, or platelets  $<25,000/mm^3$  on  $>1$  occasion 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, 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 40mg/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 ( $\geq 10\%$ ) 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  $\geq 5\%$  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. All 30 patients in the analysis were evaluable for response, with best response as follows:

Table of Contents

| Response: N = 30                  | N (%)  | Duration (wks)       | ORR (≥PR) |
|-----------------------------------|--|----------------------|-----------|
| Near Complete Response (nCR)      | 2 (7%)                                       | 79+, 15+             |           |
| Very Good Partial Response (VGPR) | 3 (10%)                                      | 62+, 34, 17          | 15 (50%)  |
| Partial Response (PR)             | 10 (33%)                                     | 26+ (range 11 - 54+) |           |
| Minimal Response (MR)             | 6 (20%)                                      | 17+ (range 9 - 30+)  |           |
| Stable Disease (SD)               | 7 (23%)                                      | 14+ (range 8 - 19)   |           |
| Progression (PD)                  | 2 (7%)                                       | 8, 4                 |           |
|                                   | stable disease: < 25% reduction in M-protein |                      |           |

Patients have tolerated the treatment regimen of Perifosine + Lenalidomide + Dexamethasone well with manageable toxicity, and with encouraging clinical activity demonstrated by an overall response rate ( ORR ) (> PR) of 50%.

Also in December 2008 during the meeting of the American Society of Hematology, Keryx presented results of a Phase 1/2 multicenter trial of perifosine + bortezomib in patients with relapsed or relapsed/refractory MM who were previously relapsed from or refractory to bortezomib ± dexamethasone. The Phase I stage of the study enrolled a total of 18 patients in 4 cohorts of 3 pts each with dosing of Perifosine 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 progressive disease (PD). For the Phase 1 portion, Dose limiting toxicity (DLT) was defined as any grade (G) 3 non-hematologic toxicity, G4 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. A total of 76 patients have been enrolled (18 patients in Phase 1 and 58 patients in Phase 2) comprised of 45 men and 31 women, median age 63 years old, (range 41-89). 84% of patients had relapsed/refractory MM, with a median of 6 lines of prior treatment (range 2-13). Prior therapy included bortezomib (100%), dexamethasone (95%), thalidomide (79%), lenalidomide (71%) and stem cell transplant (57%). 63 patients have completed at least one cycle and were evaluable for safety (13 patients are currently not evaluable; 3 were removed in cycle 1 and 10 are too early in their treatment). Most common (>10%) grade 1 / 2 events were nausea, diarrhea, fatigue and myelosuppression, which were manageable with supportive care and growth factors. Grade 3 / 4 adverse events >5% included thrombocytopenia (40%); lymphopenia (36%); neutropenia (21%); anemia (14%); hyponatremia (13%); leukopenia (11%); proteinuria (8%), and upper respiratory infection (6%). No deep vein thrombosis (DVT) has been seen, and only one worsening peripheral neuropathy from grade 1 to 3 has been reported to date. Two patients had perifosine reduced to 50 mg (nausea, fatigue) in the Phase 1 cohort, and 7 patients had bortezomib dose reductions primarily due to hematologic toxicity. 57 patients have completed at least 2 cycles and are evaluable for response, with best response to perifosine + bortezomib (+/- dexamethasone) as follows:

|                                    |             | CR       |           | PR       |            | MR        |            | ORR       |            | SD        |            |
|------------------------------------|-------------|----------|-----------|----------|------------|-----------|------------|-----------|------------|-----------|------------|
| <b>All Patients: Best Response</b> | <b>N=57</b> | <b>2</b> | <b>4%</b> | <b>7</b> | <b>12%</b> | <b>14</b> | <b>25%</b> | <b>23</b> | <b>40%</b> | <b>23</b> | <b>40%</b> |
| perifosine + bortezomib            | 57          | 1        | 2%        | 5        | 9%         | 8         | 14%        | 14        | 24%        | 17        | 30%        |
| With dexamethasone added*          | 31          | 1        | 2%        | 2        | 3%         | 6         | 11%        | 9         | 16%        | 6         | 11%        |

(\* as a subset of the evaluable population)

9 of 76 patients (12%) rapidly progressed without response or stable disease, including 6 patients in whom dexamethasone was also added. As of August 2008, the median time to progression (TTP) for patients achieving  $\geq$  PR is 34 weeks, and for all patients achieving  $\geq$  MR is 33 weeks. Perifosine in combination with bortezomib (+/- dexamethasone) was generally well tolerated and is remarkably active in a heavily pre-treated Bortezomib-exposed patient population, with an ORR of 40%, including an ORR of 37% and a median TTP of 9.25 months in responding but previously bortezomib-refractory patients. Further trials, including randomized studies in relapsed disease, are planned.

Perifosine Waldenstrom's Macroglobulinemia

Results of a Phase 2 study on perifosine in patients with Waldenstrom's Macroglobulinemia ( WM ) were presented by Keryx in June 2008 at ASCO and in December 2008 during the ASH meeting. Perifosine showed clinical activity as a single

Table of Contents

agent in patients with relapsed/refractory WM, with an ORR (partial response [PR] + minimal response [MR]) of 36%. PR occurred in 2 (6%) patients, with a median duration of response of 9+ and 18+ months, MR occurred in 11 (30%) patients, with a median duration of response of 7 months (2-21+ months). Stable disease [SD] occurred in 21 (58%) patients and progressive disease [PD] in 2 (6%) patients at 2 and 4 months. The most common adverse events were GI toxicities (nausea, vomiting and diarrhea) with grade 1 and 2 in 36% of the patients. Grade 3 and 4 events included anemia (9%) and leucopenia (9%). Grade 3 arthritis occurred in 9% of the patients; was considered likely related to therapy, (especially in rapidly responding patients), and reversed with symptomatic treatment as well as dose reduction. Dose reductions to 100 mg occurred in a total of 36% of the patients and were otherwise due to GI toxicity or cytopenias. Perifosine monotherapy induces a prolonged time to progression in relapsed or refractory WM, with a promising response rate of 36%, stabilization of disease in 58% of patients, and manageable toxicity, as well as the convenience of oral administration. Future clinical trials in combination with rituximab are planned.

## Perifosine Renal Cell Carcinoma

In June 2006, we announced positive data of perifosine in patients with advanced renal cell carcinoma ( RCC ). Keryx disclosed results from an interim analysis performed at the end of the first year of accrual, from a Phase 2, multi-center trial of perifosine that included multiple types of tumor and the results of the RCC group met protocol requirements for expansion of this cohort. Of the 13 patients with RCC, seven were evaluable for response. Three of them (43%) had a partial response and an additional two patients (29%) achieved long-term stable disease. Two patients (29%) had progressive disease. Results of a Phase 1 multicenter trial of perifosine in combination with sorafenib or in combination with sunitinib for patients with advanced cancers including RCC were disclosed by Keryx in June 2007 during the ASCO meeting and in November 2007. The trial was designed to accrue 3-6 patients in each of four cohorts. Response by RECIST criteria was a secondary endpoint. Perifosine was escalated from 50 mg once per day to 50 mg three times per day; sorafenib dose was escalated from 400 mg once per day to 400 mg twice per day; and sunitinib dose was escalated from 25 mg to 50 mg once per day for 4 weeks of treatment out of 6. Dose limiting toxicity ( DLT ) was defined as grade (G) 3 non-hematologic or G4 hematologic toxicity. Maximal tolerated dose ( MTD ) was the dose below that at which 2 out of 6 patients experienced a DLT.

For the combination perifosine + sorafenib, twenty (20) patients were enrolled (12 males / 8 females, median age 64 (range 44-87)) with a median number of 2 prior therapies (range 1-4). Three patients were inevaluable due to rapid disease progression. Diagnosis was as follows; RCC (11 pts), sarcoma (5), colorectal (2), hepatocellular (1) and neuroendocrine (1). 17 patients were evaluable for toxicity: no drug related Grade 4 adverse events (AE) were seen. Suspected DLT of hand-foot syndrome was seen in cohort 4 and additional patients were enrolled. There was no increase in hand-foot syndrome compared to sorafenib alone. Of interest, 6/9 evaluable RCC patients (67%) had stable disease (SD) >12 weeks (median 26 weeks, range 12-62+). One hepatocellular patient had SD for 36 weeks. The combination of perifosine + sorafenib was well tolerated with no increased hand-foot syndrome compared to sorafenib alone. Six out of 9 RCC patients (67%) achieved SD up to 62+ weeks. Future studies are currently in development.

For the combination perifosine + sunitinib, fourteen patients (8 males / 6 females; media range 62 years old, range 28-81) were enrolled. Disease type was as follows: RCC (3), Sarcoma (3), Other (8). Six patients were evaluable for response. After 2 treatment cycles, one patient had a partial response (PR), 3 patients showed a SD and 2 patients had disease progression (PD). In the sub-group RCC, three out of three patients were evaluable for response: one patient had a PR, 1 patient showed a SD and 1 patient had a PD. Results indicated that patients to date have well tolerated the treatment combination of perifosine + sunitinib with no unexpected toxicities and clinical activity has been noted within the first 3 cohorts with 4 of 6 (67%) evaluable patients with advanced cancer achieving at least SD for more than 6 months.

Perifosine Sarcoma

In June 2007, our partner Keryx presented results of Phase 1 and 2 studies for the treatment of patients with advanced sarcoma at the ASCO meeting. The dose schedules in the Phase 1 trials were weekly 100-800mg or loading dose 300-1800mg on Day 1 followed by 50-150 mg daily for Days 2-21 every 28 days or loading dose 400-900 mg and daily 50-100 mg continuously. In the Phase 2 trial, doses were loading dose 900 mg on Day 1 and 150mg daily for days 2-21 every 28 days; loading dose 900 mg and 100 mg daily continuously; 50 mg daily continuously without a loading dose; and 900-1500 mg weekly. 145 patients with sarcoma were entered into studies and were assessed for clinical benefit rate ( CBR ). Partial responses were seen, in one patient each, with chondrosarcoma, extra-skeletal myxoid chondrosarcoma, leiomyosarcoma and a desmoid tumor. At lower doses with 52 patients fully evaluable for CBR, the CBR was 52% with four partial responses and 23 stable disease at  $\geq 4$  months. At higher doses with 30 patients fully evaluable for CBR, CBR was 53% with 16 stable disease at  $\geq 4$  months. Toxicities were mainly gastrointestinal and/or fatigue. The percentage of patients with grade 0 nausea, vomiting, diarrhea and fatigue for lower dose perifosine (76 patients) was 46%, 49%, 38% and 55% respectively compared to 26%, 32%, 20%, and 58% for higher dose perifosine (69 patients). The proportion of patients with grade 2+ nausea,



Table of Contents

vomiting, diarrhea and fatigue was 20%, 13%, 15%, and 21% for lower dose perifosine and 49%, 35%, 42%, and 25% for higher dose perifosine.

In November 2007, Keryx announced positive preliminary Phase 2 data of perifosine in patients with chemo-insensitive sarcoma. Data demonstrated the tolerability and clinical activity of perifosine as a single agent with an overall clinical benefit of 40% (stable disease > 3 months) in patients with refractory rare sarcomas. Perifosine was well tolerated with the most common grade 1 & 2 adverse events reported as nausea, vomiting, diarrhea and fatigue.

Perifosine Gliomas

In November 2007, Keryx announced early results of a Phase 2 trial of perifosine as a single agent for the treatment of recurrent malignant gliomas (malignant glioblastoma and malignant anaplastic gliomas). Twenty-five patients with advanced malignant gliomas were treated with a loading dose of 600 mg (150 mg x4) followed by a 100 mg daily dose of perifosine. The median progression free survival and overall survival in the anaplastic glioma group was nine weeks (range 2-50 weeks) and 49 weeks respectively. Toxicity was minimal with the following reported events: one grade 1 nausea, one grade 1 diarrhea, one grade 2 pain, and one grade 4 gout exacerbation. The study was designed to enroll at least 12 evaluable malignant glioblastoma patients and at least 10 evaluable malignant anaplastic gliomas patients. If at least one patient achieves six month progression free survival, the study would continue to enrol an additional subset of patients. Therefore, the malignant glioblastoma arm has been halted and the malignant anaplastic gliomas arm will continue to enroll.

Perifosine Other indications

On March 2, 2006, our North American partner, Keryx, announced the initiation of a corporate-sponsored Phase 2 trial, multi-cancer, clinical program to evaluate perifosine as a treatment for leukemia. Dr. Frank Giles, Professor, Department of Leukemia, at the MD Anderson Cancer Center in Houston, TX, is the principal investigator. This Phase 2 trial will assess the objective response rate and evaluate the pharmacokinetics and safety and tolerability of perifosine as a single agent in relapsed or refractory acute myeloid leukemia, acute lymphocytic leukemia, chronic lymphocytic leukemia, high-risk myelodysplastic syndrome and chronic myeloid leukemia in the blastic phase.

In November 2006, Keryx presented intermediary results of the Phase 2 study of imatinib plus perifosine in patients with imatinib-resistant gastrointestinal stromal tumor ( GIST ). The primary endpoint of this study is to evaluate the efficacy and toxicity of the combination imatinib and perifosine in patients with imatinib-resistant GIST. To date, 16 patients have been enrolled in the current study. Of the 12 patients with evaluable disease, there were two partial responses by Choi criteria (17% objective response rate (ORR)) and one partial response by RECIST criteria (8% objective response rate). Grade 3 and 4 adverse events were rare and included fatigue, myalgias, ocular toxicity and nausea/emesis. The early data from the current study suggest that the addition of perifosine to imatinib is well-tolerated and may have efficacy in the treatment of patients with imatinib-resistant GIST.

*Partners for perifosine*

A Cooperative Research and Development Agreement (CRADA) was put in place with the National Institute of Health/the National Cancer Institute in May 2000. A cooperation and license agreement was signed in September 2002 with Access Oncology, Inc. ( AOI ), for the use of perifosine as an anti-cancer 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 partner s studies, as well as milestone payments and scale-up royalties to be paid to us on future net sales of perifosine in North America. We own rest of the world rights to perifosine.

#### **AEZS-127 erucylphosphocholine**

On January 6, 2005, we announced the initiation of preclinical development of erucylphosphocholine (AEZS-127), an analog of perifosine which is suitable for intravenous administration. Like perifosine, AEZS-127 belongs to a new class of compounds based on alkylphosphocholines. AEZS-127 possesses distinctive reduced haemolytic activity thus allowing for intravenous injection.

On January 6, 2005, we also licensed to Keryx certain rights to develop and market AEZS-127 in North America, South Africa, Israel, Australia and New Zealand while keeping rights for the rest of the world. According to the agreement with Keryx, the preclinical development costs of AEZS-127 are shared between Keryx (50%) and us (50%). In Q4 2008, we retrieved all rights for AEZS-127 from Keryx.

Table of Contents

In 2006, studies for acute toxicity and dose range finding of erucylphosphocholine were actively pursued. The 4-week toxicity studies in rats and dogs as well as the safety pharmacology package was completed in 2007. These preclinical data are a prerequisite for the performance of a Phase 1 clinical study.

**Erk/PI3K inhibitors and dual kinase inhibitors**

In addition to our activities with alkylphosphocholines, we are screening small molecules for activity as agonists and antagonists to lipid-protein signaling interactions, which are seen as new and potentially important therapeutic targets.

We are focusing our efforts on single and dual inhibitors of Ras-Raf-Mek-Erk and PI3K-Akt pathways. The Ras-Raf-Mek-Erk and the PI3K-Akt pathways are constitutively activated in many cancer types, and influence both tumor development and progression.

Both signaling pathways represent promising therapeutic targets for the treatment of tumors. We have now identified a new compound class with inhibitory activity against both the Erk and PI3K kinases. These small molecules inhibit the kinases at nanomolar concentrations in a dose-dependent manner by competing directly at the ATP binding site. In a broad kinase panel, the molecules are very selective against other kinases. In cellular experiments the compounds inhibit the activation of downstream targets Akt and Rsk1, and can stop the proliferation of various human cancer cell lines. Moreover, a new generation of aniline-substituted pyridopyrazine-urea derivative show highly selective PI3K inhibition. We are currently performing *in vivo* studies with front-runner compounds in four mouse xenograft models (HCT116, U87, A549 and PC3) as well as pharmacokinetic studies in rodents using an oral pre-formulation. On the basis of these studies, AEZS-126 was selected as a preclinical development candidate for *in vivo* pharmacology and pharmacokinetic studies.

***Competitor for Erk/PI3K inhibitor***

Novartis PI3K inhibitor NVP-BEZ 235, which is currently being investigated in a clinical Phase 1, was used as a reference compound for the evaluation of our candidate compounds.

**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. The development strategy was to create targeted conjugates with high cytotoxic activity based on doxorubicin, an approved and commercialized product or 2-pyrrolino-doxorubicin which is 500 to 1,000 times more active than the parent compound. We are exploring several candidates in which doxorubicin or 2-pyrrolino-doxorubicin are coupled to the peptide carriers targeting LHRH (AEZS-108 & AN-207), somatostatin (AN-238 & AN-162) or bombesin (AN-215) receptors. These conjugates are less toxic and more effective *in vivo* than the respective radicals in inhibiting tumor growth in LHRH receptor positive models of human ovarian, mammary or prostatic cancer.

Table of Contents

In AEZS-108, the most advanced of the 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 anti-tumor 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 this targeted anti-cancer agent AEZS-108.

In June 2006, we announced positive Phase 1 results for AEZS-108 in patients with gynaecological and breast cancers which showed that the compound has a good safety profile and no dose-limiting toxicities. Eight patients received AEZS-108 by intravenous infusion. Infusion was well tolerated at all dosages, without supportive treatment. Pharmacokinetic analyses showed dose-dependent plasma levels of AEZS-108 and only minor (10-20%) release of doxorubicin. Stabilization of disease was observed in one out of eight patients in the ongoing Phase 1 study.

On November 27, 2006, we disclosed additional positive Phase 1 results regarding AEZS-108 in patients with gynaecological and breast cancers. Further 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>. This dose will be the recommended dose for a Phase 2 trial. The Phase 1 open-label, multi-center, 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 anti-tumor 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. The Phase 2 trials will focus on advanced or recurrent ovarian and endometrial cancers, two forms of cancer where LHRH receptors are highly expressed. Recommended dose will be 267 mg/m<sup>2</sup> given once every three weeks.

In 2007, a Phase 2 open-label, non-comparative, multicenter two indication trial stratified with two stage Simon Design was prepared, where 82 patients are planned for this trial with up to 41 patients with either a diagnosis of platinum-resistant ovarian cancer (stratum A) or disseminated endometrial cancer (stratum B). On February 12, 2008, we reported that the treatment of first patients had commenced in this Phase 2 trial. In October 2008, we announced that we have 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 partial responses 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 complete response and two partial responses among 14 patients with a diagnosis of disseminated endometrial cancer. Further results of this trial are expected in the first half of 2009.

**AEZS-105 - Lobaplatin**

Lobaplatin is a platinum derivative that has demonstrated lower toxicity in preclinical studies compared with cisplatin, specifically renal toxicity, and incomplete cross-resistance with other platinum derivatives suggesting potential therapeutic use even in tumor indications not routinely treated with platinum derivatives.

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

Clinically, lobaplatin was well tolerated at recommended dosages. Treatment was not associated with typical side effects often seen with cisplatin, such as nephrotoxicity (impairment of kidney function), ototoxicity (loss of hearing capacity), and neurotoxicity (effects on sensory function). In addition, vomiting was less severe than published data from both cisplatin and carboplatin. Characteristic toxicity of lobaplatin is a short-lasting, spontaneously reversible drop in thrombocyte count (blood platelets).

In a Phase 2 study conducted in China that included 284 patients with a broad range of solid and non-solid tumors, safety and particularly good therapeutic efficacy were demonstrated in patients with breast cancer, small cell lung cancer ( SCLC ), and chronic myeloid leukemia ( CML ) (a cancer of the hematopoietic system). The primary endpoint in solid tumor patients was the remission rate according to WHO criteria, while response in CML was assessed according to the disease-specific criteria of Talpaz. The favorable results of this study were the basis for approval of Lobaplatin by the Chinese health authorities for the treatment of inoperable, advanced breast cancer, SCLC and CML.

Table of Contents

In December 2002, we signed a contract with Hainan Chang An Pharmaceuticals Ltd. for the marketing in China of lobaplatin. The contract includes the worldwide manufacturing rights of lobaplatin by Hainan Chang An Pharmaceuticals. The technology transfer agreement provided us with a first payment upon signature and a later manufacturing-related payment.

In 2007, lobaplatin was licensed to Atani for the territory of Japan. Atani is performing preclinical studies and is planning to conduct a Phase I clinical trial.

**TUBULIN INHIBITORS / VASCULAR TARGETING AGENTS**

**AEZS-112 - Development of a low molecular weight tubulin inhibitor with anti-angiogenic 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 anti-tumor 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 in animal models improved efficacy, 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 an excellent tolerability profile showing excellent *in vivo* activity in various tumor models including mammary, colon, melanoma and leukemia cancers after oral administration. This compound acts through three mechanisms of action. Strong anti-cancer activity is combined with pro-apoptotic and anti-angiogenic 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 nanomolar concentration and induced apoptosis. AEZS-112 is not cross-resistant to cisplatin, vincristine and doxorubicine in cell lines resistant to these drugs. Given orally once weekly, AEZS-112 proved to be a potent inhibitor of *in vivo* tumor growth in melanoma, mammary, colon, lung, renal as well as in leukemia cancers at acceptable and very well tolerated doses. Furthermore AEZS-112 showed favorable safety and toxicity profiles. 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, multi-center, intermittent treatment Phase 1 trial is being conducted in the United States with Daniel D. Von Hoff, MD, Senior Investigator at the Translational Genomics Research Institute in Phoenix, AZ, as the lead investigator. The trial includes up to 50 patients who have either failed standard therapy or for whom no standard therapy exists. 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.

As of December 2008, 35 patients have entered this Phase 1 dose escalating clinical trial. To date no Maximum Tolerated Dose ( MTD ) has been achieved and no clinical relevant drug-related adverse events have been encountered. We also expect to report first results at the Annual Meeting of the American Association for Cancer Research (AACR) in Denver in late April 2009.

#### **Growth hormone secretagogue**

Ghrelin ligand AEZS-130 ( ghrelin agonist )

Growth hormone secretagogues ( GHS ) represent a new class of pharmacological agents that directly stimulate growth hormone ( GH ) secretion from the pituitary gland without the involvement of growth hormone-releasing hormone GH-RH or somatostatin. We believe that there is currently no GHS on the pharmaceutical market. Since GH is a potent regulator of lipid, sugar and protein metabolism, the potential clinical uses of GHS are numerous. They include growth retardation in children and treatment of cachexia in AIDS patients, which are currently the only approved uses of therapy of GH. The administration of GH, which has to be injected every day, is cumbersome. Therefore, we believe that there would be a demand for new orally active drugs like GHS.



Table of Contents

As part of our university collaboration, we accessed new peptidomimetic compounds with GH secretagogue properties. The lead development candidate, AEZS-130 (EP-1572), is a novel peptidomimetic GHS with potent and selective GH-releasing activity in humans. AEZS-130 underwent limited clinical pharmacology tests that demonstrated a potent stimulation of the GH secretion after oral administration in human volunteers. This product has been licensed to Ardana Bioscience Ltd. (Ardana) (ARD-07), which initiated an open, randomized, placebo-controlled Phase 1 dose-ranging study in April 2004. Thirty-six healthy subjects were included in this study to receive either the reference hormone GH-RH by intravenous route or one of the following dose levels of AEZS-130: 0.005, 0.05 or 0.5 mg/kg by oral route. AEZS-130 at the dose of 0.5 mg/kg orally caused an increase in growth hormone release equivalent to that induced by GH-RH intravenously. The compound was well tolerated and no other hormones showed a significant modification after any dose of AEZS-130.

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 status for AEZS-130, which it is developing as a diagnostic for growth hormone deficiency in adults. The clinical development and toxicology programs are ongoing and, subject to clinical outcome, 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 was suspended.

We announced the recovery of worldwide rights from Ardana for the compound AEZS-130 in the third quarter of 2008. Future development options are currently being evaluated for the use of this compound in growth hormone deficiencies.

**Ghrelin receptor ligands**

Ghrelin is a peptide predominantly produced by the stomach. Apart from a potent GH-releasing action, ghrelin has other activities including stimulation of lactotroph and corticotroph function, influence on the pituitary gonadal axis, stimulation of appetite, control of energy balance, influence on sleep and behavior, control of gastric motility and acid secretion, and influence on pancreatic exocrine and endocrine function as well as on glucose metabolism. The recent discovery of ghrelin and its receptors opens up new opportunities for the development of drugs that will treat metabolic disorders. There is indeed a possibility that ghrelin analogs, acting as either agonists or antagonists, might have clinical impact without affecting GH level. The use of ghrelin antagonists as appetite suppressants or inhibitors of lipogenesis could open up new opportunities for the treatment of obesity and associated diseases (e.g. diabetes, cardiovascular diseases). The use of ghrelin agonists could have therapeutic benefits which are expected to offer hope for cachexic or anorexic patients.

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

In 2004, we established a research and license collaboration agreement with Le Centre National de la Recherche Scientifique and University Montpellier I and II, France, acting in their own names, as well as in the name and on behalf of the Laboratoire des Aminoacides, Peptides et Protéines (LAPP) (UMR 5810), directed by Dr. Jean Martinez, for the synthesis and characterization of new chemical entities acting as ghrelin receptor ligands. According to the agreement, we have the worldwide rights to develop and exploit the new compounds for any indication. Compounds with the most potent affinity for the ghrelin receptors will be investigated further through an international network of academic investigators with expertise in the field of endocrinology in order to identify clinical development candidates.

Additionally, we also established a research contract with the Department of Experimental and Environmental Medicine of the University of Milan, Italy, under the direction of Prof. Vittorio Locatelli, for the pharmacological characterization of potentially ghrelin receptor ligands.

In August 2005, we filed a first patent application to protect a series of new chemical entities characterized as ghrelin receptor ligands.

Table of Contents

In May 2006, we established a research project agreement with the University of Montreal. This research project will focus on the characterization of ghrelin receptor ligands on fat tissue. This project is led by Huy Ong, Professor at the Faculty of Pharmacy, at the University of Montreal.

In August 2006, we also initiated a research collaboration with the Hôpital Laval (Québec) under the direction of Dr. Denis Richard. This research collaboration will focus on the pharmacological characterization of ghrelin receptor ligands *in vivo* (e.g. the effects in diet-induced obesity models).

In October 2006, we presented for the first time our *in vivo* data on the capacity of ghrelin antagonists of selectively inhibiting food intake. This study, using a rat model, outlined the capacity of ghrelin antagonists' ability to inhibit appetite without affecting growth hormone secretion and represents evidence that ghrelin antagonist compounds can selectively inhibit food intake. It further supports the hope that ghrelin antagonist compounds have the potential to be useful for the treatment of obesity.

In 2007 and 2008, we presented at scientific meetings preclinical candidates having the interesting property to decrease body weight gain and fat accumulation in diet induced obesity models. The ongoing work will focus on the improvement of oral bioavailability.

**IMMUNOTHERAPY / VACCINES**

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 that we have filed. The most advanced products are bacterial tumor vaccines which are based on the approved human vaccine strain *Salmonella typhi* Ty21a. The principle of these recombinant vaccine strains is the secretion of the tumor antigen using a so-called Type I secretion machinery derived from *Escherichia coli*. To date, two different vaccine strains have been generated up to GMP scale production – a melanoma vaccine encompassing a mutated form of the oncogene B-Raf, which is present in more than 65% of melanomas, and a prostate cancer vaccine strain expressing and secreting PSA. For both vaccines, the preclinical proof of principle has been demonstrated in distinct animal models and the immunogenicity could be further enhanced compared to our already published strains (patent application filed in November 2006).

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

In 2007, the PSA vaccine (AEZS-120) was selected as the first preclinical development candidate of an anti-tumor vaccine. In September, scientific advice from the Paul Ehrlich Institute, the German health authority for vaccines, was sought and the preclinical development program presented by us was in principle accepted.

A grant application was filed in Germany and was approved in 2008. 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. The preclinical development and manufacture of material for clinical trial was initiated in 2008.

### **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.

Table of Contents

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, i.e. 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 more than 60 own and in licensed patent families (issued, granted or pending in the United States, Europe and other jurisdictions).

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

Cetrorelix:

- U.S. patent 5,198,533 provides protection in the United States for the compound cetrorelix and other LHRH antagonists. This U.S. patent will expire in October 2010 pursuant to a granted request 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 cetrorelix. This U.S. patent will expire in December 2021.
- U.S. patent 5,773,032 covers a long-acting formulation of cetrorelix consisting of poorly soluble particles of 5 µm to 200 µm in size. The patent not only protects cetrorelix pamoate as a long-acting formulation but also prevents the development of other LHRH antagonist drugs that are based on this drug-delivery system. This U.S. patent will expire in November 2014. A patent term extension of up to five years may be possible and will be requested upon marketing approval of cetrorelix pamoate.

- U.S. patent 6,054,432 is a method-of-use patent covering a therapeutic regimen for treating BPH, where cetorelix is administered at a dosage of about 0.5 mg per day over time without effecting testosterone castration. The U.S. patent will expire in August, 2017.

- U.S. patent 7,005,418 is a method-of-use patent covering the therapeutic management of extrauterine proliferation of endometrial tissue (endometriosis), chronic pelvic pain and/or fallopian tube obstruction by administering an LHRH antagonist in the form of a short-term induction treatment for a period of about 4 to 12 weeks. The U.S. patent will expire in August 2022.

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 and will be requested upon receiving marketing approval of perifosine.

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 and will be requested upon marketing approval of ozarelix.

AEZS-108:

- U.S. patent 5,843,903 provides protection in the United States for the compound AN-152 and other related targeted cytotoxic anthracycline analogs, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This U.S. patent expires in November, 2015. A patent term extension of up to five years may be possible and will be requested upon receiving marketing approval of AEZS-108.

Table of Contents

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

| Patent No                | Title  | Country   | Expiry Date |
|--------------------------|--|---|-------------|
| <b><u>Cetrorelix</u></b> |  |   |             |
| EP 0 299 402             | LHRH antagonists   | Germany, United Kingdom, France, Switzerland and others | 2013-07-10  |
| U.S. 5,198,533           | LHRH antagonists   | United States   | 2010-10-24  |
| 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  |
| EP 1 150 717             | Sustained release salts of pharmaceutically active peptides and their production                                   | Germany, United Kingdom, France, Switzerland and others | 2020-01-29  |
| EP 1 309 607             | Method for producing LHRH antagonists  | Germany, United Kingdom, France, Switzerland and others | 2021-08-09  |
| U.S. 6,780,972           | Method for the synthesis of peptide salts, their use and the pharmaceutical preparations, containing peptide salts | United States   | 2021-08-24  |
| U.S. 5,773,032           | Long-acting injection suspensions and a process for their preparation  | United States   | 2014-11-25  |

**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 of March 20, 2009.





Table of Contents**D. Property, plants and equipment**

Our corporate head office and facilities are located in Québec, Province of Quebec, Canada. The following table sets forth information with respect to our main facilities as of March 20, 2009.

| Location   | Use of space  | Square Footage | Type of interest |
|--|---|----------------|------------------|
| 1405 Parc Technologique Blvd.<br>Québec (Quebec), Canada   | Fully occupied for management, R&D and administration                       | 4,400          | Leased           |
| 20 Independence Blvd<br>Warren, New Jersey, United States  | Partially occupied for management, R&D and business development             | 10,741         | Leased           |
| Weismüllerstr. 50<br>D-60314<br>Frankfurt am Main, Germany | Fully occupied for management, R&D, business development and administration | 46,465         | Leased           |

**Item 4A. Unresolved Staff Comments**

None.

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

Table of Contents

**Highlights**



- In February 2008, we reported that a first group of patients had been treated with AEZS-108 for a Phase 2 trial in advanced ovarian and endometrial cancers.
- In March 2008, we reported that dosing had commenced with cetorelix in the second efficacy study of our Phase 3 program in benign prostatic hyperplasia ( BPH ).
- In March 2008, we completed the sale to Paladin Labs Inc. ( Paladin ) of our marketed product, Impavido® (miltefosine), for approximately \$9.2 million.
- In April 2008, appointment of Juergen Ernst, the Company s Chairman of the Board at the time, as Interim President and Chief Executive Officer, following the departure of our former President and Chief Executive Officer.
- In April 2008, we reported the completion of patient recruitment with cetorelix, for the first efficacy study of our Phase 3 program in BPH.
- In May 2008, we reported that a first group of patients had been treated with cetorelix for the safety trial of our Phase 3 program in BPH.
- In June 2008, we completed the sale of our Quebec City property for a purchase price of \$7.1 million.
- In September 2008, Juergen Engel, Ph.D., was appointed as the Company s President and Chief Executive Officer, succeeding Juergen Ernst who, at the same time, was appointed as Executive Chairman of the Company.
- In October 2008, we reported the completion of patient recruitment for the second efficacy trial of our Phase 3 program with cetorelix in BPH.
- In October and November 2008, we reported that we had entered the second stage of patient recruitment for our AEZS-108 trials in advanced ovarian and endometrial cancers, respectively.

Table of Contents

- In December 2008, we sold our rights to royalties on future sales of Cetrotide®, covered by our license agreement with Merck Serono, to Cowen Healthcare Royalty Partners L.P. ( Cowen ) for gross consideration of \$52.5 million.
- In December 2008, we reported the completion of patient recruitment for the safety trial of our Phase 3 program in BPH with cetrotirelix.
- In December 2008, Matthias Seeber, MBA, was nominated Company Senior Vice President, Administration and Legal Affairs.
- Subsequent to year-end, we entered into a development, commercialization and license agreement with sanofi-aventis for the development, registration and marketing of cetrotirelix in BPH for the United States market. The agreement includes an initial upfront payment of \$30.0 million and a total of \$135.0 million in payments upon achieving certain pre-established regulatory and commercial milestones, as well as escalating double-digit royalties on future net sales of cetrotirelix for BPH in the United States.

**Introduction**

The following analysis provides a review of the consolidated results of operations, financial condition and cash flows of Aeterna Zentaris Inc. for the three-month period and full year ended December 31, 2008. In this Management's Discussion and Analysis ( MD&A ), the Company, we, us, and our mean Aeterna Zentaris Inc. and its subsidiaries. This discussion should be read in conjunction with the information contained in the Company's annual consolidated financial statements and related notes as at and for the years ended December 31, 2008, 2007 and 2006. Our consolidated financial statements, reported in United States dollars ( US dollars ), have been prepared in accordance with Canadian Generally Accepted Accounting Principles ( Canadian GAAP ), which differ in certain respects from United States Generally Accepted Accounting Principles ( US GAAP ), as discussed below.

All amounts presented in this MD&A are in US dollars, except where otherwise noted.

### **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, believe, could, expect, goal, guidance, intend, may, objective, outlook, plan, seek, should, strive, target and will.

Forward-looking statements involve risks and uncertainties, many of which are discussed in this MD&A. Results or performances 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 such regulatory authorities as the US Food

Table of Contents

and Drug Administration, 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 such forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, unless requested to do so by a governmental authority or applicable law.

**About Material Information**

This MD&A includes the information we believe to be material to investors after considering all circumstances, including potential market sensitivity. We consider information and disclosures to be material if they result in, or would reasonably be expected to result in, a significant change in the market price or value of our shares, or where it is quite 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 is registered in the United States and is, therefore, required to file continuous disclosure documents such as interim and annual financial statements, an MD&A, a Proxy Circular, an Annual Report 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 on request from the office of the Secretary of the Company 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/edgar.shtml](http://www.sec.gov/edgar.shtml).

**Company Overview**

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

Aeterna Zentaris Inc. (TSX: AEZ, NASDAQ: AEZS) is a global biopharmaceutical company focused on endocrine therapy and oncology.

**Our pipeline encompasses compounds at all stages of development, from drug discovery through marketed products. The two highest priorities in drug development are our Phase 3 program in BPH with our lead endocrinology compound, cetrorelix, and our Phase 2 program in advanced endometrial and ovarian cancers with our lead oncology compound, AEZS-108.**





Table of Contents

**Key Developments for the Year Ended December 31, 2008**

**Drug Development**

Status of our Drug Pipeline as at March 30, 2009

| Discovery                | Preclinical  | Phase 1                  | Phase 2                                    | Phase 3          | Commercial                                  |
|--------------------------|--|--------------------------|--|------------------|---|
| 120,000 compound library | AEZS-115   | AEZS-112 (oncology)      | AEZS-108 (endometrial and ovarian cancers) | Cetrorelix (BPH) | Cetrotide® ( <i>in vitro</i> fertilization) |
|                          | Non-peptide luteinizing hormone-releasing hormone ( LHRH ) antagonists (endometriosis & urology) | AEZS-130 (endocrinology) | Cetrorelix (endometriosis) (BPH in Japan)  |                  |   |
|                          | AEZS-120 (oncology vaccine)  |                          | Ozarelix (BPH, prostate cancer)            |                  |   |
|                          | AEZS-126 Erk & PI3K Inhibitors (oncology)  |                          | Perifosine (multiple cancers)              |                  |   |
|                          | AEZS-127   |                          |  |                  |   |
|                          | ErPC (oncology)  |                          |  |                  |   |
|                          | Ghrelin receptor ligands (endocrinology)   |                          |  |                  |   |

Partners (as defined in subsequent sections of this MD&A)

|  |  |                              |   |
|--|--|------------------------------|---|
|  | Cetrorelix:  | Cetrorelix (BPH):            | Cetrotide®:   |
|  | Shionogi in Japan  | Sanofi-aventis in the U.S.A. | <b>Merck Serono</b> (World ex-Japan)<br><b>Shionogi and Nippon Kayaku</b> (Japan) |
|  | Ozarelix:  | Handok in Korea              |   |
|  | <b>Spectrum</b> in North-America and India, <b>Nippon Kayaku</b> in Japan (oncology) |                              |   |

Ozarelix (BPH):

**Handok** in  
Korea,  
Indonesia,  
Malaysia, the  
Philippines and  
Singapore

Perifosine:

**Keryx** in North  
America

Table of Contents

***Cetrorelix***

In April 2008, we reported completion of patient recruitment for the first efficacy study of our Phase 3 program in BPH with cetrorelix. This one year placebo-controlled study, involving 667 patients located mainly in North America, is assessing an intermittent dosage regimen of cetrorelix as a potential safe and tolerable treatment providing prolonged improvement in BPH-related signs and symptoms. Results of this trial are expected in the third quarter of 2009.

In July 2008, we signed a license and cooperation agreement for the commercialization of cetrorelix in BPH with Handok Pharmaceuticals Co., Ltd., ( Handok ) for the Korean market.

In October 2008, we reported the completion of patient recruitment for the second efficacy trial of the Phase 3 program with cetrorelix in BPH. This trial, during which dosing had commenced in March 2008, has a similar design to the first efficacy trial and involves 420 patients located in Europe. Results of this trial are expected in the fourth quarter of 2009.

In December 2008, we reported completion of patient recruitment for the safety trial of the Phase 3 program with cetrorelix in BPH. Results of this study, involving 529 patients located in North America, as well as those of a QTc study, are expected by the end of 2009.

***Cetrotide®***

In December 2008, as discussed below, we sold our rights to royalties on future sales of Cetrotide®, covered by our license agreement with Merck Serono, to Cowen for gross consideration of \$52.5 million. Under the terms of the agreement with Cowen, the Company is entitled to an additional payment of \$2.5 million from Cowen contingent on 2010 net sales of Cetrotide® reaching a specified level.

***AEZS-108***

In February 2008, we reported that a first group of patients had been treated with our cytotoxic conjugate compound linked to doxorubicin, AEZS-108, for a European open-label, non-comparative multi-center Phase 2 trial in advanced ovarian and endometrial cancers.

In October 2008, we announced that we had entered the second stage of patient recruitment for our Phase 2 trial in ovarian cancer, after first stage data had shown two partial responses. In November 2008, we reported that we had entered the second stage of patient recruitment for our Phase 2 trial in endometrial cancer with AEZS-108. The decision to enter the second stage of patient recruitment was made following recent first

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

stage data reporting one complete response and two partial responses among 14 patients with a diagnosis of disseminated endometrial cancer. The open-label, non-comparative multi-center Phase 2 program will treat up to 82 women with LHRH-receptor

Table of Contents

positive ovarian and endometrial cancerous tumors, and results of the trial are expected in the fourth quarter of 2009.

***AEZS-112***

AEZS-112 is currently in a Phase 1 trial in patients with solid tumors and lymphoma. The Company is sponsoring and conducting this open-label, dose-escalation, multi-center, intermittent treatment trial in the United States. The trial will include up to 50 patients who have either failed standard therapy or for whom no alternative therapy exists. The primary endpoints of the trial will focus on determining the safety and tolerability of AEZS-112 as well as establishing the recommended Phase 2 dose and regimen. We expect progression of this trial in 2009 to identify maximum tolerated dose of AEZS-112.

AEZS-112 is the first anticancer drug in development involving two mechanisms of action, tubulin and topoisomerase II inhibition. AEZS-112 expresses different actions, such as pro-apoptotic and antiangiogenic properties.

***Ozarelix***

Our partner, Spectrum Pharmaceuticals, Inc. ( Spectrum ) released the results of a North American Phase 2 trial with ozarelix, a fourth generation LHRH antagonist in BPH. Spectrum indicated that ozarelix demonstrated sufficient clinical activity to justify its continued development. In early 2009, Spectrum initiated a North American multi-center, randomized, double-blind, placebo-controlled study in lower urinary tract symptoms due to BPH that will involve over 800 patients.

During the third quarter of 2008, we signed an agreement with Handok for the commercialization of ozarelix in BPH for the Korean and other Asian markets.

***Perifosine***

We are currently conducting a randomized, double-blind, placebo-controlled European multi-center Phase 2 trial with perifosine, an oral signal transduction inhibitor, combined with radiotherapy, in 160 patients with inoperable Stage III non-small cell lung cancer. We expect to disclose results related to this trial in the second quarter of 2009.

During 2008, our partner, Keryx Biopharmaceuticals, Inc. ( Keryx ), continued the development of perifosine with multiple Phase 1 and Phase 2 studies in North America in various cancers. Keryx expects to move perifosine into Phase 3 in at least one indication in North America in 2009.





Table of Contents

***AEZS-130***

During the third quarter of 2008, we recovered worldwide rights from Ardana Bioscience Ltd. ( Ardana ) for the Growth Hormone Secretagogue compound, AEZS-130. Future development options are currently being evaluated for the use of this compound in growth hormone deficiencies.

**Corporate Developments**

***Sale of Impavido®***

On March 1, 2008, we entered into a definitive purchase and sale agreement with respect to all rights related to the manufacture, production, distribution, marketing, sale and/or use of Impavido® (miltefosine) with Paladin for an aggregate purchase price of approximately \$9.2 million, payable in cash, subject to certain post-closing purchase price adjustments. The transaction, which closed on March 31, 2008, generated net cash proceeds of \$8.3 million, resulting in a gain of \$0.8 million.

***Sale of Building and Land***

On June 26, 2008, we sold our Quebec City building and land for a gross amount of \$7.1 million, payable in cash. The net proceeds received amounted to \$6.5 million, resulting in an additional loss on sale of \$0.8 million. In connection with this sale, we entered into a long-term lease agreement with the principal tenant of the building, agreeing to pay the principal tenant CAN\$300,000 (approximately \$246,305) as an incentive and service fee. This fee is included in the additional loss on sale, and the resulting payable is non interest-bearing and is due in bi-annual instalments of CAN\$30,000 (approximately \$24,630) over the next five years.

***Sale of Cetrotide® Royalty Stream***

In June 2003, we amended certain sections of our license and supply agreement with ARES Trading S.A. ( Merck Serono ) in which the latter was granted worldwide marketing, distribution and selling rights, except in Japan, for Cetrotide®, a compound used for *in vitro* fertilization (referred to as the License Agreement). Under the License Agreement, Merck Serono agreed to pay to us certain lump sum payments each calendar year up to and including December 31, 2010, as well as certain variable royalties through the expiry date of the Company's underlying patent rights.

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

In November 2008, we entered into a purchase and sales agreement ( PSA ) with Cowen relating to our rights to royalties on future sales of Cetrotide® covered by the License Agreement.

Table of Contents

In connection with the PSA, which was effective on October 1, 2008 and finalized in December 2008, we received \$52.5 million from Cowen, less certain transaction costs of \$1.0 million that had been advanced by Cowen to certain third-party firms and institutions on our behalf, resulting in net proceeds of \$51.5 million. Under the terms of the PSA, we are entitled to an additional payment of \$2.5 million contingent on 2010 net sales of Cetrotide® reaching a specified level.

Per the PSA, if cetrotide, the active substance in Cetrotide®, is approved for sale by European regulatory authorities in an indication other than *in vitro* fertilization, we have agreed to make a one-time cash payment to Cowen in an amount ranging from \$5.0 million up to a maximum of \$15.0 million. The amount which may be due to Cowen will be higher in proportion to the timing of the product's receiving European regulatory approval; that is, the earlier the product receives regulatory approval, the higher the amount payable to Cowen will be.

Also per the PSA, for each calendar quarter in which a royalty rate reduction defined as the actual reduction by Merck Serono, for any calendar quarter(s), of the rate applied in calculating variable royalties under the License Agreement, to amounts less than pre-established percentages has occurred or is continuing, we will pay Cowen a quarterly make-whole payment in an amount equal to the lesser of (i) the variable royalties in respect of such quarter that would have been received by Cowen if the aforementioned royalty rate reduction had not occurred or been continuing, and (ii) the difference of \$15.0 million less Cowen's net reduction payments, as defined.

Pursuant to the aforementioned transactions, we have certain obligations in the royalty agreement, including the supply of Cetrotide® to Merck Serono, the payment of royalties under the License Agreement, overseeing Merck Serono's compliance with the License Agreement, cooperation in handling any adverse claims or litigation involving the License Agreement and monitoring and defending any patent or trademark infringement.

We have recorded the proceeds as deferred revenues, which are recognizable as royalty revenues over the life of the License Agreement under the units-of-revenue method. Under that method, periodic royalty revenues are calculated by multiplying 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 by the royalty payments due to Cowen for the period.

We incurred a total of approximately \$4.8 million in financial advisor, legal and other transaction costs associated with the negotiation and finalization of the PSA. These costs have been capitalized in our consolidated balance sheet and are amortizable as part of selling, general and administrative (SG&A) expenses in the same manner and over the same period in which the related deferred revenues are recognized as royalty revenues.

Table of Contents

In this MD&A, the events and transactions associated with this sale are collectively referred to as the Cowen Transaction.

*Subsequent Event:*

*Cetorelix Development, Commercialization and Licensing Agreement*

On March 5, 2009, we entered into a development, commercialization and license agreement with sanofi-aventis for the development, registration and marketing of cetorelix in BPH for the US market. Under the terms of the agreement, sanofi-aventis made an initial upfront payment to us of \$30.0 million on March 18, 2009. Also per the agreement, we will be entitled to receive a total of \$135.0 million in payments upon achieving certain pre-established regulatory and commercial milestones. Furthermore, we will be entitled to receive escalating double-digit royalties on future net sales of cetorelix for BPH in the United States, while retaining the option to co-promote the product in that territory.

**Consolidated Results of Operations**

**Quarterly Summary Consolidated Results of Operations Information (unaudited)**

| (in thousands, except per share data) | Quarters ended    |                    |               |                |
|---------------------------------------|-------------------|--------------------|---------------|----------------|
|                                       | December 31, 2008 | September 30, 2008 | June 30, 2008 | March 31, 2008 |
|                                       | \$                | \$                 | \$            | \$             |
| Revenues                              | 7,244             | 11,029             | 10,457        | 9,748          |
| Loss from operations                  | (16,315)          | (12,386)           | (19,525)      | (14,158)       |
| Net loss                              | (14,493)          | (13,879)           | (20,579)      | (10,866)       |
| Net loss per share                    |                   |                    |               |                |
| Basic and diluted                     | (0.27)            | (0.26)             | (0.39)        | (0.20)         |

|   | Quarters ended    |                    |               |                |
|---|-------------------|--------------------|---------------|----------------|
|   | December 31, 2007 | September 30, 2007 | June 30, 2007 | March 31, 2007 |
|   | \$                | \$                 | \$            | \$             |
| Revenues                                      | 10,240            | 11,044             | 11,551        | 9,233          |
| Loss from operations                          | (11,664)          | (9,461)            | (5,326)       | (8,303)        |
| Net loss from continuing operations           | (13,854)          | (8,112)            | (4,928)       | (5,143)        |
| Net loss                                      | (13,636)          | (8,704)            | (4,846)       | (5,110)        |
| Net loss per share from continuing operations |                   |                    |               |                |
| Basic and diluted                             | (0.26)            | (0.16)             | (0.09)        | (0.10)         |
| Net loss per share                            |                   |                    |               |                |
| Basic and diluted                             | (0.26)            | (0.16)             | (0.09)        | (0.10)         |



Table of Contents

**Fourth Quarter 2008 Results**

**Consolidated revenues** were \$7.2 million for the quarter ended December 31, 2008, compared to \$10.2 million for the same quarter in 2007. The decrease in revenues is primarily due to lower quarter-over-quarter royalties related to our license agreement with Merck Serono. Subsequent to the Cowen Transaction, which was effective for royalty determination purposes on October 1, 2008, our periodic amortization of the gross proceeds received from Cowen, while still recognized as royalty revenues, have been lower than the royalty revenues recognized in the past, as receivable directly from Merck Serono. Additionally, quarter-over-quarter sales and royalties decreased due to the absence of sales of Impavido® in the fourth quarter of 2008, while license revenues witnessed a decrease due to the non-recurrence in 2008 of milestone payments received from Keryx, related to the perifosine Phase 2 trials.

**Consolidated SG&A expenses** were \$3.0 million for the quarter ended December 31, 2008, compared to \$5.1 million for the same quarter in 2007. The decrease in SG&A expenses is mainly related to the continued results of cost-saving measures that were implemented beginning in the second quarter of 2008.

**Consolidated research and development ( R&D ) expenses** were \$12.3 million for the quarter ended December 31, 2008, compared to \$13.6 million for the same quarter in 2007. The decrease in R&D expenses primarily relates to the comparative reduction in expenses incurred in connection with our Phase 3 program with cetorelix in BPH, which by the fourth quarter of 2008 was fully enrolled and less subject to larger front-end expenditures that were necessary in the earlier, fourth quarter 2007 stage of the program.

**Consolidated net loss** was \$14.5 million or \$0.27 per basic and diluted share for the quarter ended December 31, 2008, compared to \$13.6 million, or \$0.26 per basic and diluted share, for the same quarter in 2007. The increase in the consolidated net loss is largely attributable to a combination of lower sales and royalties, lower license fee revenues, lower manufacturing margins on Cetrotide® due in part to a \$0.7 million write-down to net realizable value of certain components of inventory, as well as to higher amortization expense due to the impairment of teverelix, as discussed below, partly offset by lower quarter-over-quarter SG&A expenses, higher net foreign exchange gains and lower income tax expense.

We expect that the consolidated net loss for the first quarter of 2009, excluding any impact of foreign exchange gains or losses, will be similar to the last quarter of 2008.

Table of Contents**Annual Consolidated Statements of Earnings**

| (in thousands, except per share data)                             | Years ended December 31, |          |          |
|---|--------------------------|----------|----------|
|   | 2008                     | 2007     | 2006     |
|   | \$                       | \$       | \$       |
| <b>Revenues</b>   |                          |          |          |
| Sales and royalties   | 29,462                   | 28,825   | 25,123   |
| License fees  | 8,504                    | 12,843   | 13,652   |
| Other   | 512                      | 400      | 24       |
|   | <b>38,478</b>            | 42,068   | 38,799   |
| <b>Operating expenses</b>   |                          |          |          |
| Cost of sales   | 19,278                   | 12,930   | 11,270   |
| Selling, general and administrative expenses                      | 17,325                   | 20,403   | 16,478   |
| Research and development costs                                    | 57,448                   | 39,248   | 27,422   |
| R&D tax credits and grants  | (343)                    | (2,060)  | (1,564)  |
| Depreciation and amortization                                     |                          |          |          |
| Property, plant and equipment                                     | 1,515                    | 1,562    | 2,816    |
| Intangible assets   | 5,639                    | 4,004    | 6,148    |
| Impairment of long-lived asset held for sale                      |                          | 735      |          |
|   | <b>100,862</b>           | 76,822   | 62,570   |
| <b>Loss from operations</b>                                       | <b>(62,384)</b>          | (34,754) | (23,771) |
| <b>Other income (expenses)</b>                                    |                          |          |          |
| Interest income   | 868                      | 1,904    | 1,441    |
| Interest expense  | (118)                    | (85)     | (1,433)  |
| Foreign exchange gain (loss)                                      | 3,071                    | (1,035)  | 319      |
| Other   | (79)                     | (28)     | 409      |
|   | <b>3,742</b>             | 756      | 736      |
| <b>Share in the results of an affiliated company</b>              |                          |          | 1,575    |
| <b>Loss before income taxes from continuing operations</b>        | <b>(58,642)</b>          | (33,998) | (21,460) |
| <b>Income tax (expense) recovery</b>                              | <b>(1,175)</b>           | 1,961    | 29,037   |
| <b>Net (loss) earnings from continuing operations</b>             | <b>(59,817)</b>          | (32,037) | 7,577    |
| <b>Net (loss) earnings from discontinued operations</b>           |                          | (259)    | 25,813   |
| <b>Net (loss) earnings for the year</b>                           | <b>(59,817)</b>          | (32,296) | 33,390   |
| <b>Net (loss) earnings per share from continuing operations</b>   |                          |          |          |
| Basic   | (1.12)                   | (0.61)   | 0.14     |
| Diluted   | (1.12)                   | (0.61)   | 0.14     |
| <b>Net (loss) earnings per share from discontinued operations</b> |                          |          |          |
| Basic   |                          |          | 0.50     |
| Diluted   |                          |          | 0.48     |
| <b>Net (loss) earnings per share</b>                              |                          |          |          |
| Basic   | (1.12)                   | (0.61)   | 0.64     |
| Diluted   | (1.12)                   | (0.61)   | 0.62     |



Table of Contents

**Consolidated Revenues**

**Consolidated revenues** are derived from sales and royalties as well as from license fees. Sales are derived from Cetrotide® (cetrotirelix acetate solution for injection), marketed for reproductive health assistance for *in vitro* fertilization and, prior to March 2008, Impavido® (miltefosine), marketed for the treatment of leishmaniasis, as well as from active pharmaceutical ingredients. Royalties are derived from Cetrotide® and, prior to the Cowen Transaction, payable by our partner, Merck Serono. Effective October 1, 2008, royalty revenues have been and will continue to be recognized as the deferred gross proceeds received from Cowen, and are amortized under the units-of-revenue method, as discussed above.

License fees are derived from non-periodic milestone payments, R&D contract fees and amortization of upfront payments received from our different licensing partners.

Consolidated sales and royalties increased to \$29.5 million for the year ended December 31, 2008, compared to \$28.8 million and \$25.1 million for each of the years ended December 31, 2007 and 2006, respectively. The increase in consolidated sales and royalties from 2007 to 2008 is mainly attributable to a large increase in sales of Cetrotide®, partly offset by lower sales of Impavido®.

The increase in consolidated sales and royalties from 2006 to 2007 is related to new sales of Cetrotide®, following the September 2006 product launch in the Japanese market, as well as year-over-year increased sales of Impavido®.

Consolidated sales and royalties are expected to decrease in 2009, due to lower royalty revenues expected to be recognized from the amortization of the deferred revenues received in connection with the Cowen Transaction.

Consolidated license fee revenues decreased to \$8.5 million for the year ended December 31, 2008, compared to \$12.8 million and \$13.7 million for each of the years ended December 31, 2007 and 2006, respectively. The decrease in consolidated license fee revenues from 2007 to 2008 is mainly attributable to non-recurring milestone payments received in 2007 from Ardana and from Keryx. Also, the decrease is related to the termination of our licensing agreement with Solvay Pharmaceuticals BV (Solvay) in 2007. We regained the worldwide ex-Japan rights for endometriosis from Solvay during 2007.

The decrease in consolidated license fee revenues from 2006 to 2007 is mainly attributable to a reduction in revenues related to services rendered through our collaboration with Solvay. We regained the worldwide ex-Japan rights for cetrotirelix in BPH from Solvay during 2006.

Table of Contents

Consolidated license fee revenues are expected to increase in 2009, due in part to the amortization of the upfront payment to be received in connection with the cetrotidex development, commercialization and licensing agreement entered into in March 2009 with sanofi-aventis, as discussed above.

**Consolidated Operating Expenses**

**Consolidated cost of sales** increased to \$19.3 million for the year ended December 31, 2008, compared to \$12.9 million and \$11.3 million for each of the years ended December 31, 2007 and 2006, respectively. The year-over-year increases in the cost of sales are directly related to additional generated sales and royalties.

The higher percentage of cost of sales in 2008 compared to 2007 and 2006 is largely related to the product mix, which includes a high concentration of sales related to Cetrotide®, a product that is more expensive to produce. In addition, we wrote down certain elements of our inventory to their net realizable value at the end of 2008, which contributed approximately \$0.7 million to the increase in consolidated cost of sales compared to 2007.

We expect cost of sales as a percentage of consolidated sales and royalties to increase to approximately 75% in 2009, given the continued increased sales expectations relating to Cetrotide®.

**Consolidated SG&A expenses** decreased to \$17.3 million for the year ended December 31, 2008, compared to \$20.4 million and \$16.5 million for each of the years ended December 31, 2007 and 2006, respectively. The decrease in SG&A expenses in 2008 compared to 2007 is primarily related to the organizational changes and cost-saving measures that were implemented beginning in the second quarter of 2008.

The increase in SG&A expenses for the year 2007 compared to 2006 is primarily due to non-recurring corporate expenses of nearly \$2.7 million related to the appointment of David J. Mazzo, Ph.D., as the President and CEO of the Company, as well as Juergen Ernst as Chairman of the Board, the departure of the former CEO, Gilles Gagnon, as well as the departure of the founder and former Executive Chairman, Éric Dupont, Ph.D. The increase in SG&A is also attributable to increased royalties and commissions expenses directly related to sales and royalties of Cetrotide®.

We expect our SGA expenses to decrease in 2009 due to continuing cost-saving measures and despite additional royalty expense, which is payable related to proceeds received in connection with our recently signed development, commercialization and license agreement with sanofi-aventis, as discussed above.

**Consolidated R&D costs** were \$57.4 million for the year ended December 31, 2008, compared to \$39.2 million and \$27.4 million for each of the years ended December 31, 2007 and 2006, respectively. The increase in consolidated R&D costs for the year 2008 compared to 2007 is mainly attributable to the advancement of our Phase 3 program with our lead compound, cetorelix, in BPH.

Table of Contents

Additional R&D expenses of \$11.8 million spent in 2007 compared to 2006 are mainly related to the advancement of our lead product cetrorelix, our LHRH antagonist in Phase 3 for BPH; as well as to further advancement of targeted, earlier-stage development programs including AEZS-108, our cytotoxic conjugate and AEZS-112, our tubulin inhibitor, both of which are in oncology.

The following table summarizes third-party R&D costs, by product, incurred by the Company during the year ended December 31, 2008.

(in thousands, except percentages)

| Product                   | Status             | Indication                      | Net R&D costs<br>(unaudited)<br>\$ | %     |
|---------------------------|--------------------|---------------------------------|------------------------------------|-------|
| Cetrorelix                | Phase 3<br>Phase 2 | BPH and endometriosis           | 25,697                             | 71.1  |
| AEZS-108                  | Phase 2            | Endometrial and ovarian cancers | 1,259                              | 3.5   |
| Perifosine                | Phase 2            | Oncology                        | 2,425                              | 6.7   |
| Ozarelix                  | Phase 2            | BPH and prostate cancer         | 253                                | 0.7   |
| AEZS-112                  | Phase 1            | Cancer                          | 981                                | 2.7   |
| AEZS-126/ Erk PI3K        | Preclinical        | Cancer                          | 1,609                              | 4.5   |
| Ghrelin receptor          | Preclinical        | Endocrinology and oncology      | 1,154                              | 3.2   |
| AEZS-115/ LHRH antagonist | Preclinical        | Endocrinology and oncology      | 843                                | 2.3   |
| Other                     | Preclinical        | Multiple                        | 1,913                              | 5.3   |
|                           |                    |                                 | 36,134                             | 100.0 |

We expect R&D investments to decrease by between \$4.0 million and \$6.0 million in 2009. This decrease will be related to the finalization of our three studies in our Phase 3 program for our lead compound, cetrorelix, in BPH, expected to occur in the third and fourth quarters of 2009, despite the continuing expenditures that will be required in connection with the filing of a New Drug Admission with the U.S. Food and Drug Administration and corresponding European agencies.

Table of Contents

R&D investments in AEZS-108 are expected to increase slightly in 2009 in connection with our Phase 2 trials in advanced ovarian and endometrial cancers.

Our other programs will represent a lower portion of our investment in R&D for 2009, as our focus is on advancing our later-stage lead compounds cetorelix in BPH and AEZS-108 in advanced ovarian and endometrial cancers.

**R&D tax credits and grants** were \$0.3 million for the year ended December 31, 2008, compared to \$2.1 million and \$1.6 million for each of the years ended December 31, 2007 and 2006, respectively. The decrease of R&D tax credits and grants in 2008 compared to 2007 is attributable to our having utilized only Quebec provincial tax credits in 2008, while in 2007, we also reduced our income tax payable by more than \$1.6 million, following the elimination of income taxes related to the distributions made to our shareholders in connection with our disposal of Atrium.

The increase from 2006 to 2007 is related to non-recurring R&D tax credits which were used in 2007 and 2006 to reduce estimated income taxes that would otherwise have been payable on the gain on disposal of our former subsidiary Atrium through a secondary transaction in October 2006 and the distribution of our remaining interest in 2007.

We expect the utilization of R&D tax credits and grants to decrease slightly in 2009.

**Consolidated depreciation and amortization** increased to \$7.2 million for the year ended December 31, 2008, compared to 5.6 million and \$9.0 million for each of the years ended December 31, 2007 and 2006, respectively.

The increase from 2007 to 2008 was primarily related to a non-recurring impairment charge of approximately \$2.4 million, recorded as amortization expense, taken in the fourth quarter of 2008 and related to teverelix, which had been deemed impaired following Ardana's entering into voluntary administration. Ardana is party to an assignment agreement on which the cash recoverability of teverelix depends, and, as such, this customer's entering into voluntary administration has triggered the likelihood that no future cash flows will be received by the Company in connection with the aforementioned license agreement. This increase in amortization expense was partially offset by reductions in depreciation and amortization expenses related to long-lived assets held for sale, including the Quebec City building and land, and Impavido®, on which depreciation and amortization ceased during the final months of 2007. The underlying assets were sold in 2008, as discussed above.

The decrease in 2007 is primarily due to an impairment loss of \$2.9 million taken in 2006 on manufacturing equipment, patents and trademarks related to the termination of non-core pharmaceutical development projects.



Table of Contents

**Impairment of long-lived asset held for sale** amounted to \$0.7 million for the year ended December 31, 2007. This impairment was related to the building and land held for sale for which the estimated fair value had been based on offers received by third parties.

**Consolidated loss from operations** increased to \$62.4 million for the year ended December 31, 2008, compared to \$34.8 million and \$23.8 million for each of the years ended December 31, 2007 and 2006, respectively. The increase in consolidated loss from operations in 2008 as compared to 2007 is largely attributable to a combination of lower license fee revenues, lower manufacturing margins, higher depreciation and amortization and higher R&D costs, partly offset by lower SG&A expenses.

The increase in loss from operations in 2007 as compared to 2006 is attributable to a combination of lower license revenues, increase in non-recurring G&A corporate expenses and additional R&D expenses mainly related to the advancement of our Phase 3 program with cetorelix in BPH. This increase in loss from operations in 2007 was partly offset by increased sales and royalties, as well as lower depreciation and amortization expenses.

We expect our consolidated loss from operations to decrease in 2009, mainly due to an expected increase in license fee revenues combined with continued decreasing SG&A and R&D expenses.

**Consolidated other income (expenses)**

**Consolidated interest income** amounted to \$0.9 million for the year ended December 31, 2008, compared to \$1.9 million and \$1.4 million for each of the years ended December 31, 2007 and 2006, respectively. Interest income is derived from our cash, cash equivalents and short-term investments, which totaled \$49.7 million as at December 31, 2008, \$41.4 million as at December 31, 2007 and \$60.5 million as at December 31, 2006. The decrease in consolidated interest income from 2007 to 2008 is due to the fact that less cash had been invested during 2008, with the exception of a large portion of the proceeds received in connection with the Cowen Transaction, though only in December 2008. The increase in consolidated interest income from 2006 to 2007 is directly related to the additional investment of net proceeds of \$45.0 million received in connection with the disposal of approximately 3.5 million shares of Atrium Innovations Inc. ( Atrium ), a former subsidiary of which we disposed in October 2006.

**Consolidated interest expense** amounted to \$0.1 million for the year ended December 31, 2008, compared to \$0.1 million and \$1.4 million for each of the years ended December 31, 2007 and 2006, respectively. The decrease from 2006 to 2007 is directly related to the full conversion of term loans into common shares completed in February 2006. Our long-term debt related to a non-interest bearing loan from the Canadian and Quebec Governments, for which the balance was paid in full in 2008.





Table of Contents

**Consolidated foreign exchange gain (loss)** amounted to \$3.1 million for the year ended December 31, 2008, compared to (\$1.0 million) and \$0.3 million for each of the years ended December 31, 2007 and 2006, respectively. The increase in foreign exchange gains in 2008 is mainly attributable to advances to our German subsidiary, denominated in Euro, and with our US-based subsidiary, denominated in US dollars, and the corresponding strengthening of the Euro and the US dollar compared to the Canadian dollar.

The decrease from 2006 to 2007 is mainly related to advances, made in Euro, to our German subsidiary and the corresponding weakness of the Euro compared to the Canadian dollar.

The year-end conversion rates from the Euro and Canadian dollar to the US dollar can be summarized as follows:

| 1 US dollar equivalent to: | As at December 31, |            |            |
|----------------------------|--------------------|------------|------------|
|                            | 2008<br>\$         | 2007<br>\$ | 2006<br>\$ |
| Euro                       | 0.7145             | 0.6870     | 0.7579     |
| Canadian dollar            | 1.2180             | 0.9913     | 1.1654     |

**Share in the results of an affiliated company** of \$1.6 million for the period ended December 31, 2006 relates to the investment in Atrium, recorded under the equity method, for the period from October 18 to December 31, 2006. As of January 2, 2007, the Company distributed its remaining interest in Atrium to our shareholders as a return of capital.

**Consolidated income tax (expense) recovery** was (\$1.2 million) for the year ended December 31, 2008, compared to \$2.0 million and \$29.0 million for each of the years ended December 31, 2007 and 2006, respectively. The increase in income tax expense from 2007 to 2008 is largely attributable to a minimum tax that is payable in Germany due to the tax accounting ramifications of transactions effected in connection with the Cowen Transaction and to the utilization, in 2007, of some of our future income tax assets following the non-recurring taxable capital gain realized in connection with the spin-off of Atrium.

The decrease in income tax recovery from 2006 to 2007 was related to the significant decrease in the valuation allowance with respect to the utilization of some of our future income tax assets against future tax liabilities related to the taxable capital gains that were realized by the Company in connection with the sale of Atrium shares in 2006 and the special distribution of our remaining interest at the beginning of 2007.

Table of Contents

In 2009, we do not expect to record any significant income tax recovery or expense in our foreign or domestic entities.

**Consolidated net (loss) earnings from continuing operations** was (\$59.8 million) for the year ended December 31, 2008, compared to (\$32.0 million) and \$7.6 million for each of the years ended December 31, 2007 and 2006, respectively. The increase in net loss from 2007 to 2008 is largely attributable to a combination of lower license fee revenues, the increase in R&D costs related to the advancement of our Phase 3 program with cetorelix in BPH, lower manufacturing margins, higher depreciation and amortization and higher income tax expense in 2008, partly offset by lower SG&A expenses and higher net foreign exchange gains.

The increased consolidated net loss from continuing operations in 2007 is directly related to the increased loss from operations of nearly \$10.0 million, a one-time share in the results of Atrium of nearly \$1.6 million recorded in 2006 and a non-recurring future income tax recovery of nearly \$25.0 million recorded in 2006 related to the sale of Atrium shares and the special distribution of our remaining interest in January 2007.

**Consolidated net (loss) earnings from discontinued operations** amounted to (\$0.3 million) for the year ended December 31, 2007, compared to \$25.8 million for the year ended December 31, 2006. The year-over-year variation relates almost exclusively to the divesture, in October 2006, of our interest in Atrium, whose results of operations were reported as discontinued operations for the year ended December 31, 2006 and detailed as follows:

| (in thousands)                                   | \$       |
|--|----------|
| <b>Revenues</b>                                  | 239,535  |
| <b>Earnings before the following items</b>       | 28,360   |
| Gain on disposal of Atrium shares                | 29,248   |
| Income tax expense                               | (19,923) |
| Loss on dilution of investments                  | (628)    |
| <b>Earnings before non-controlling interest</b>  | 37,057   |
| <b>Non-controlling interest</b>                  | (10,967) |
| <b>Net earnings from discontinued operations</b> | 26,090   |

Table of Contents

Also impacting consolidated net loss from discontinued operations were the results of operations related to Echelon Biosciences, Inc. ( Echelon ), which we disposed of in November 2007 and whose results were included in our consolidated statements of earnings (loss) for the year ended December 31, 2007, as follows:

| (in thousands)   | Years ended December 31, |              |
|--|--------------------------|--------------|
|  | 2007                     | 2006         |
|  | \$                       | \$           |
| <b>Revenues</b>  | <b>2,358</b>             | <b>2,593</b> |
| <b>Loss before the following items</b>                                       | <b>(206)</b>             | <b>(369)</b> |
| Goodwill impairment  | (500)                    |              |
| Loss on disposal of Echelon shares, net of cumulative translation adjustment | (44)                     |              |
| Income tax recovery  | 491                      | 92           |
| <b>Net loss from discontinued operations</b>                                 | <b>(259)</b>             | <b>(277)</b> |

The year-over-year decrease in revenues from discontinued operations related to Echelon from 2006 to 2007 is due to the fact that 2007 revenues represent eleven months compared to twelve months for the year 2006.

**Consolidated net loss** was \$59.8 million, or \$1.12 per basic and diluted share, for the year ended December 31, 2008, compared to \$32.3 million, or \$0.61 per basic and diluted share, for the year ended December 31, 2007. The increase in consolidated net loss in 2008 as compared to 2007 is attributable to a combination of lower license fee revenues, lower manufacturing margins, higher depreciation and amortization, higher income tax expense and higher R&D costs, partly offset by lower SG&A expenses and higher net foreign exchange gains.

The increased net loss in 2007 is related to a higher loss from operations of nearly \$10.0 million, lower income tax recovery of nearly \$27.0 million related to the recognition of future income tax assets mainly attributable to the sale of Atrium shares in 2006 and the special distribution of our remaining interest in January 2007, as well as lower net earnings from discontinued operations of Atrium of nearly \$26.0 million.

We expect that the consolidated net loss for the year 2009 will decrease, mainly due to increased license fee revenues, to be recognized in connection with the cetorelix development, commercialization and licensing agreement entered into with sanofi-aventis, and with the expected continued reduction of R&D and SG&A expenses.

Table of Contents

The weighted average number of shares outstanding used to calculate basic net earnings (loss) per share for both of the years ended December 31, 2008 and 2007 was 53.2 million shares, compared to 52.1 million shares for the year ended December 31, 2006. For diluted net earnings (loss) per share, the weighted average number of shares outstanding used for this calculation was 53.2 million shares for both of the years ended December 31, 2008 and 2007, compared to 52.5 million shares for the year ended December 31, 2006.

**Consolidated Balance Sheet Information***(Unaudited)*

| (in thousands)                                   | 2008<br>\$     | As at December 31,<br>2007<br>\$ | 2006<br>\$     |
|--|----------------|----------------------------------|----------------|
| Cash and cash equivalents                        | 49,226         | 10,272                           | 8,939          |
| Short-term investments                           | 493            | 31,115                           | 51,550         |
| Accounts receivable and other current assets     | 12,005         | 18,193                           | 41,234         |
| Property, plant and equipment, net               | 6,682          | 7,460                            | 13,001         |
| Other long-term assets                           | 39,936         | 56,323                           | 108,767        |
| <b>Total assets</b>                              | <b>108,342</b> | <b>123,363</b>                   | <b>223,491</b> |
| Accounts payable and other current liabilities   | 22,121         | 21,480                           | 15,624         |
| Current portion of long-term debt and payable    | 49             | 775                              | 686            |
| Long-term debt and payable                       | 172            | -                                | 687            |
| Non-financial long-term liabilities              | 64,525         | 12,517                           | 27,615         |
| <b>Total liabilities</b>                         | <b>86,867</b>  | <b>34,772</b>                    | <b>44,612</b>  |
| <b>Shareholders equity</b>                       | <b>21,475</b>  | <b>88,591</b>                    | <b>178,879</b> |
| <b>Total liabilities and shareholders equity</b> | <b>108,342</b> | <b>123,363</b>                   | <b>223,491</b> |

The increase in cash and cash equivalents and the decrease in short-term investments from 2007 to 2008 are discussed in more detail below. The decrease in accounts receivable and other current assets from 2007 to 2008 is largely attributable to lower customer billings in December 2008 compared to the same period in 2007, lower grants receivable at the end of 2008 and the write-down to net realizable value of certain components of inventory in December 2008, as discussed above.

The decrease in other long-term assets is primarily due to the disposal, in 2008, of the long-lived assets which had been reported as held for sale as at December 31, 2007, as discussed above and the impairment charge that was taken relative to teverelix in the fourth quarter of 2008, partially offset by a net increase in deferred charges, due mainly to the capitalization of financial advisor, legal and other costs incurred in connection with the Cowen Transaction. The increase in non-financial long-term liabilities is primarily attributable to the increase in deferred revenues following the receipt of proceeds from the Cowen Transaction, as well as an increase in employee future benefits related mainly to employees in our German subsidiary.

Table of Contents

The decrease in shareholders' equity from 2007 to 2008 is almost entirely attributable to the increase in consolidated deficit due to the current year net loss and the decrease of accumulated other comprehensive income, which in turn is largely made up of cumulative translation adjustments.

The increase in cash and cash equivalents and the decrease in short-term investments from 2006 to 2007 are discussed in more detail below. The decrease in accounts receivable and other current assets from 2006 to 2007 is mainly attributable to the utilization of future tax assets following the taxable capital gain realized in connection with the spin-off of Atrium, as well as the reduction of current assets of discontinued operations related to Echelon. The decrease in net property, plant and equipment from 2006 to 2007 is primarily the result of the reclassification of long-lived assets held for sale to other long-term assets, which resulted in an increase in 2007 to the latter, offset by a significant decrease due to the disposal of Atrium, which had been carried in the balance sheet as of December 31, 2006 under the equity method at a value of \$57.1 million.

Accounts payable and other current liabilities increased from 2006 to 2007 largely as a result of an increased volume of supplier invoices in December 2007 compared to the same period in 2006, while the decrease in non-financial long-term liabilities was mainly attributable to the decrease in long-term deferred tax liabilities and a decrease in the long-term portion of deferred revenues not yet amortized at year-end.

The overall decrease in shareholders' equity from 2006 to 2007 relates to the reduction of share capital in the amount of \$137.9 million as a result of the distribution to our shareholders of our remaining interest in Atrium. This decrease was offset by an increase in other capital to adjust for the effects of the corresponding difference between the fair value and the book value of Atrium, net of income taxes and cumulative translation adjustment, of \$71.1 million. Also contributing to the reduction in shareholders' equity from 2006 to 2007 was the contribution of the annual net loss to the consolidated deficit as well as an increase in the cumulative translation adjustment.

Table of Contents**Financial Liabilities, Obligations and Commitments**

We have certain contractual obligations and commercial commitments. Commercial commitments mainly include R&D services and manufacturing agreements related to the execution of our Phase 3 program with cetorelix in BPH. The following table summarizes future cash requirements with respect to these obligations.

| (in thousands)                | Carrying<br>amount<br>\$ | Payments due in |                 |                 |                  |
|-------------------------------|--------------------------|-----------------|-----------------|-----------------|------------------|
|                               |                          | 2009<br>\$      | 2010-2011<br>\$ | 2012-2013<br>\$ | After 2013<br>\$ |
| <b>Long-term payable</b>      | 221                      | 49              | 98              | 74              |                  |
| <b>Operating leases</b>       | 10,366                   | 2,191           | 4,241           | 2,503           | 1,431            |
| <b>Commercial commitments</b> | 20,528                   | 15,743          | 3,974           | 811             |                  |
| <b>Total</b>                  | 31,115                   | 17,983          | 8,313           | 3,388           | 1,431            |

**Outstanding Share Data**

As at March 9, 2009, there were 53,187,470 common shares issued and outstanding, and there were 4,667,428 stock options outstanding.

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 one time and on the availability of funding from investors and prospective commercial partners.

**Capital disclosures**

Our objective in managing capital composed of shareholders' equity is to ensure a sufficient liquidity position to finance our R&D activities, SG&A expenses, working capital and overall capital expenditures. We make every effort to manage our liquidity to minimize dilution to our shareholders.

Initially, we had funded our activities through public offerings of common shares and convertible term loans. More recently, however, we have tried to optimize our liquidity needs by non-dilutive sources, including the sale of non-core assets and future rights to royalties, investment tax credits and grants, interest income, licensing, service and royalties.

During 2008, we fulfilled our obligation on the loan from the federal and provincial governments with a nominal value of CAN\$800,000.



Table of Contents

In connection with the sale of the Quebec City building and land discussed above, we entered into a long-term lease agreement with the principal tenant of the building. As part of the agreement, we agreed to pay the principal tenant CAN\$300,000 (approximately \$246,305) as an incentive and service fee. The resulting payable is non-interest bearing and is due in bi-annual installments of CAN\$30,000 (approximately \$24,630) over the next five years.

Our capital management objective remains the same as that of previous years. The policy on dividends is to retain cash to keep funds available to finance the activities required to advance our product development pipeline, prioritizing our lead product candidate, cetorelix, in Phase 3 for BPH.

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

**Liquidity, Cash Flows and Capital Resources**

Our operations and capital expenditures are mainly financed through cash flows from operating activities, selling of non-core assets and other non-dilutive activities.

Our cash, cash equivalents and short-term investments amounted to \$49.7 million as at December 31, 2008, compared to \$41.4 million as at December 31, 2007. Possible additional operating losses and/or possible investments in the acquisition of complementary businesses or products may require additional financing. As at December 31, 2008, cash, cash equivalents and short-term investments of the Company included CAN\$3.8 million and EUR32.8 million.

Short-term investments do not include asset-backed commercial paper affected by liquidity issues.

Based on our assessment, which takes into account the proceeds received in connection with the Cowen Transaction, the signing of the development, commercialization and license agreement with sanofi-aventis, 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 the next 12-month period following the balance sheet date of December 31, 2008.

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

The variation of our liquidity by activity is explained below, not considering any cash flows used in or provided by discontinued operations.





Table of Contents

**Operating Activities**

Cash flows used in our continuing operating activities amounted to \$1.3 million for the year ended December 31, 2008, compared to \$25.7 million and \$15.9 million for each of the years ended December 31, 2007 and 2006, respectively. The significant decrease in cash used in operating activities from 2007 to 2008 relates in large proportion to the net cash proceeds received in connection with the Cowen Transaction, in addition to higher upfront payments received from certain customers and higher cash collections of trade accounts receivable. These cash inflows were partially offset by increased cash expenditures that contributed to the increase in our net loss, as well as by payments made, which were mainly related to financial advisor, legal and other costs incurred in connection with the Cowen Transaction, as well as to a higher volume of trade accounts payable settlements.

The increase in net cash used in 2007 compared to 2006 is primarily attributable to lower license revenues, increased non-recurring corporate expenses, additional investments in R&D related to the initiation of our Phase 3 program in BPH for cetorelix, as well as to the further advancement of targeted, earlier-stage development programs.

We expect net cash used in continuing operating activities to increase in 2009 due to the absence of cash royalty receipts that were payable in connection with the License Agreement with Merck Serono prior to the Cowen Transaction and as we continue our Phase 3 clinical program with cetorelix in BPH and further advance our targeted, earlier-stage development programs. These cash outflows will be partially offset by the receipt of the upfront payment from sanofi-aventis in connection with the cetorelix development, commercialization and licensing agreement, as discussed above.

**Financing Activities**

Net cash used in continuing financing activities was \$1.2 million for the year ended December 31, 2008, compared to \$1.1 million and \$0.7 million for each of the years ended December 31, 2007 and 2006, respectively. These funds were used mainly for the repayments of our long-term debt and payable, as well as in connection with the filing of a shelf prospectus.

**Investing Activities**

Cash provided by continuing investing activities (excluding the changes in short-term investments) amounted to \$13.6 million for the year ended December 31, 2008, while cash flows used in continuing investing activities (excluding the changes in short-term investments) was \$3.0 million for the year ended December 31, 2007, compared to \$0.5 million for the year ended December 31, 2006. The increase in cash provided by investing activities from 2007 to 2008 relates primarily to the disposals of the Quebec City building and land and of Impavido®, both of which had been reported as long-lived assets held for sale as at December 31, 2007.

Table of Contents

The increase in net cash used in continuing investing activities in 2007 compared to 2006 is mainly related to the acquisition of equipment that is necessary to support clinical trials.

We expect that cash provided by investing activities (excluding the changes in short-term investments) will decrease in 2009, mainly due to the expected non-recurrence of cash proceeds received in connection with the disposal of long-lived assets held for sale.

**Critical Accounting Policies and Estimates**

Our financial statements are prepared in accordance with Canadian GAAP. A summary of significant and pertinent measurement and disclosure differences between Canadian and US GAAP is provided in note 27 to our 2008 annual consolidated financial statements. The preparation of financial statements in accordance with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting years. Significant estimates are generally made in connection with the calculation of revenues, research and development expenses, stock-based compensation expense, as well as in determining the allowance for doubtful accounts, inventory and provisions for obsolete inventory, future income tax assets and liabilities, the useful lives of property, plant and equipment and intangible assets with finite lives, the valuation of intangible assets and goodwill, the fair value of stock options granted, employee future benefits and certain accrued liabilities. We base our estimates on historical experience, where relevant, and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

The following summarizes our critical accounting policies and other policies that require the most significant judgment and estimates in the preparation of our consolidated financial statements.

**Revenue Recognition and Deferred Revenues**

The Company is currently in a phase in which potential products are being further developed or marketed jointly with strategic partners. Existing licensing agreements usually foresee one-time payments (upfront payments), payments for research and development 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

Table of Contents

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 or using the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

License fees representing non-refundable payments received upon the execution of license agreements are recognized as revenue upon execution of the license agreements when we have no significant future performance obligations and when collectibility of the fees is assured. Upfront payments received at the beginning of licensing agreements are not recorded as revenue when received but are amortized based on the progress to the related research and development work. This progress is based on estimates of total expected time or duration to complete the work, which is compared to the period of time incurred to date in order to arrive at an estimate of the percentage of revenue earned to date.

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 there are no significant future performance obligations in connection with the milestones.

In those instances where we have collected upfront or milestone payments but have ongoing future obligations related to the development of the drug product, we consider the milestone payments and the remaining obligations under the contract as a single unit of accounting. In those circumstances where the collaboration does not require specific deliverables at specific times or at the end of the contract term, but rather our obligations are satisfied over a period of time, revenue recognition is deferred and amortized over the period of its future obligations.

Royalty revenue, based on a percentage of sales of certain declared products sold by third parties, is recorded when we have fulfilled the terms in accordance with the contractual agreement and have no future obligations, the amount of the royalty fee is determinable and collection is reasonably assured.

Proceeds received in connection with the Cowen Transaction are deferred and recognized over the life of the license agreement pursuant to the units-of-revenue method, as discussed above.

Revenues from sales of products are recognized, net of estimated sales allowances and rebates, when title passes to customers, which is at the time goods are shipped, when there are no future performance obligations, when the purchase price is fixed and determinable, and collection is reasonably assured.

**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, which are



Table of Contents

capitalized and amortized against operations over the estimated period of benefit. To date, no costs have been deferred.

Table of Contents

**Impairment of Long-Lived Assets and Goodwill**

Property, plant and equipment and intangible assets with finite lives are reviewed for impairment when events or circumstances indicate that carrying values may not be recoverable. Impairment exists when the carrying value of the asset is greater than the undiscounted future cash flows expected to be provided by the asset. The amount of impairment loss, if any, is the excess of its carrying value over its fair value, which in turn is determined based upon discounted cash flows or appraised values, depending of the nature of assets.

Goodwill, which represents the excess of the purchase price over the fair values of the net assets of entities acquired at the respective dates of acquisition, is tested for impairment annually or more frequently if events or changes in circumstances indicate that it might be impaired. Testing for impairment is accomplished mainly by determining whether the fair value of a reporting unit exceeds the net carrying amount of that reporting unit as of the assessment date. If the fair value is greater than the carrying amount, no impairment is necessary. In the event that the carrying amount of a reporting unit exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. Fair value of goodwill is estimated in the same way as goodwill is determined at the date of the acquisition in a business combination, that is, the excess of the fair value of the reporting unit over the fair value of the identifiable net assets of the reporting unit.

**Income Taxes**

We operate in multiple jurisdictions, and our earnings are taxed pursuant to the tax laws of these jurisdictions. Our effective tax rate may be affected by the changes in, or interpretations of, tax laws in any given jurisdiction, utilization of net operating losses and tax credit carry-forwards, changes in geographical mix of income and expense, and changes in management's assessment of matters, such as the ability to realize future tax assets. As a result of these considerations, we must estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure, together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in future tax assets and liabilities, which are included in our consolidated balance sheet. We must then assess the likelihood that our future tax assets will be recovered from future taxable income and establish a valuation allowance if, based on available information, it is more likely than not that some or all of the future income tax assets will not be realized. Establishing or increasing a valuation allowance increases our income tax expense.

Significant management judgment is required in determining our provision for income taxes, our income tax assets and liabilities, and any valuation allowance recorded against our net income tax assets. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our income tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to amend our valuation allowance, which could materially impact our financial position and results of operations.

Table of Contents

**Stock-Based Compensation Costs**

We account for all forms of employee stock-based compensation using the fair value-based method. This method requires that we make estimates about the risk-free interest rate, the expected volatility of our shares and the expected life of the awards.

**New Accounting Standards**

*Impact of accounting standards adopted in 2008*

On January 1, 2008, we adopted the Canadian Institute of Chartered Accountants, ( CICA ) Handbook Section 1535, *Capital Disclosures* ( Section 1535 ); Section 3862, *Financial Instruments - Disclosures* ( Section 3862 ); Section 3863, *Financial Instruments - Presentation* ( Section 3863 ); and Section 3031, *Inventories* ( Section 3031 ).

Section 1535 establishes guidelines for disclosure of information regarding an entity's capital which will enable users of its financial statements to evaluate an entity's objectives, policies and processes for managing capital, including disclosures of any externally imposed capital requirements and the consequences of non-compliance.

Section 3862 and Section 3863, which replace Section 3861, *Financial Instruments - Disclosure and Presentation*, require the disclosure of additional details of financial asset and liability categories as well as a detailed discussion on the risks associated with our financial instruments. The presentation requirements are carried forward unchanged.

The CICA issued Section 3031, which replaced Section 3030 of the same title. This standard requires that inventories be measured at the lower of cost and net realizable value and includes guidance on the determination of cost, including allocation of overheads and other costs. The standard also requires that similar inventories within a consolidated group be measured using the same method. Section 3031 also requires the reversal of previous write-downs to net realizable value when there is a subsequent increase in the value of inventories. We have adopted this standard effective January 1, 2008, and there has been no impact on the consolidated financial statements.

*Impact of accounting pronouncements not yet adopted*

In February 2008, the CICA issued Handbook Section 3064, *Goodwill and Intangible Assets*. This standard provides guidance on the recognition of intangible assets and the criteria for asset recognition, clarifying the applications of the concept of matching revenues and expenses, whether these assets are separately acquired or are developed internally. The standard will apply to our interim and annual financial statements for periods beginning on January 1, 2009. We do not expect that adoption of this standard will have a significant impact on the consolidated financial statements.





Table of Contents

In January 2009, the CICA issued Handbook Section 1582, *Business Combinations*, which replaces the existing standards. This section establishes the standards for the accounting of business combinations and states that all assets and liabilities of an acquired business will be recorded at fair value. Obligations for contingent considerations and contingencies will also be recorded at fair value at the acquisition date. The standard also states that acquisition-related costs will be expensed as incurred and that restructuring charges will be expensed in the periods after the acquisition date. This standard is applied prospectively to business combinations with acquisition dates on or after January 1, 2011. Earlier adoption is permitted. We are currently evaluating the impact, if any, that adopting this standard will have on our consolidated financial statements.

In January 2009, the CICA issued Handbook Section 1601, *Consolidated Financial Statements*, which replaces the existing standards and establishes the standards for preparing consolidated financial statements and is effective for 2011. Earlier adoption is permitted. We are currently evaluating the impact, if any, that adopting this standard will have on our consolidated financial statements.

In January 2009, the CICA issued Handbook Section 1602, *Non-controlling Interests*, which establishes standards for the accounting of non-controlling interests of a subsidiary in the preparation of consolidated financial statements subsequent to a business combination. This standard is effective for 2011. Earlier adoption is permitted. We are currently evaluating the impact, if any, that adopting this standard will have on our consolidated financial statements.

In January 2009, the CICA's Emerging Issue Committee ( EIC ) issued Abstract EIC-173, *Credit Risk and the Fair Value of Financial Assets and Liabilities*, which requires entities to take both counterparty credit risk and their own credit risk into account when measuring the fair value of financial assets and liabilities, including derivatives. EIC-173 will be effective for interim and annual periods beginning on or after January 1, 2009. We do not expect that adoption of this guidance will have a significant impact on our consolidated financial statements.

**International Financial Reporting Standards ( IFRS )**

We are currently evaluating the potential impact that could result from preparing our consolidated financial statements in accordance with IFRS, given that the Canadian Accounting Standards Board confirmed that IFRS will replace current Canadian standards and interpretations as Canadian GAAP for publicly accountable enterprises. The adoption of IFRS will have an impact on our consolidated financial statements, as well as on a wide range of operational and performance measures, beginning on January 1, 2011.

Table of Contents

To date, we have performed a high-level diagnostic that has identified pertinent differences between IFRS and current accounting policies and procedures that conform to Canadian GAAP. We have also developed a formal plan for IFRS conversion and the related transition from current standards. Activities under that plan will include, among other things, the identification and documentation of pertinent accounting and reporting differences between IFRS and Canadian GAAP; the choice of IFRS accounting policies, including consideration of elections available under IFRS 1, *First-time Adoption of International Financial Reporting Standards*; determination of the impact of conversion on internal controls, accounting systems and other business solutions and processes; and the development of training to assist appropriate employees in the transition to and ongoing compliance with IFRS.

Activities in connection with our IFRS implementation plan will continue throughout 2009, and we will provide required disclosures regarding the status of our plan.

**Outlook for 2009**

We expect to disclose first efficacy results of our Phase 3 program in BPH with our lead endocrinology compound, cetrorelix, in the third quarter of 2009. Results for the second efficacy trial of this same program are expected in the fourth quarter of 2009. Results for the safety trial and the QTc trial are expected by the end of 2009.

In Q4 2009, we expect to disclose Phase 2 results with AEZS-108 in advanced ovarian and endometrial cancers.

We will continue to seek business development opportunities from our extensive product pipeline.

As pertaining to liquidity, our expectation is that cash flows from operations will not proceed linearly throughout the year, but will instead be positively impacted in the first half of 2009 due to the receipt of the \$30.0 million upfront payment from sanofi-aventis, as discussed above, partly offset by payments expected to be made in connection with the pivotal long-term safety trial and the thorough QTc trial for cetrorelix in BPH.

**Financial and Other Instruments**

**Foreign Currency Risk**

Since we operate on an international scale, we are exposed to currency risks as a result of potential exchange rate fluctuations. For the year ended December 31, 2008, we were not a party to any forward-exchange contracts, and no forward-exchange contracts were outstanding as at March 9, 2009.



Table of Contents

Beginning on January 1, 2009, due to changes in facts and circumstances, the Company and all its subsidiaries will use the euro as their functional currency. As such, all foreign currency exposure risk on inter-company transactions will be eliminated.

**Credit Risk**

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents, short-term investments and accounts receivable. Cash and cash equivalents are maintained with high-credit quality financial institutions. Short-term investments consist primarily of bonds and notes issued by high-credit quality corporations and institutions. Consequently, management considers the risk of non-performance related to cash and cash equivalents and investments to be minimal.

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.

**Interest Rate Risk**

We are exposed to market risk relating to changes in interest rates with regard to our short-term investments.

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

We did not enter into transactions with any related parties during the year ended December 31, 2008.

As at December 31, 2008, we did not have any interest 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*

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

The following table sets forth information about our directors and senior officers as at March 20, 2009.

| Name and Place of Residence                     | Position with Aeterna Zentaris                                  |
|---|---|
| Marcel Aubut<br>Quebec, Canada                  | Director  |
| Paul Blake<br>Pennsylvania, United States       | Senior Vice President and Chief Medical Officer                 |
| Martha Byorum<br>New York, United States        | Director  |
| José P. Dorais<br>Quebec, Canada                | Director  |
| Juergen Engel<br>Alzenau, Germany               | President and Chief Executive Officer and Board Director        |
| Juergen Ernst<br>Brussels, Belgium              | Executive Chairman of the Board and Director                    |
| Pierre Laurin<br>Quebec, Canada                 | Director  |
| Gérard Limoges<br>Quebec, Canada                | Director  |
| Pierre MacDonald<br>Quebec, Canada              | Director  |
| Gerald J. Martin<br>California, United States   | Director  |
| Nicholas Pelliccione<br>New York, United States | Senior Vice President, Regulatory Affairs and Quality Assurance |
| Matthias Seeber<br>Frankfurt, Germany           | Senior Vice President, Administration and Legal Affairs         |
| Dennis Turpin<br>Quebec, Canada                 | Senior Vice President and Chief Financial Officer               |
| Claude Vadboncoeur<br>Quebec, Canada            | Corporate Secretary   |

The following is a brief biography of each of our directors and senior officers.

*Marcel Aubut* has served as a director on our Board since 1996. A key figure in Canadian business and an icon in the world of sports, Marcel Aubut, O.C., O.Q., Q.C. ADE, has been a corporate and litigation lawyer for more than thirty years. A partner with Heenan Blaikie Aubut, he is a member of the firm's National Management Committee and its Executive Committee. In 1983, Mr. Aubut founded the firm of Aubut Chabot. He was President and Chief Executive Officer of *Le Club de Hockey Les Nordiques de Québec*, as well as founding president and chief executive officer of



*Parc technologique du Québec métropolitain.* Many companies have called on Mr. Aubut to be a director, including such high-profile ones as Boralex Power Income Fund, Boralex Inc., Atomic Energy Canada, Cinar, Hydro-Québec, The Laurentian Group, Investors Group of Mutual Funds, Sodic

Table of Contents

Québec Inc., International Continental Insurers Ltd, the National Hockey League Pension Society, Olybro Inc. (previously known as Olymel), TransForce Inc., La Fondation Nordiques and Purolator.

*Paul Blake* was appointed our Senior Vice President and Chief Medical Officer on August 5, 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.

*Martha Byorum* has served as a director on our Board since 2001. Ms. Byorum is currently Senior Managing Director of Stephens Cori Capital Advisors, a division of Stephens, Inc., a U.S.-based investment bank and financial services company. Before 1996, Ms. Byorum held various positions at Citicorp. Ms. Byorum is a member of the board of director of Northwest Natural Gas Company and M&F Worldwide Corp. Ms. Byorum holds a Master's of Business Administration (MBA) degree from the University of Pennsylvania.

*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, the Société Générale de Financement and Chairman of the Board of Recyc-Québec. He holds a law degree from the University of Ottawa and is a member of the Quebec Bar.

*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 Corporation's principal subsidiary, since the beginning of 2001. Before that, he was in charge of all research and development activities of ASTA Medica AG.

*Juergen Ernst* was appointed Executive Chairman of the Board, effective September 1, 2008, after having served as Chairman of the Board from August 13, 2007 until April 10, 2008 and as 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 is now a member of the Board of Directors of Solvay S.A.

*Pierre Laurin* has served as a director on our Board since 1998, Mr. Laurin has been Director of the Hautes Études Commerciales Business School in Montreal (HEC Montréal) since January 1999. He was elected Chairman of the Board of Directors of our former subsidiary, Atrium, in February 2001. From 1969 to 1982, Mr. Laurin held successively the positions of teacher and Dean with the Hautes Études Commerciales. Since then, he has acted as Vice President, General Manager, Planning and Administration for Alcan. During this term, he was the founding President and CEO of Socrent, a venture capital firm in Saguenay-Lac-St-Jean. He has also spent 13 years as Vice Chairman of the Board and President for Quebec of Merrill Lynch. Mr. Laurin is a member of several boards of directors of corporations including Quebecor Inc., Microcell Telecommunications Inc., Aeterna Zentaris and the Fondation J.-Armand Bombardier. Mr. Laurin holds a Ph.D. degree in business from Harvard University, a Licence ès Sciences Commerciales from the Hautes Études Commerciales Business School, and Bachelor's degree ès Art from the Séminaire de Philosophie de Montréal. He also holds a Doctorate Honoris Causa from Concordia University. He is an officer of the Order of Canada, and holds L'ordre du Mérite of the Republic of 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 became a chartered accountant and partner of Ernst & Young in 1971. Mr. Limoges is a board member and chairman of the audit committees of the following public companies: Aeterna Zentaris Inc. (Nasdaq and TSX), Atrium Innovations Inc. (TSX), Hart Stores Inc. (TSX), Hartco Income Trust (TSX) and he is a board member, chairman of the governance committee and member of the audit committee of Noranda Income Fund (TSX). He is also a board member of various private companies and charities.

Table of Contents

*Pierre MacDonald* Mr. MacDonald is President and CEO of MacD Consult Inc., a management consulting firm in international finance and marketing, based in Montreal. He is also Chairman of the Board of Eurocopter Canada Ltd. and a director of Invesco Trimark (Canada), a funds management firm. He served as the Senior Vice President for Eastern Canada for Bank of Montreal, a position which involved the review and evaluation of the financial statements and creditworthiness of borrowers in a wide variety of industries. In December 1995, he was elected to the National Assembly of Quebec and became Minister of International Trade and Technology. He was also named Vice Chairman of the Treasury Board of the Government of Quebec. He also served as the Chairman of the Audit Committee of Teleglobe Inc. for six years. Mr. MacDonald received Bachelor of Arts, Bachelor of Commerce and Master of Commerce degrees from Laval University in Québec.

*Gerald J. Martin* has served as a director on our Board since 2006. Former Vice President, Corporate Licensing and Technology Alliances at Abbott Laboratories, Mr. Martin is currently Board Member of Life Sciences Information Technology Global Institute, a not-for-profit public benefit corporation chartered to identify and develop Good Informatics Practices (GIP) with a focus on the establishment of GIP in drug development. Until recently, he was Chairman of the Board of Milkhaus Laboratory based in Providence, Rhode Island, a biotechnology company specialized mainly in male health. During his career in the biopharmaceutical and pharmaceutical sectors, Mr. Martin, in addition to his general management functions, developed a strong expertise in sales and marketing, business development, as well as in clinical development.

*Nicholas J. Pelliccione* was appointed our Senior Vice President, Regulatory Affairs and Quality Assurance on May 7, 2007. Dr. Pelliccione has demonstrated the ability to be a multi-faceted leader in the areas of global Regulatory Affairs, Quality Assurance and Pharmaceutical Development for more than 20 years. 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 also served as Senior Vice President, Regulatory and Pharmaceutical Sciences at Chugai Pharma United States 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.

*Matthias Seeber* was appointed our Senior Vice President, Administration and Legal Affairs on December 9, 2008. Mr. Seeber has 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.

*Dennis Turpin* was appointed our Senior Vice President and Chief Financial Officer on August 16, 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.

*Claude Vadboncoeur* was appointed our Corporate Secretary on May 6, 2008. In the past 5 years, Mr. Vadboncoeur has acted as consultant mainly for public companies. Prior to that, he was Vice President Legal and Corporate Secretary of Aeterna Zentaris to which he brought a broad experience in commercial and business law, having served as Vice President Legal and Corporate Secretary of various large Canadian companies. Mr. Vadboncoeur earned his law degree from Université de Montréal and has been a member of the Quebec Bar since 1973.

Table of Contents

**B. Compensation**

A. Compensation of Outside Directors

The compensation paid to the Corporation'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 Corporation'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 Governance Committee. During the most recently completed financial year, the Governance Committee was composed of four (4) directors, all of whom are independent directors, namely Messrs. Pierre MacDonald, José P. Dorais, Juergen Ernst and Pierre Laurin. One of the members of the Governance Committee, namely Juergen Ernst, is an executive officer of the Corporation.

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.

In 2007, the Governance Committee retained Aon Consulting and Radford Surveys and Consulting (AON) as consultants. AON was retained to assist the Governance Committee with our compensation programs, particularly our executive short-term and long-term incentive programs and the remuneration of members of the Board. AON analyzed our past practices and defined a peer group of companies in order to understand the competitive compensation practices and to propose a program designed to deliver both cash and equity compensation components of our directors and officers. Our director compensation structure was benchmarked against market compensation data gathered from U.S. biopharmaceutical organizations of comparable size.

Based on the results of the benchmarking study, and taking into consideration that the structure of directors' compensation in the market has undergone considerable change amid the growing demands and risks of serving as a corporate steward in today's complex business and governance environment, the Governance Committee recommended, and the Board approved, an adjustment to the compensation of both the Executive Chairman and the Vice Chairman of the Board corresponding to a redefinition of the functions associated with such positions.

We did not employ the services of any external compensation consultant during the financial year ended December 31, 2008.

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. Directors are paid in their home country's currency. Amounts have been converted from certain directors' home country currency to US dollars based on the following average exchange rates for the financial year ended December 31, 2008: 1.00 = US\$1.464; and CAN\$1.00 = US\$0.937.

| Type of compensation                    | Annual compensation<br>for the year 2008<br>(\$) | Annual compensation<br>starting January 1, 2009<br>(\$) |
|---|--|---|
| <b>Executive Chairman's Retainer(1)</b> |  |   |
| - European resident member              | 109,800  | 109,800   |
| <b>Vice Chairman Retainer(2)</b>        |  |   |
| - Canadian resident member              | 23,425   | 23,425  |
| <b>Board Retainer</b>                   |  |   |
| - US resident members                   | 25,000   | 25,000  |
| - Canadian resident members             | 23,425   | 23,425  |
| - European resident member              | 36,600   | 36,600  |
| <b>Committee Chair Retainer</b>         |  |   |
| - Audit Committee                       |  |   |
| - Canadian resident member              | 18,740   | 18,740  |
| - Governance Committee                  |  |   |
| - Canadian resident member              | 14,055   | 14,055  |
| <b>Committee Member Retainer</b>        |  |   |
| - Audit Committee                       |  |   |
| - US resident member                    | 5,000  | 5,000   |
| - Canadian resident members             | 4,685  | 4,685   |
| - Governance Committee                  |  |   |
| - Canadian resident members             | 2,343  | 2,343   |
| - European resident member              | 3,660  | 3,660   |
| <b>Meeting Attendance Fees(3)</b>       |  |   |
| - Board meeting                         |  |   |
| - US resident members                   | 2,000  | 2,000   |
| - Canadian resident members             | 1,874  | 1,874   |
| - European resident member              | 2,928  | 2,928   |
| - Committee meeting                     |  |   |
| - US resident member                    | 2,000  | 2,000   |
| - Canadian resident members             | 1,874  | 1,874   |
| - European resident member              | 2,928  | 2,928   |

- (1) The Executive Chairman's retainer was increased from \$73,200 to \$109,800 effective September 1, 2008 as a result of the incumbent's appointment as Executive Chairman of the Board.
- (2) The Vice Chairman's retainer was increased from \$14,055 to \$23,425 as of August 12, 2008 due to increased responsibilities.
- (3) Attendance fees are reduced by 50% per meeting attended telephonically.

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 Executive 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.





Table of Contents**Outstanding Option-Based Awards and Share-Based Awards**

The following table shows all awards outstanding to each Outside Director up to the end of the financial year ending December 31, 2008:

| Name           | Issuance Date | Option-based Awards  |                               |                        | Value of Unexercised In-the-money Options(2) (CAN\$) | Issuance Date | Share-based Awards   |  |
|----------------|---------------|--|-------------------------------|------------------------|--|---------------|--|--|
|                |               | Number of Securities Underlying Unexercised Options(1) (#) | Option Exercise Price (CAN\$) | Option Expiration Date |  |               | Number of Shares or Units of shares that have Not Vested (#) | Market or Payout Value of Share-based Awards that have Not Vested (\$) |
| Marcel Aubut   | Dec. 4, 01    | 5,000  | 6.18                          | Dec. 31, 11            |  |               |  |  |
|                | Dec. 16, 02   | 15,000   | 3.68                          | Dec. 15, 12            |  |               |  |  |
|                | Dec. 11, 03   | 30,000   | 1.74                          | Dec. 10, 13            |  |               |  |  |
|                | Dec. 14, 04   | 15,000   | 5.83                          | Dec. 13, 14            |  |               |  |  |
|                | Dec. 13, 05   | 15,000   | 3.53                          | Dec. 12, 15            |  |               |  |  |
|                | Jan. 4, 07    | 5,000  | 4.65                          | Jan. 3, 17             |  |               |  |  |
|                | Dec. 11, 07   | 25,000   | 1.82                          | Dec. 10, 17            |  |               |  |  |
|                | Dec. 8, 08    | 15,000   | 0.55                          | Dec. 8, 18             | 450.00   |               |  |  |
| Martha Byorum  | Dec. 4, 01    | 5,000  | 6.18                          | Dec. 31, 11            |  |               |  |  |
|                | Dec. 16, 02   | 15,000   | 3.68                          | Dec. 15, 12            |  |               |  |  |
|                | Dec. 11, 03   | 30,000   | 1.74                          | Dec. 10, 13            |  |               |  |  |
|                | Dec. 14, 04   | 15,000   | 5.83                          | Dec. 13, 14            |  |               |  |  |
|                | Dec. 13, 05   | 15,000   | 3.53                          | Dec. 12, 15            |  |               |  |  |
|                | Jan. 4, 07    | 5,000  | 4.65                          | Jan. 3, 17             |  |               |  |  |
|                | Dec. 11, 07   | 25,000   | 1.82                          | Dec. 10, 17            |  |               |  |  |
|                | Dec. 8, 08    | 15,000   | 0.55                          | Dec. 8, 18             | 450.00   |               |  |  |
| José P. Dorais |               |  |                               |                        |  |               |  |  |
| Juergen Ernst  | Feb. 25, 05   | 15,000   | 5.09                          | Feb. 24, 15            |  |               |  |  |
|                | Dec. 13, 05   | 15,000   | 3.53                          | Dec. 12, 15            |  |               |  |  |
|                | Jan. 4, 07    | 5,000  | 4.65                          | Jan. 3, 17             |  |               |  |  |
|                | Dec. 11, 07   | 25,000   | 1.82                          | Dec. 10, 17            |  |               |  |  |
|                | Nov. 14, 08   | 100,000  | 0.65                          | Nov. 13, 18            |  |               |  |  |
|                | Dec. 8, 08    | 15,000   | 0.55                          | Dec. 8, 18             | 450.00   |               |  |  |
| Pierre Laurin  | Dec. 4, 01    | 5,000  | 6.18                          | Dec. 31, 11            |  |               |  |  |
|                | Dec. 16, 02   | 24,000   | 3.68                          | Dec. 15, 12            |  |               |  |  |
|                | Dec. 11, 03   | 30,000   | 1.74                          | Dec. 10, 13            |  |               |  |  |
|                | March 29, 04  | 3,000  | 6.26                          | March 28, 14           |  |               |  |  |
|                | Dec. 14, 04   | 15,000   | 5.83                          | Dec. 13, 14            |  |               |  |  |
|                | Dec. 13, 05   | 15,000   | 3.53                          | Dec. 12, 15            |  |               |  |  |
|                | Jan. 4, 07    | 5,000  | 4.65                          | Jan. 3, 17             |  |               |  |  |
|                | Dec. 11, 07   | 25,000   | 1.82                          | Dec. 10, 17            |  |               |  |  |
|                | Dec. 8, 08    | 15,000   | 0.55                          | Dec. 8, 18             | 450.00   |               |  |  |
| Gérard Limoges | Dec. 14, 04   | 15,000   | 5.83                          | Dec. 13, 14            |  |               |  |  |
|                | Dec. 13, 05   | 15,000   | 3.53                          | Dec. 12, 15            |  |               |  |  |
|                | Jan. 4, 07    | 5,000  | 4.65                          | Jan. 3, 17             |  |               |  |  |

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

|           |             |        |      |             |        |
|-----------|-------------|--------|------|-------------|--------|
|           | Dec. 11, 07 | 25,000 | 1.82 | Dec. 10, 17 |        |
|           | Dec. 8, 08  | 15,000 | 0.55 | Dec. 8, 18  | 450.00 |
|           | Dec. 4, 01  | 5,000  | 6.18 | Dec. 31, 11 |        |
|           | Dec. 16, 02 | 24,000 | 3.68 | Dec. 15, 12 |        |
|           | Dec. 11, 03 | 30,000 | 1.74 | Dec. 10, 13 |        |
| Pierre    | Dec. 14, 04 | 15,000 | 5.83 | Dec. 13, 14 |        |
| MacDonald | Dec. 13, 05 | 15,000 | 3.53 | Dec. 12, 15 |        |
|           | Jan. 4, 07  | 5,000  | 4.65 | Jan. 3, 17  |        |
|           | Dec. 11, 07 | 25,000 | 1.82 | Dec. 10, 17 |        |
|           | Dec. 8, 08  | 15,000 | 0.55 | Dec. 8, 18  | 450.00 |
|           | Jan. 25, 06 | 15,000 | 5.04 | Dec. 12, 15 |        |
| Gérald J. | Jan. 4, 07  | 5,000  | 4.65 | Jan. 3, 17  |        |
| Martin    | Dec. 11, 07 | 25,000 | 1.82 | Dec. 10, 17 |        |
|           | Dec. 8, 08  | 15,000 | 0.55 | Dec. 8, 18  | 450.00 |

(1) The number of securities underlying unexercised options that have not vested represent all awards outstanding as at December 31, 2008, including awards granted before the first day of the most recently completed financial year.

Table of Contents

(2) Value of unexercised in-the-money options at financial year-end is calculated based on the difference between the closing price of our common shares on the TSX on the last trading day prior to fiscal year-end (December 31, 2008) of CAN\$0.58 and the exercise price of the options, multiplied by the number of unexercised options.

**Total Compensation of Outside Directors**

The table below summarizes the total compensation earned by the Outside Directors during the financial year ended December 31, 2008 (all amounts are in US dollars):

| Name                | Fees earned<br>(\$) |               | Share-<br>based<br>Awards<br>(\$) | Option-<br>based<br>Awards<br>(\$) | Non-Equity<br>Incentive Plan<br>Compensation<br>(\$) | Pension<br>Value<br>(\$) | All Other<br>Compensation(2)<br>(\$) | Total<br>(\$) |
|---------------------|---------------------|---------------|-----------------------------------|------------------------------------|--|--------------------------|--------------------------------------|---------------|
|                     | Retainer(1)         | Attendance(1) |                                   |                                    |  |                          |                                      |               |
| Marcel Aubut        | 23,427              | 12,182        |                                   |                                    |  |                          | 1,406                                | 37,015        |
| Martha Byorum, MBA  | 30,000              | 21,000        |                                   |                                    |  |                          |                                      | 51,000        |
| José P. Dorais      | 24,599              | 19,679        |                                   |                                    |  |                          | 2,811                                | 47,089        |
| Juergen Ernst, MBA  | 115,083             | 30,705        |                                   |                                    |  |                          | 4,387                                | 150,175       |
| Pierre Laurin, PhD  | 25,770              | 19,679        |                                   |                                    |  |                          | 2,811                                | 48,260        |
| Gérard Limoges, FCA | 42,170              | 22,490        |                                   |                                    |  |                          | 2,811                                | 67,471        |
| Pierre MacDonald    | 50,942              | 26,239        |                                   |                                    |  |                          | 9,839                                | 87,020        |
| Gerald J. Martin    | 25,000              | 16,000        |                                   |                                    |  |                          |                                      | 41,000        |

- (1) These amounts represent the portion paid in cash to the Outside Directors and are paid in each director's home country's currency.  
(2) These amounts represent fees paid in cash for special tasks and are also paid in each director's home country's currency.

During the financial year ended December 31, 2008, the Corporation paid an aggregate amount of \$529,030 to all of its Outside Directors for services rendered, excluding reimbursement of out-of-pocket expenses. Outside Directors are paid in their home country's currency and are reimbursed for travel and other out-of-pocket expenses incurred while attending Board or committee meetings.

**B. 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 personnel 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.

**B. Compensation**

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. 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.

*Compensation Consultant*

The Governance Committee engages its own independent consultant to advise it with respect to executive compensation matters. During the financial year ended December 31, 2007, the Corporation retained the services of AON to provide advice on the competitiveness and appropriateness of compensation programs for the Chief Executive Officer and our other senior executive officers.

The fees paid to AON for compensation consulting services provided to the Governance Committee and to the Corporation with respect to services provided for the financial year ended December 31, 2007 were \$81,550. The Governance Committee did not employ the services of any external compensation consultant with respect to the financial year ended December 31, 2008.

Table of Contents

While the Governance Committee may rely on external information and advice, all of the decisions with respect to executive compensation are made by the Board upon the recommendations of the Governance Committee and may reflect factors and considerations other than, or that may differ from, the information and recommendations provided by any external compensation consultants that may be retained.

**Compensation Discussion & Analysis**

*Compensation Philosophy and Objectives*

The Corporation'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.

*Benchmarking*

In order to meet our objectives of providing market competitive compensation opportunities, our executive compensation plan, based on a study provided by AON, is benchmarked against market compensation data gathered from organizations of comparable size and other companies with which we compete for executive talent (the Reference Group). The composition of the Reference Group is reviewed by the Governance Committee for its ongoing business relevance to the Company. An overview of the characteristics of the Reference Group is provided in the following table:

*(In millions)*

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

|                              | Æterna Zentaris<br>(\$) | Survey Reference Group<br>(\$) |
|------------------------------|-------------------------|--------------------------------|
| <b>Location</b>              | Canada                  | North America                  |
| <b>Industries</b>            | Biopharmaceutical       | Biopharmaceutical              |
| <b>Revenues</b>              |                         |                                |
| Last fiscal year             | 38.80(2)                | 64.10(1)                       |
| <b>Market Capitalization</b> |                         |                                |
| As at October 16, 2007       | 99.46                   | 442.00                         |
| <b>Net (Loss) earning</b>    |                         |                                |
| Last fiscal year             | 33.40(2)                | (39.50)(1)                     |

- 
- (1) The Reference Group for the financial year ended December 31, 2008 was selected in October 2007 and these data are based on their last fiscal year at that time.
- (2) As of December 31, 2006.

The Reference Group used in respect of the financial year ended December 31, 2008 was composed of the following companies: Acadia Pharmaceuticals Inc.; Acorda Therapeutics Inc.; Array Biopharma Inc.; Bradley Pharmaceutical; Caraco Pharmaceutical Labs; Cell Genesys Inc.; Cell Therapeutics Inc.; Enzon Pharmaceuticals Inc.; Genomic Health Inc.; Indevus Pharmaceuticals Inc.; Ista Pharmaceuticals Inc.; Ligand Pharmaceutical, Monogram Biosciences Inc.; Natestch Pharmaceutical; Neurocrine Biosciences Inc.; Nps Pharmaceuticals Inc.; Omrix Biopharmaceuticals; Salix Pharmaceuticals Ltd; Savient Pharmaceuticals Inc.; Viacell Inc.; and Xoma Ltd.

*Positioning*

The Corporation's compensation policy is for executive compensation to be generally aligned with the 50th 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 our executive officers generally falls within the market 50th percentile competitive range.

Table of Contents

*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 has a different function, but all elements are intended to work in concert to maximize company and individual performance by establishing specific, competitive operational and financial 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
- (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. They are reviewed annually by the Governance Committee.

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 our product development and strategic objectives. These objectives are set at the beginning of each financial year as part of the annual review of corporate strategies.

In the case of executive officers, a program is designed to maximize corporate and individual performance by establishing specific operational and financial goals and to provide financial incentives to executive officers based on their level of attainment of these goals. The granting of cash incentives require the approval of both the Governance Committee and the Board and are based upon an assessment of each individual's performance, as well as the performance of the Company.

For the financial year ended December 31, 2008, cash bonuses paid to all of our executive officers under our short-term non-equity incentive compensation plan represented 96.93% of the target payout established by the Governance Committee under such plan. The bonus payout level for 2008 was relatively high since it included non-budgeted bonus payments made to two of our executive officers, namely Juergen Engel and Matthias Seeber, our President and Chief Executive Officer and Senior Vice President, Administration and Legal Affairs, respectively, for special work performed by such officers in connection with the negotiation, management and successful completion of two important transactions in 2008. See notes 5 and 8 to the Summary Compensation Table set forth below. Excluding the aforementioned special bonuses that amounted to an aggregate of \$117,094, the ratio of cash bonuses paid to the target payout would have been 81.73%. In addition, the 96.93% ratio of cash bonuses paid to the target payout excludes an aggregate amount of \$50,000 paid to our executive officers in March 2008 as a special bonus to have been applied exclusively for the purchase of our common shares on the market in order to encourage greater share ownership by senior management.

Table of Contents

*Long-term Equity Compensation Plan of Executive Officers*

The long-term component of the compensation of our executive officers is based exclusively on the Stock Option Plan, which permits the award of a number of options that varies in accordance with 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. Stock options are usually granted to executive officers in December of each year.

***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 applying to it 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 will be determined 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 options, 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 and the NASDAQ 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.

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).

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

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.

Table of Contents

The Stock Option Plan currently provides that the following amendments may be made to the Stock Option Plan upon approval of each of the Board 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 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 :
- 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;
- except in respect of certain permitted adjustments, such as in the case of stock splits, consolidations or reclassifications:

- any extension to the term of an option beyond its Outside Expiry Date to an option holder who is an insider (except for extensions made in the context of a blackout period );
- any amendment to the method of determining the exercise price of an option granted pursuant to the Stock Option Plan;
- the addition of any form of financial assistance or any amendment to a financial assistance provision which is more favourable to employees; and
- any amendment to the foregoing amending provisions requiring Board, shareholder and regulatory approvals.

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

- amendments of a housekeeping or clerical nature or to clarify the provisions of the Stock Option Plan;
- amendments regarding any vesting period of an option;
- amendments regarding the extension of an option beyond an Early Expiry Date in respect of any option holder, or the extension of an option beyond the Outside Expiry Date in respect of any option holder who is a non-insider of the Company;
- adjustments to the number of issuable common shares underlying, or the exercise price of, outstanding options resulting from a split or a consolidation of the common shares, a reclassification, the payment of a stock dividend, the payment of a special cash or non-cash distribution to our shareholders on a *pro rata* basis provided such distribution is approved by our shareholders in accordance with applicable law, a recapitalization, a reorganization or any other event which necessitates an equitable adjustment to the outstanding options in proportion with corresponding adjustments made to all outstanding common shares;
- discontinuing or terminating the Stock Option Plan; and

Table of Contents

- 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 10, 2009, represented 6,063,372 common shares. There are currently 4,667,428 options outstanding under the Stock Option Plan representing 8.8% 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 our security-based compensation arrangements, cannot exceed 10% of our issued and outstanding securities and (ii) no single option holder may hold options to purchase, from time to time, more than 5% of our issued and outstanding common shares.

Table of Contents**Outstanding Option-Based Awards and Share-Based Awards**

The following table shows all awards outstanding to each of our President and Chief Executive Officer, Executive Chairman (and former Interim President and Chief Executive Officer), former President and Chief Executive Officer, the Chief Financial Officer and our three (3) other most highly compensated executive officers during the most recently completed financial year (collectively, the Named Executive Officers ) as of December 31, 2008:

| Name                | Issuance Date | Option-based Awards  |                               |                        | Share-based Awards                                   |               | Market or Payout Value of Share-based Awards that have Not Vested (\$) |
|---------------------|---------------|--|-------------------------------|------------------------|--|---------------|--|
|                     |               | Number of Securities Underlying Unexercised Options(1) (#) | Option Exercise Price (CAN\$) | Option Expiration Date | Value of Unexercised In-the-money Options(2) (CAN\$) | Issuance Date |  |
| Juergen Engel (3)   | Feb. 20, 03   | 60,000   | 2.43                          | Dec. 31, 12            |  |               |  |
|                     | Dec. 11, 03   | 60,000   | 1.74                          | Dec. 10, 13            |  |               |  |
|                     | Dec. 14, 04   | 100,000  | 5.83                          | Dec. 13, 14            |  |               |  |
|                     | Dec. 13, 05   | 50,000   | 3.53                          | Dec. 12, 15            |  |               |  |
|                     | Jan. 4, 07    | 50,000   | 4.65                          | Jan. 3, 17             |  |               |  |
|                     | Dec. 11, 07   | 50,000   | 1.82                          | Dec. 10, 17            |  |               |  |
|                     | Nov. 14, 08   | 200,000  | 0.65                          | Nov. 13, 18            |  |               |  |
|                     | Dec. 8, 08    | 75,000   | 0.55                          | Dec. 8, 18             | 2,250.00   |               |  |
| Juergen Ernst (3)   | Feb. 25, 05   | 15,000   | 5.09                          | Feb. 24, 15            |  |               |  |
|                     | Dec. 13, 05   | 15,000   | 3.53                          | Dec. 12, 15            |  |               |  |
|                     | Jan. 4, 07    | 5,000  | 4.65                          | Jan. 3, 17             |  |               |  |
|                     | Dec. 11, 07   | 25,000   | 1.82                          | Dec. 10, 17            |  |               |  |
|                     | Nov. 14, 08   | 100,000  | 0.65                          | Nov. 13, 18            |  |               |  |
|                     | Dec. 8, 08    | 15,000   | 0.55                          | Dec. 8, 18             | 450.00   |               |  |
| David J. Mazzo (3)  | March 23, 07  | 100,000  | 3.54(4)                       | March 22, 17           |  |               |  |
| Dennis Turpin       | Dec. 4, 01    | 30,000   | 6.18                          | Dec. 4, 11             |  |               |  |
|                     | Nov. 1, 02    | 90,000   | 3.94                          | Oct. 31, 12            |  |               |  |
|                     | Dec. 16, 02   | 50,000   | 3.68                          | Dec. 15, 12            |  |               |  |
|                     | Dec. 11, 03   | 60,000   | 1.74                          | Dec. 10, 13            |  |               |  |
|                     | Dec. 14, 04   | 90,000   | 5.83                          | Dec. 13, 14            |  |               |  |
|                     | Dec. 13, 05   | 50,000   | 3.53                          | Dec. 12, 15            |  |               |  |
|                     | Jan. 4, 07    | 50,000   | 4.65                          | Jan. 3, 17             |  |               |  |
|                     | Dec. 11, 07   | 50,000   | 1.82                          | Dec. 10, 17            |  |               |  |
| Paul Blake          | Jul. 27, 07   | 45,000   | 3.05(4)                       | July 26, 17            |  |               |  |
|                     | Dec. 11, 07   | 50,000   | 1.82(4)                       | Dec. 10, 17            |  |               |  |
|                     | Dec. 8, 08    | 50,000   | 0.55                          | Dec. 8, 18             | 1,500.00   |               |  |
| Matthias Seeber (5) | Feb. 20, 03   | 15,000   | 2.43                          | Dec. 31, 12            |  |               |  |
|                     | Dec. 11, 03   | 45,000   | 1.74                          | Dec. 10, 13            |  |               |  |
|                     | Dec. 14, 04   | 50,000   | 5.83                          | Dec. 13, 14            |  |               |  |
|                     | Dec. 13, 05   | 40,000   | 3.53                          | Dec. 12, 15            |  |               |  |
|                     | Jan. 4, 07    | 30,000   | 4.65                          | Jan. 3, 17             |  |               |  |

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

|                         |             |        |         |             |        |
|-------------------------|-------------|--------|---------|-------------|--------|
|                         | Dec. 11, 07 | 25,000 | 1.82    | Dec. 10, 17 |        |
|                         | Dec. 8, 08  | 30,000 | 0.55    | Dec. 8, 18  | 900.00 |
| Nicholas J. Pelliccione | May 7, 07   | 25,000 | 3.96(4) | May 6, 17   |        |
|                         | Dec. 11, 07 | 50,000 | 1.82(4) | Dec. 10, 17 |        |
|                         | Dec. 8, 08  | 20,000 | 0.55    | Dec. 8, 18  | 600.00 |

- 
- (1) The number of securities underlying unexercised options that have not vested represents all awards outstanding at December 31, 2008, including awards granted before the first day of the most recently completed financial year.
  - (2) Value of unexercised in-the-money options at financial year-end is calculated based on the difference between the closing price of our common shares on the TSX on the last trading day prior to year-end (December 31, 2008) of CAN\$0.58 and the exercise price of the options, multiplied by the number of unexercised options.
  - (3) David J. Mazzo served as President and Chief Executive Officer up until April 11, 2008, on which date Juergen Ernst was appointed Interim President and CEO. Juergen Engel was appointed President and Chief Executive Officer effective September 1, 2008.
  - (4) These amounts are expressed in US dollars.
  - (5) Mr. Seeber serves as Managing Director of AEZS Germany, our principal subsidiary. On December 9, 2008, he was also appointed Senior Vice President, Administration and Legal Affairs of Aeterna Zentaris.



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 ending December 31, 2008.

| Name                    | Option-based awards -<br>Value<br>vested during the year(1)<br>(\$) | Share-based awards -<br>Value<br>vested during the year<br>(\$) | Non-equity incentive plan<br>compensation - Value<br>earned<br>during the year<br>(\$) |
|-------------------------|---|---|--|
| Juergen Engel           |   |   | 248,093(2) (3) (4)   |
| Juergen Ernst           |   |   | 182,962(5)   |
| David J. Mazzo          |   |   | 10,000(3)  |
| Dennis Turpin           |   |   | 30,000(3)  |
| Paul Blake              |   |   | 135,000(3)   |
| Matthias Seeber         |   |   | 120,755(4)   |
| Nicholas J. Pelliccione |   |   | 70,000(3)  |

- 
- (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 our common shares on the TSX and the exercise price on such vesting date.
  - (2) This amount paid to Dr. Engel includes his annualized bonus as Executive Vice President and Chief Scientific Officer for the first eight months and as President and Chief Executive Officer for the last four months of 2008.
  - (3) Includes a one-time cash payment, which amounted to \$10,000, that was awarded in March 2008 to each of our Named Executive Officers with the exception of Messrs. Ernst and Seeber. This award, to have been used solely to purchase our common shares on the NASDAQ, was granted by the Board in order to encourage share ownership of our common shares by senior management.
  - (4) Amounts paid to Messrs. Engel and Seeber include a special bonus awarded in connection with the successful completion of two major commercial transactions in 2008 (Cetrotide® and Impavido®).
  - (5) This amount paid to Mr. Juergen Ernst represents entirely a bonus awarded in connection with the successful completion of the monetization of Cetrotide® as scheduled.

**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.

*Pension Plan*

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

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 (12) months during the first five working years after initial participation in this plan and increase by 0.4% for each additional year of employment.

Table of Contents

The normal retirement age is 65 years, but early retirement in accordance with Germany's social pension insurance is possible without reduction (or clawback) of the benefit. 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. Only base salary is taken into consideration in calculating pension benefits.

**Pension Plan Table**

| Average Remuneration (\$)* | Years of Service |            |            |            |            |  |
|----------------------------|------------------|------------|------------|------------|------------|--|
|                            | 15               | 20         | 25         | 30         | 35         |  |
| 200,000                    | \$ 88,000        | \$ 92,000  | \$ 96,000  | \$ 100,000 | \$ 104,000 |  |
| 300,000                    | \$ 132,000       | \$ 138,000 | \$ 144,000 | \$ 150,000 | \$ 156,000 |  |
| 400,000                    | \$ 176,000       | \$ 184,000 | \$ 192,000 | \$ 200,000 | \$ 208,000 |  |
| 500,000                    | \$ 220,000       | \$ 230,000 | \$ 240,000 | \$ 250,000 | \$ 260,000 |  |

\* Remuneration refers to annual base salary.

As at December 31, 2008, Dr. Engel had 32 years and 4 months of credited service in the aforementioned non-contributory defined benefit pension plan.

**Defined benefit plans table**

| Name          | Number of years 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 (\$) |  |                          |                              |                                     |
| Juergen Engel | 32.33                                | 186,680                 | 188,862        | 2,492,742                                | 473,277                  | 32,753                       | 2,998,772                           |

*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 and \$10,250 for those over 50 years old. This plan was implemented in 2008. Employees based in Frankfurt, Germany already 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 year ended December 31, 2008. Our executive officers are generally paid in their home country's currency. All amounts in the Summary Compensation Table below are in US dollars and have been converted from the Named Executive Officers' home country currencies to US dollars based on the following average exchange rates for the financial year ended December 31, 2008: 1.00 = US\$1.464; and CAN\$1.00 = US\$0.937.

For compensation related to previous years, please refer to our management information circulars filed with the Canadian securities regulatory authorities and available at [www.sedar.com](http://www.sedar.com) and furnished to the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov).

Table of Contents**SUMMARY COMPENSATION TABLE**

| Name and principal position   | Year | Salary (\$) | Share based awards (\$) | Option based awards(1) (\$) | Non-equity incentive plan compensation |                                | Pension value (\$) | All other compensation(3) (\$) | Total compensation (\$) |
|---|------|-------------|-------------------------|-----------------------------|--|--------------------------------|--------------------|--------------------------------|-------------------------|
|   |      |             |                         |                             | Annual incentive plan(2) (\$)          | Long-term incentive plans (\$) |                    |                                |                         |
| Juergen Engel<br>President and CEO  | 2008 | 405,925(4)  |                         | 67,777                      | 248,093(5)                             |                                | 473,277            | 3,366(6)                       | 1,198,438               |
| Juergen Ernst<br>Executive Chairman of the Board and former Interim President and CEO     | 2008 | 152,465(7)  |                         | 29,034                      | 182,962(8)                             |                                |                    | 150,175(9)                     | 514,636                 |
| David J. Mazzo<br>Former President and CEO  | 2008 | 135,000(10) |                         |                             | 10,000(11)                             |                                |                    | 843,219(12)                    | 988,219                 |
| Dennis Turpin<br>Senior Vice President and CFO  | 2008 | 317,352     |                         |                             | 30,000                                 |                                |                    | 95,780(13)                     | 443,132                 |
| Paul Blake<br>Senior Vice President and Chief Medical Officer                             | 2008 | 355,250     |                         | 10,788                      | 135,000                                |                                |                    | 10,250(14)                     | 511,288                 |
| Matthias Seeber<br>Senior Vice President, Administration and Legal Affairs                | 2008 | 307,372     |                         | 6,473                       | 120,755(5)                             |                                |                    | 61,881(6)                      | 496,481                 |
| Nicholas J. Pelliccione<br>Senior Vice President Regulatory Affairs and Quality Assurance | 2008 | 317,300     |                         | 4,315                       | 70,000                                 |                                |                    | 10,250(14)                     | 401,865                 |

- (1) The value of the option-based awards reflects the closing price of our common shares on the TSX at the date of grant (CAN\$0.55 for options granted on December 8, 2008 and CAN\$0.65 for options granted on November 14, 2008) multiplied by the Black-Scholes factor as at such date (41.82% for options granted on December 8, 2008 and 42.31% for options granted on November 14, 2008) and the number of stock options granted in 2008.
- (2) Includes a one-time cash payment of \$10,000 that was awarded in March 2008 to the Named Executive Officers with the exception of Messrs. Ernst and Seeber. This award, to have been used solely to purchase our common shares on the NASDAQ, was granted by the Board in order to encourage share ownership of our common shares by senior management.
- (3) 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, 2008. 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.
- (4) Represents Dr. Engel's annual base salary as Executive Vice President and Chief Scientific Officer that was paid to him up until September 1, 2008 plus an adjusted annual base salary following his appointment as President and CEO between September 1 and December 31, 2008.
- (5) Includes special bonuses paid to Dr. Engel and Mr. Seeber in connection with the negotiation, management and successful completion of two important transactions in 2008, namely the monetization of Cetrotide® and the sale of all rights related to Impavido®.
- (6) Represents DUPK/RUK (Germany) employer contributions to Dr. Engel's and Mr. Seeber's retirement savings plans.
- (7) Represents salary paid to Mr. Ernst as Interim President and CEO from April 11 to September 1, 2008.
- (8) Represents in its entirety a special bonus paid to Mr. Ernst in connection with the negotiation, management and successful completion of an important transaction in 2008, namely the monetization of Cetrotide®.
- (9) Represents amounts paid to Mr. Ernst as an Outside Director.
- (10) Represents the salary actually earned by and paid to Mr. Mazzo in his capacity as President and Chief Executive Officer until his departure from the Company effective April 11, 2008 based on an annual base salary in 2008 of \$468,000.

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

- (11) Represents in its entirety a one-time bonus paid to our executive officers in March 2008, including Mr. Mazzo, to have been applied exclusively for the purchase of our common shares on the NASDAQ in order to encourage greater share ownership by senior management.
- (12) Under the terms of a termination agreement, Mr. Mazzo received a severance package of \$840,219, which included an amount equivalent to twelve months of his annual base salary, an amount equivalent to the annual bonus received for fiscal year 2007, an amount equivalent to twelve months of the cost of the benefits that were in force at the time of his departure, an amount representing the employer's contribution to the employee's 401(k) retirement savings and an amount equivalent to his vacation payout and car

Table of Contents

allowance. 550,000 options granted to Mr. Mazzo in 2007 were cancelled as a consequence of his departure from the Company.

Mr. Mazzo was, however, entitled to retain 100,000 options, all of which expire on or before March 22, 2012.

(13) Represents \$91,765 of relocation costs and \$4,015 in employer's contribution to Mr. Turpin's 401(k) retirement savings plan.

(14) Represents 401(k) employer contributions to Messrs. Blake's and Pelliccione's retirement savings plans.

*Compensation of the Chief Executive Officer*

The compensation of the President and Chief Executive Officer is governed by our executive compensation policy described in Section 6.2,

Compensation of Executive Officers, and the President and Chief Executive Officer participates together with the other Named Executive Officers in all of our incentive plans.

Dr. Engel has been our President and Chief Executive Officer since September 1, 2008. Under Dr. Engel's leadership, we received an initial payment of \$52.5 million (subject to certain clawbacks and less \$1.0 million in transaction costs) from CHRP upon completion of a monetization transaction in which AEZS Germany assigned its rights to royalties on future sales under its license agreement with Merck Serono.

While he was our Executive Vice President and Chief Scientific Officer, Dr. Engel earned \$253,703 during the first eight months of 2008 based on an annual base salary of \$380,555. Effective September 1, 2008, when he was appointed President and Chief Executive Officer, Dr. Engel's annual base salary was increased to \$456,667, thus representing a 20% increase over his former salary. Consequently, Dr. Engel's total earned salary for 2008 was \$405,925. The President and Chief Executive Officer's salary for 2008 places him at approximately 18% below the 50<sup>th</sup> percentile in relation to the companies in the Reference Group of Radford's Global Life Sciences Executive Compensation Survey. He also received 100% of his target bonus of \$164,910 for his performance in the context of our corporate objectives. Such bonus reflected the advancement of our product pipeline as well as our performance in relation to strategic objectives and business development. He also received a \$10,000 award which was used solely to purchase our common shares on the market, which was granted by the Board to encourage share ownership by senior management. Additionally, he received a special bonus of \$73,183 as a reward for managing the successful completion of the Cetrotide® monetization transaction as scheduled.

Prior to the appointment of Dr. Engel as President and Chief Executive Officer, we had appointed our Chairman of the Board, Mr. Juergen Ernst, as interim President and Chief Executive Officer, effective April 11, 2008 as a consequence of the departure of David Mazzo. Mr. Ernst's annual base salary as interim President and Chief Executive Officer was \$365,919 and an amount of \$152,465 was actually paid to him during the interim period. Mr. Ernst also received a special bonus of \$182,962 for the successful completion of the Cetrotide® monetization transaction as scheduled.

The Governance Committee periodically considers the advice of an independent compensation consultant in determining the grants to be awarded to the President and Chief Executive Officer.

In conjunction with the Long Term Equity Compensation Plan, the President and Chief Executive Officer was awarded grants of 200,000 and 75,000 stock options on November 14 and December 8, 2008, respectively. The stock options granted on November 14, 2008 were awarded at an exercise price of CAN\$0.65 and those granted on December 8, 2008 were awarded at an exercise price of CAN\$0.55. Those stock options will vest in accordance with the provisions of the Stock Option Plan.

**C. Board practices**

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

Under the terms of contractual agreements among the Company and SGF Santé Inc. concerning, among other matters, the election of directors, provided that SGF Santé Inc. holds at least 5% of our issued and outstanding voting shares, (a) we will propose for election as a director, at each annual meeting of the shareholders, one candidate designated by SGF Santé Inc., provided that the candidate receives a favourable recommendation from the Corporate Governance, Nominating and Human Resources Committee (the Governance Committee ).



Table of Contents

**Committees of the Board of Directors**

Audit Committee

Our Board has established an Audit Committee and the 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, it is neither the duty of the committee to plan or to conduct audits or to determine that the company's financial statements are complete, accurate and in accordance with generally accepted accounting principles, nor to maintain internal controls and procedures.

The current members of the Audit Committee are Martha Byorum, Gérard Limoges and Pierre MacDonald.

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. 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, Pierre Laurin and Pierre MacDonald.

**D. Employees**

As of March 1, 2009, we had a total of 109 employees, of which 88 are based in Frankfurt, Germany, 9 in New Jersey, United States, and 12 in Québec, Canada. 42 are involved in discovery, preclinical and pharmaceutical development, 37 are involved in medical and regulatory affairs, quality assurance and intellectual property, and 30 are involved in business operations, communications, finances, 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. Some of our employees based in Frankfurt, Germany are represented by the Chemical Union of Germany. As such, their compensation is largely driven by the outcome of the negotiations between the Chemical Union and the Association of Employers for the chemical industry which is then binding for all German companies in the industry. The current collective bargaining agreement (*Tarifvertrag*) that applies to all tariff-employees of AEZS Germany expires on March 31, 2010. We have never experienced a work stoppage and we believe that relations with our employees as well as with the works council representing our German employees are generally good.

Table of Contents**E. Share ownership**

The information in the table below is provided as of March 20, 2009:

| Name  | No. of common shares owned or held | Percent | No. of stock options Held(1) | No. of currently exercisable options |
|---|------------------------------------|---------|------------------------------|--------------------------------------|
| Marcel Aubut  | 57,500                             | *       | 125,000                      | 95,001                               |
| Paul Blake  | 60,720                             | *       | 145,000                      | 31,667                               |
| Martha Byorum                                       | 12,000                             | *       | 125,000                      | 95,001                               |
| José P. Dorais                                      |                                    | *       |                              |                                      |
| Juergen Engel                                       | 79,779                             | *       | 645,000                      | 320,001                              |
| Juergen Ernst                                       | 58,850                             | *       | 175,000                      | 45,001                               |
| Pierre Laurin                                       | 50,200                             | *       | 137,000                      | 107,001                              |
| Gérard Limoges                                      | 9,000                              | *       | 75,000                       | 45,001                               |
| Pierre MacDonald                                    | 26,500                             | *       | 134,000                      | 104,001                              |
| Gerald J. Martin                                    | 14,000                             | *       | 60,000                       | 30,001                               |
| Nicholas J. Pelliccione                             | 25,000                             | *       | 95,000                       | 25,001                               |
| Matthias Seeber                                     |                                    | *       | 235,000                      | 178,334                              |
| Dennis Turpin                                       | 13,250                             | *       | 470,000                      | 420,001                              |
| All of our directors and senior officers as a group | 389,799                            | 0.73    | 2,421,000                    | 1,496,011                            |

\*: Less than 1%

(1) For information regarding option expiration dates and exercise price refer to the tables set forth on pages 80 and 87 of this annual report.

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

We are not directly or indirectly owned or controlled by another corporation or by any foreign government.

Based on filings with the Securities and Exchange Commission and the Canadian securities regulatory authorities, as of February 17, 2009, set out below are the only persons/entities who beneficially owned, directly or indirectly, or exercised control or direction over our common shares carrying more than 5% of the voting rights attached to all our common shares. As used in the table below, beneficial ownership means sole or

**D. Employees**

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

shared power to vote or direct the voting of the security, or the sole or shared investment power with respect to a security (i.e., the power to dispose, or direct a disposition, of a security). A person is deemed at any date to have beneficial ownership of any security that the person has a right to acquire within 60 days. More than one person may be deemed to have beneficial ownership of the same group of securities.

| <b>Name of shareholder</b> | <b>Common Shares<br/>(#)</b> | <b>Total Percentage<br/>of Voting Rights<br/>(%)</b> |
|----------------------------|------------------------------|--|
| Solidarity Fund (QFL)      | 9,752,069                    | 18.33  |
| SGF Santé Inc.             | 8,810,878                    | 16.57  |
| Eric Dupont                | 3,767,413                    | 7.08   |

None of the shareholders set out above has different voting rights from the other shareholders.

Table of Contents

**United States Shareholders**

As of December 31, 2008, there were a total of 234 holders of record of our common shares, of which seven were registered with addresses in the United States holding in the aggregate approximately 2.08% 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 of record 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.

**Valuation and qualifying accounts are as follows (in thousands of US dollars):**

*Valuation allowance on future income tax assets*

|  | Years ended December 31, |      |      |
|--|--------------------------|------|------|
|  | 2008                     | 2007 | 2006 |

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

|  |    |         |    |        |    |          |
|--|----|---------|----|--------|----|----------|
| Balance - Beginning of year            | \$ | 23,289  | \$ | 13,337 | \$ | 35,719   |
| Change in valuation allowance          |    | 17,554  |    | 6,963  |    | (22,644) |
| Foreign currency transation adjustment |    | (4,262) |    | 2,989  |    | 262      |
| Balance - End of year                  | \$ | 36,581  | \$ | 23,289 | \$ | 13,337   |

**Export Sales**

Export and domestic sales in thousands of US dollars and as percentage of total sales as follows:

|                | 2008 |        | Years ended December 31,<br>2007 |    | 2006   |         |    |        |         |
|----------------|------|--------|----------------------------------|----|--------|---------|----|--------|---------|
| Export Sales   | \$   | 38,145 | 99.13%                           | \$ | 41,668 | 99.05%  | \$ | 38,774 | 99.93%  |
| Domestic Sales | \$   | 333    | 0.87%                            | \$ | 400    | 0.95%   | \$ | 25     | 0.07%   |
|                | \$   | 38,478 | 100.00%                          | \$ | 42,068 | 100.00% | \$ | 38,799 | 100.00% |

**Dividend Policy**

Since our incorporation, we have not paid any dividends and we do not anticipate paying any dividends in the foreseeable future.

Table of Contents**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)

|                        | NASDAQ (US\$) |      | TSX (CAN\$) |      |
|------------------------|---------------|------|-------------|------|
|                        | High          | Low  | High        | Low  |
| 2008                   | 1.85          | 0.26 | 1.92        | 0.44 |
| 2007                   | 4.40          | 1.33 | 5.21        | 1.37 |
| 2006                   | 7.55          | 3.93 | 8.79        | 4.51 |
| 2005                   | 6.47          | 4.00 | 7.89        | 4.85 |
| 2004                   | 8.42          | 3.17 | 11.5        | 4.12 |
| <b>2007</b>            |               |      |             |      |
| Fourth quarter         | 2.73          | 1.33 | 2.74        | 1.37 |
| Third quarter          | 3.65          | 2.27 | 3.90        | 2.40 |
| Second quarter         | 4.18          | 3.25 | 4.75        | 3.45 |
| First quarter          | 4.40          | 2.90 | 5.21        | 3.41 |
| <b>2008</b>            |               |      |             |      |
| Fourth quarter         | 1.10          | 0.26 | 0.83        | 0.44 |
| Third quarter          | 1.37          | 0.58 | 1.44        | 0.60 |
| Second quarter         | 1.85          | 0.97 | 1.92        | 0.98 |
| First quarter          | 1.80          | 0.76 | 1.80        | 0.75 |
| <b>Last six months</b> |               |      |             |      |
| Feb-09                 | 1.10          | 0.60 | 1.15        | 0.72 |
| Jan-09                 | 0.73          | 0.46 | 0.88        | 0.57 |
| Dec-08                 | 0.60          | 0.26 | 0.72        | 0.44 |
| Nov-08                 | 1.10          | 0.44 | 0.74        | 0.54 |
| Oct-08                 | 0.79          | 0.35 | 0.83        | 0.44 |
| Sept-08                | 1.18          | 0.58 | 1.27        | 0.60 |

**B. Plan of distribution****D. Employees**

Not applicable.

**C.                    *Markets***

Our common shares are listed and posted for trading on the TSX under the symbol *AEZ* and are quoted on the NASDAQ under the symbol *AEZS*. On October 24, 2008, we announced that we had received a notification from NASDAQ regarding the failure by the Company to comply with NASDAQ's minimum bid price requirements. Although NASDAQ has temporarily suspended enforcement of its minimum bid price requirements, such requirements will be reinstated on April 19, 2009, or pending approval by the Securities and Exchange Commission of NASDAQ's proposed rule change, July 19, 2009. If we fail to meet any of NASDAQ's continued listing requirements and NASDAQ attempts to enforce compliance with its rules, our common shares may be delisted from NASDAQ. If our shares were delisted from TSX or NASDAQ, investors may have difficulty in disposing of our common shares held by them.

**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.

**D.                    Employees**

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

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 Company's bylaws and 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 impose any mandatory retirement requirements for directors.

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

Under the Company's bylaws and the Restated Articles of Incorporation, a director of the Company need not be a shareholder.

Table of Contents

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 Company's bylaws provide that a director shall promptly disclose to the Company any interest he or she has in any undertaking or association that is likely to place him or her in a situation of conflict of interest, as well as the rights he or she may assert against the Company, indicating, should such be the case, the nature and value thereof. Likewise, the CBCA and the Company's bylaws provide 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 and the Company's bylaws prohibit 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.

In addition, the Company's bylaws provide that the Board may:

- subject to the provisions of the Company's Restated Articles of Incorporation, accept subscriptions, allot, issue all or part of the unissued shares of the Company, grant options in respect of such shares or otherwise dispose thereof to such persons, on such terms and conditions and for such consideration and in such manner not contrary to the CBCA or the Restated Articles of Incorporation of the Company as the directors think fit; and
- from time to time as it may deem advisable and to the extent permitted by the CBCA, declare and pay to the shareholders, according to their rights, dividends in money or property or in the form of shares of the Company.

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 Company's bylaws, 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 Act, 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 Corporate Governance, Nominating and Human Resources Committee.

Subject to the limitations provided by the CBCA, the Company must 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**

The Company's Restated Articles of Incorporation authorize the issuance of an unlimited number of common shares and an unlimited number of Preferred Shares. All classes are without nominal or par value. The Restated Articles of Incorporation do not authorize the issuance of any other class of shares. On March 20, 2009, there were 53,187,470 common shares and no Preferred Shares issued and outstanding.

*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 Board on the common shares. Finally, the holders of the common shares are entitled to receive the remaining property of the Company upon any liquidation, dissolution or winding-up of the affairs of the Company, whether voluntary or involuntary. Shareholders have no liability to further capital calls as all shares issued and outstanding are fully paid and non-assessable.

*Preferred Shares:* The First and Second Preferred Shares are issuable in series with rights and privileges specific to each class. The holders of Preferred Shares are not entitled to receive notice of or to attend or vote at meetings of shareholders. No Preferred Shares of the Company have been issued to date.

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 in regards 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

Table of Contents

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.

The Board may, from time to time, provide for series of Preferred Shares to be created and issued, but the issuance of any Preferred Share 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. The issuance of any Preferred Shares in the face of a take-over bid for the Company would be examined in light of these duties of the directors and other applicable case law.

**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", which requires a take-over bid to satisfy certain minimum standards designed to promote fairness, or with the concurrence of the Company's 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 potential acquiror, will be able to purchase additional common shares at a significant discount to market, thus exposing the potential acquiror of common shares to substantial dilution of its holdings.

*Summary of the Rights Plan*

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

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. 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 as at the close of business on March 29, 2004 (the Record Time). In addition, one right will be issued for each additional common share issued after the Record Time and prior to the earlier of the Expiration Time and the Separation 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 adjustments, and they are not exercisable until the Separation Time. Upon the occurrence of a Flip-in Event (as defined below), each right will entitle the holder thereof, other than an Acquiring Person (as defined below), to purchase from the Company one common share upon payment to the Company of 50% of the Market Price of the common shares on the TSX on the date of consummation or occurrence of such Flip-in Event, subject to certain anti-dilution adjustments.



Table of Contents

***Trading of Rights***

Until the Separation Time, the rights trade 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:

- the first date (the Stock Acquisition Date) of a public announcement of facts indicating that a person has become an Acquiring Person (as defined below);
- 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); and
- the date upon which a Permitted Bid or a Competing Permitted Bid ceases to be a Permitted Bid or a Competing Permitted Bid, as the case may be.

The Separation Time can also be such later time as may from time to time be determined by the Board.

***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.

***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 average of the daily closing prices per common share on each of the 20 consecutive Trading Days (as defined below) through and including the Trading Day immediately preceding such date of determination; subject to certain exceptions. Trading Day is generally defined as the day on which the principal Canadian or United States stock exchange (as determined by the Board acting in good faith) on which the common shares are listed or admitted to trading is open for the transaction of business.

***Exercise of Rights***

Upon the Separation Time or the effective date of the Flip-in Event, whichever occurs first, each right (other than those held by the Acquiring Person) will entitle the holder thereof to purchase from the Company one common share upon payment to the Company of 50% of the Market Price of the common shares of the Company on the Stock Acquisition Date subject to certain anti-dilution adjustments.

***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

Table of Contents

- 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 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 10 days from the date of such public announcement.

The Rights Plan 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 requirements set out in clauses (3) and (6) above and must not permit common shares tendered or deposited pursuant to the bid to be taken up or paid for (a) prior to the close of business on a date which is not earlier than the latter of the last day on which the bid must be open for acceptance after the date of the bid under applicable Canadian provincial securities legislation and the earliest date on which common shares of the Company may be taken up and paid for under any earlier Permitted Bid or Competing Permitted Bid that is then in existence, and (b) then only if at such date more than 50% of the then outstanding common shares held by the Independent Shareholders have been deposited or tendered to the take-over bid and not withdrawn. In the event that the requirement set forth in (b) of this paragraph is satisfied, the competing bidder must make a public announcement of the fact and the take-over bid must remain open for deposits and tenders of common shares for not less than 10 days from the date of such public announcement.

***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, at any time prior to the Separation Time, elect to redeem all but not less than all of the outstanding rights at a price of CAN\$0.00001 each.

***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. The Rights Plan, including the amendments thereto and the restatement thereof, was approved by the Board on March 2, 2007, was signed on March 5, 2007 and was ratified and confirmed by the Company's

shareholders on May 2, 2007.

***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.

Table of Contents

***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 under the Rights Plan from triggering a Flip-in Event, provided that they are not making, or are not part of a group making, a take-over bid.

**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, directly or indirectly, voting securities of a reporting issuer or who exercises control or direction over 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 ten 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**

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

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 president of the Company has the power to call a meeting of shareholders.

While the bylaws provide that one or more shareholders who hold at least 20% 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, the CBCA provides that the holders of not less than 5% of the outstanding voting shares of the Company may so requisition the directors of the Company. 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 20% 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 20% 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\$5.0 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\$312 million (for 2009). 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 has recently adopted certain amendments (the Amendments) to the Investment Act. Some of the Amendments, which came into force on February 6, 2009, introduce a national security test and review process, authorizing the Canadian Minister of Industry to review investments that could be injurious to national security, regardless of the size of the transaction. Some of the other Amendments will come into force on a day to be fixed by order of the Canadian Governor in Council, including the increase to the thresholds that trigger governmental review for WTO Investors. Therefore, the thresholds for the review of direct acquisitions of control by WTO Investors would increase from the current CAN\$312 million (based on book value) to CAN\$600 million (to be based on the enterprise value of the

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

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.



**Table of Contents**

**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 other than the employment agreements and change of control agreements with our executive officers as described below.

**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 Germany, our principal subsidiary, which service contract expires on August 31, 2010. Furthermore, 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 twelve months of his then applicable base salary, an amount equivalent to 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 (such amounts increasing to the equivalent of 24 months of his then applicable base salary and twice his annual bonus received for the last completed year, commencing in March 2010). In the case of Mr. Turpin, the lump sum 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 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 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 the executive terminates his or her employment for Good Reason .

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; and

- for Mr. Turpin, 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):

Table of Contents

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

**Other Material Contracts**

On March 5, 2009, we entered into a development, commercialization and licensing agreement with sanofi-aventis for the development, registration and marketing of cetorelix in benign prostatic hyperplasia (BPH) for the U.S. market. Under the terms of the agreement, sanofi-aventis made an initial \$30 million upfront payment to us, and we will also be entitled to receive up to \$135 million in additional payments upon achieving certain pre-established regulatory and commercial milestones. We will also be entitled to receive escalating double-digit royalties on future net sales of cetorelix for BPH in the United States.

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 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,

contingent on 2010 net sales of Cetrotide® reaching a specified level, we would receive an additional payment of \$2.5 million from CHRP. Under the terms of the agreement, if cetrotirelix 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.

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

**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.

Table of Contents

The following summary describes the principal Canadian federal income tax consequences to a purchaser who acquires common shares (a holder ) who, for the purposes of the Canadian federal *Income Tax Act*, R.S.C. 1985, as amended (The Tax Act ), deals at arm's length with, and is not affiliated with, the Corporation and holds common shares as capital property. The common shares will generally be considered to be capital property for this purpose unless either the holder holds such common shares in the course of carrying on a business, 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 an interest in which is a tax shelter investment as defined in the Tax Act, or to a holder which is a financial institution as defined in the Tax Act subject to the mark-to-market rules set out therein. Such holders should consult their own tax advisors.

This summary is based upon the current provisions of the Tax Act and the regulations thereunder and the Company's understanding of the current published administrative practices and policies 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) ( 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, whether by way of legislative, judicial or administrative action or interpretation, nor does it address any provincial, 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 and any applicable income tax treaty or convention, 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 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 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 holder is not entitled to relief under the applicable income tax treaty or convention. As long as the common shares are then listed on a designated stock exchange (which currently includes the NASDAQ and the TSX), the common shares generally will not constitute taxable Canadian property of a Non-Resident holder, unless at any time during the 60-month period immediately preceding the disposition, 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 capital stock of the Corporation. If the common shares were to cease being listed on the 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. An exemption from such requirements is available on the disposition of treaty-protected property, which is property any income or gain on the disposition of which is exempt from tax under Part I of the Tax Act as a result of an applicable income tax treaty or convention.

**Taxation of Dividends on Common Shares**

Dividends paid or credited or deemed to be paid or credited on the common shares to a Non-Resident holder will be subject to a Canadian withholding tax in the amount of 25%. Such withholding tax may be reduced by virtue of the provisions of an income tax treaty or convention between Canada and the country of which the Non-Resident holder is a resident. Under the Canada-United States Income Tax Convention (the

Table of Contents

Convention ), the rate of withholding tax in respect of dividends or deemed dividends beneficially owned by a resident of the United States entitled to the benefits of the Convention is generally reduced to 15%.

**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 and any applicable income tax treaty or convention, is 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 other Canadian securities as defined in the Tax Act, 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 be 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 be 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 to the enhanced gross-up and dividend tax credit if the recipient receives written notice from the corporation designating the dividend as an eligible dividend (within the meaning of the Tax Act). There may be limitations on the ability of the Corporation to designate dividends as eligible dividends. A Canadian holder that is a corporation will 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 be received on the common shares to the extent such dividends are deductible in computing the holder's taxable income.

*Disposition of Common Shares*

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

*Additional Refundable Tax*

A Canadian holder that is a Canadian-controlled private corporation (as such term is defined in the Tax Act) may be liable to pay an additional refundable tax of 62/3% 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 of a common share may be reduced by the amount of dividends received or deemed to be 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 by a Canadian holder who is an individual may give rise to liability for alternative minimum tax.



Table of Contents

**Certain U.S. Federal Income Tax Considerations**

The following discussion is a summary of certain U.S. federal income tax consequences applicable to the ownership and disposition of common shares ( 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, Internal Revenue Service ( 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 discuss any aspect of state, local or foreign law, or U.S. federal estate or gift tax law as applicable to U.S. Holders. In addition, this discussion is limited to U.S. Holders holding Shares as capital assets. For purposes of this summary, U.S. Holder means a beneficial holder of 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 to be treated as a U.S. person.

If a partnership or other entity or arrangement classified as a partnership for U.S. federal income tax purposes holds 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. Such a partner should consult its own tax advisor as to the tax consequences of the partnership owning and disposing of Shares.

***Dividends***

Subject to the passive foreign investment company ( PFIC ) rules discussed below, 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

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

non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in the 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, 2011, 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 for any year in which the Company is treated as a PFIC. 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 (1980) ( the Treaty ) is reduced to a maximum of 15 percent.

Dividends paid in Canadian dollars will be included in income in a U.S. dollar amount calculated by reference to the exchange rate in effect on the day the dividends are received by the U.S. Holder, regardless of whether the Canadian dollars are converted into U.S. dollars at that time. If dividends received in Canadian dollars are converted into U.S. dollars on the day they are received, the U.S. Holder generally will not be required to recognise foreign currency gain or loss in respect of the dividend income.

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. U.S. Holders should consult their tax advisors concerning the foreign tax credit implications of the payment of Canadian taxes.

***Sale or Other Taxable Disposition***

Subject to the PFIC rules discussed below, upon a sale or other taxable disposition of 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 Shares.

This capital gain or loss will be long-term capital gain or loss if the U.S. Holder's holding period in the Shares exceeds one year. Long-term capital gains of non-corporate U.S. Holders are currently eligible for reduced rates of taxation. 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.

Table of Contents

***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 percent of its gross income is passive income or (ii) at least 50 percent of the average value of its assets is attributable to assets which produce passive income or are held for the production of passive income.

If the Company is classified as a PFIC for any taxable year during which a U.S. Holder owns Shares, the U.S. Holder, absent certain elections (including a mark-to-market election), 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 Shares in a taxable year that are greater than 125 percent 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 Shares) and (ii) any gain realized on the sale or other disposition of 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.

The Company believes it was not a PFIC for the 2008 taxable year. However, since the fair market value of the Company's assets may be determined in large part by the market price of the 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, no assurance can be provided that the Company would not be classified as a PFIC for the 2009 taxable year and for any future taxable year.

U.S. Holders should consult their tax advisors regarding the potential application of the PFIC regime.

***Information Reporting and Backup Withholding***

The proceeds of a sale or other disposition, as well as dividends paid with respect to 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 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 (including, among others, corporations) 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 obtaining an exemption.

**F. Dividends and paying agents.**

Not applicable.

**G. Statement by experts.**

Not applicable.

**H. Documents on display.**

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 United States Securities and Exchange Commission. These materials, including this annual report on Form 20-F and the exhibits thereto, may be inspected and copied at the Commission'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 Commission's Public Reference Room by calling the Commission in the United States at 1-800-SEC-0330. The Commission 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 Commission. The Company's annual reports and some of the other information submitted by the Company to the Commission may be accessed through this website. In addition, material filed by the Company can be inspected on the Canadian Securities Administrators' electronic filing system, SEDAR, accessible at the website [www.sedar.com](http://www.sedar.com). This material includes the Company's Management

Table of Contents

Information Circular for its annual meeting to be held on May 6, 2009 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 annual financial statements for the year ended December 31, 2008 and our Management's Discussion and Analysis relating to these statements. 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**

**Foreign Currency Risk**

Since the Company operates on an international scale, it is exposed to currency risks as a result of potential exchange rate fluctuations. For the year ended December 31, 2008, there were no operations using forward-exchange contracts and no forward-exchange contract is outstanding as of the date of this annual report.

**Credit Risk**

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents, short-term investments and accounts receivable. Cash and cash equivalents are maintained with high-credit quality financial institutions. Short-term investments consist primarily of bonds issued by high-credit quality corporations and institutions. Consequently, management considers the risk of non-performance related to cash and cash equivalents and investments to be minimal.

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.

**Interest Rate Risk**

We are exposed to market risk relating to changes in interest rates with regard to our short-term investments.

**Item 12. Description of Securities Other than Equity Securities**

**A. Debt securities.**

Not applicable.

**B. Warrants and rights.**

Not applicable.

**C. Other securities.**

Not applicable.

**D. American depositary shares.**

Not applicable.

**PART II**

**Item 13. Defaults, Dividend Arrearages and Delinquencies**

None.

**Item 14. Material Modification to the Rights of Security Holders and Use of Proceeds**

Table of Contents

None.

**Item 15. Controls and Procedures**

Under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures as at December 31, 2008. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures are effective as at December 31, 2008.

**Management's Report on Internal Control over Financial Reporting**

Æterna Zentaris management is responsible for establishing and maintaining adequate internal control over financial reporting. Our 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. (1)

Our 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 Æterna Zentaris; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles (1), and that receipts and expenditures of the Company are being made only in accordance with authorizations of Company management; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of Company 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 our 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 (COSO). Based on this evaluation, management concluded that our internal control over financial reporting was effective as at December 31, 2008.

---

(1) Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in Canada ( Canadian GAAP ) and significant differences in measurement and disclosure from generally accepted principles in United States ( US GAAP ) are set out in Note 27 to our consolidated financial statements included elsewhere in this annual report



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, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

During 2008, in the course of our evaluation, we identified significant deficiencies in our internal control over financial reporting which we do not believe, either individually or in the aggregate, resulted in a material weakness to our internal control over financial reporting.

The design of any system of controls and procedures is based in part upon certain assumptions about the likelihood of certain events. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, including conditions that are remote.

**Item 16.**     *[Reserved]*

**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 16(b) of General Instruction B to Form 20-F). The name of the audit committee financial expert of the Registrant is Mr. Gérard Limoges, FCA, the Audit Committee's Chairman. The Commission has indicated that the designation of Mr. Limoges as the audit committee financial expert of the Registrant does not: (i) make Mr. Limoges an expert for any purpose, including without limitation for purposes of Section 11 of the Securities Act of 1933, as amended, as a result of this designation; (ii) impose any duties, obligations or liability on Mr. Limoges that are greater than those imposed on him as a member of the Audit Committee and the Board in the absence of such designation; or (iii) affect the duties, obligations or liability of any other member of the Audit Committee or the Board. The other members of the Audit committee are Ms. Martha Byorum and Mr. Pierre MacDonald who are all independent. 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 attached 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 (16)(b) of General Instruction B 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 Corporate Secretary of the Registrant, at its head office at 1405 du Parc-Technologique Boulevard, Québec, 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, 2008 and 2007, our principal accountant, PricewaterhouseCoopers LLP, billed us aggregate amounts of \$332,495 and \$284,973, respectively, for the audit of our annual consolidated financial statements and services in connection with statutory and regulatory filings.

**Table of Contents**

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

During the financial years ended December 31, 2008 and 2007, our principal accountant, PricewaterhouseCoopers LLP, billed us aggregate amounts of \$219,407 and \$306,804, respectively, for audit or attest services not required by statute or regulation, employee benefit plan audits, due diligence services, and accounting consultations on proposed transactions, including the review of prospectuses and the delivery of customary consent and comfort letters in connection therewith.

***C. Tax Fees***

During the financial years ended December 31, 2008 and 2007, our principal accountant, PricewaterhouseCoopers LLP, billed us aggregate amounts of \$96,017 and \$43,182, respectively, for services related to tax compliance, tax planning and tax advice.

***D. All Other Fees***

During the financial years ended December 31, 2008 and 2007, our principal accountant, Pricewaterhouse Coopers LLP, billed us aggregate amounts of \$12,962 and \$4,508, 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, we are required to disclose whether our 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 (filed as Exhibit 11.6 to this annual report) 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, 2008 and 2007, none of the non-audit services provided by our external auditor were approved by the Audit Committee pursuant to the de minimis exception to the pre-approval requirement for non-audit services.

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

During the financial year ended on December 31, 2008, only full-time permanent employees of our principal accountant, PricewaterhouseCoopers LLP, performed work to audit our financial statements.

**Item 16D. Exemptions from the Listing Standards for Audit Committees**

None.

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

**Item 16F. Changes in Registrant's Certifying Accountant**

None.

**Item 16G. Corporate Governance**

The Registrant is in compliance with the corporate governance requirements of the NASDAQ except as described below. The Registrant is not in compliance with the NASDAQ requirement that a quorum for a meeting of the holders of the common stock of the Registrant be no less than 33 1/3% of such outstanding shares. The by-laws of the Registrant provide that a quorum for purposes of any meeting of shareholders of the Registrant consists of at least 20% of the outstanding voting shares. The Registrant received 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 principal market on which the Registrant's voting shares are traded.

Table of Contents

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 four members, four of whom are independent directors. 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.

**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 116 through 173.

Table of Contents

**Aeterna Zentaris Inc.**

Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(expressed in thousands of US dollars)

Table of Contents

**Report of the Independent Registered Public Accounting Firm**

**To the Shareholders of**

**Æterna Zentaris Inc.**

We have completed integrated audits of Æterna Zentaris Inc.'s 2008 and 2007 consolidated financial statements and of its internal control over financial reporting as at December 31, 2008 and an audit of its 2006 consolidated financial statements. Our opinions, based on our audits, are presented below.

**Consolidated financial statements**

We have audited the accompanying consolidated balance sheets of Æterna Zentaris Inc. as at December 31, 2008 and December 31, 2007, and the related consolidated statements of earnings (loss), comprehensive income (loss), changes in shareholders' equity and cash flows for each of the years in the three-year period ended December 31, 2008. We have also audited the financial statement schedules, Valuation and Qualifying Accounts and Export Sales, in Item 8.A. of this Annual Report on Form 20-F. These consolidated financial statements and financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedules based on our audits.

We conducted our audits of the Company's financial statements 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 financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. A financial statement audit also includes assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as at December 31, 2008 and December 31, 2007 and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2008 in accordance with Canadian generally accepted accounting principles. Furthermore, in our opinion, the financial statement schedules, Valuation and Qualifying Accounts and Export Sales, in Item 8.A. of this Annual Report on Form 20-F present fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

**Internal control over financial reporting**

We have also audited Æterna Zentaris Inc.'s internal control over financial reporting as at December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The

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

Company's 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 Management's Report on Internal Control over Financial Reporting appearing on page 112 of the Annual Report on Form 20-F. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.



Table of Contents

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.

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.

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.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as at December 31, 2008 based on criteria established in Internal Control – Integrated Framework issued by the COSO.

(1)

**Chartered Accountants**

Québec, Quebec, Canada

March 10, 2009

---

(1) Chartered accountant auditor permit No. 11070



Table of Contents**Aeterna Zentaris Inc.**

## Consolidated Balance Sheets

(expressed in thousands of US dollars)

|  | As at December 31, |          |
|--|--------------------|----------|
|  | 2008               | 2007     |
|  | \$                 | \$       |
| <b>ASSETS</b>  |                    |          |
| <b>Current assets</b>  |                    |          |
| Cash and cash equivalents                                    | 49,226             | 10,272   |
| Short-term investments (note 24)                             | 493                | 31,115   |
| Accounts receivable  |                    |          |
| Trade  | 3,425              | 6,170    |
| Other (note 8)   | 1,100              | 3,044    |
| Income taxes   | 48                 |          |
| Inventory (note 9)   | 3,385              | 5,406    |
| Prepaid expenses and other current assets                    | 4,047              | 3,573    |
|  | 61,724             | 59,580   |
| <b>Property, plant and equipment (note 11)</b>               | 6,682              | 7,460    |
| <b>Long-lived assets held for sale (note 6)</b>              |                    | 13,999   |
| <b>Deferred charges and other long-term assets (note 10)</b> | 5,959              | 1,441    |
| <b>Intangible assets (note 12)</b>                           | 23,894             | 30,391   |
| <b>Goodwill (note 13)</b>                                    | 10,083             | 10,492   |
|  | 108,342            | 123,363  |
| <b>LIABILITIES</b>   |                    |          |
| <b>Current liabilities</b>                                   |                    |          |
| Accounts payable and accrued liabilities (note 14)           | 13,690             | 16,084   |
| Income taxes   | 800                | 23       |
| Deferred revenues (note 7)                                   | 7,631              | 5,373    |
| Current portion of long-term debt and payable                | 49                 | 775      |
|  | 22,170             | 22,255   |
| <b>Deferred revenues (note 7)</b>                            | 54,433             | 3,333    |
| <b>Long-term debt and payable (notes 6 and 15)</b>           | 172                |          |
| <b>Employee future benefits (note 16)</b>                    | 10,092             | 9,184    |
|  | 86,867             | 34,772   |
| <b>Commitments and contingencies (note 25)</b>               |                    |          |
| <b>Subsequent event (note 26)</b>                            |                    |          |
| <b>SHAREHOLDERS' EQUITY</b>                                  |                    |          |
| Share capital (note 17)                                      | 30,566             | 30,566   |
| Other capital  | 79,669             | 79,306   |
| Deficit  | (102,814)          | (42,997) |
| Accumulated other comprehensive income                       | 14,054             | 21,716   |
|  | 21,475             | 88,591   |

Evaluation of going concern (note 2)

**Approved by the Board of Directors**

Juergen Ernst, MBA  
Director

Gérard Limoges, FCA  
Director

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

Table of Contents**Aeterna Zentaris Inc.****Consolidated Statements of Changes in Shareholders' Equity****For the years ended December 31, 2008, 2007 and 2006**

(tabular amounts in thousands of US dollars, except common share data)

|  | Common<br>shares<br>(number of) | Share<br>capital<br>\$ | Other<br>capital<br>\$ | Deficit<br>\$   | Accumulated<br>other<br>comprehensive<br>income<br>\$ | Total<br>\$    |
|--|---------------------------------|------------------------|------------------------|-----------------|---|----------------|
| <b>Balance December 31, 2005</b>   | <b>46,139,814</b>               | <b>130,344</b>         | <b>10,474</b>          | <b>(43,224)</b> | <b>11,937</b>   | <b>109,531</b> |
| Net earnings for the year  |                                 |                        |                        | 33,390          |   | 33,390         |
| Conversion of convertible term loans (note 17b)                            | 6,955,088                       | 37,786                 | (6,339)                | (280)           |   | 31,167         |
| Foreign currency translation adjustment                                    |                                 |                        |                        |                 | 4,007   | 4,007          |
| Foreign currency translation adjustment related to disposal of Atrium      |                                 |                        |                        |                 | (1,643)   | (1,643)        |
| Issued pursuant to the stock option plan                                   |                                 |                        |                        |                 |   |                |
| For cash (note 17d)  | 22,000                          | 81                     |                        |                 |   | 81             |
| Ascribed value from Other capital  |                                 | 29                     | (29)                   |                 |   |                |
| Issued pursuant to acquisition of Echelon (note 5)                         | 23,789                          | 163                    |                        |                 |   | 163            |
| Issued pursuant to acquisition of a patent from a senior officer (note 22) | 28,779                          | 175                    |                        |                 |   | 175            |
| Share issue expenses   |                                 | (112)                  |                        |                 |   | (112)          |
| Stock-based compensation costs   |                                 |                        | 2,120                  |                 |   | 2,120          |
| <b>Balance December 31, 2006</b>   | <b>53,169,470</b>               | <b>168,466</b>         | <b>6,226</b>           | <b>(10,114)</b> | <b>14,301</b>   | <b>178,879</b> |
| Effect of the application of new accounting standards                      |                                 |                        |                        | (587)           | (41)  | (628)          |
| Distribution of Atrium (note 4)  |                                 | (137,959)              | 71,122                 |                 | (5,624)   | (72,461)       |
| Net loss for the year  |                                 |                        |                        | (32,296)        |   | (32,296)       |
| Foreign currency translation adjustment                                    |                                 |                        |                        |                 | 13,783  | 13,783         |
| Variation in the fair value of short-term investments, net of income taxes |                                 |                        |                        |                 | 51  | 51             |
| Issued pursuant to the stock option plan                                   |                                 |                        |                        |                 |   |                |
| For cash (note 17d)  | 18,000                          | 33                     |                        |                 |   | 33             |
| Ascribed value from Other capital  |                                 | 26                     | (26)                   |                 |   |                |
| Disposal of Shares of Echelon (note 5)                                     |                                 |                        |                        |                 | (754)   | (754)          |
| Stock-based compensation costs   |                                 |                        | 1,984                  |                 |   | 1,984          |
| <b>Balance December 31, 2007</b>   | <b>53,187,470</b>               | <b>30,566</b>          | <b>79,306</b>          | <b>(42,997)</b> | <b>21,716</b>   | <b>88,591</b>  |

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

Table of Contents**Aeterna Zentaris Inc.**

## Consolidated Statements of Changes in Shareholders' Equity

For the years ended December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars, except common share data)

|   | Common<br>shares<br>(number of) | Share<br>capital<br>\$ | Other<br>capital<br>\$ | Deficit<br>\$             | Accumulated<br>other<br>comprehensive<br>income<br>\$ | Total<br>\$   |
|---|---------------------------------|------------------------|------------------------|---------------------------|---|---------------|
| <b>Balance December 31, 2007</b>  | <b>53,187,470</b>               | <b>30,566</b>          | <b>79,306</b>          | <b>(42,997)</b>           | <b>21,716</b>   | <b>88,591</b> |
| Net loss for the year   |                                 |                        |                        | (59,817)                  |   | (59,817)      |
| Foreign currency translation adjustment                                       |                                 |                        |                        |                           | (7,655)   | (7,655)       |
| Variation in the fair value of short-term investments, net of income taxes    |                                 |                        |                        |                           | (7)   | (7)           |
| Stock based compensation costs  |                                 |                        | 363                    |                           |   | 363           |
| <b>Balance December 31, 2008</b>  | <b>53,187,470</b>               | <b>30,566</b>          | <b>79,669</b>          | <b>(102,814)</b>          | <b>14,054</b>   | <b>21,475</b> |
|   |                                 |                        | <b>2008</b>            | <b>As at December 31,</b> | <b>2007</b>   | <b>2006</b>   |
|   |                                 |                        | \$                     | \$                        | \$  | \$            |
| <b>Accumulated Other Comprehensive Income</b>                                 |                                 |                        |                        |                           |   |               |
| Consisting of the following:  |                                 |                        |                        |                           |   |               |
| Foreign currency translation adjustments                                      |                                 |                        | 14,051                 | 21,706                    | 14,301  |               |
| Variation in fair market value of short-term investments, net of income taxes |                                 |                        | 3                      | 10                        |   |               |
| Accumulated Other Comprehensive income  |                                 |                        | 14,054                 | 21,716                    | 14,301  |               |
| <b>Deficit</b>  |                                 |                        | (102,814)              | (42,997)                  | (10,114)  |               |
| <b>Total Accumulated Other Comprehensive Income and Deficit</b>               |                                 |                        | (88,760)               | (21,281)                  | 4,187   |               |

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

Table of Contents**Aeterna Zentaris Inc.****Consolidated Statements of Earnings (Loss)****For the years ended December 31,**

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

|   | 2008<br>\$ | 2007<br>\$ | 2006<br>\$ |
|---|------------|------------|------------|
| <b>Revenues</b>   | 38,478     | 42,068     | 38,799     |
| <b>Operating expenses</b>   |            |            |            |
| Cost of sales (note 9)  | 19,278     | 12,930     | 11,270     |
| Selling, general and administrative expenses                            | 17,325     | 20,403     | 16,478     |
| Research and development costs  | 57,448     | 39,248     | 27,422     |
| Research and development tax credits and grants                         | (343)      | (2,060)    | (1,564)    |
| Depreciation and amortization   |            |            |            |
| Property, plant and equipment   | 1,515      | 1,562      | 2,816      |
| Intangible assets (note 12)   | 5,639      | 4,004      | 6,148      |
| Impairment of long-lived asset held for sale (note 6)                   |            | 735        |            |
|   | 100,862    | 76,822     | 62,570     |
| <b>Loss from operations</b>   | (62,384)   | (34,754)   | (23,771)   |
| <b>Other income (expenses)</b>  |            |            |            |
| <b>Interest income</b>  | 868        | 1,904      | 1,441      |
| Interest expense  |            |            |            |
| Long-term debt and convertible term loans                               |            | (85)       | (1,270)    |
| Other   | (118)      |            | (163)      |
| Foreign exchange (loss) gain  | 3,071      | (1,035)    | 319        |
| Loss on disposal of long-lived assets held for sale (note 6)            | (35)       |            |            |
| Loss on disposal of equipment   | (44)       | (28)       |            |
| Gain on disposal of a long-term investment                              |            |            | 409        |
|   | 3,742      | 756        | 736        |
| <b>Share in the results of an affiliated company</b>                    |            |            | 1,575      |
| <b>Loss before income taxes from continuing operations</b>              | (58,642)   | (33,998)   | (21,460)   |
| <b>Income tax (expense) recovery (note 19)</b>                          | (1,175)    | 1,961      | 29,037     |
| <b>Net (loss) earnings from continuing operations</b>                   | (59,817)   | (32,037)   | 7,577      |
| <b>Net (loss) earnings from discontinued operations (notes 4 and 5)</b> |            | (259)      | 25,813     |
| <b>Net (loss) earnings for the year</b>                                 | (59,817)   | (32,296)   | 33,390     |
| <b>Net (loss) earnings per share from continuing operations</b>         |            |            |            |
| Basic   | (1.12)     | (0.61)     | 0.14       |
| Diluted   | (1.12)     | (0.61)     | 0.14       |
| <b>Net (loss) earnings per share from discontinued operations</b>       |            |            |            |
| Basic   |            |            | 0.50       |
| Diluted   |            |            | 0.48       |
| <b>Net (loss) earnings per share</b>                                    |            |            |            |
| Basic   | (1.12)     | (0.61)     | 0.64       |
| Diluted   | (1.12)     | (0.61)     | 0.62       |
| <b>Weighted average number of shares (note 21)</b>                      |            |            |            |
| Basic   | 53,187,470 | 53,182,803 | 52,099,290 |
| Diluted   | 53,187,470 | 53,182,803 | 52,549,260 |

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

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



Table of Contents**Aeterna Zentaris Inc.****Consolidated Statements of Comprehensive Income (Loss)****For the years ended December 31,**

(expressed in thousands of US dollars)

|   | 2008<br>\$ | 2007<br>\$ | 2006<br>\$ |
|---|------------|------------|------------|
| Net earnings (loss) for the year  | (59,817)   | (32,296)   | 33,390     |
| Other comprehensive income (loss):  |            |            |            |
| Foreign currency translation adjustments                                      | (7,655)    | 13,783     | 4,007      |
| Reclassification adjustment related to disposal of Atrium                     |            |            | (1,643)    |
| Reclassification adjustment related to disposal of Echelon                    |            | (754)      |            |
| Variation in fair market value of short-term investments, net of income taxes | (7)        | 51         |            |
| Comprehensive income (loss)   | (67,479)   | (19,216)   | 35,754     |

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,**

(expressed in thousands of US dollars)

|   | 2008<br>\$ | 2007<br>\$ | 2006<br>\$ |
|---|------------|------------|------------|
| <b>Cash flows from operating activities</b>                           |            |            |            |
| Net earnings (loss) for the year                                      | (59,817)   | (32,296)   | 33,390     |
| Net (earnings) loss from discontinued operations                      |            | 259        | (25,813)   |
| Net earnings (loss) from continuing operations                        | (59,817)   | (32,037)   | 7,577      |
| Items not affecting cash and cash equivalents                         |            |            |            |
| Depreciation and amortization   | 7,154      | 5,566      | 8,964      |
| Stock-based compensation costs  | 363        | 1,984      | 2,120      |
| Future income taxes   |            | (1,868)    | (29,160)   |
| Gain on disposal of a long-term investment                            |            |            | (409)      |
| Share in the results of an affiliated company                         |            |            | (1,575)    |
| Inventory write-down (note 9)   | 726        |            |            |
| Employee future benefits  | 984        | 164        | (115)      |
| Amortization of deferred charges and other long term assets           | 729        | 510        | 150        |
| Amortization of deferred revenues                                     | (6,213)    | (7,012)    | (5,141)    |
| Accretion on long term borrowings                                     |            | 82         | 1,227      |
| Loss on disposal of long-lived assets held for sale                   | 35         |            |            |
| Loss on disposal of equipment   | 44         | 28         |            |
| Impairment of long-lived asset held for sale                          |            | 735        |            |
| Foreign exchange loss (gain) on items denominated in foreign currency | (3,801)    | 641        | (587)      |
| Changes in operating assets and liabilities (note 18)                 | 58,524     | 5,545      | 1,079      |
| Net cash used in continuing operating activities                      | (1,272)    | (25,662)   | (15,870)   |
| Net cash provided by discontinued operating activities                |            | 132        | 23,827     |
| Net cash provided by (used in) operating activities                   | (1,272)    | (25,530)   | 7,957      |
| <b>Cash flows from financing activities</b>                           |            |            |            |
| Repayment of long-term debt and long-term payable                     | (784)      | (751)      | (718)      |
| Issuance of shares pursuant to the exercise of stock options          |            | 33         | 81         |
| Share issue expenses  | (408)      | (366)      | (112)      |
| Net cash used in continuing financing activities                      | (1,192)    | (1,084)    | (749)      |
| Net cash used in discontinued financing activities                    |            | (230)      | (7,825)    |
| Net cash used in financing activities                                 | (1,192)    | (1,314)    | (8,574)    |
| <b>Cash flows from investing activities</b>                           |            |            |            |
| Purchase of short-term investments                                    | (1,664)    | (6,180)    | (79,300)   |
| Proceeds from sale and maturity of short-term investments             | 30,027     | 33,405     | 49,267     |
| Proceeds from sale of a long-term investment                          |            |            | 1,387      |
| Business acquisitions, net of cash and cash equivalents acquired      |            |            | (32)       |
| Purchase of property, plant and equipment                             | (1,147)    | (3,702)    | (1,845)    |
| Net proceeds from sale of long-lived assets held for sale             | 14,854     |            |            |
| Proceeds from sale of property, plant and equipment                   |            | 729        |            |
| Acquisition of amortizable intangible assets                          | (67)       | (67)       | (5)        |
| Net cash provided by (used in) continuing investing activities        | 42,003     | 24,185     | (30,528)   |
| Net cash provided by discontinued investing activities                |            | 2,238      | 11,878     |
| Net cash provided by (used in) in investing activities                | 42,003     | 26,423     | (18,650)   |
| <b>Effect of exchange rate changes on cash and cash equivalents</b>   | (585)      | 1,337      | 1,356      |

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

|  |        |        |          |
|--|--------|--------|----------|
| <b>Net change in cash and cash equivalents</b>     | 38,954 | 916    | (17,911) |
| <b>Cash and cash equivalents Beginning of year</b> | 10,272 | 9,356  | 27,267   |
| <b>Cash and cash equivalents End of year</b>       | 49,226 | 10,272 | 9,356    |
| <b>Cash and cash equivalents related to:</b>       |        |        |          |
| Continuing operations                              | 49,226 | 10,272 | 8,939    |
| Discontinued operations                            |        |        | 417      |
|  | 49,226 | 10,272 | 9,356    |
| <b>Cash and cash equivalents components:</b>       |        |        |          |
| Cash   | 13,256 | 10,195 | 9,174    |
| Cash equivalents                                   | 35,970 | 77     | 182      |
|  | 49,226 | 10,272 | 9,356    |

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

Table of Contents

**Aeterna Zentaris Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2008, 2007 and 2006**

**(tabular amounts in thousands of US dollars,**

**except share/option and per share/option data and as otherwise noted)**

**1 Incorporation and nature of activities**

Aeterna Zentaris Inc. (Aeterna Zentaris or the Company), incorporated under the Canada Business Corporations Act, is a global biopharmaceutical company focused on endocrine therapy and oncology with expertise in drug discovery, development and commercialization.

Our pipeline encompasses compounds at all stages of development, from drug discovery through marketed products. The two highest priority clinical programs are our lead value driver, cetorelix for benign prostatic hyperplasia (BPH) and our lead oncology program, AEZS-108, for endometrial and ovarian cancers.

**2 Summary of significant accounting policies**

**Basis of presentation**

The accompanying consolidated financial statements have been prepared in accordance with Canadian generally accepted accounting principles (Canadian GAAP). These consolidated financial statements differ in certain respects from those prepared in accordance with United States generally accepted principles (US GAAP). The recognition, measurement and disclosure differences as they relate to the Company are described in note 27 Summary of differences between generally accepted accounting principles in Canada and in the United States.

**Evaluation of going concern, results of operations and management's plans:**

In May 2007, the Accounting Standards Board amended CICA Handbook Section 1400, *General Standards of Financial Statement Presentation*, to change the guidance related to management's responsibility to assess the ability of the entity to continue as a going concern. Management is required to make an assessment of an entity's ability to continue as a going concern and should take into account all available information about the future, which is at least, but is not limited to, 12 months from the balance sheet dates. Disclosure is required of material uncertainties related to events or conditions that may cast significant doubt upon the entity's ability to continue as a going concern. The Company adopted these amendments, which were effective for years beginning on or after January 1, 2008. Management's assessment took into account the sale of rights to future royalties described in note 7, the signing of the development, commercialization and license agreement with sanofi-aventis on March 5, 2009, which is disclosed in note 26, as well as the Company's strategic plan and corresponding budgets for 2009, 2010 and 2011. As a result of this assessment, management believes that the Company has sufficient financial resources to fund planned expenditures and other working capital needs for at least the next 12-month period from the balance sheet date.

**Basis of consolidation**

These consolidated financial statements include all companies in which the Company, directly or indirectly holds more than 50% of the voting rights or over which it exercises control. Companies are included in the consolidation from the date that control is transferred to the Company, while companies sold are excluded from the consolidation from the date that control ceases. The purchase method of



Table of Contents

**Aeterna Zentaris Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2008, 2007 and 2006**

**(tabular amounts in thousands of US dollars,**

**except share/option and per share/option data and as otherwise noted)**

accounting is used to account for acquisitions. All intercompany balances and transactions are eliminated on consolidation.

**Investments in affiliated companies**

Where applicable, investments in companies over which the Company exercises significant influence (generally where the Company holds 20% to 50% of the investee's voting rights) but over which it does not exercise control are accounted for using the equity method. The Company's share of its affiliated results of operations is recognized in the statement of earnings (loss). Also where applicable, investments where the Company holds less than 20% of the investee's voting rights and does not have the ability to exercise significant influence are accounted for using the cost method.

**Accounting estimates**

The preparation of financial statements in conformity with Canadian generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Those estimates and assumptions also affect the disclosure of contingencies at the date of the financial statements as well as the reported amounts of revenues and expenses during the reported years. Significant estimates are generally made in connection with the calculation of revenues, research and development expenses, stock-based compensation cost, as well as in determining the allowance for doubtful accounts, inventory and provisions for obsolete inventory, future income tax assets and liabilities, the useful lives of property, plant and equipment and intangible assets with finite lives, the valuation of intangible assets and goodwill, the fair value of stock options granted, employee future benefits and certain accrued liabilities. The Company bases its estimates on historical experience, where relevant, and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

**Foreign currency translation**

*Reporting currency and self-sustaining subsidiaries*

The Company uses the US dollar as its reporting currency. Assets and liabilities of the Company and of its self-sustaining subsidiaries whose functional currency is other than the US dollar are translated using the exchange rate in effect at the balance sheet date. Revenues and expenses are translated at the average rate in effect during the year. Translation gains and losses are included in the statement of comprehensive income.

*Foreign currency transactions and integrated foreign subsidiary*

The financial statements of integrated foreign operations and transactions denominated in currencies other than the functional currency are re-measured into the functional currency using the temporal method. Under this method, monetary assets and liabilities are re-measured to their functional currency at the exchange rate in effect on the date of the balance sheet. Non-monetary assets and liabilities are re-measured at historical rates, unless such assets and liabilities are carried at market, in which case, they are remeasured using the exchange rate in effect on the date of the balance sheet. Revenues and expenses are

Table of Contents**Aeterna Zentaris Inc.****Notes to Consolidated Financial Statements****December 31, 2008, 2007 and 2006****(tabular amounts in thousands of US dollars,****except share/option and per share/option data and as otherwise noted)**

re-measured at the monthly average exchange rate. Transaction gains and losses resulting from such re-measurement are reflected in the statements of earnings (loss).

**Cash and cash equivalents**

Cash and cash equivalents consist of cash on hand and balances with banks, excluding bank advances, as well as short-term, interest-bearing deposits with a term of less than three months at the acquisition date.

**Short-term investments**

Short-term investments consist mainly of notes and bonds which do not meet the Company's definition of cash and cash equivalents.

In accordance with the new requirements of the Canadian Institute Chartered Accountants (CICA) Handbook Section 3855, *Financial Instruments*, adopted by the Company on January 1, 2007, short-term investments are classified as available-for-sale investments. The Company recognizes transactions on the settlement date. These investments are recognized at fair value. Unrealized gains and losses are recognized, net of income taxes, if any, in comprehensive income. Upon the disposal or impairment of these investments, these gains or losses are reclassified in the consolidated statement of earnings (loss). See also note 3.

Prior to 2007, short-term investments were valued at the lower of amortized cost and market 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 costs necessary to make the sale. 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.

**Property, plant and equipment and depreciation**

Property, plant and equipment are recorded at cost, net of related government grants and accumulated depreciation. Depreciation is calculated using the following methods and annual rates:

|                        | Methods                             | Annual rates         |
|------------------------|-------------------------------------|----------------------|
| Building               | Straight-line                       | 5 %                  |
| Equipment              | Declining balance and straight-line | 20 %                 |
| Office furniture       | Declining balance and straight-line | 10 and 20 %          |
| Computer equipment     | Straight-line                       | 25 and 33 1/3 %      |
| Automotive equipment   | Straight-line                       | 20 %                 |
| Leasehold improvements | Straight-line                       | Remaining lease term |





Table of Contents

**Aeterna Zentaris Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2008, 2007 and 2006**

**(tabular amounts in thousands of US dollars,**

**except share/option and per share/option data and as otherwise noted)**

**Royalty sale transaction expenses and other deferred charges**

The Company has deferred direct and incremental costs associated with its transaction to sell its future rights to a royalty stream and are accounted for as discussed in note 7.

Other deferred charges relate to deferred upfront payments made related to research and development collaborations. These charges are included in deferred charges and other long-term assets and are amortized in the consolidated statement of earnings (loss) over the duration of the research and development work related to the contracts. Also included in deferred charges and other long-term assets are transaction costs that have been incurred in connection with a shelf prospectus, which was filed in 2007. These costs are not amortized but instead will be included in share capital once proceeds are raised in a related transaction. If no transaction is consummated by the expiry date of the shelf prospectus, which will occur at the end of 2009 or earlier, should management determine that no transaction will be pursued, these transaction costs will be recorded as an expense in the consolidated statement of earnings (loss) (see also note 10).

**Intangible assets**

Intangible assets with finite useful lives consist of in-process research and development, acquired in business combinations, patents and trademarks, technology and other. Patents and trademarks comprise 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 and accumulated amortization. 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 research and development and patents, ten years for trademarks and from three to ten years for technology and other.

**Goodwill**

Goodwill represents the excess of the purchase price over the fair values of the net assets of entities acquired at the respective dates of acquisition. Goodwill is not amortized but is tested for impairment annually or more frequently if events or changes in circumstances indicate that it might be impaired. Testing for impairment is accomplished mainly by determining whether the fair value of a reporting unit exceeds the net carrying amount of that reporting unit as of the assessment date. If the fair value is greater than the carrying amount, no impairment is necessary. In the event that the carrying amount of a reporting unit exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. Fair value of goodwill is estimated in the same way as goodwill is determined at the date of the acquisition in a business combination, that is, the excess of the fair value of the reporting unit over the fair value of the identifiable net assets of the reporting unit.

**Impairment of long-lived assets**

Property, plant and equipment and intangible assets with finite lives are reviewed for impairment when events or circumstances indicate that carrying values may not be recoverable. Impairment exists when the carrying value of the asset is greater than the undiscounted future cash flows expected to be provided by the asset. The amount of impairment loss, if any, is the excess of its carrying value over its fair value,



Table of Contents

**Aeterna Zentaris Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2008, 2007 and 2006**

**(tabular amounts in thousands of US dollars,**

**except share/option and per share/option data and as otherwise noted)**

which in turn is determined based upon discounted cash flows or appraised values, depending on the nature of assets.

**Employee future benefits**

The Company's subsidiary in Germany maintains defined contribution and unfunded defined benefit plans as well as other benefit plans for its employees. Its obligations are accrued under employee benefit plans and the related costs. In this regard, the following policies have been adopted:

- the cost of pension and other benefits earned by employees is actuarially determined using the projected unit credit method and benefit method prorated on length of service and management's best estimate of salary escalation, retirement ages of employees and employee turnover;
- the net actuarial gain (loss) of the benefit obligation is recorded in the statement of earnings (loss) as it arises.

For defined contribution plans, the pension expenses recorded in the statement of earnings (loss) is the amount of contribution the Company is required to pay for services rendered by employees.

**Deferred revenues**

Deferred revenues relate to the unamortized portion of the cash proceeds received in connection with the Company's sale of future rights to a royalty stream. Those proceeds are recognized as royalty revenue based on the "units-of-revenue" method, as discussed in note 7. Also included in deferred revenues are upfront payments received primarily in connection with license cooperation agreements. Those payments are recognized as revenues, as discussed below.

**Revenue recognition**

The Company is currently in a phase in which potential products are being further developed or marketed jointly with strategic partners. Existing licensing agreements usually foresee one-time payments (upfront payments), payments for research and development 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 or using the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

License fees representing non-refundable payments received upon the execution of license agreements are recognized as revenue upon execution of the license agreements when the Company has no significant future performance obligations and collectibility of the fees is assured. Upfront payments received at the beginning of licensing agreements are not recorded as revenue when received but are amortized based on



Table of Contents

**Aeterna Zentaris Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2008, 2007 and 2006**

**(tabular amounts in thousands of US dollars,**

**except share/option and per share/option data and as otherwise noted)**

the progress to the related research and development work. This progress is based on estimates of total expected time or duration to complete the work, which is compared to the period of time incurred to date in order to arrive at an estimate of the percentage of revenue earned to date.

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 there are no significant future performance obligations in connection with the milestones.

In those instances where the Company has collected upfront or milestone payments but has ongoing future obligations related to the development of the drug product, management considers the milestone payments and the remaining obligations under the contract as a single unit of accounting. In those circumstances where the collaboration does not require specific deliverables at specific times or at the end of the contract term, but rather the Company's obligations are satisfied over a period of time, revenue recognition is deferred and amortized over the period of its future obligations.

Royalty revenue, based on a percentage of sales of certain declared products sold by third parties, is recorded when the Company has fulfilled the terms in accordance with the contractual agreement, has no future obligations, the amount of the royalty fee is determinable and collection is reasonably assured.

As discussed in note 7, the Company has sold its rights to certain future royalties. The Company defers recognition of the proceeds it receives for the royalty stream and recognizes these deferred revenues over the life of the license agreement, pursuant to the units-of-revenue method.

Revenues from sales of products are recognized, net of estimated sales allowances and rebates, when title passes to customers, which is at the time goods are shipped, when there are no future performance obligations, when the purchase price is fixed and determinable, and collection is reasonably assured.

**Stock-based compensation costs**

Since January 1, 2003, the Company accounts for all forms of employee stock-based compensation using the fair value-based method.

The fair value of stock options is determined on the date of grant using the Black-Scholes option pricing model and stock-based compensation costs are recognized over the vesting period of the options and credited to Other Capital, and any consideration received by the Company on the exercise of stock options is credited to Share Capital. Other capital component of the stock-based compensation is transferred to Share Capital upon the issuance of shares.

**Income taxes**

The Company follows the liability method of accounting for income taxes. Under this method, future income tax assets and liabilities are determined based on the temporary differences between the carrying amounts and tax bases of the assets and liabilities. Future income tax assets and liabilities are measured using substantively enacted and enacted tax rates expected to apply in the years in which the differences are expected to reverse.



Table of Contents

**Aeterna Zentaris Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2008, 2007 and 2006**

**(tabular amounts in thousands of US dollars,**

**except share/option and per share/option data and as otherwise noted)**

The Company establishes a valuation allowance against future income tax assets if, based on available information, it is more likely than not that some or all of the future income tax assets will not be realized.

**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 earnings over the estimated period of benefit. No costs have been deferred during any periods.

**Research and development tax credits and grants**

The Company is entitled to scientific research and experimental development ( SR&ED ) tax credits granted by the Canadian federal government ( Federal ) and the government of the Province of Quebec ( Provincial ). Federal SR&ED tax credits are earned on qualified Canadian SR&ED expenditures at a rate of 20% and can only be used to offset Federal income taxes otherwise payable. Refundable Provincial SR&ED tax credits are generally earned on qualified SR&ED salaries, subcontracting and university contract expenses incurred in the Province of Quebec, at a rate of 35% of eligible base amounts.

SR&ED tax credits and grants are accounted for using the cost reduction method. Accordingly, tax credits and grants are recorded as a reduction of the related expenses or capital expenditures in the period the expenses are incurred. The refundable portion of SR&ED tax credits is recorded in the year in which the related expenses or capital expenditures are incurred and the non-refundable portion of SR&ED tax credits and grants is recorded at such time, provided the Company has reasonable assurance the credits or grants will be realized.

**Earnings (loss) per share**

Basic net earnings (loss) per share is calculated using the weighted average number of common shares outstanding during the year.

Diluted net earnings (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 options and convertible term loans. This method requires that diluted net earnings (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 New accounting standards and pronouncements**

a)

**Accounting changes adopted in 2008**

On January 1, 2008, the Company adopted CICA Handbook Section 1535, *Capital Disclosures*; Section 3862, *Financial Instruments Disclosures*; Section 3863, *Financial Instruments Presentation*; and Section 3031, *Inventories*, which replaces Section 3030.





Table of Contents

**Aeterna Zentaris Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2008, 2007 and 2006**

**(tabular amounts in thousands of US dollars,**

**except share/option and per share/option data and as otherwise noted)**

Section 1535, *Capital Disclosures*, establishes guidelines for disclosure of information regarding an entity's capital which will enable users of its financial statements to evaluate an entity's objectives, policies and processes for managing capital, including disclosures of any externally imposed capital requirements and the consequences of non-compliance (see note 23).

Section 3862 and Section 3863, which replace Section 3861, *Financial Instruments - Disclosure and Presentation*, require the disclosure of additional details of financial asset and liability categories as well as a detailed discussion on the risks associated with the Company's financial instruments. The presentation requirements are carried forward unchanged (see note 24).

The CICA issued Section 3031, *Inventories*, which replaced Section 3030 with the same title. This standard requires that inventories be measured at the lower of cost and net realizable value and includes guidance on the determination of cost, including allocation of overheads and other costs. The standard also requires that similar inventories within a consolidated group be measured using the same method. Section 3031 also requires the reversal of previous write-downs to net realizable value when there is a subsequent increase in the value of inventories. The Company has adopted this standard effective January 1, 2008, and there has been no impact on the consolidated financial statements.

**b) Future Accounting Changes**

In February 2008, the CICA issued Handbook Section 3064, *Goodwill and Intangible Assets*. This standard provides guidance on the recognition of intangible assets and the criteria for asset recognition, clarifying the applications of the concept of matching revenues and expenses, whether these assets are separately acquired or are developed internally. The standard will apply to the Company's interim and annual financial statements for periods beginning on January 1, 2009. The Company does not expect that adoption of this standard will have a significant impact on the consolidated financial statements.

In January 2009, the CICA issued Handbook Section 1582, *Business Combinations*, which replaces the existing standards. This section establishes the standards for the accounting of business combinations and states that all assets and liabilities of an acquired business will be recorded at fair value. Obligations for contingent considerations and contingencies will also be recorded at fair value at the acquisition date. The standard also states that acquisition-related costs will be expensed as incurred and that restructuring charges will be expensed in the periods after the acquisition date. This standard is applied prospectively to business combinations with acquisition dates on or after January 1, 2011. Earlier adoption is permitted. The Company is currently evaluating the impact, if any, that adoption of this standard will have on its consolidated financial statements.

In January 2009, the CICA issued Handbook Section 1601, *Consolidated Financial Statements*, which replaces the existing standards and establishes the standards for preparing consolidated financial statements and is effective for 2011. Earlier adoption is permitted. The Company is currently evaluating the impact, if any, that adoption of this standard will have on its consolidated financial statements.

Table of Contents

**Æterna Zentaris Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2008, 2007 and 2006**

**(tabular amounts in thousands of US dollars,**

**except share/option and per share/option data and as otherwise noted)**

In January 2009, the CICA issued Handbook Section 1602, *Non-controlling Interests*, which establishes standards for the accounting of non-controlling interests of a subsidiary in the preparation of consolidated financial statements subsequent to a business combination. This standard is effective for 2011. Earlier adoption is permitted. The Company is currently evaluating the impact, if any, that adoption of this standard will have on its consolidated financial statements.

In January 2009, the CICA's Emerging Issue Committee ( EIC ) issued Abstract EIC-173, *Credit Risk and the Fair Value of Financial Assets and Liabilities*, which requires entities to take both counterparty credit risk and their own credit risk into account when measuring the fair value of financial assets and liabilities, including derivatives. EIC-173 will be effective for interim and annual periods beginning on or after January 1, 2009. The Company does not expect that adoption of this guidance will have a significant impact on its consolidated financial statements.

**4 Distribution of the remaining interest in Atrium Biotechnologies Inc.**

During 2006, the Company completed a lengthy and detailed review process whereby it examined a number of strategic alternatives for how best to pursue and implement its business plan of becoming a pure play biopharmaceutical company with a focus on endocrine therapy and oncology. Among the alternatives considered was the divestiture of Æterna Zentaris' interest in Atrium Biotechnologies Inc., now Atrium Innovation Inc. ( Atrium ) and the resulting focus on advancing its development pipeline.

On September 19, 2006, the Company initiated a Secondary Offering to sell 3,485,000 Atrium Subordinate Voting Shares at a price of CAN\$15.80 per share.

On October 18, 2006, the Company closed this Secondary Offering for net proceeds of approximately \$45,000,000. The gain on the disposal of this investment amounted to \$29,248,000 including \$1,643,000 related to cumulative translation adjustments.

Concurrently with the closing of the Secondary Offering and in accordance with the articles of Atrium, the Company's remaining Atrium Multiple Voting Shares were automatically converted into Atrium Subordinate Voting Shares on a one-for-one basis such that the Company subsequently owned 11,052,996 Atrium Subordinate Voting Shares representing approximately 36.1% of the issued and outstanding shares of Atrium.

As of October 18, 2006, Atrium was excluded from the consolidation since the Company's control ceased. Furthermore, given the distribution of the remaining Atrium shares discussed below, all historical operations and cash flows recorded through the consolidation of Atrium until that date have been reported as discontinued operations and therefore, these operations and cash flows are presented as such in the statement of earnings (loss) and in the statement of cash flows.

On December 15, 2006, the Company's shareholders approved a reduction in the stated capital of the Company in an amount equal to the fair market value of its remaining interest in Atrium for the purpose of effecting a special distribution in kind of all 11,052,996 subordinate voting shares of Atrium held by the Company. On January 2, 2007, Æterna Zentaris' shareholders received approximately 0.2079 of an Atrium subordinate voting share for each one of their common shares.



Table of Contents**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

This special distribution was accounted for as a nonreciprocal transfer to shareholders measured at the carrying value of the investment in Atrium on January 2, 2007. As the special distribution is considered as a taxable transaction for the Company and treated as a reduction of the stated capital for tax purposes, the share capital of the Company was reduced by the fair value of the Atrium shares distributed of \$137,959,000, the long-term investment in Atrium of \$57,128,000 was removed from the balance sheet, and the difference, taking into account the related income taxes of \$15,333,000 and cumulative translation adjustment of \$5,624,000, was recorded as Other Capital in the amount of \$71,122,000.

For the year ended December 31, 2006, previously consolidated revenues and expenses of Atrium, representing the former Active Ingredients & Specialty Chemicals Segment as well as the Health & Nutrition Segment, have been reclassified from continuing operations to discontinued operations, as follows:

|  | \$       |
|--|----------|
| <b>Revenues</b>                                  | 239,535  |
| <b>Earnings before the following items</b>       | 28,360   |
| Gain on disposal of Atrium shares                | 29,248   |
| Income tax expense (a)                           | (19,923) |
| Loss on dilution of investments (b)              | (628)    |
| <b>Earnings before non-controlling interest</b>  | 37,057   |
| <b>Non-controlling interest</b>                  | (10,967) |
| <b>Net earnings from discontinued operations</b> | 26,090   |

---

(a) An amount of \$7,006,000 is related to the gain on disposal of Atrium shares and an amount of \$5,692,000 is related to future income tax liabilities on unremitted earnings of Atrium.

except share/option and per share/option data and as otherwise noted)



(b) Loss on dilution of investments.



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

Following the exercise of Atrium's stock options, Atrium issued 627,500 subordinate voting shares between January 1 and October 18, 2006. As a consequence, a loss on dilution amounting to \$628,000 was recognized.

5 Acquisition and disposal of Echelon Biosciences Inc.





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

On January 1, 2005, the Company completed the acquisition of 100% of the issued and outstanding common shares of Echelon Biosciences Inc. ( Echelon ) for a total consideration of \$2,935,522, of which an amount of \$36,718 including all acquisition-related costs, was paid cash, net of cash and cash equivalents acquired of \$161,734, and the balance was paid through the issuance of 443,905 common shares of the Company, the price per share corresponded to the weighted moving average trading prices of the Company for the last fifteen consecutive trading days ending on December 31, 2004. The acquisition was subject to contingent payments specified in the agreement for an approximate amount of \$3,500,000 of which an amount of \$2,900,000 was payable in shares and the balance of \$600,000 payable in cash at the latest in January 2008, based on contractual conditions being met. During 2005, an amount

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

of \$196,000 had been recorded as contingent consideration payable, thus having the effect of increasing goodwill. This amount has been settled through a cash payment of \$32,000 and the issuance of 23,789 common shares of the Company. As of January 1, 2008 the remaining conditions were not met, and as such, no additional consideration has been paid.

During 2007, the Company continued its review process whereby it examined a number of strategic alternatives for how best continue the pursuit and implementation of its business plan of becoming a pure play biopharmaceutical company with a focus on endocrine therapy and oncology. Among the alternatives considered was the divestiture of Aeterna Zentaris investment in Echelon and the resulting focus on advancing its development pipeline.

At September 30, 2007, the Company performed a preliminary impairment test on the goodwill related to Echelon. According to the preliminary test results, an estimated impairment loss of \$500,000 was recorded.

On November 30, 2007, Aeterna Zentaris sold all issued and outstanding shares of Echelon to Frontier Scientific, Inc. for an upfront payment of \$2,600,000 and \$600,000 of contingent consideration. From that date, Echelon was excluded from the consolidation, and all historical operations and cash flows recorded through the consolidation of Echelon until that date have been reported as discontinued operations. The contingent consideration is based on the Echelon reaching specific sales levels in 2008 and 2009, and no contingent consideration is payable relative to 2008.

For the years ended December 31, 2007 and 2006, consolidated revenues and expenses of Echelon have been reclassified from continuing operations to discontinued operations, as follows:

|  | Years ended December 31, |       |
|--|--------------------------|-------|
|  | 2007                     | 2006  |
|  | \$                       | \$    |
| <b>Revenues</b>  | 2,358                    | 2,593 |
| <b>Loss before the following items</b>                                       | (206)                    | (369) |
| Goodwill impairment  | (500)                    |       |
| Loss on disposal of Echelon shares, net of cumulative translation adjustment | (44)                     |       |
| Income tax recovery  | 491                      | 92    |

except share/option and per share/option data and as otherwise noted)

|  |       |       |
|--|-------|-------|
| <b>Net loss from discontinued operations</b> | (259) | (277) |
|--|-------|-------|

135

---

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**6** Long-lived assets held for sale

**In September 2007, as part of its strategy to finance with non-dilutive vehicles, using non-core assets, the Company decided to dispose of its building and land located in Quebec City, as well as its rights to intangible property, Impavido® (miltefosine) and certain equipment. As at December 31, 2007, the assets reclassified as long-lived assets held for sale can be summarized as follows:**

| Asset                      | Cost<br>\$ | Accumulated<br>depreciation and<br>amortization<br>\$ | Net book value<br>\$ |
|----------------------------|------------|---|----------------------|
| Building and Land          | 11,181     | 3,919   | 7,262                |
| Equipment                  | 1,347      | 1,164   | 183                  |
| Intangible property        | 11,851     | 5,297   | 6,554                |
| Total assets held for sale | 24,379     | 10,380  | 13,999               |

In 2006, following the decision to terminate the pharmaceutical development of one of its products, the Company recorded an impairment on related manufacturing equipment in order to bring it down to its fair value, which was based on the Company's best estimate of realizable value. Accordingly, during 2006, an amount of \$1,060,856 was recorded as an impairment loss included in depreciation of property, plant and equipment.

**In December 2007, management evaluated the net realizable value of the Quebec City building and land based on certain preliminary offers received from third parties. That evaluation resulted in the determination that the assets held for sale were impaired, and, accordingly, the Company recorded an impairment charge of \$735,000 against the assets held for sale.**





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

On March 1, 2008, the Company entered into a definitive purchase and sale agreement with respect to all rights related to the manufacture, production, distribution, marketing, sale and/or use of Impavido® (miltefosine) with Paladin Labs Inc., for an aggregate purchase price of approximately \$9,200,000, payable in cash, subject to certain post-closing purchase price adjustments. The transaction, which closed on March 31, 2008, generated net cash proceeds of \$8,309,000, resulting in a gain of \$775,000.

On June 26, 2008, the Company sold the Quebec City building and land for a gross amount of \$7,061,000, payable in cash. The net proceeds received amounted to \$6,545,000, resulting in an additional loss on sale of \$810,000.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

In connection with the sale of the Quebec City building and land, the Company entered into a long-term lease agreement with the principal tenant of the building. As part of the agreement, the Company agreed to pay the principal tenant CAN\$300,000 (approximately \$246,305) as an incentive and service fee. This fee is included in the additional loss on sale, and the resulting payable is non interest-bearing and is due in bi-annual instalments of CAN\$30,000 (approximately \$24,630) over the next five years (see also note 15).

7                      Sale of Cetrotide® royalty stream



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

In June 2003, the Company had amended certain sections of a license and supply agreement with ARES Trading S.A. ( Merck Serono ) in which the latter was granted worldwide marketing, distribution and selling rights, except in Japan, for Cetrotide®, a compound used for *in vitro* fertilization (referred to as the License Agreement). Under the License Agreement, Merck Serono had agreed to pay certain lump sum payments to the Company each calendar year up to and including December 31, 2010 as well as certain variable royalties through the expiry date of Company's underlying patent rights.

In November 2008, the Company entered into a purchase and sale agreement ( PSA ) with Cowen Healthcare Royalty Partners L.P. ( Cowen ) relating to the Company's rights to royalties on future sales of Cetrotide® covered by the License Agreement.

In connection with the PSA, which was effective for royalty determination purposes on October 1, 2008 and finalized in December 2008, the Company received \$52,500,000 from Cowen, less certain transaction costs of \$1,000,000 that had been advanced by Cowen to certain third-party firms and institutions on the Company's behalf, resulting in net proceeds of \$51,500,000. Under the terms of the PSA, the Company is entitled to an additional payment of \$2,500,000 contingent on 2010 net sales of Cetrotide® reaching a specified level.

Per the PSA, if cetrotirelix, the active substance in Cetrotide®, is approved for sale by European regulatory authorities in an indication other than *in vitro* fertilization, the Company has agreed to make a one-time cash payment to Cowen in an amount ranging from \$5,000,000 up to a maximum of \$15,000,000. The amount which may be due to Cowen will be higher in proportion to the timing of the product's receiving European regulatory approval; that is, the earlier the product receives regulatory approval, the higher the amount payable to Cowen will be.

Also per the PSA, for each calendar quarter in which a royalty rate reduction defined as the actual reduction by Merck Serono, for any calendar quarter(s), of the rate applied in calculating variable royalties under the License Agreement, to amounts less than pre-established percentages has occurred or is continuing, the Company will pay Cowen a quarterly make-whole payment in an amount equal to the lesser of (i) the variable royalties in respect of such quarter that would have been received by Cowen if the aforementioned royalty rate reduction had not occurred or been continuing, and (ii) the difference of \$15,000,000 less Cowen's net reduction payments, as defined.

Pursuant to the aforementioned transactions, the Company has certain obligations in the royalty arrangement, including the supply of Cetrotide® to Merck Serono, the payment of royalties to a third party under the License Agreement, overseeing Merck-Serono's compliance with the License Agreement,

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

cooperation in handling any adverse claims or litigation involving the License Agreement and monitoring and defending any patent or trademark infringement.

The Company has recorded the proceeds, as per the provisions of Issue No. 88-18, "Sales of Future Revenues", as promulgated by the Financial Accounting Standards Board's (FASB) Emerging Issues Task Force (EITF) in the United States, as deferred revenues, which are recognizable as royalty revenues over the life of the License Agreement under the "units-of-revenue" method. Under that method, periodic royalty revenues are calculated by multiplying 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 by the royalty payments due to Cowen for the period.

The Company has and will continue to recognize royalty expenses in each period based on the transaction costs, which have been capitalized as deferred charges in the accompanying balance sheet as of December 31, 2008 (see note 10), in the same manner and over the same period in which the related deferred revenues are recognized as royalty revenues.

During the quarter ended December 31, 2008, the Company has recorded approximately \$1,355,000 as royalty revenues and \$124,000 as royalty expense, which is included in selling, general and administrative expenses in the accompanying consolidated statement of earnings (loss).

8 Other receivables

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

|  | As at December 31, |       |
|--|--------------------|-------|
|  | 2008               | 2007  |
|  | \$                 | \$    |
| Interest   |                    | 272   |
| Grants   |                    | 1,060 |
| Research and development tax credits recoverable | 82                 | 252   |
| Commodity taxes                                  | 870                | 453   |
| Other  | 148                | 1,007 |
|  | 1,100              | 3,044 |

9 Inventory

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

|                  | As at December 31, |       |
|------------------|--------------------|-------|
|                  | 2008               | 2007  |
|                  | \$                 | \$    |
| Raw materials    | 2,367              | 3,399 |
| Work in progress | 682                | 1,602 |
| Finished goods   | 336                | 405   |
|                  | 3,385              | 5,406 |

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

For the years ended December 31, 2008, 2007 and 2006, cost of sales, as presented in the accompanying consolidated statements of earnings (loss), almost exclusively represents the amount of inventory recognized as an expense during the year.

In December 2008, the Company wrote down certain inventory items, consisting predominantly of raw materials, to their estimated net realizable values. The adjustment, which amounted to approximately \$726,000 (nil in 2007), has been recorded as an additional cost of sales in the accompanying consolidated statement of earnings (loss).

**10** Deferred charges and other long-term assets





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

|   | As at December 31, |       |
|---|--------------------|-------|
|   | 2008               | 2007  |
|   | \$                 | \$    |
| Royalty sale transaction expenses (notes 2 and 7) | 4,655              |       |
| Deferred charges                                  | 929                | 1,051 |
| Other   | 375                | 390   |
|   | 5,959              | 1,441 |

Included in the above deferred charges as at December 31, 2008 is \$680,111 of cost related to the filing of a shelf prospectus (\$392,000 as at December 31, 2007).

11 Property, plant and equipment

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

|                          | As at December 31, |              |        |              |
|--------------------------|--------------------|--------------|--------|--------------|
|                          | 2008               | 2008         | 2007   | 2007         |
|                          | Cost               | Accumulated  | Cost   | Accumulated  |
|                          | \$                 | depreciation | \$     | depreciation |
|                          |                    | \$           |        | \$           |
| Equipment                | 9,384              | 4,737        | 9,379  | 3,923        |
| Office furniture         | 1,394              | 410          | 1,261  | 648          |
| Computer equipment       | 1,071              | 874          | 1,174  | 805          |
| Automotive equipment     |                    |              | 38     | 36           |
| Leasehold improvements   | 1,139              | 285          | 1,170  | 150          |
|                          | 12,988             | 6,306        | 13,022 | 5,562        |
| Less:                    |                    |              |        |              |
| Accumulated depreciation | 6,306              |              | 5,562  |              |
| Net amount               | 6,682              |              | 7,460  |              |

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**12** Intangible assets

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

|   | 2008       |                                   | As at December 31, |                                   | 2007       |                                   |
|---|------------|-----------------------------------|--------------------|-----------------------------------|------------|-----------------------------------|
|   | Cost<br>\$ | Accumulated<br>amortization<br>\$ | Cost<br>\$         | Accumulated<br>depreciation<br>\$ | Cost<br>\$ | Accumulated<br>depreciation<br>\$ |
| In-process research and development, patents and trademarks | 42,146     | 18,391                            | 47,758             | 17,514                            |            |                                   |
| Technology and other  | 767        | 628                               | 740                | 593                               |            |                                   |
|   | 42,913     | 19,019                            | 48,498             | 18,107                            |            |                                   |
| Less: Accumulated amortization                              | 19,019     |                                   | 18,107             |                                   |            |                                   |
| Net amount  | 23,894     |                                   | 30,391             |                                   |            |                                   |

In 2002, the Company granted an exclusive license to Ardana Bioscience Ltd. ( Ardana ) for the development and commercialization of teverelix, a luteinizing hormone-releasing hormone ( LHRH ) antagonist, for all therapeutic uses worldwide with the exception of Japan, Korea and Taiwan. On April 2, 2004, Ardana acquired full worldwide rights and was assigned the intellectual property rights relating to teverelix and the underlying microcrystalline suspension technology for the use of teverelix and any other potential LHRH antagonists.

The agreement with Ardana provides, among other things, certain guaranteed payments and additional milestone payments upon successful achievement of a certain level of sales and low single-digit royalties on future worldwide net sales.

In June 2008, Ardana communicated that it was entering into voluntary administration, and, consequently, clinical studies and future development efforts were suspended. Additional correspondence was received in January 2009 from Ardana s appointed administrators, providing further evidence that future cash flows are no longer likely to be received by the Company in connection with the aforementioned license agreement, on which the recoverability of teverelix exclusively depends.

Given these facts, the Company has determined that teverelix was impaired, and consequently, an impairment charge to amortize the full remaining carrying value of the intangible asset, or approximately \$2,362,000, was recorded in the accompanying consolidated statement of earnings (loss), and the asset was written off. Additionally, the remaining balance of deferred revenues, amounting to approximately \$1,047,000, was fully recognized in the accompanying consolidated statement of earnings (loss).

Amortization expense for intangible assets in each of the next five fiscal years will amount to approximately \$2,808,040 in 2009, and \$2,780,430 in 2010, 2011, 2012 and 2013.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**13**                      Goodwill

The change in the carrying value is as follows:

|  | Continuing<br>operations<br>\$ | Discontinued<br>operations<br>\$ |
|--|--------------------------------|----------------------------------|
| <b>Balance as at December 31, 2006</b>                                       | 9,509                          | 1,239                            |
| Impact of foreign exchange rate changes                                      | 983                            | 212                              |
| Reduction and impairment of goodwill related to disposal of Echelon (note 5) |                                | (1,451)                          |
| <b>Balance as at December 31, 2007</b>                                       | 10,492                         |                                  |
| Impact of foreign exchange rate changes                                      | (409)                          |                                  |
| <b>Balance as at December 31, 2008</b>                                       | 10,083                         |                                  |

14                      Accounts payable and accrued liabilities

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

|                                | As at December 31, |        |
|--------------------------------|--------------------|--------|
|                                | 2008               | 2007   |
|                                | \$                 | \$     |
| Trade payables                 | 10,256             | 11,404 |
| Salaries and employee benefits | 899                | 1,628  |
| Other accrued liabilities      | 2,535              | 3,052  |
|                                | 13,690             | 16,084 |



Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**15** Long-term debt and payable

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

|   | As at December 31, |      |
|---|--------------------|------|
|   | 2008               | 2007 |
|   | \$                 | \$   |
| Loan from the federal and provincial governments, nominal value of CAN\$800 discounted at an effective rate of 8.43% (nil in 2008 and CAN\$769 in 2007) non-interest bearing, payable in five annual equal and consecutive instalments since July 2004. |                    | 775  |
| Long-term payable (note 6)  | 221                |      |
|   | 221                | 775  |
| Less: Current portion   | 49                 | 775  |
|   | 172                |      |

16 Employee future benefits



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

The Company's subsidiary in Germany provides unfunded defined benefit pension plans and unfunded postemployment 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 plans' accrued benefits obligations:

|            |   | Pension benefit plans |       |       | Other benefit plans |      |      |
|------------|---|-----------------------|-------|-------|---------------------|------|------|
|            |   | 2008                  | 2007  | 2006  | 2008                | 2007 | 2006 |
|            |   | \$                    | \$    | \$    | \$                  | \$   | \$   |
| Obligation | Beginning of year                                   | 8,390                 | 7,547 | 6,932 | 794                 | 620  | 523  |
|            | Current service cost                                | 216                   | 352   | 293   | 47                  | 29   | 39   |
|            | Interest cost                                       | 473                   | 269   | 293   | 44                  | 52   | 22   |
|            | Actuarial loss (gain)                               | 544                   | (490) | (674) | 230                 | 104  | 53   |
|            | Benefits paid                                       | (89)                  | (70)  | (64)  | (163)               | (81) | (70) |
|            | Effect of foreign currency<br>exchange rate changes | (357)                 | 782   | 767   | (37)                | 70   | 53   |
| Obligation | End of year   | 9,177                 | 8,390 | 7,547 | 915                 | 794  | 620  |
|            | Expenses (recovery) recognized                      | 1,233                 | 131   | (88)  | 321                 | 185  | 114  |

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

The significant actuarial assumptions adopted to determine the Company's accrued benefit obligations are as follows:

|                               | Pension benefit plans |              |              | Other benefit plans |      |      |
|-------------------------------|-----------------------|--------------|--------------|---------------------|------|------|
|                               | 2008                  | 2007         | 2006         | 2008                | 2007 | 2006 |
|                               | %                     | %            | %            | %                   | %    | %    |
| <b>Actuarial assumptions</b>  |                       |              |              |                     |      |      |
| Discount rate for expenses    | 5.60                  | 4.50         | 4.00         | 5.60                | 4.50 | 4.00 |
| Discount rate for liabilities | 5.60                  | 5.70         | 4.50         | 5.60                | 5.70 | 4.50 |
| Pension benefits increase     | 2.00                  | 2.00         | 1.25         | 2.00                | 2.00 | 1.25 |
| Rate of compensation increase | 2.75 to 3.75          | 2.75 to 3.75 | 2.75 to 3.75 | 2.75                | 2.75 | 2.75 |

The last actuarial reports give effect to the pension and postemployment benefit obligations as at December 31, 2008. The next actuarial reports are planned for December 2009.

In accordance with the assumptions used as at December 31, 2008, the benefits expected to be paid in each of the next five fiscal years will amount to \$278,391 in 2009, \$283,490 in 2010, \$322,858 in 2011, \$453,659 in 2012 and \$477,081 in 2013. Furthermore, total benefits amounting to \$2,724,020 are expected to be paid from 2014 to 2018.

Cash required in the next year to fund the plans will approximate the amount of expected benefits.

**Defined contribution plans**

Total expenses for defined contribution pension plans amounted to \$344,237 in 2008 (\$285,824 in 2007 and \$263,810 in 2006).

except share/option and per share/option data and as otherwise noted)

The Company sponsors a matching defined benefit plan in its Canadian headquarters. Under this plan, the Company may contribute amounts equal to a percentage of employee contributions to the plan. During the year ended December 31, 2008, matching contributions to the plan totalled \$67,184. For the years ended December 31, 2007 and 2006, the Company did not record any contributions.

The Company also sponsors a 401K plan in its US subsidiary. Under this plan, the Company may contribute a discretionary amount equal to a percentage of employee contributions to the plan and may also make discretionary profit sharing contributions. During the year ended December 31, 2008, matching contributions to the plan amounted to \$69,155. During the years ended December 31, 2007 and 2006, the Company did not record any contributions.

Total cash payments for employee future benefits in 2008, consisting of cash contributed by the Company to its defined contribution plans as well as direct payments to retired employees, amount to \$595,638 (\$436,696 in 2007 and \$398,340 in 2006).

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**17**                      Share capital





(a) Authorized



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

Unlimited number of shares of the following classes:

Common, voting and participating, one vote per share, no par value Preferred, first and second ranking, issuable in series, with rights and privileges specific to each class.

(b) Common share issues



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

Pursuant to the exercise of stock options, the Company issued, during fiscal 2007, 18,000 common shares for total proceeds of \$33,200. Consequently, stock-based compensation costs of \$26,000 relating to those exercised options have been reclassified from other capital to share capital.

On February 14 and 17, 2006, the Solidarity Fund QFL (the Fund ) and SGF Santé inc. ( SGF ), respectively, exercised early their right to convert the entirety of their convertible term loans in the principal amount of CAN\$12,500,000 each that they had extended to the Company in April 2003 and that were to mature on March 31, 2006. In accordance with the terms of the convertible term loans and additional arrangements between the Company, the Fund and SGF, Aeterna Zentaris issued to each of the loan holders 3,477,544 of its common shares upon conversion of their loans, representing the principal and interest due to the stated maturity date under the loans, based on the conversion price that had been agreed upon in the loan agreements.

For accounting purposes, the convertible term loans are separated between debt and equity, the equity portion representing the value of the holders' conversion options. As a consequence of this transaction, the Company recorded a loss on settlement of long-term debt amounting to \$599,190, representing an inducement to the original terms of the loan agreements. An amount of \$280,000 was recorded in the statement of deficit, and the remainder was charged to expense in the statement of earnings (loss) and was included in the accretion on convertible term loans in the statement of cash flows.

(c) Shareholder right plan



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

On March 29, 2004, the Company adopted a shareholder right plan (the Rights Plan ). The continuation of the Rights Plan and its amendments and restatement has been approved by the Board of Directors on March 5, 2007. 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 its related party(ies), 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

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

(d) Company's stock option plan





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

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, as per a resolution approved by the Company's Board of Directors on March 4, 2008, cannot exceed eleven point four percent (11.4%) of the total number of issued and outstanding common shares at any given time.

On June 26, 2008, the Toronto Stock Exchange accepted a stock option pool totalling 6,063,371. In 2008, 735,000 options were granted in Canadian dollars, and no options were granted in US dollars. 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. The following table summarizes the stock option activity under the Stock Option Plan:

### Canadian dollar denominated awards

|                     |                       | 2008      |   | Years ended December 31,<br>2007 |   | 2006      |   |
|---------------------|-----------------------|-----------|---|----------------------------------|---|-----------|---|
|                     |                       | Number    | Weighted average exercise price (CAN\$) | Number                           | Weighted average exercise price (CAN\$) | Number    | Weighted average exercise price (CAN\$) |
| Balance             | Beginning of year (*) | 4,136,092 | 3.83                                    | 3,490,092                        | 4.00                                    | 3,843,592 | 6.16                                    |
| Granted             |                       | 735,000   | 0.59                                    | 815,000                          | 3.24                                    | 45,000    | 6.41                                    |
| Exercised           |                       |           |   | (18,000)                         | 1.96                                    | (22,000)  | 3.98                                    |
| Forfeited           |                       | (165,000) | 3.41                                    | (151,000)                        | 4.93                                    | (30,500)  | 6.21                                    |
| Expired             |                       | (215,333) | 4.51                                    |                                  |   | (346,000) | 7.68                                    |
| Balance             | End of year           | 4,490,759 | 3.28                                    | 4,136,092                        | 3.83                                    | 3,490,092 | 6.02                                    |
| Options exercisable | End of year           | 3,462,441 | 3.91                                    | 3,300,593                        | 4.02                                    | 2,736,099 | 5.88                                    |

(\*) Following the one-time distribution of the Company's remaining interest in Atrium on January 2, 2007 and as contemplated under the Stock Option Plan (see note 4), the Board of Directors of the Company approved an equitable adjustment to all unexercised options outstanding pursuant to the Stock Option Plan. The adjustment was a reduction in the exercise price of all outstanding stock options of CAN\$2.02 per common share. Furthermore, in 2007 the Board of Directors approved the extension of the option period from 1 month to 3 years on 875,000 options in connection with the departure of executive members.

The total intrinsic value for stock options exercised in 2006 and 2007 was CAN\$68,959 and CAN\$24,040, respectively. There is no tax benefit realized by the Company, since the compensation cost related to stock options is not deductible for income tax purposes.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

The following tables summarize the stock options outstanding and exercisable as at December 31, 2008:

| Exercise price<br>(CAN\$) | Number    | Options outstanding  |   | Global<br>intrinsic value<br>(CAN\$) |
|---------------------------|-----------|--|---|--------------------------------------|
|                           |           | Weighted average<br>remaining<br>contractual life<br>(years) | Weighted average<br>exercise price<br>(CAN\$) |                                      |
| 0.55 to 1.70              | 735,000   | 9.91   | 0.59  | 12                                   |
| 1.71 to 2.40              | 1,018,093 | 6.03   | 1.77  |                                      |
| 2.41 to 3.60              | 863,500   | 5.25   | 3.22  |                                      |
| 3.61 to 5.00              | 790,333   | 5.04   | 4.09  |                                      |
| 5.01 to 8.88              | 1,083,833 | 4.77   | 5.99  |                                      |
|                           | 4,490,759 | 6.04   | 3.28  | 12                                   |

| Exercise price<br>(CAN\$) | Number    | Options currently exercisable                 |      | Global<br>intrinsic<br>value<br>(CAN\$) |
|---------------------------|-----------|---|------|---|
|                           |           | Weighted average<br>exercise price<br>(CAN\$) |      |   |
| 0.55 to 1.70              |           |   |      |   |
| 1.71 to 2.40              | 808,100   |   | 1.75 |   |
| 2.41 to 3.60              | 863,500   |   | 3.22 |   |
| 3.61 to 5.00              | 707,008   |   | 4.02 |   |
| 5.01 to 8.88              | 1,083,833 |   | 5.99 |   |
|                           | 3,462,441 |   | 3.91 |   |

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**US dollar denominated awards**

|                     |                   | 2008      |  | Years ended December 31, 2007 |  | 2006   |  |
|---------------------|-------------------|-----------|--|-------------------------------|--|--------|--|
|                     |                   | Number    | Weighted average exercise price (US\$) | Number                        | Weighted average exercise price (US\$) | Number | Weighted average exercise price (US\$) |
| Balance             | Beginning of year | 870,000   | 2.79                                   |                               |  |        |  |
|                     | Granted           |           |  | 870,000                       | 2.79                                   |        |  |
|                     | Forfeited         | (556,666) | 2.80                                   |                               |  |        |  |
| Balance             | End of year       | 313,334   | 2.76                                   | 870,000                       | 2.79                                   |        |  |
| Options exercisable | End of year       | 176,669   | 3.08                                   |                               |  |        |  |

| Exercise price (US\$) | Number  | Options outstanding                                 |  | Global intrinsic value |
|-----------------------|---------|---|--|------------------------|
|                       |         | Weighted average remaining contractual life (years) | Weighted average exercise price (US\$) |                        |
| 1.68 to 1.87          | 135,000 | 8.93  | 1.82                                   |                        |
| 1.88 to 3.96          | 178,334 | 8.34  | 3.48                                   |                        |
|                       | 313,334 | 8.59  | 2.76                                   |                        |

| Exercise price (US\$) | Number  | Options currently exercisable          |  | Global intrinsic value |
|-----------------------|---------|--|--|------------------------|
|                       |         | Weighted average exercise price (US\$) |  |                        |
| 1.68 to 1.87          | 45,001  | 1.82                                   |  |                        |
| 1.88 to 3.96          | 131,668 | 3.52                                   |  |                        |
|                       | 176,669 | 3.08                                   |  |                        |



Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

As at December 31, 2008, the total compensation cost related to nonvested stock options not yet recognized amounted to \$347,390 (\$1,366,409 in 2007). This amount is expected to be recognized over a weighted average period of 1.56 years (1.88 years in 2007).

The Company settles stock options exercised through the issuance of common shares from treasury.

The factors considered in developing the assumptions used in the Black-Scholes option pricing model are the following:

- (a) The risk-free interest rate is based on Canadian Government Bond constant maturity interest rate whose term is consistent with the expected life of the stock options.



(b) The historical volatility of the Company's stock price as well as future expectations are used to establish the expected stock price volatility.





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

(c) The Company estimates the expected life of stock options based upon employee s historical data related to the exercise of stock options and post-vesting employment terminations.



**Assumptions used in determining stock-based compensation costs**

The table below shows the assumptions used in determining stock-based compensation costs under the Black-Scholes option pricing model:

|  | 2008      | Years ended December 31,<br>2007 | 2006      |
|--|-----------|----------------------------------|-----------|
| Dividend yield                         | Nil       | Nil                              | Nil       |
| Expected volatility                    | 60.0%     | 57.2%                            | 58.1%     |
| Risk-free interest rate                | 1.98%     | 3.88%                            | 4.06%     |
| Expected life (years)                  | 3.04      | 4.62                             | 5.77      |
| Weighted average grant date fair value | CAN\$0.25 | US\$1.93 and<br>CAN\$2.25        | CAN\$3.67 |

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**18**                      Statements of cash flows

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

|   | Years ended December 31, |         |         |
|---|--------------------------|---------|---------|
|   | 2008                     | 2007    | 2006    |
|   | \$                       | \$      | \$      |
| <b>Changes in operating assets and liabilities:</b> |                          |         |         |
| Accounts receivable                                 | 4,353                    | 1,371   | 2,686   |
| Inventory   | 1,171                    | 148     | 650     |
| Prepaid expenses and other current assets           | (55)                     | (708)   | 263     |
| Deferred charges and other long-term assets         | (4,689)                  |         | (991)   |
| Accounts payable and accrued liabilities            | (1,089)                  | 5,340   | 1,848   |
| Income taxes  | 775                      | (1,250) | (5,260) |
| Deferred revenues                                   | 58,058                   | 644     | 1,883   |
|   | 58,524                   | 5,545   | 1,079   |

|                               | Years ended December 31, |       |       |
|-------------------------------|--------------------------|-------|-------|
|                               | 2008                     | 2007  | 2006  |
|                               | \$                       | \$    | \$    |
| <b>Additional information</b> |                          |       |       |
| Interest paid                 |                          |       |       |
| From continuing operations    | 29                       |       | 4     |
| From discontinued operations  |                          | 9     | 7,784 |
| Income taxes paid (recovered) |                          |       |       |
| From continuing operations    | 293                      | (937) | 5,756 |
| From discontinued operations  |                          | 7     | 8,698 |

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**19**                      Income taxes





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

The reconciliation of the combined Canadian federal and Quebec provincial income tax rate to the income tax (expense) recovery from continuing operations is as follows:

|   | 2008     | Years ended December 31,<br>2007 | 2006    |
|---|----------|----------------------------------|---------|
| Combined federal and provincial statutory income tax rate             | 30.90%   | 32.02%                           | 32.02%  |
|   | \$       | \$                               | \$      |
| Income tax recovery based on statutory income tax rate                | 18,120   | 10,886                           | 6,872   |
| Change in valuation allowance   | (17,554) | (6,963)                          | 22,644  |
| Minimum tax attributable to German subsidiary                         | (1,175)  |                                  |         |
| Accretion on convertible term loans                                   |          |                                  | (258)   |
| Stock-based compensation costs  | (112)    | (635)                            | (679)   |
| Difference in statutory income tax rate of foreign subsidiaries       | 576      | (16)                             | 994     |
| Permanent difference attributable to unrealized foreign exchange gain | 494      |                                  |         |
| Change in enacted rates used  | (985)    | (1,345)                          | 2,428   |
| Tax loss consolidation strategy                                       |          |                                  | (2,376) |
| Other   | (539)    | 34                               | (588)   |
|   | (1,175)  | 1,961                            | 29,037  |

### *Loss before income taxes*

The loss before income taxes from continuing operations is allocated as follows:

|               | 2008     | Years ended December 31,<br>2007 | 2006     |
|---------------|----------|----------------------------------|----------|
|               | \$       | \$                               | \$       |
| Canada        | (5,103)  | (10,556)                         | (10,436) |
| Germany       | (52,730) | (23,276)                         | (11,024) |
| United States | (809)    | (166)                            |          |
|               | (58,642) | (33,998)                         | (21,460) |

Table of Contents**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

|  | 2008    | Years ended December 31,<br>2007 | 2006   |
|--|---------|----------------------------------|--------|
|  | \$      | \$                               | \$     |
| Income tax recovery (expense) is represented by: |         |                                  |        |
| Current  | (1,175) | 93                               | (123)  |
| Future   |         | 1,868                            | 29,160 |
|  | (1,175) | 1,961                            | 29,037 |
| Current:   |         |                                  |        |
| Foreign  | (1,175) | 93                               | (123)  |
| Future:  |         |                                  |        |
| Domestic   |         | (284)                            | 25,036 |
| Foreign  |         | 2,152                            | 4,124  |
|  |         | 1,868                            | 29,160 |
|  | (1,175) | 1,961                            | 29,037 |

Foreign operations are predominantly in Germany.

Table of Contents**Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

Significant components of future income tax assets and liabilities are as follows:

|   | As at December 31, |          |
|---|--------------------|----------|
|   | 2008               | 2007     |
|   | \$                 | \$       |
| Future income tax assets                    |                    |          |
| Current                                     |                    |          |
| Deferred revenues                           | 2,459              | 1,738    |
| Inventory                                   | 526                | 658      |
|   | 2,985              | 2,396    |
| Long-term                                   |                    |          |
| Research and development costs              | 8,961              | 12,119   |
| Share issue expenses                        | 129                | 91       |
| Operating losses carried forward            | 15,543             | 17,145   |
| Property, plant and equipment               | 576                | 1,973    |
| Intangible assets and goodwill              | 10,817             | 206      |
| Employee future benefits                    | 747                | 648      |
| Deferred revenues                           |                    | 1,211    |
| Other                                       |                    | 144      |
|   | 36,773             | 33,537   |
| Valuation allowance                         | (36,581)           | (23,289) |
|   | 192                | 10,248   |
|   | 3,177              | 12,644   |
| Future income tax liabilities               |                    |          |
| Long-term                                   |                    |          |
| Accounts receivable                         | 65                 | 48       |
| Property, plant and equipment               | 330                | 190      |
| Deferred charges and other long-term assets | 1,566              | 2,434    |
| Intangible assets                           |                    | 9,376    |
| Deferred revenues                           | 528                |          |
| Investment tax credits                      |                    | 573      |
| Other                                       | 688                | 23       |

except share/option and per share/option data and as otherwise noted)

3,177

12,644

**Future income tax assets (liabilities), net**

152

---

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

As at December 31, 2008, the Company has estimated non-refundable research and development tax credits of \$5,741,778 which can be carried forward to reduce Canadian federal income taxes payable and expire from 2011 to 2028. No tax benefit has been accounted for in connection with those credits.

As at December 31, 2008, the Company had available operating losses in Canada. The following table summarizes the year of expiry of these operating losses by tax jurisdiction:

|      | <b>Federal</b><br>\$ | <b>Canada</b> | <b>Provincial</b><br>\$ |
|------|----------------------|---------------|-------------------------|
| 2010 | 6,337                |               |                         |
| 2014 | 7,977                |               |                         |
| 2015 | 5,645                |               | 26                      |
| 2028 | 11,516               |               | 9,520                   |
|      | 31,475               |               | 9,546                   |

Furthermore, the Company has available operating losses in Germany amounting to approximately \$33,304,000, for which there is no expiry date, as well as in the United States, totalling \$791,163 and expiring as follows:

|      | <b>United States</b><br>\$ |
|------|----------------------------|
| 2027 | 175                        |
| 2028 | 616                        |
|      | 791                        |

The carryforwards and the tax credits claimed could be subjected to a review and a possible adjustment by tax authorities.



Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**20** Segment information for continuing operations

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

Subsequent to the divestiture of Atrium in 2006, the Company operates in one single operating segment, being the biopharmaceutical segment.

### Information by geographic region

Revenues by geographic region are detailed as follows:

|                | 2008<br>\$ | Years ended December 31,<br>2007<br>\$ | 2006<br>\$ |
|----------------|------------|--|------------|
| Canada         | 333        | 400                                    | 25         |
| United States  | 2,987      | 5,911                                  | 4,094      |
| Europe         |            |  |            |
| Switzerland    | 22,770     | 23,316                                 | 20,681     |
| United Kingdom | 3,823      | 5,343                                  | 5,257      |
| Netherlands    | 2,158      | 2,031                                  | 1,748      |
| Other          | 874        | 70                                     | 809        |
| Japan          | 4,029      | 1,862                                  | 6,114      |
| Other          | 1,504      | 3,135                                  | 71         |
|                | 38,478     | 42,068                                 | 38,799     |

Revenues have been allocated to geographic regions based on the country of residence of the related customers.

Customers who represent more than 10% of revenues are as follows:

|            | 2008<br>% | Years ended December 31,<br>2007<br>% | 2006<br>% |
|------------|-----------|---------------------------------------|-----------|
| Customer 1 | 66        | 59                                    | 52        |
| Customer 2 | 10        | 13                                    | 13        |



Table of Contents**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

The following table presents revenues by source:

|                     | 2008   | Years ended December 31,<br>2007 | 2006   |
|---------------------|--------|----------------------------------|--------|
|                     | \$     | \$                               | \$     |
| Revenues            |        |                                  |        |
| Sales and royalties | 29,462 | 28,825                           | 25,123 |
| License fees        | 8,504  | 12,843                           | 13,652 |
| Other               | 512    | 400                              | 24     |
|                     | 38,478 | 42,068                           | 38,799 |

Long-lived assets by geographic region are detailed as follows:

|               | As at December 31, |        |
|---------------|--------------------|--------|
|               | 2008               | 2007   |
|               | \$                 | \$     |
| Canada        | 110                | 7,643  |
| United States | 615                | 841    |
| Germany       | 39,934             | 53,858 |
|               | 40,659             | 62,342 |

Long-lived assets consist of property, plant and equipment, long-lived assets held for sale (2007 only), intangible assets and goodwill.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**21** Earnings (loss) per share

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

The information utilized in the computation of net earnings (loss) per share, as presented in the accompanying consolidated statements of earnings (loss), is as follows:

|  | 2008<br>\$ | Years ended December 31,<br>2006<br>\$ | 2007<br>\$ |
|--|------------|--|------------|
| <b>Net earnings (loss) from continuing operations</b>  | (59,817)   | (32,037)                               | 7,577      |
| <b>Net earnings (loss) from discontinued operations</b>  |            | (259)                                  | 25,813     |
| Impact of assumed conversion of dilutive stock options of Atrium   |            |  | (754)      |
| <b>Net earnings (loss) from discontinued operations, adjusted for dilution effects</b>   |            | (259)                                  | 25,059     |
| <b>Net earnings (loss) adjusted for dilution effects</b>   | (59,817)   | (32,296)                               | 32,636     |
| <b>Basic weighted average number of shares outstanding</b>   | 53,187,470 | 53,182,803                             | 52,099,290 |
| Dilutive effect of stock options   | 18,315     | 500,171                                | 449,970    |
| <b>Diluted weighted average number of shares outstanding</b>   | 53,205,785 | 53,682,974                             | 52,549,260 |
| <b>Items excluded from the calculation of diluted net earnings (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  | 4,069,093  | 3,164,499                              | 1,893,539  |
| Common shares which would have been issued following the conversion of the convertible term loans  |            |  | 776,237    |

For the years ended December 31, 2008 and 2007, the diluted amounts per share were the same amounts as the basic amounts per share since the dilutive effect of stock options and convertible term loans was not included in the calculation; otherwise, the effect would have been anti-dilutive. Accordingly, the diluted amounts per share for those years were calculated using the basic weighted average number of shares outstanding.

Table of Contents**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**22 Related party transactions**

|  | Years ended December 31, |      |      |
|--|--------------------------|------|------|
|  | 2008                     | 2007 | 2006 |
|  | \$                       | \$   | \$   |
| Administrative revenues                            | Nil                      | Nil  | 35   |
| Lease revenues                                     | Nil                      | Nil  | 304  |
| Subcontracting revenues and sales of raw materials | Nil                      | Nil  | 66   |
| Subcontracting expenses                            | Nil                      | Nil  | 44   |
| Patent acquired from a senior officer              | Nil                      | Nil  | 175  |

On December 15, 2006, the Company's shareholders approved a reduction in the stated capital of the Company in an amount equal to the fair market value of its remaining interest in Atrium for the purpose of effecting a special distribution in kind of all 11,052,996 Subordinate Voting Shares of Atrium held by the Company. This transaction was completed on January 2, 2007, thus eliminating the related party relationship.

These above transactions in 2006 with our former subsidiary Atrium and a senior officer were in the normal course of operations. They were measured at the exchange amount, which is the amount of consideration established and agreed upon by the related parties. The price of the shares issued for the acquisition of the patent was based on the closing trading price of the Company's shares on February 28, 2006, being the day before the signing of the agreement.

The transactions with Atrium include amounts that occurred before October 18, 2006 and that were previously eliminated from the consolidated financial statements but continue to occur after the disposal.

**23 Capital disclosures**

The Company's objective in managing capital composed of shareholders' equity is to ensure a sufficient liquidity position to finance its research and development activities, general and administrative expenses, working capital and overall capital expenditures. The Company makes every effort to manage its liquidity to minimize dilution to its shareholders.

except share/option and per share/option data and as otherwise noted)

Initially, the Company had funded its activities through public offerings of common shares and convertible term loans. More recently, however, the Company has tried to optimize its liquidity needs by non-dilutive sources, including the sale of non-core assets and future rights to royalties, investment tax credits and grants, interest income, licensing, service and royalties.

During 2008, the Company fulfilled its obligation on the loan from the federal and provincial governments with a nominal value of CAN\$800,000, as discussed in note 15.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

The capital management objective of the Company remains the same as that of previous years. The policy on dividends is to retain cash to keep funds available to finance the activities required to advance our product development pipeline, prioritizing our lead product candidate, cetrotorelix, in Phase 3 for BPH. The Statements of Changes in Shareholders' Equity describe the activity impacting the Company's capital.

The Company is not subject to any capital requirements imposed by any regulators or any other external source.

**24 Financial instruments and financial risk management**

**Short-term investments**

The Company's short-term investments as at December 31, 2008 and 2007 were comprised of the following:

|   | As at December 31, |        |
|---|--------------------|--------|
|   | 2008               | 2007   |
|   | \$                 | \$     |
| Discount notes bearing interest at an annual rate of 2.06% in 2008 and at effective annual rates ranging from 3.94% to 4.23% in 2007. The 2008 balances will mature in December 2009, and the 2007 balances matured on different dates from May to December 2008. | 493                | 5,178  |
| Bonds, bearing interest at effective annual rates ranging from 2.81% to 4.43% in 2007, maturing on different dates from January to November 2008.   |                    | 25,937 |
|   | 493                | 31,115 |

Short-term investments totalled CAN\$601,766 in 2008 and CAN\$30,844,365 in 2007.

except share/option and per share/option data and as otherwise noted)

**Fair value**

Cash and cash equivalents, short-term investments, accounts receivable and accounts payable and accrued liabilities are financial instruments whose fair value approximates their carrying value due to their short-term maturity. While the Company had no long-term debt as at December 31, 2008, the approximate fair value of long-term debt as at December 31, 2007 was \$775,000. The fair value of long-term debt was established by discounting the future cash flows at an interest rate corresponding to that which the Company would currently be able to obtain for loans with similar maturity dates and terms.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**Financial risk management**

Disclosures relating to the nature and extent of the Company's exposure to risks arising from financial instruments, including credit risk, liquidity risk, foreign currency risk and interest rate risk, and how the Company manages those risks, are presented below.

(a) *Credit risk*

Credit risk is the risk of an unexpected loss if a customer or third party to a financial instrument fails to meet its contractual obligations. The Company regularly monitors its credit risk exposure and takes steps to mitigate the likelihood of these exposures from resulting in actual loss.

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents, short-term investments and accounts receivable. Cash and cash equivalents are maintained with high-credit quality financial institutions. Short-term investments consist primarily of bonds and notes issued by high-credit quality corporations and institutions. Consequently, management considers the risk of non-performance related to cash and cash equivalents and short-term investments to be minimal.

(b) *Foreign Currency Risk*

Since the Company operates on an international scale, it is exposed to currency risks as a result of potential exchange rate fluctuations. Fluctuations in the US dollar ( US\$ ), Canadian dollar ( CAN\$ ) and the Euro ( EUR ) exchange rates 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 variation of -5% (depreciation of CAN\$) and +5% (appreciation of CAN\$) against the EUR, from a period-end rate of EUR1 = CAN\$1.7046.

except share/option and per share/option data and as otherwise noted)



- Foreign exchange rate variation of -5% (depreciation of US\$) and +5% (appreciation of US\$) against the EUR. From a period-end rate of EUR1 = US\$1.3995.

If these variations were to occur, the impact on the Company's consolidated net loss for each category of financial instruments held at December 31, 2008 would be as follows:

Table of Contents**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**Parent location using CAN\$ as functional currency**

|  | Carrying<br>amount<br>\$ | Transactions denominated<br>in EUR |            |
|--|--------------------------|------------------------------------|------------|
|  |                          | -5%<br>\$                          | +5%<br>\$  |
| <b>Assets</b>  |                          |                                    |            |
| Advance to German subsidiary (1)                                   | 7,889                    | (394)                              | 394        |
| Accounts receivable from German subsidiary (2)                     | 6,271                    | (314)                              | 314        |
| <b>Total impact on consolidated net loss - (increase)/decrease</b> |                          | <b>(708)</b>                       | <b>708</b> |

(1) Aeterna Zentaris parent company, located in Canada, has an advance due from its German subsidiary of EUR5,637,246 (CAN\$9,609,250, using a period-end exchange rate 1 EUR = CAN\$1.7046, and US\$7,889,326, using a period-end exchange rate 1 EUR = US\$1.3995), which is eliminated in the consolidated balance sheet. A foreign exchange gain/loss is periodically recorded in the consolidated statement of earnings (loss), since this advance has not been considered to be part of a net investment in a self-sustaining subsidiary.

(2) Accounts receivable, due in the ordinary course of business, amount to EUR4,480,959 (or CAN\$7,638,243, or US\$6,271,102).

**Subsidiary location using EUR as functional currency**

|  | Carrying<br>amount<br>\$ | Transactions denominated<br>in US\$ |              |
|--|--------------------------|-------------------------------------|--------------|
|  |                          | -5%<br>\$                           | +5%<br>\$    |
| <b>Liabilities</b>   |                          |                                     |              |
| Accounts payable due to affiliate (1)                              | 9,989                    | 499                                 | (499)        |
| Trade accounts payable   | 1,451                    | 73                                  | (73)         |
| <b>Total impact on consolidated net loss - (increase)/decrease</b> |                          | <b>572</b>                          | <b>(572)</b> |

except share/option and per share/option data and as otherwise noted)

---

(1) *Aeterna Zentaris* German subsidiary has accounts payable, due in the ordinary course of business, to its US-based affiliate of US\$9,989,076 (EUR7,137,603). Effective on January 1, 2009, due to a change in economic facts and circumstances arising in the first quarter of 2009, the parent company, as well as its US subsidiary, will change its functional currency from the Canadian dollar to the euro. Such change will be reported prospectively.

(c) *Liquidity risk*

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company manages liquidity risk through the management of its capital structure and financial leverage, as outlined in note 23. The Company also manages liquidity risk by continuously monitoring

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

actual and projected cash flow. The Board of Directors reviews and approves the Company's operating and capital budgets, and reviews any material transactions outside of the normal course of business.

The Company's investment policy ensures the safety and preservation of its principal, as outlined in section (a) above, to ensure the Company's liquidity needs are met.

(d) *Financial liabilities as at December 31, 2008*

|  | Carrying<br>Amount<br>\$ | 2009<br>\$    | 2010-2011<br>\$ | After 2011<br>\$ |
|--|--------------------------|---------------|-----------------|------------------|
| Accounts payable and accrued liabilities | 13,690                   | 13,690        |                 |                  |
| Long-term payable                        | 221                      | 49            | 98              | 74               |
|  | <b>13,911</b>            | <b>13,739</b> | <b>98</b>       | <b>74</b>        |

25 Commitments, contingencies and guarantee

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

In addition to the long-term payable discussed in notes 6 and 15, the Company is committed to various operating leases for its premises plus service and manufacturing contracts, as follows:

| Year       | Minimum Lease<br>Commitments<br>\$ | Service &<br>Manufacturing<br>Commitments<br>\$ | Total<br>Commitments<br>\$ |
|------------|------------------------------------|---|----------------------------|
| 2009       | 2,191                              | 15,743  | 17,934                     |
| 2010       | 2,117                              | 3,129   | 5,246                      |
| 2011       | 2,124                              | 845   | 2,969                      |
| 2012       | 2,131                              | 811   | 2,942                      |
| 2013       | 372                                |   | 372                        |
| Thereafter | 1,431                              |   | 1,431                      |
| Total      | 10,366                             | 20,528  | 30,894                     |

As discussed in note 7, in connection with the PSA entered into with Cowen, the Company has agreed to make a one-time cash payment to Cowen in the event that cetorelix is approved for sale by European regulatory authorities in an indication other than *in vitro* fertilization. Such a payment, which is not probable or reasonably estimable as at December 31, 2008, could range from \$5,000,000 to a maximum of \$15,000,000. Also as discussed in note 7, the Company could also be required to pay Cowen a quarterly make-whole payment.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

Rent expense for operating leases, which may have escalating rentals over the term of the lease, are recorded on a straight-line basis over the term of the lease. The rent expense under the operating leases for the periods ended December 31, 2008, 2007 and 2006 was \$1,700,647, \$1,937,000 and \$1,878,000, respectively.

In October 2004, the Company entered into a \$2,500,000 ( 1,750,000) bank guarantee in favour of one of its landlords in Germany with respect to the Company's lease obligation. This guarantee will expire in 2009 and is expected to be renewed at that time.

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. This letter of credit, which would be drawn down and payable by the Company in the event the Company fails to perform any of its obligations under the lease agreement, will expire in August 2009 and will be renewed at or before that time.

**Contingencies**

In the normal course of operations, the Company may become involved in various claims and legal proceedings mainly related to contract terminations, employee lay-offs and other employee-related matters. As at December 31, 2008, there are no known or anticipated contingencies or disputes pending against the company.

**26**                      Subsequent event

On March 5, 2009, the Company entered into a development, commercialization and license agreement with sanofi-aventis for the development, registration and marketing of cetorelix in BPH for the United States market. Under the terms of the agreement, sanofi-aventis will make an initial upfront payment to the Company of \$30,000,000. Also per the agreement, the Company will be entitled to receive a total of \$135,000,000 in payments upon achieving certain pre-established regulatory and commercial milestones. Furthermore, the Company will be entitled to receive escalating double-digit royalties on future net sales of cetorelix for BPH in the United States, while retaining the option to co-promote the product in that territory.

27 Summary of differences between generally accepted accounting principles in Canada and in the United States

As a company listed on the NASDAQ Global Market, the Company is required to reconcile its financial statements for significant measurement differences between Canadian GAAP and US GAAP. Furthermore, additional significant disclosures required under US GAAP and Regulation S-X of the Securities and Exchange Commission in the United States ( SEC ) are also provided in the accompanying financial statements and notes. The following summarizes the significant quantitative differences between Canadian and US GAAP, as well as other significant disclosures required under US GAAP and Regulation S-X of the SEC not already provided in the accompanying financial statements.



Table of Contents**Aeterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

The following summary sets out the material adjustments to the Company's reported net earnings (loss), net earnings (loss) per share and shareholders' equity that would be made to conform with US GAAP:

**Consolidated Statements of Earnings (Loss)**

|  | <b>Years ended December 31,</b> |             |             |
|--|---------------------------------|-------------|-------------|
|  | <b>2008</b>                     | <b>2007</b> | <b>2006</b> |
|  | <b>\$</b>                       | <b>\$</b>   | <b>\$</b>   |
| Net earnings (loss) for the year under Canadian GAAP             | (59,817)                        | (32,296)    | 33,390      |
| Amortization of in-process research and development (a)          | 3,747                           | 1,546       | 2,348       |
| Accretion on convertible term loans (b)                          |                                 |             | 502         |
| Loss on conversion of convertible term loans (b)                 |                                 |             | (280)       |
| Deferred taxes (c)   |                                 | (5,430)     | (959)       |
| Reclassification adjustment related to the sale of Echelon (d)   |                                 | (754)       |             |
| Other  |                                 |             | (10)        |
| Income tax effects of the above adjustments                      |                                 | (494)       | (729)       |
| Net earnings (loss) for the year under US GAAP                   | (56,070)                        | (37,428)    | 34,262      |
| Out of which:  |                                 |             |             |
| Net earnings (loss) from continuing operations                   | (56,070)                        | (36,415)    | 8,449       |
| Net earnings (loss) from discontinued operations                 |                                 | (1,013)     | 25,813      |
| Basic net earnings (loss) per share                              | (1.05)                          | (0.70)      | 0.66        |
| From continuing operations                                       | (1.05)                          | (0.68)      | 0.16        |
| From discontinued operations                                     |                                 | (0.02)      | 0.50        |
| Diluted net earnings (loss) per share                            | (1.05)                          | (0.70)      | 0.65        |
| From continuing operations                                       | (1.05)                          | (0.68)      | 0.16        |
| From discontinued operations                                     |                                 | (0.02)      | 0.49        |
| <b>Weighted average number of shares (note 21) under US GAAP</b> |                                 |             |             |
| Basic  | 53,187,470                      | 53,182,803  | 52,099,290  |
| Diluted  | 53,187,470                      | 53,182,803  | 52,549,260  |

except share/option and per share/option data and as otherwise noted)

For the years ended December 31, 2008 and 2007, the diluted amounts per share were the same amounts as the basic amounts per share since the dilutive effect of stock options and convertible term loans was not included in the calculation; otherwise, the effect would have been anti-dilutive. Accordingly, the diluted amounts per share for those years were calculated using the basic weighted average number of shares outstanding.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**Reconciliation of shareholders' equity to conform to US GAAP**

The following summary sets out the significant differences between the Company's reported shareholders' equity under Canadian GAAP as compared to US GAAP.

|   | <b>Years ended December 31,</b> |             |
|---|---------------------------------|-------------|
|   | <b>2008</b>                     | <b>2007</b> |
|   | <b>\$</b>                       | <b>\$</b>   |
| Shareholders' equity in accordance with Canadian GAAP | 21,475                          | 88,591      |
| In-process research and development (a)               | (8,341)                         | (14,181)    |
| Shareholders' equity in accordance with US GAAP       | 13,134                          | 74,410      |

**Statements of cash flows**

For the years ended December 31, 2008, 2007 and 2006, there are no significant differences between the statements of cash flows under Canadian GAAP as compared to US GAAP.

(a) Research and development costs



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

Under US GAAP, in-process research and development acquired in a business combination is written off at the time of acquisition. Under Canadian GAAP, in-process research and development acquired in a business combination is capitalized and amortized over its estimated useful life. The balances presented as at December 31, 2007 include intangible assets held for sale.

**(b) Convertible term loans**



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

Under Canadian GAAP, proceeds from the issuance of convertible term loans are allocated among long-term convertible term loans and shareholders' equity, resulting in a debt discount that is amortized to expense over the term of the loans. The financing costs related to those loans have been allocated on a pro-rata basis between deferred charges and other capital. Under US GAAP, those costs are all included in deferred charges and amortized over the term of the loans, and convertible term loans are considered as long-term debt. Furthermore, under US GAAP, the entire incremental consideration to induce conversion is recorded in earnings.

(c) **Deferred income taxes**





This adjustment reflects differences related to the accounting for valuation allowance for US GAAP purposes that arise from timing differences.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

(d) **Cumulative translation adjustment related to the sale of Echelon**

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

Under Canadian GAAP, a gain or loss equivalent to a proportionate amount of the exchange gain or loss accumulated in the translation adjustment is recognized in income when there has been a reduction of a net investment in a foreign operation. Under US GAAP, a gain or loss should only be recognized in income in the case of a substantial or complete liquidation of a net investment in a foreign operation being the substantial or complete liquidation of the Company.

(e) **New accounting standards and pronouncements**

i) **Adopted in 2008**

**FASB Statement of Financial Accounting Standards ( SFAS ) No. 157, *Fair Value Measurements* ( SFAS 157 )**

In September 2006, the FASB issued SFAS 157, which defines fair value, establishes a framework for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but, rather, eliminates inconsistencies in guidance found in various prior accounting pronouncements. In February 2008, the FASB amended SFAS 157 to exclude leasing transactions and to delay the effective date by one year for non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a non-recurring basis. The Company has adopted this statement as of January 1, 2008, and there has been no significant impact on the Company's consolidated financial statements as a result of such adoption.

**SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an amendment of FASB Statement No. 115* ( SFAS 159 )**

On February 15, 2007, the FASB issued SFAS 159, which permits entities to choose to measure many financial instruments and certain other items at fair value. Most of the provisions of this statement apply only to entities that elect the fair value option. However, the amendment to SFAS 115, *Accounting for Certain Investments in Debt and Equity Securities*, applies to all entities with available-for-sale and trading securities. This statement is effective for fiscal years beginning after November 15, 2007. The Company has adopted this statement as of January 1, 2008 and has not elected to use the fair value option. Accordingly, there has not been any impact as a result of adopting SFAS 159.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**EITF Issue No. 07-3, Accounting for Advance Payments for Goods or Services to be Received for Use in Future Research and Development Activities ( EITF 07-3 )**

EITF 07-3, issued in June 2007, provides clarification surrounding the accounting for non-refundable research and development advance payments, whereby such payments should be recorded as an asset when the advance payment is made and recognized as an expense when the research and development activities are performed. EITF 07-3 is effective for interim and annual reporting periods beginning after December 15, 2007. The Company adopted the provisions of EITF 07-3 on January 1, 2008, and there has been no impact on the Company's consolidated financial statements as a result of adopting this guidance.

ii) **Future Accounting Changes**

**EITF Issue No. 07-1, Accounting for Collaborative Agreements Related to the Development and Commercialization of Intellectual Property ( EITF 07-01 )**

The EITF has issued guidance for accounting for arrangements under which companies participate in the development and commercialization of intellectual property into commercially viable products. The EITF defines a collaborative arrangement as a contractual arrangement that involves a joint operating activity. These arrangements involve two or more parties who are both (a) active participants in the activity and (b) exposed to significant risks and rewards dependent on the commercial success of the activity. A company may receive revenues and incur costs under such arrangements as well as make or received payments from the other participant in the arrangement. The EITF concluded that revenues earned and costs incurred by a company should be presented gross or net depending on whether the company is the principal participant in the arrangement. The EITF ratified EITF 07-1 in December 2007, and it will become effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company is currently assessing the impact on the presentation of revenues and costs within the Company's consolidated financial statements.

**SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities Including an amendment of FASB Statement No. 133 ( SFAS 161 )**

except share/option and per share/option data and as otherwise noted)

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

In March 2008, the FASB issued SFAS No. 161, which amends and expands the disclosure requirements in SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and other related literature. SFAS 161 is effective for financial statements issued for periods beginning after November 15, 2008, with early application encouraged. The Company believes that the updated disclosures will not have a material impact on its consolidated financial statements.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

**SFAS No. 141 (revised 2007), *Business Combinations*, ( SFAS 141R )**

In December 2007, the FASB issued SFAS No. 141R, which is a revision of previously existing guidance on accounting for business combinations. SFAS 141R retains the fundamental concept of the purchase method of accounting and introduces new requirements for the recognition and measurement of assets acquired, liabilities assumed and non-controlling interests. SFAS 141R is effective for fiscal years beginning after December 15, 2008. The Company will adopt SFAS 141R for any business combinations entered into, where applicable, on or after January 1, 2009.

**SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB. No. 51***

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* ( SFAS 160 ). SFAS 160 changes the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. This new consolidation method significantly changes the accounting for transactions with minority interest holders. SFAS 160 is effective prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The Company will adopt SFAS 160 for any business combinations entered into, where applicable, on or after January 1, 2009.

**SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS 162 )**

In May 2008, the FASB issued SFAS 162, which is intended to improve financial reporting by identifying a consistent framework for selecting accounting principles to be used in preparing financial statements that are presented in conformity with US GAAP for non-governmental entities. The guidance in SFAS 162 replaces that which is prescribed by the American Institute of Certified Public Accountants ( AICPA ) Statement on Auditing Standards ( SAS ) No. 69, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles, for Nongovernmental Entities* . SFAS 162 will become effective 60 days following the SEC 's approval of the Public Company Accounting Oversight Board 's ( PCAOB ) amendment to the AICPA 's *Professional Standards*, vol. 1, AU sec. 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles* . The Company is currently evaluating the potential impact, if any, that the adoption of SFAS 162 will have on its consolidated financial statements.

except share/option and per share/option data and as otherwise noted)

**FASB Staff Position No. FAS 142-3, Determination of the Useful Life of Intangible Assets ( FSP FAS 142-3 )**

On April 25, 2008, the FASB issued FSP FAS 142-3, which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets* ( SFAS 142 ). The intent of FSP FAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R and as per other US GAAP guidance. FSP FAS 142-3 is effective for financial years beginning after December 15, 2008 and interim periods within those



Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

fiscal years, and early adoption is prohibited. The guidance for determining the useful life of a recognized intangible asset shall be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements shall be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. The Company is currently evaluating the impact of adoption of FSP FAS 142-3 will have on its consolidated financial statements.

**(f) Other disclosures**



*Research and development tax credits*

Under Canadian GAAP, all research and development tax credits are recorded as a reduction of costs in the consolidated statements of earnings (loss). Under US GAAP, tax credits that reduce current income taxes payable are recorded in income taxes. These tax credits amounted to \$nil in 2008, \$1,862,000 in 2007 and \$1,684,000 in 2006. This accounting difference has no impact on the net earnings (loss) and the net earnings (loss) per share figures for the reporting years.

Furthermore, under US GAAP, the future income tax assets related to the unrecognized tax credits totalled \$5,742,000 in 2008 and \$7,004,000 in 2007. However, a valuation allowance corresponding to the same amounts has been accounted for in 2008 and 2007.

*Long-lived assets*

Under US GAAP, long-lived assets by geographic region only consist of property, plant and equipment which are detailed as follows:

|               | As at December 31, |        |
|---------------|--------------------|--------|
|               | 2008               | 2007   |
|               | \$                 | \$     |
| Canada        | 99                 | 7,631  |
| Germany       | 5,968              | 6,436  |
| United States | 615                | 838    |
|               | 6,682              | 14,905 |

*Available-for-sale securities*

The Company uses the specific identification method in order to reclassify the gains or losses realized out of accumulated other comprehensive income into the statement of earnings (loss).

Table of Contents**Æterna Zentaris Inc.**

## Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

The gross realized gains and gross realized losses included in the statement of earnings (loss), the unrealized holding gain or loss on available-for-sale securities as well as the amount of gains and losses reclassified out of accumulated other comprehensive income into the statement of earnings (loss) are as follows:

|                       | For the years ended December 31, |      |      |
|-----------------------|----------------------------------|------|------|
|                       | 2008                             | 2007 | 2006 |
|                       | \$                               | \$   | \$   |
| Gross realized gains  | 3                                |      | 410  |
| Gross realized losses | 10                               | 67   | 21   |
| Unrealized gains      |                                  |      | 126  |
| Unrealized losses     |                                  | 42   | 67   |
| Gains reclassified    |                                  | 53   | 390  |
| Losses reclassified   |                                  | 30   | 78   |

As at December 31, 2008, available-for-sale securities were composed of short-term notes totalling approximately \$493,000, as discussed in note 24. The fair value of short-term notes is based on Level 1 information, as required by SFAS 157.

*Research and collaboration agreements*

As part of Æterna Zentaris' strategy to enhance its development capabilities and to partially fund capital requirements, the Company has entered into research and development collaboration agreements with several pharmaceutical companies. Pursuant to these collaboration arrangements, the Company oftentimes receives upfront payments, license fees and milestone payments and has the potential to receive royalty payments in the future. Upfront payments are typically non-refundable, received upon the signature of an agreement, or shortly thereafter, and are amortized over the estimated corresponding research and development period. License fees typically are contractually obligated payments that the Company receives and uses to fund research and development activities over the term of collaboration and include milestone payments, as well as contract services. Milestone payments are contingent payments that are made upon the achievement of specified milestones, such as at the time of selection of candidates for drug development, the commencement or termination of clinical trials or the receipt of regulatory approvals and achievement of a certain level of sales. If drugs are successfully developed and commercialized as a result of collaboration agreements, the Company will receive royalty payments based upon net sales of those drugs developed under the collaboration. Finally, contract service fees relate to research and development activities performed by the Company on behalf of the counterparty to the related arrangement and for which the Company has the right to receive compensation.

except share/option and per share/option data and as otherwise noted)



Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

*Ardana*

In 2002, the Company entered into a license and collaboration agreement with Ardana, a subsidiary of Ardana plc. Ardana was granted an exclusive worldwide license to develop and commercialize a growth hormone secretagogue ( EP-1572 ). Ardana has undertaken, at its own cost, all activities necessary to obtain regulatory and marketing approvals for the substance. In return, the Company had received approximately \$1,700,000 as an upfront payment upon signing of the agreement. The Company has been eligible to receive payments of up to an aggregate of approximately \$9,200,000 upon Ardana's successful achievement of clinical development and regulatory milestones, in addition to low double-digit royalties on future net worldwide net sales of EP-1572.

Revenues recognized under this agreement with Ardana for the years ended December 31, 2008, 2007 and 2006 were approximately \$197,000, \$3,000,000 and \$1,500,000, respectively.

No corresponding research and development costs were incurred by the Company under the agreement for any of the three years ended December 31, 2008.

In 2002, the Company granted an exclusive license to Ardana for the development and commercialization of teverelix, a LHRH antagonist, for all therapeutic uses worldwide with the exception of Japan, Korea and Taiwan. On April 2, 2004, Ardana acquired full worldwide rights and was assigned the intellectual property rights relating to teverelix and the underlying microcrystalline suspension technology for the use of teverelix and any other potential LHRH antagonists.

The Company received approximately \$3,200,000 in 2002 and approximately \$6,100,000 in 2004 as an upfront payment upon signature of the agreement and upon the assignment of the substance, respectively. The agreement provided, among other things, approximately \$9,200,000 of guaranteed payments through December 2006, approximately \$19,800,000 upon successful achievement of a certain level of sales and low single-digit royalties on future worldwide net sales.

Revenues recognized under this agreement with Ardana for the years ended December 31, 2008, 2007 and 2006 were approximately \$3,621,000, \$3,500,000 and \$3,600,000, respectively.

except share/option and per share/option data and as otherwise noted)

Corresponding research and development costs incurred under the agreement for the years ended December 31, 2008, 2007 and 2006 were approximately \$61,000, \$100,000 and \$300,000, respectively.

As discussed in note 12, in June 2008, Ardana communicated that it was entering into voluntary administration, and, consequently, clinical studies and future development efforts were suspended. Additional correspondence was received by the Company in January 2009 from Ardana's appointed administrators, providing further evidence that future cash flows associated with the aforementioned license and collaboration arrangements are no longer likely to be received. As such, management does not expect to generate any revenues in the foreseeable future under either of the aforementioned agreements from Ardana.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

*Keryx Biopharmaceuticals, Inc.*

The Company is party to a license and collaboration agreement with Keryx Biopharmaceuticals, Inc. ( Keryx ). Per this agreement, Keryx undertakes, at its own cost, all clinical 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, among other things, availability of data generated by both parties free of charge. In September 2002, the company received an upfront payment of approximately \$500,000 and is eligible to receive payments of up to an aggregate of \$18,300,000 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.

Revenues recognized under the agreement with Keryx for the years ended December 31, 2008, 2007 and 2006 were approximately \$410,000, \$1,700,000 and \$700,000, respectively.

Corresponding research and development costs incurred under the agreement for the years ended December 31, 2008, 2007 and 2006 were approximately \$448,000, \$900,000 and \$900,000, respectively.

*Nippon Kayaku Co. Ltd.*

In 2006, the Company entered into a licensing and collaboration agreement with Nippon Kayaku Co. Ltd. ( Nippon Kayaku ). Under the terms of the agreement, Nippon Kayaku was granted an exclusive license to develop and market ozarelix, a LHRH antagonist, for all potential oncological indications in Japan. In return, the Company received approximately \$1,900,000 as an upfront payment upon signature. The agreement provides, among other things, availability of data generated by both parties free of charge. The Company is entitled to receive payments of up to an aggregate of approximately \$23,800,000 upon Nippon Kayaku s successful achievement of clinical development, regulatory milestones and a certain level of sales, in addition to low double-digit royalties on potential net sales. In turn, as indicated below regarding the Spectrum Pharmaceuticals, Inc. ( Spectrum ) agreement, Spectrum is entitled to receive fifty percent of any upfront, milestone payments and royalties received from any research and collaboration agreement signed by the Company for the development and commercialization of ozarelix in Japan.

except share/option and per share/option data and as otherwise noted)



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

Revenues recognized under the agreement for the years ended December 31, 2008, 2007 and 2006 were approximately \$445,000, \$500,000 and \$200,000, respectively.

Corresponding research and development costs incurred under the agreement for the years ended December 31, 2008, 2007 and 2006 were \$nil, approximately \$100,000 and \$100,000, respectively.

Table of Contents

**Aeterna Zentaris Inc.**

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

*Shionogi and Co.*

In 1995, the Company entered into a research and collaboration agreement with Shionogi and Co. ( Shionogi ). The Company granted Shionogi a license to develop, use, commercialize and manufacture cetrorelix, an LHRH antagonist, in Japan and for all human indications. Under the agreement, Shionogi is responsible, at its own cost, for all activities necessary to obtain regulatory and marketing approvals for cetrorelix. The agreement provides, among other things, availability of data generated by both parties free of charge. Upon signature of this agreement, the Company received approximately \$1,400,000 as an upfront payment and was eligible to receive milestone payments of up to an aggregate of approximately \$7,100,000 upon Shionogi's successful achievement of clinical development and regulatory milestones. To date, the Company has received approximately \$5,800,000 of these milestone payments. Since the development of cetrorelix is completed in *in vitro* fertilization ( IVF ), Control Ovarian Stimulation ( COS ) and Assisted Reproductive Technology ( ART ) in Japan, the Company does not expect to receive any additional milestone payments.

In addition, upon commercialization of cetrorelix in BPH, the Company will be entitled to a manufacturing margin.

Revenues recognized under the agreement with Shionogi for the years ended December 31, 2008, 2007 and 2006 were approximately \$1,000, \$nil and \$3,800,000, respectively.

Corresponding research and development costs incurred under the agreement for the years ended December 31, 2008, 2007 and 2006 were approximately \$13,000, \$nil and \$1,000,000, respectively.

*Solvay Pharmaceuticals BV*

In 2002, the Company entered into a research and collaboration agreement with Solvay Pharmaceuticals BV, a subsidiary of Solvay SA ( Solvay ). The Company granted Solvay an exclusive license to develop, use, commercialize and manufacture cetrorelix worldwide (ex-Japan) and for all indications excluding IVF/COS/ART. Under the agreement, Solvay was responsible, at its own cost, for all activities necessary to obtain regulatory and marketing approvals for cetrorelix in different indications including, uterine myoma, endometriosis and BPH. The agreement provides, among other things, availability of data generated by both parties free of charge. Upon signature of this agreement, the Company received approximately \$6,200,000 as an upfront payment and was eligible to receive milestone payments of up to an aggregate of

except share/option and per share/option data and as otherwise noted)

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

approximately \$23,800,000 upon Solvay's successful achievement of clinical development and regulatory milestones, in addition to low double-digit royalties on future worldwide (ex-Japan) net sales of cetrorelix.

In December 2005, Aeterna Zentaris and Solvay amended the aforementioned agreement such that the Company regained exclusive worldwide (ex-Japan) rights for cetrorelix for the BPH indication solely, without any financial compensation payable to Solvay. In May 2007, the parties entered into a termination agreement whereby the Company regained exclusive worldwide (ex-Japan) rights for cetrorelix in all indications, including endometriosis and uterine myoma, without any financial compensation payable to Solvay.

Table of Contents

***Aeterna Zentaris Inc.***

Notes to Consolidated Financial Statements

December 31, 2008, 2007 and 2006

(tabular amounts in thousands of US dollars,

except share/option and per share/option data and as otherwise noted)

Revenues recognized under the agreement with Solvay for the years ended December 31, 2007 and 2006 were approximately \$2,000,000 and \$1,200,000, respectively.

Corresponding research and development costs incurred under the agreement for the years ended December 31, 2007 and 2006 were approximately \$1,900,000 and \$600,000, respectively.

*Spectrum*

In 2004, the Company entered into a licensing and collaboration agreement with Spectrum for ozarelix, a LHRH antagonist. Under the terms of the agreement, the Company granted Spectrum an exclusive license to develop and commercialize ozarelix for all potential indications in North America (including Canada and Mexico) as well as in India. The agreement provides, among other things, availability of data generated by both parties free of charge. Upon signature of this agreement, the Company received approximately \$2,400,000 as an upfront payment, of which approximately \$1,200,000 was paid in cash and the balance paid through the issuance of shares of the capital of Spectrum. The Company is entitled to receive payments of up to an aggregate of approximately \$24,400,000 upon Spectrum's successful achievement of clinical development and regulatory milestones, in addition to royalties (scale-up royalties from high single to low double-digit) on potential net sales. In consideration of the amounts paid by Spectrum under this agreement, Spectrum is entitled to receive fifty percent of any upfront, milestone payments and royalties received from any research and collaboration agreement signed by the Company for the development and commercialization of ozarelix in Japan.

Revenues recognized under the agreement with Spectrum for the years ended December 31, 2008, 2007 and 2006 were approximately \$678,000, \$1,900,000 and \$2,900,000, respectively.

Corresponding research and development costs incurred under the agreement for the years ended December 31, 2008, 2007 and 2006 were approximately \$255,000, \$600,000 and \$1,700,000, respectively.

*Tulane Educational Fund*

except share/option and per share/option data and as otherwise noted)

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

In 2002, the Company signed license agreements with the Tulane Educational Fund ( Tulane ) with regard to various substances, including cetorelix. Under the agreements, we obtained exclusive worldwide licenses to use Tulane s patents to develop, manufacture, market and distribute these substances.

The agreement provides the payment by the Company of single-digit royalties on future worldwide net sales for all indications, except BPH, where it provides the payment of low single-digit royalties. Tulane is entitled to receive a low double-digit royalty on any lump sum, periodic or other cash payments received by the Company from sub-licensees.

Costs incurred under the agreement with Tulane for the years ended December 31, 2008, 2007 and 2006 were approximately \$311,000 \$100,000 and \$300,000, respectively.

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 1.1 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)
- 1.2 Code of General By-Laws adopted by the Registrant on November 29, 1995 (incorporated by reference to Exhibit 1.2 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)
- 2 Amended and Restated Shareholder Rights Plan Agreement between the Registrant and Computershare Trust Company of Canada dated as of March 5, 2007 (incorporated by reference to Exhibit 2 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2008 filed with the Commission on March 28, 2008)
- 4.1 Stock Option Plan of the Registrant
- 4.2 Employment Agreement dated July 18, 2007 between Paul Blake, M.D. and the Registrant (incorporated by reference to Exhibit 4.2 of the Registrant's annual report on Form 20-F for the financial year ended December 31, 2007 filed with the Commission on March 28, 2008)
- 4.3 Service Contract dated December 5, 2007 between Aeterna Zentaris GmbH and Prof. Juergen Engel, Ph.D. (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.
- 4.5 Employment Agreement dated September 1, 2008 between the Registrant and Prof. Juergen Engel, Ph.D.
- 4.6 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)
- 4.7 Service Contract dated May 18, 2006 among Aeterna Zentaris GmbH, the Registrant and Matthias Seeber
- 4.8 Amendment #1 to Service Contract dated December 9, 2008 among Aeterna Zentaris GmbH, the Registrant and Matthias Seeber
- 4.9 Amendment to Amended Employment Agreement dated as of 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)
- 4.10 Purchase Agreement by and among 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)
- 4.11 Development, Commercialisation and License Agreement between Aeterna Zentaris GmbH and sanofi-aventis U.S. LLC dated March 5, 2009 (incorporated by reference to Exhibit 99.2 to the Registrant's report on Form 6-K furnished to the Commission on March 17, 2009)
- 4.12 Guarantee agreement between the Registrant and sanofi-aventis U.S. LLC dated March 5, 2009 (incorporated by reference to Exhibit 99.3 to the Registrant's report on Form 6-K furnished to the Commission on March 17, 2009)
- 8.1 Subsidiaries of the Registrant
- 11.1 Code of Ethical Conduct of the Registrant
- 11.2 Audit Committee Charter of the Registrant
- 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 Certificate 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 Certificate 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 Registrant's Independent Registered Public Accounting Firm



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.

ÆTERNA ZENTARIS INC.

/s/ Dennis Turpin

Dennis Turpin  
Senior Vice President and Chief Financial Officer

**Date: March 30, 2009**

---