

Aeterna Zentaris Inc.  
Form SUPPL  
May 22, 2013  
**Table of Contents**

Filed pursuant to General Instruction II.L. of Form F-10  
File No. 333-181714

*This prospectus supplement, together with the accompanying short form base shelf prospectus dated June 8, 2012 to which it relates, as amended or supplemented and each document incorporated or deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus, constitutes a public offering of these securities only in those jurisdictions where such securities may be lawfully offered for sale and therein only by persons permitted to sell such securities. No securities regulatory authority has expressed an opinion about these securities and it is an offense to claim otherwise.*

*Information has been incorporated by reference into this prospectus supplement and in the short form base shelf prospectus dated June 8, 2012 from documents filed with the United States Securities and Exchange Commission and with securities commissions or similar authorities in Canada. Copies of the documents incorporated herein by reference may be obtained on request without charge from the secretary of Aeterna Zentaris Inc. at 1405 du Parc-Technologique Boulevard, Quebec City, Quebec, Canada, G1P 4P5, tel. (418) 652-8525 and are also available electronically at [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml) or [www.sedar.com](http://www.sedar.com).*

NEW ISSUE

May 22, 2013

**PROSPECTUS SUPPLEMENT NO. 2**

**(TO SHORT FORM BASE SHELF PROSPECTUS DATED JUNE 8, 2012)**

## **Up to 2,500,000 Common Shares**

Aeterna Zentaris Inc. ( we , us or the Company ) has entered into an At Market Issuance Sales Agreement dated May 21, 2013 (the Sales Agreement ) with MLV & Co. LLC ( MLV ), relating to sales of our common shares (the Common Shares ) offered by this prospectus supplement and the accompanying prospectus. In accordance with the terms of the Sales Agreement, we may offer and sell up to 2,500,000 of our Common Shares up to a maximum aggregate offering price of \$4.6 million, from time to time through MLV, as agent.

**Unless otherwise stated, currency amounts in this prospectus supplement are stated in United States dollars, or \$ or US\$ .**

Our Common Shares are listed on the NASDAQ Global Market ( NASDAQ ) under the symbol AEZS and on the Toronto Stock Exchange ( TSX ) under the symbol AEZ . On May 21, 2013, the last reported sales price of our Common Shares on NASDAQ was \$2.08 per share and on TSX was C\$2.12 per share. There is no arrangement for funds to be received in escrow, trust or similar arrangement.

Upon delivery of a placement notice by us, if any, MLV may sell the Common Shares, in the United States ( U.S. ) only, and such sales will only be made by any method permitted by law deemed to be an at-the-market distribution as defined in National Instrument 44-102 *Shelf Distributions* ( NI 44-102 ), including, without limitation, sales made directly on NASDAQ, or on any other existing trading market for the Common Shares in the U.S. MLV will make all sales using commercially reasonable efforts consistent with its normal sales and trading practices and on mutually agreed upon terms between MLV and us. The Common Shares will be distributed at the market prices prevailing at the time of the sale of such Common Shares. As a result, prices may vary as between purchasers and during the period of distribution.

The compensation to MLV for sales of our Common Shares under this prospectus supplement will be equal to three percent (3%) of the gross proceeds from the sale of such Common Shares. See Plan of Distribution . The net proceeds, if any, from sales under this prospectus supplement will be used as described under the section titled Use of Proceeds in this prospectus supplement. The proceeds we receive from sales will depend on the number of Common Shares actually sold and the offering price of such Common Shares. In connection with the sale of the Common Shares on our behalf, MLV will be deemed to be an underwriter within the meaning of the United States *Securities Act of 1933*, as amended (the

## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

Securities Act ), and the compensation of MLV will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to MLV against certain liabilities, including liabilities under the Securities Act.

Neither MLV, any affiliate of MLV nor any person or company acting jointly or in concert with MLV, has over-allotted, or will over-allot, Common Shares in connection with this offering or effect any other transactions that are intended to stabilize or maintain the market price of the Common Shares.

## **Table of Contents**

The Common Shares will be listed on NASDAQ. The TSX has conditionally approved the listing of the Common Shares offered for sale pursuant to this prospectus supplement. Listing is subject to the Company fulfilling all of the requirements of the TSX on or before the business day immediately following the date on which this prospectus supplement is filed.

**Investing in our Common Shares involves a high degree of risk. See Risk Factors beginning on page S-8 and the risk factors described in the documents incorporated by reference herein for information that should be considered before investing in our Common Shares.**

**We are a foreign private issuer under the securities laws of the U.S. and are permitted, under a multi-jurisdictional disclosure system ( MJDS ) adopted in the U.S. and Canada, to prepare this prospectus supplement and the accompanying prospectus in accordance with Canadian regulatory disclosure requirements. You should be aware that such requirements are different from those in the U.S. The financial statements included in or incorporated by reference into this prospectus supplement and the accompanying prospectus have been prepared in accordance with International Financial Reporting Standards ( IFRS ) as issued by the International Accounting Standards Board. Our consolidated financial statements are subject to Canadian generally accepted auditing standards and auditor independence standards, in addition to the standards of the Public Company Accounting Oversight Board (United States) and the U.S. Securities and Exchange Commission ( SEC ) independence standards, and thus may not be comparable to financial statements of U.S. companies.**

**Purchasing our Common Shares may subject you to tax consequences both in the U.S. and Canada. This prospectus supplement and the accompanying prospectus may not describe these tax consequences fully. You should read the tax discussion in this prospectus supplement and the accompanying prospectus fully and consult with your own tax advisors.**

**Your ability to enforce civil liabilities under U.S. federal securities laws may be affected adversely by the fact that we are incorporated under the laws of Canada, many of our officers and directors and some of the experts named in this prospectus supplement and the accompanying prospectus are residents of Canada or elsewhere outside of the U.S., and a substantial portion of our assets and the assets of such persons are located outside the U.S.**

**NEITHER THE SEC NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OF THIS PROSPECTUS SUPPLEMENT AND THE ACCOMPANYING PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

Our registered address is located at 1405 du Parc-Technologique Boulevard, Quebec City, Quebec, Canada, G1P 4P5, and our telephone number is (418) 652-8525.

The date of this prospectus supplement is May 22, 2013

**Table of Contents**

**TABLE OF CONTENTS**

<u>About this Prospectus Supplement</u>	S-3
<u>Currency and Exchange Rates</u>	S-4
<u>Special Note on Forward-Looking Statements</u>	S-4
<u>Prospectus Supplement Summary</u>	S-6
<u>Risk Factors</u>	S-8
<u>Use of Proceeds</u>	S-26
<u>Price Range and Trading Volume</u>	S-27
<u>Prior Sales</u>	S-27
<u>Consolidated Capitalization</u>	S-28
<u>Description of Securities Offered Under this Prospectus Supplement</u>	S-28
<u>Plan of Distribution</u>	S-29
<u>Certain Income Tax Considerations</u>	S-30
<u>Legal Matters</u>	S-36
<u>Experts</u>	S-37
<u>Exemptive Relief Granted by the Autorité des Marchés Financiers</u>	S-37
<u>Where You Can Find More Information</u>	S-37
<u>Incorporation of Certain Documents by Reference</u>	S-37
<i>This prospectus supplement is not an offer to sell or a solicitation of an offer to buy securities in any jurisdiction in which such offer or solicitation is illegal.</i>	

**ABOUT THIS PROSPECTUS SUPPLEMENT**

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of our Common Shares and supplements information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part is the accompanying prospectus, which gives more general information about us and the Common Shares we may offer from time to time under our base shelf prospectus and our shelf registration statement.

We have not authorized any dealer, salesperson or other person to give any information or to make any representation other than those contained or incorporated by reference into this prospectus supplement, the accompanying prospectus and any related free writing prospectus that we may authorize to be provided to you. You should not rely upon any information or representation not contained or incorporated by reference into this prospectus supplement, the accompanying prospectus or any free writing prospectus that we may authorize to be provided to you. If information in this prospectus supplement is inconsistent with the accompanying prospectus or the information incorporated by reference, you should rely on this prospectus supplement. This prospectus supplement, the accompanying prospectus and any related free writing prospectus that we may authorize to be provided to you do not constitute an offer to sell or a solicitation of an offer to buy Common Shares, in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus supplement, the accompanying prospectus and any related free writing prospectus that we may authorize to be provided to you is accurate on any date other than the date set forth on the front cover of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference regardless of the date of delivery of this prospectus supplement, the accompanying prospectus and any related free writing prospectus that we may authorize to be provided to you or any sale of Common Shares. Our business, financial condition, results of operations and prospects may have changed since those dates.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference into this prospectus supplement and the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose

**Table of Contents**

of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

The financial statements included in or incorporated by reference into this prospectus supplement and the accompanying prospectus have been prepared in accordance with IFRS as issued by the International Accounting Standards Board. Our consolidated financial statements are subject to Canadian generally accepted auditing standards and auditor independence standards, in addition to the standards of the Public Company Accounting Oversight Board (United States) and the SEC independence standards.

As used in this prospectus supplement, the terms we, us, our, Company and Aeterna Zentaris refer to Aeterna Zentaris Inc. and its subsidiaries on a consolidated basis.

**CURRENCY AND EXCHANGE RATES**

The following table sets out the high and low exchange rates for one U.S. dollar expressed in Canadian dollars, for the period indicated and, the average of such exchange rates, and the exchange rate at the end of such period, in each case, based upon the noon rates as quoted by the Bank of Canada:

	Year-to-date 2013 <sup>(1)</sup>	Month ended April 30, 2013	Three-month period ended March 31, 2013	Year ended December 31,		
				2012	2011	2010
High	1.0314	1.0270	1.0314	1.0418	1.0604	1.0778
Low	0.9839	1.0072	0.9839	0.9710	0.9449	0.9946
Rate at end of period	1.0277	1.0072	1.0156	0.9949	1.0170	0.9946
Average rate per period	1.0112	1.0187	1.0083	0.9996	0.9891	1.0299

(1) Up to and including May 21, 2013.

On May 21, 2013, the exchange rate for one U.S. dollar expressed in Canadian dollars based upon the noon rate of the Bank of Canada was C\$1.0277.

**SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS**

This prospectus supplement, the accompanying prospectus and the documents incorporated herein by reference contain forward-looking statements concerning the business, operations, financial performance and condition of the Company. When used in this prospectus supplement, the accompanying prospectus and the documents incorporated herein by reference, words such as may, will, should, could, expects, plans, anticipates, intends, believes, estimates, predicts, potential or continue or the negative of these terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such words. These forward-looking statements are based on current expectations and are naturally subject to uncertainty and changes in circumstances that may cause actual results to differ materially from those expressed or implied by such forward-looking statements. Such statements, based as they are on the current expectations of management, inherently involve numerous risks and uncertainties, known and unknown, many of which are beyond our control. Such risks include but are not limited to:

investments in biopharmaceutical companies are generally considered to be speculative;

we may never achieve or maintain operating profitability;

our clinical trials may not yield results which will enable us to obtain regulatory approval for our products and we may suffer setbacks in any of our clinical trials;



**Table of Contents**

we may not be able to successfully complete our clinical trial programs, or such clinical trials could take longer to complete than we project;

the impact of the stringent ongoing government regulation to which our product candidates are subject and future changes in such regulatory environment;

we may not be able to generate significant revenues if our products do not gain market acceptance;

we may require significant additional financing, and we may not have access to sufficient capital;

we may not be able to maintain compliance with the continued listing standards of The NASDAQ Stock Market;

we may cease to continue operating as we do if we are unsuccessful in increasing our revenues and/or raising additional funding;

failure to achieve our projected development goals in the time-frames we announce and expect;

the impact of any failure on our part to obtain acceptable prices or adequate reimbursement for our products on our ability to generate revenues;

competition in our targeted markets;

we may not obtain adequate protection for our products through our intellectual property;

we may infringe the intellectual property rights of others;

we may incur liabilities from our involvement in any patent litigation;

we may not obtain trademark registrations in connection with our product candidates;

we may not be able to make adequate arrangements with third parties for the purpose of commercializing our product candidates;

the failure to perform satisfactorily by third parties upon which we rely to conduct, supervise and monitor our clinical trials;

the failure to perform satisfactorily by third parties upon which we rely to manufacture and supply products;

## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

our ability to retain or attract key personnel;

our strategic partners' manufacturing capabilities may not be adequate to effectively commercialize our product candidates;

risks related to product liability and other claims;

risks related to our holding company structure;

risks related to the pledge by our German subsidiary of all rights related to Cetrotide®;

the impact of healthcare reform measures on our business prospects or future financial condition;

fluctuations in currency exchange rates;

the impact of pending and future claims and litigation on our business, financial condition or results of operations;

the impact of legislative actions, new accounting pronouncements and higher insurance costs on our future financial position or results of operations; and

stock market volatility and the possibility that our Common Shares may be delisted from the stock exchanges on which they currently trade.

More detailed information about these and other factors is included under "Risk Factors" in this prospectus supplement and the accompanying prospectus as well as in other documents incorporated herein by reference. Many of these factors are beyond our control. Future events may vary substantially from what we currently foresee. You should not place undue reliance, if any, on such forward-looking statements. The Company disavows and is under no obligation to update or alter such forward-looking statements whether as a result of new information, future events or otherwise, other than as required by applicable securities legislation.



---

**Table of Contents**

**PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights selected information contained elsewhere in or incorporated by reference into this prospectus supplement and the accompanying prospectus. The summary may not contain all of the information that you should consider before investing in our Common Shares. You should read the entire prospectus supplement and the accompanying prospectus carefully, including Risk Factors contained in this prospectus supplement and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, before making an investment decision. This prospectus supplement may add to, update or change information in the accompanying prospectus.*

**Our Business**

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

In oncology, we are in the initiation process of a Phase 3 study under a Special Protocol Assessment ( SPA ) with the U.S. Food and Drug Administration (the FDA ) for AEZS-108, a doxorubicin Luteinizing Hormone Releasing Hormone-targeted conjugate compound, in endometrial cancer, for which we have successfully completed a Phase 2 trial in advanced endometrial and advanced ovarian cancer. We are also advancing Phase 2 trials with AEZS-108 in triple-negative breast cancer, refractory bladder cancer and castration- and taxane-resistant prostate cancer. Our oncology pipeline also encompasses other earlier-stage programs, including AEZS-112, an oral anticancer agent which involves three mechanisms of action (tubulin, topoisomerase II and angiogenesis inhibition), which has completed a Phase 1 trial in advanced solid tumors and lymphoma. Additionally, several novel targeted anticancer candidates such as AEZS-120, a live recombinant oral tumor vaccine candidate, as well as our PI3K/Erk inhibitors, including AEZS-129, AEZS-134 and AEZS-136, are currently in preclinical development.

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

**Corporate Information**

Aeterna Zentaris Inc. was incorporated on September 12, 1990 under the laws of Canada. Our registered office is located at 1405 du Parc-Technologique Blvd., Quebec City, Quebec, Canada, G1P 4P5, our telephone number is (418) 652-8525 and our website is [www.aezsinc.com](http://www.aezsinc.com). None of the documents or information found on our website shall be deemed to be included in or incorporated into this prospectus supplement or the accompanying prospectus, unless such document is specifically incorporated herein or therein by reference.

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

**Table of Contents**

**The Offering**

Common Shares offered by us pursuant to this prospectus supplement:	Up to 2,500,000 Common Shares, up to a maximum aggregate offering price of \$4.6 million.
Manner of offering:	At-the-market offering that may be made from time to time solely in the U.S. through our agent, MLV. See Plan of Distribution on page S-29.
Use of proceeds:	We intend to use the net proceeds raised in connection with this offering to continue to fund our ongoing drug development activities, particularly for the advancement of our AEZS-108 and macimorelin acetate programs, as well as for future negative cash flow, general corporate purposes and working capital. See Use of Proceeds on page S-26.
NASDAQ Global Market and TSX symbols:	NASDAQ: AEZS; TSX: AEZ
Risk factors:	An investment in our Common Shares involves a high degree of risk. See Risk Factors beginning on page S-8 of this prospectus supplement as well as the other information included in or incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of factors that you should consider carefully before making an investment decision.

---

**Table of Contents**

**RISK FACTORS**

*Before making an investment decision, you should carefully consider the risks described in this prospectus supplement, together with all of the other information incorporated by reference into this prospectus supplement and the accompanying prospectus, including those described in our most recent Annual Report on Form 20-F and subsequent consolidated financial statements and corresponding management's discussion and analysis filed with the Canadian securities regulatory authorities and our Reports on Form 6-K furnished to the SEC including our unaudited interim consolidated financial statements and corresponding management's discussion and analysis. The risks mentioned below are presented as of the date of this prospectus supplement and we expect that these will be updated from time to time in our various continuous disclosure documents filed with the Canadian securities regulatory authorities and our periodic and current reports filed with or furnished to the SEC, as applicable, which will be incorporated herein by reference. Please refer to these subsequent reports for additional information relating to the risks associated with investing in our Common Shares.*

*Our business, financial condition or results of operations could be materially adversely affected by any of these risks. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. The trading price of our Common Shares could decline due to any of these risks, and you may lose part or all of your investment. This prospectus supplement, the accompanying prospectus and the incorporated documents also contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks mentioned below. Forward-looking statements included in this prospectus supplement are based on information available to us on the date hereof, and all forward-looking statements in documents incorporated by reference are based on information available to us as of the date of each such document. We disclaim any intent to update any forward-looking statements.*

**Risks Relating to Us and Our Business**

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

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

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

Our product candidates remain at the development stage, and we have incurred substantial expenses in our efforts to develop products. Consequently, we have incurred recurrent operating losses and, as disclosed in our unaudited interim consolidated financial statements as at March 31, 2013 and for the three-month periods ended March 31, 2013 and 2012 we had an accumulated deficit of approximately US\$211.2 million as at March 31, 2013. Our operating losses have adversely impacted, and will continue to adversely impact, our working capital, total assets and shareholders' deficiency. We do not expect to reach operating profitability in the immediate future, and our expenses are likely to increase as we continue to expand our 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 Common Shares could result in a significant or total loss.

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

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

---

**Table of Contents**

years to complete testing, and failure can occur at any stage of testing. Results attained in preclinical testing and early clinical studies, or trials, may not be indicative of results that are obtained in later studies.

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

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

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

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

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

must meet the requirements of these authorities;

must meet requirements for informed consent; and

must meet requirements for good clinical practices.

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

---

**Table of Contents**

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

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

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

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

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

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

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

We and our contract manufacturers will be required to comply with applicable current Good Manufacturing Practice 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

## **Table of Contents**

must be approved before we can use them in the commercial manufacturing of our products and are subject to subsequent periodic inspection by regulatory authorities. In addition, material changes in the methods of manufacturing or changes in the suppliers of raw materials are subject to further regulatory review and approval.

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

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

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

demonstration of clinical efficacy and safety;

the prevalence and severity of any adverse side effects;

limitations or warnings contained in the product's approved labeling;

availability of alternative treatments for the indications we target;

the advantages and disadvantages of our products relative to current or alternative treatments;

the availability of acceptable pricing and adequate third-party reimbursement; and

the effectiveness of marketing and distribution methods for the products.

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

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

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

We may require additional capital to pursue planned clinical trials, regulatory approvals, as well as further R&D and marketing efforts for our product candidates and potential products. Except as expressly described in this prospectus supplement, the accompanying prospectus and the

## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

documents incorporated by reference herein and therein, we do not anticipate generating significant revenues from operations in the near future and we currently have no committed sources of capital.

We may attempt to raise additional funds through public or private financings, collaborations with other pharmaceutical companies or financing from other sources. Additional funding may not be available on terms which are acceptable to us. If adequate funding is not available to us on reasonable terms, we may need to delay, reduce or

S-11

## **Table of Contents**

eliminate one or more of our product development programs or obtain funds on terms less favorable than we would otherwise accept. To the extent that additional capital is raised through the sale of equity securities or securities convertible into or exchangeable for equity securities, the issuance of those securities could result in dilution to our shareholders. Moreover, the incurrence of debt financing could result in a substantial portion of our future operating cash flow, if any, being dedicated to the payment of principal and interest on such indebtedness and could impose restrictions on our operations. This could render us more vulnerable to competitive pressures and economic downturns.

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

the duration and results of our clinical trials for our various product candidates going forward;

unexpected delays or developments in seeking regulatory approvals;

the time and cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

other unexpected developments encountered in implementing our business development and commercialization strategies;

the outcome of litigation, if any; and

further arrangements, if any, with collaborators.

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

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

We have had sustained losses, accumulated deficits and negative cash flows from operations since our inception and we expect that this will continue throughout 2013. Although our unaudited interim consolidated financial statements as at March 31, 2013 and for the three-month periods ended March 31, 2013 and 2012 have been prepared on a going concern basis, which contemplates the realization of assets and liquidation of liabilities during the normal course of operations, our ability to continue as a going concern is dependent on the successful execution of our business plan, which will require an increase in revenue and/or additional funding to be provided by potential investors as well as non-traditional sources of financing. Although we stated in our unaudited interim consolidated financial statements as at March 31, 2013 and for the three-month periods ended March 31, 2013 and 2012 that management believed that the Company had, as at March 31, 2013, sufficient financial resources to fund planned expenditures and other working capital needs for at least, but not limited to, the 12-month period following such date, there can be no assurance that management will be able to reiterate such belief in the future, particularly in the event that we do not or are unable to raise additional capital, as we do not expect our operations to generate sufficient cash flow to fund our obligations.

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



## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

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

S-12

## **Table of Contents**

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

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

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

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

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

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

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

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

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

The biomedical field is highly competitive. New products developed by other companies in the industry could render our products or technologies non-competitive. Competitors are developing and testing products and technologies that would compete with the products that we are developing. Some of these products may be more effective or have an entirely different approach or means of accomplishing the desired effect than our products. We expect competition from biopharmaceutical and pharmaceutical companies and academic research institutions to

---

**Table of Contents**

increase over time. Many of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Our competitors may succeed in developing products earlier and in obtaining regulatory approvals and patent protection for such products more rapidly than we can or at a lower price.

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

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

In addition, our patents may be challenged by third parties in patent litigation, which is becoming widespread in the biopharmaceutical industry. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There may also be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that our patents would, if challenged, be held by a court to be valid or enforceable or that a competitor's technology or product would be found by a court to infringe our patents. Our granted patents could also be challenged and revoked in post-grant proceedings in the U.S. and in opposition or nullity proceedings in certain countries outside the U.S. 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 U.S. and many other jurisdictions are typically not published until eighteen months after their first effective filing date, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensing partners can be certain that we or they were the first to make the inventions claimed in our or their issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. If a third party has also filed a patent application in the U.S. covering our product candidates or a similar invention, we may have to participate in adversarial proceedings, such as interferences and derivation proceedings, before the United States Patent and Trademark Office to determine which party is entitled to a U.S. patent claiming the disputed invention. The costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful, resulting in a loss of our U.S. patent position.

In addition to patent protection, we may utilize orphan drug regulations, pediatric exclusivity or other provisions of the United States *Food, Drug and Cosmetic Act of 1938*, as amended, such as new chemical entity exclusivity or new formulation exclusivity, to provide market exclusivity for a drug candidate. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first

## **Table of Contents**

FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity provides an additional six months which are added to the term of data protection as well as to the term of any relevant patents, to the extent these protections have not already expired. We may also seek to utilize market exclusivities in other territories, such as in the EU. We cannot assure that any of our drug candidates will obtain such orphan drug designation, pediatric exclusivity, new chemical entity exclusivity or any other market exclusivity in the U.S., EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection.

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

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

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

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

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

If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business. Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be accused of infringing one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may subsequently be issued and to which we do not hold a license or other rights. Third parties may own or control these patents or patent applications in the U.S. 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.

## **Table of Contents**

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

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

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

the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals to commercialize our product candidates;

the timing of regulatory submissions and approvals;

the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize our product candidates;

the revenue available from royalties derived from our strategic partners;

licensing fees revenues;

tax credits and grants (R&D);

the outcome of litigation, if any;

changes in foreign currency fluctuations;

the timing of achievement and the receipt of milestone payments from current or future collaborators; and

failure to enter into new or the expiration or termination of current agreements with collaborators.

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

**Table of Contents**

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

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

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

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

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

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

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

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

not all of our strategic partners are contractually prohibited from developing or commercializing, either alone or with others, products and services that are similar to or competitive with our product candidates, and, with respect to our strategic partnership agreements that do contain such contractual prohibitions or restrictions, prohibitions or restrictions do not always apply to our partners' affiliates and they may elect to pursue the development of any additional product candidates and pursue technologies or products either on their own or in collaboration with other parties, including our competitors, whose technologies or products may be competitive with ours;

our strategic partners may under-fund or fail to commit sufficient resources to marketing, distribution or other development of our products;

we may not be able to renew such agreements;

our strategic partners may not properly maintain or defend certain intellectual property rights that may be important to the commercialization of our products;

our strategic partners may encounter conflicts of interest, changes in business strategy or other issues which could adversely affect their willingness or ability to fulfill their obligations to us (for example, pharmaceutical companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in this industry);

## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

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

S-17



---

**Table of Contents**

time-consuming and expensive, or causing our strategic partners to act in their own self-interest and not in our interest or those of our shareholders or other stakeholders.

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

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

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

For example, on April 10, 2013, we announced that we had entered into a co-development and profit-sharing agreement with Ergomed Clinical Research Ltd. ( Ergomed ) for AEZS-108 in endometrial cancer. Ergomed was selected as the contract clinical development organization to conduct the multicenter, multinational, randomized Phase 3 trial with AEZS-108 in endometrial cancer. Under the terms of this agreement, Ergomed will assume 30% (up to \$10 million) of the clinical and regulatory costs for the Phase 3 trial of AEZS-108 in endometrial cancer, which are currently estimated at approximately \$30 million over the course of the study, and it will receive its return on investment based on an agreed single digit percentage of any net income received by us for AEZS-108 in this indication, up to a specified maximum amount.

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

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

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

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

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

## **Table of Contents**

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

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

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

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

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

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

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

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

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

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

---

## **Table of Contents**

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

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

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

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

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

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

Our subsidiaries may incur additional indebtedness and other liabilities.

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

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

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

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

In the event we were to default on certain of our payment or other material obligations owed to HRP under the Purchase Agreement, or in the event any bankruptcy, insolvency, reorganization, liquidation, dissolution, or similar

**Table of Contents**

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

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

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

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

The business prospects and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the U.S. and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as proposals relating to the pricing of healthcare products and services in the U.S. or internationally, the reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price), and the amount of reimbursement available from governmental agencies or other third party payers. For example, drug manufacturers are required to have a national rebate agreement with the Department of Health and Human Services in order to obtain state Medicaid coverage, which requires manufacturers to pay a rebate on drugs dispensed to Medicaid patients. On January 27, 2012, the Centers for Medicare and Medicaid Services (CMS) issued a proposed regulation covering the calculation of Average Manufacturer Price (AMP) which is the key variable in the calculation of these rebates.

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

---

**Table of Contents**

capital or to obtain strategic partnerships or licenses. Government-financed comparative efficacy research could also result in new practice guidelines, labeling or reimbursement policies that discourages use of our products.

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

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

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

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

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

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

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

---

## **Table of Contents**

Under U.S. tax legislation and subject to future guidance, if the Company is a PFIC, U.S. Holders will be required to file an annual information return with the Internal Revenue Service (the IRS) (on IRS Form 8621, which PFIC shareholders will be required to file with their U.S. federal income tax or information returns) relating to their ownership of Common Shares. The IRS has suspended this new filing requirement pending the issuance of additional guidance. This new filing requirement is in addition to any preexisting reporting requirements that apply to a U.S. Holder's interest in a PFIC (which the tax legislation does not affect).

For a more detailed discussion of the potential tax impact of us being a PFIC, see Certain Material U.S. Federal Income Tax Considerations below. The PFIC rules are complex. Prospective purchasers of any of our securities should consult their tax advisors regarding the potential application of the PFIC regime and any reporting obligations to which they may be subject under that regime.

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

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

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

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

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

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

### **Risks Relating to the Common Shares and the Offering**

#### ***Our share price is volatile, which may result from factors outside of our control. If our Common Shares were to be delisted from NASDAQ or TSX, investors may have difficulty in disposing of our Common Shares held by them.***

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

As adjusted for and giving effect to our six-to-one share consolidation on October 2, 2012, between January 1, 2012 and March 31, 2013, the closing price of our Common Shares ranged from \$1.87 to \$12.90 per share on NASDAQ and from C\$1.87 to C\$12.84 per share on TSX and, between April 1, 2013 and May 21, 2013, it ranged from \$1.73 to \$2.10 per share on NASDAQ and from C\$1.74 to C\$2.18 per share on TSX. See Price Range and Trading Volume on page S-27 of this prospectus supplement. Our share price may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. The stock market generally,

**Table of Contents**

and the biopharmaceutical sector in particular, are vulnerable to abrupt changes in investor sentiment. Prices of shares and trading volume of companies in the biopharmaceutical industry can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, operating performance. Our share price and trading volume may fluctuate based on a number of factors including, but not limited to:

clinical and regulatory developments regarding our product candidates;

delays in our anticipated development or commercialization timelines;

developments regarding current or future third-party collaborators;

other announcements by us regarding technological, product development or other matters;

arrivals or departures of key personnel;

governmental or regulatory action affecting our product candidates and our competitors' products in the U.S., 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 U.S., Canada or abroad.

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

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

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

If our Common Shares trade for 30 consecutive business days below the required \$1.00 minimum closing bid price, we expect that NASDAQ would then send us a deficiency notice and provide us with a period of 180 calendar days to regain compliance with the minimum bid price requirement. In order to regain compliance, the closing bid price of our Common Shares would have to be at least US\$1.00 for a minimum of 10 consecutive business days. If we did not regain compliance within the initial 180-day period, but otherwise met the continued listing requirement for market value of publicly held shares and all other initial listing standards for the NASDAQ Capital Market, except for the bid price requirement, and we provided NASDAQ with notice of our intention to cure the bid price deficiency, the NASDAQ rules may then permit us to

## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

transfer to the NASDAQ Capital Market, which would give us an additional 180 calendar days to regain compliance. If we were not eligible for an additional compliance period, NASDAQ will notify us that our securities are subject to delisting. At that time, we could appeal the determination to delist our securities to a Listing Qualifications Panel.

In addition to the minimum bid price requirement, NASDAQ's continued listing rules require us to meet at least one of the following listing standards: (i) stockholders' equity of at least \$10 million (the Equity Standard), (ii) market value of listed securities (calculated by multiplying the daily closing bid price of our Common Shares by our total outstanding Common Shares) of at least \$50 million (the Market Value Standard) or (iii) total assets and total revenue of at least \$50 million each (the Total Assets/Total Revenue Standard). If our total market capitalization decreases to an amount less than \$50 million for 30 consecutive trading days, we may no longer meet any of these three listing standards. Similar to the process described above in the minimum bid price context, if we fail



## **Table of Contents**

to meet the Market Value Standard for 30 consecutive trading days and do not otherwise meet the Equity Standard or the Total Assets/Total Revenue Standard, we expect that we would then receive a notification letter from NASDAQ advising us that we fail to comply with the Market Value Standard and providing us a period of 180 calendar days to regain compliance with the Market Value Standard. In order to regain compliance with the Market Value Standard, the market value of our listed securities would have to be at least \$50 million for a period of 10 consecutive business days. Otherwise, our securities may then be subject to delisting.

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

### ***You will experience immediate and substantial dilution.***

Since the public offering price of the Common Shares offered pursuant to this prospectus supplement and the accompanying prospectus is higher than the net tangible book value per Common Share, you will suffer substantial dilution in the net tangible book value of the Common Shares you purchase in this offering.

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

To date, we have not declared or paid any dividends on our Common Shares. We currently intend to retain our future earnings, if any, to finance further research and the expansion of our business. As a result, the return on an investment in our Common Shares will, for the foreseeable future, depend upon any future appreciation in value. There is no guarantee that our Common Shares will appreciate in value or even maintain the price at which shareholders have purchased them.

### ***Management will have broad discretion as to the use of the proceeds of any offering. We may invest or spend the proceeds of any offering in ways with which investors may not agree and in ways that may not earn a profit.***

Our management team will have broad discretion concerning the use of the proceeds of any offering of securities under this prospectus supplement and the accompanying prospectus as well as the timing of their expenditure. As a result, investors will be relying on the judgment of management for the application of the proceeds of any offering of Common Shares under the Sales Agreement and under this prospectus supplement and the accompanying prospectus. We intend to use the proceeds from any offering primarily for general corporate purposes which may include, but are not limited to, our current clinical development programs. Investors may not agree with the ways we decide to use these proceeds, and our use of the proceeds may not yield any results or profits.

### ***Future issuances of securities and hedging activities may depress the trading price of our Common Shares.***

Any additional or future issuance of equity securities or securities convertible into or exchangeable for equity securities, including the issuance of Common Shares upon the exercise of stock options and upon the exercise of outstanding warrants, could dilute the interests of our existing shareholders, and could substantially decrease the trading price of our Common Shares. We may issue equity securities in the future for a number of reasons, including to finance our operations and business strategy, to satisfy our obligations upon the exercise of options or warrants or for other reasons. Our stock option plan generally permits us to have outstanding, at any given time, stock options that are exercisable for a maximum number of Common Shares equal to 11.4% of all then issued and outstanding Common Shares. As at March 31, 2013, there were:

25,329,288 Common Shares issued and outstanding;

no issued and outstanding Preferred Shares (as defined below);

4,407,410 Common Shares issuable upon exercise of outstanding warrants; and

2,040,267 stock options outstanding.



---

**Table of Contents**

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

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

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

*The outcome of pending and future claims and litigation could have a material adverse impact on our business, financial condition and results of operations.*

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

On December 21, 2012, a second amended securities class action complaint (the U.S. Class Action ) was filed against the Company and certain of its senior officers in the purported class action lawsuit initially filed in June 2012 in the United States District Court, Southern District of New York. On February 1, 2013, we filed a motion to dismiss the U.S. Class Action. This motion was fully briefed as of April 5, 2013. This lawsuit, alleging material misrepresentations or omissions under U.S. federal securities laws, is being prosecuted by a lead plaintiff on behalf of shareholders who acquired our common shares between June 1, 2009 and April 1, 2012 and does not claim a specified amount of damages. We have not recorded any liability related to the U.S. Class Action. The Company's directors and officers' insurance policy provides for reimbursement of costs and expenses incurred in connection with this lawsuit, including legal and professional fees, as well as potential damages awarded, if any, subject to certain policy restrictions, limits and deductibles. While we continue to believe that there is no basis for the lawsuit and we intend to defend ourselves vigorously, no assurance can be given with respect to the ultimate outcome of such proceedings, and the amount of any damages awarded in such lawsuit could be substantial.

**USE OF PROCEEDS**

Except as otherwise provided in any free writing prospectus that we may authorize to be provided to you, we intend to use the net proceeds from the sale of the Common Shares to continue to fund our ongoing drug development activities, particularly for the advancement of our AEZS-108 and macimorelin acetate programs, as well as for future negative cash flow, general corporate purposes and working capital. Pending the application of the net proceeds, we expect to invest the proceeds in investment grade, interest bearing securities.

As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses for the net proceeds we will have upon completion of this offering. Accordingly, our management will have broad discretion in the application of net proceeds, if any.

**Table of Contents****PRICE RANGE AND TRADING VOLUME**

Our Common Shares are listed and posted for trading on NASDAQ under the symbol **AEZS** and on TSX under the symbol **AEZ**. The following table indicates the monthly range of high and low closing prices of a Common Share and the average daily volumes traded on NASDAQ and on TSX during the period beginning on May 1, 2012 and ending on May 21, 2013, as adjusted to reflect and give effect to our six-to-one share consolidation on October 2, 2012:

	NASDAQ (US\$) <sup>(1)</sup>			TSX (C\$) <sup>(1)</sup>		
	High	Low	Volume	High	Low	Volume
<b>2012</b>						
May	3.78	2.58	168,804	3.72	2.76	6,920
June	3.24	2.29	206,388	3.24	2.40	8,868
July	3.06	2.44	120,958	3.12	2.40	4,667
August	3.06	2.35	136,491	3.06	2.34	4,950
September	5.06	2.90	567,534	5.04	2.82	15,155
October	4.12	2.15	886,858	4.08	2.07	27,082
November	2.32	1.87	441,086	2.29	1.87	12,995
December	2.47	2.17	778,225	2.49	2.14	17,026
<b>2013</b>						
January	3.23	2.53	1,042,958	3.27	2.48	23,532
February	3.04	2.41	657,955	3.03	2.45	15,826
March	2.62	1.88	541,009	2.67	1.90	12,960
April	1.98	1.73	213,368	2.02	1.74	7,623
May <sup>(2)</sup>	2.10	1.77	213,485	2.18	1.80	4,055

(1) Between May 1, 2012 and October 5, 2012, the high and low prices have been multiplied by six (6) to retroactively give effect to and reflect the share consolidation described above and, for the same period, the volumes have been divided by six (6).

(2) Up to and including May 21, 2013.

**PRIOR SALES**

During the twelve-month period preceding the date of this prospectus supplement, we issued or granted, as applicable:

an aggregate of 162,591 Common Shares under our at-the-market issuance program implemented in January 2012 at an average issuance price of \$2.98 per share, for aggregate gross proceeds of approximately \$0.48 million, less cash and previously deferred transaction costs totaling approximately \$71,000;

an aggregate of 6.6 million Common Shares at an issuance price of \$2.50 per share, as well as 2.97 million warrants to acquire Common Shares at an exercise price of \$3.45 per share;

1,333 Common Shares pursuant to the exercise of stock options granted under our stock option plan at a weighted average exercise price of C\$3.30 per share; and

1,317,445 stock options exercisable at a weighted average price of \$2.26 per share (excluding 10,500 options granted during such twelve-month period that were forfeited prior to the date of this prospectus supplement).



**Table of Contents****CONSOLIDATED CAPITALIZATION**

The following table presents the number of our issued and outstanding Common Shares and our consolidated cash and cash equivalents and capitalization as at March 31, 2013 on an actual basis and as adjusted to give effect to the sale of our Common Shares in the aggregate amount of \$4.6 million at an assumed offering price of \$1.82 per share. The last reported sale price of our Common Shares on NASDAQ on April 30, 2013 was \$1.82 per share. The adjustments present the expected impact on the number of our issued and outstanding shares, our consolidated cash and cash equivalents and our capitalization as at March 31, 2013 of the issuances described above and after the payment by us of MLV's compensation and our estimated transaction expenses. There has been no material change to our share and loan capital since March 31, 2013. See "Prior Sales" above. In addition, as at March 31, 2013, we had no outstanding long-term debt.

The information below has been derived from and should be read in conjunction with, and is qualified in its entirety by, our unaudited interim consolidated financial statements as at March 31, 2013 and for the three-month periods ended March 31, 2013 and 2012 and Management's Discussion and Analysis thereon, incorporated by reference into this prospectus supplement. Figures are in thousands of U.S. dollars except share data.

All historical share, warrant and option data in the tables below, including number of securities issued and outstanding and applicable exercise prices, have been retroactively adjusted to reflect and give effect to our six-to-one share consolidation on October 2, 2012.

	As at March 31, 2013	
	Actual	As Adjusted <sup>(1)</sup>
Number of Common Shares issued and outstanding	25,329,288 <sup>(2)</sup>	27,829,288 <sup>(2)</sup>
Cash and cash equivalents	\$ 33,183	\$ 37,427
Shareholders' (deficiency) equity:		
Share capital	\$ 122,791	\$ 127,035
Other capital	\$ 84,500	\$ 84,500
Deficit	\$ (211,200)	\$ (211,200)
Accumulated other comprehensive loss	\$ (52)	\$ (52)
Total shareholders' (deficiency) equity and total capitalization	\$ (3,961)	\$ 283

(1) As adjusted assumes and gives effect to the issuance of 2,500,000 Common Shares to be offered from time to time under this prospectus supplement at an assumed price of \$1.82 per Common Share (the last reported sale price of our Common Shares on NASDAQ on April 30, 2013 being \$1.82 per share) and the payment by us of MLV's compensation and our estimated transaction expenses. In light of the continuous distribution nature of this at-the-market offering, there can be no assurance that we will in fact issue all or any number of the 2,500,000 Common Shares offered under this prospectus supplement or, if we do issue any Common Shares under this prospectus supplement, that they will be issued at \$1.82 per share. The figures provided in the "as adjusted" column are thus solely for illustrative purposes.

(2) In addition, as of March 31, 2013, 4,407,410 Common Shares were issuable upon exercise of warrants that we previously issued in various registered direct offerings in October 2009, April 2010 and June 2010 and in a public offering in October 2012. As of March 31, 2013, there were also 2,040,267 Common Shares that underlie outstanding stock options granted under our stock option plan. As of May 21, 2013, there were 25,329,288 Common Shares issued and outstanding. Assuming the issuance of all 2,500,000 Common Shares under this prospectus supplement, there would be 27,829,288 issued and outstanding Common Shares.

**DESCRIPTION OF SECURITIES OFFERED UNDER THIS PROSPECTUS SUPPLEMENT****Share Capital**

Our authorized share capital structure consists of an unlimited number of shares of the following classes (all classes are without nominal or par value): Common Shares; and first preferred shares (the "First Preferred Shares") and second preferred shares (the "Second Preferred Shares" and, together with the First Preferred Shares, the "Preferred Shares"), both issuable in series. As at March 31, 2013, there were 25,329,288 Common

Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

Shares issued and outstanding. No Preferred Shares of the Company have been issued to date.

S-28

---

## Table of Contents

### Common Shares

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

Additional information on our share capital is provided in Item 10. Additional Information in our Annual Report on Form 20-F for the financial year ended December 31, 2012 and is incorporated by reference into this prospectus supplement.

### PLAN OF DISTRIBUTION

We have entered into a Sales Agreement with MLV under which we may issue and sell from time to time through MLV, acting as agent, up to 2,500,000 Common Shares up to a maximum aggregate offering price of \$4.6 million hereunder. A form of the Sales Agreement has been filed on SEDAR with the Canadian securities regulatory authorities and furnished to the SEC as Exhibit 99.2 to our Report on Form 6-K dated May 21, 2013. **The sales, if any, of Common Shares made under the Sales Agreement will be made in the U.S. and will only be made by any method permitted by law deemed to be an at-the-market distribution as defined in NI 44-102, including without limitation sales made directly on NASDAQ or on any other existing trading market for the Common Shares in the U.S.** We may instruct MLV not to sell Common Shares if the sales cannot be effected at or above the price designated by us from time to time. We or MLV may suspend the offering of Common Shares upon notice and subject to other conditions. Neither MLV, any affiliate of MLV nor any person or company acting jointly or in concert with MLV, has over-allotted, or will over-allot, Common Shares in connection with this offering or effect any other transactions that are intended to stabilize or maintain the market price of the Common Shares.

We will pay MLV commissions for its services in acting as agent in the sale of Common Shares. MLV will be entitled to compensation at a fixed commission rate of three percent (3%) of the gross proceeds from the sale of such Common Shares. We estimate that the total expenses for the offering, excluding compensation payable to MLV under the terms of the Sales Agreement, will be approximately \$0.2 million. Each of the Company and MLV is responsible for paying its own out-of-pocket expenses and legal and other advisory fees.

Settlement for sales of Common Shares will occur on the third business day following the date on which any sales are made, or on some other date that is agreed upon by us and MLV in connection with a particular transaction, in return for payment of the net proceeds to us.

The Common Shares will be listed on NASDAQ. The TSX has conditionally approved the listing of the Common Shares offered for sale pursuant to this prospectus supplement. Listing is subject to the Company fulfilling all of the requirements of the TSX on or before the business day immediately following the date on which this prospectus supplement is filed.

MLV will act as sales agent and will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the Common Shares. In connection with the sale of the Common Shares on our behalf, MLV will be deemed to be an underwriter within the meaning of the Securities Act and the compensation of MLV will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to MLV against certain civil liabilities, including liabilities under the Securities Act.

The Sales Agreement further provides that, during its term, neither MLV nor any of its affiliates or subsidiaries shall engage in (i) any short sale of any security of the Company, or (ii) any sale of any security of the Company that MLV does not own or any sale which is consummated by the delivery of a security of the Company borrowed by, or for the account of, MLV, and that neither MLV nor any of its affiliates or subsidiaries shall engage in any proprietary trading or trading for MLV's (or its affiliates' or subsidiaries') own account.



## **Table of Contents**

The offering pursuant to the Sales Agreement will terminate on the two-year anniversary of the date of the Sales Agreement or earlier upon (i) the sale of all Common Shares subject to the agreement, or (ii) termination of the Sales Agreement by the Company or MLV as permitted therein.

The address of MLV is 1251 Avenue of the Americas, 41<sup>st</sup> Floor, New York, NY 10020.

MLV and its affiliates may in the future provide various investment banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, MLV will not engage in any market making activities involving our Common Shares while the offering is ongoing under this prospectus supplement.

## **CERTAIN INCOME TAX CONSIDERATIONS**

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

The following discussion is a summary of certain material U.S. federal income tax consequences applicable to the purchase, ownership and disposition of Common Shares being offered by this prospectus supplement and the accompanying prospectus by a U.S. Holder (as defined below), but does not purport to be a complete analysis of all potential U.S. federal income tax effects. This summary is based on the Internal Revenue Code of 1986, as amended (the Code), U.S. Treasury regulations promulgated thereunder, IRS rulings and judicial decisions in effect as of the date of this prospectus supplement. All of these are subject to change, possibly with retroactive effect, or different interpretations. This summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation that, if enacted, could be applied on a retroactive basis. This summary is not binding on the IRS, and the IRS is not precluded from taking a position that is different from, and contrary to, the positions taken in this summary.

This summary does not address all aspects of U.S. federal income taxation that may be relevant to particular U.S. Holders in light of their specific circumstances (for example, U.S. Holders subject to the alternative minimum tax or Medicare contribution tax provisions of the Code) or to holders that may be subject to special rules under U.S. federal income tax law, including:

dealers in stocks, securities or currencies;

securities traders that use a mark-to-market accounting method;

banks and financial institutions;

insurance companies;

regulated investment companies;

real estate investment trusts;

tax-exempt organizations;

retirement plans, individual plans, individual retirement accounts and tax-deferred accounts;

## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

partnerships or other pass-through entities for U.S. federal income tax purposes and their partners or members;

persons holding Common Shares as part of a hedging or conversion transaction straddle or other integrated or risk reduction transaction;

persons who or that are, or may become, subject to the expatriation provisions of the Code;

persons whose functional currency is not the U.S. dollar; and

direct, indirect or constructive owners of 10% or more of the total combined voting power of all classes of our voting stock.

S-30

---

## **Table of Contents**

This summary also does not discuss any aspect of state, local or foreign law, or estate or gift tax law as applicable to U.S. Holders. In addition, this discussion is limited to U.S. Holders purchasing Common Shares pursuant to this prospectus supplement and that will hold such Common Shares as capital assets. For purposes of this summary, U.S. Holder means a beneficial holder of Common Shares who or that for U.S. federal income tax purposes is:

an individual citizen or resident of the U.S.;

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 U.S., any state thereof or the District of Columbia;

an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or

a trust, if (a) a court within the U.S. is able to exercise primary supervision over the administration of such trust and one or more U.S. persons (within the meaning of the Code) have the authority to control all substantial decisions of the trust, or (b) a valid election is in effect to be treated as a U.S. person for U.S. federal income tax purposes.

If a partnership or other entity or arrangement classified as a partnership for U.S. federal income tax purposes holds Common Shares, the U.S. federal income tax treatment of a partner generally will depend on the status of the partner and the activities of the partnership. This summary does not address the tax consequences to any such partner. Such a partner should consult its own tax advisor as to the tax consequences of the partnership purchasing, owning and disposing of Common Shares.

**PROSPECTIVE U.S. INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH REGARD TO THE APPLICATION OF THE TAX CONSEQUENCES DESCRIBED BELOW TO THEIR PARTICULAR SITUATIONS AS WELL AS THE APPLICATION OF ANY STATE, LOCAL, FOREIGN OR OTHER TAX LAWS, INCLUDING GIFT AND ESTATE TAX LAWS.**

### ***Taxation of U.S. Holders of Common Shares***

#### ***Dividends***

Subject to the PFIC rules discussed below, any distributions paid by the Company out of current or accumulated earnings and profits (as determined for U.S. federal income tax purposes), before reduction for any Canadian withholding tax paid with respect thereto, will generally be taxable to a U.S. Holder as foreign source dividend income, and will not be eligible for the dividends received deduction generally allowed to corporations. Distributions in excess of current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in the Common Shares and thereafter as capital gain. Prospective purchasers should consult their own tax advisors with respect to the appropriate U.S. federal income tax treatment of any distribution received from the Company.

Dividends paid by the Company should be taxable to a non-corporate U.S. Holder at the special reduced rates normally applicable to long-term capital gains, provided that certain conditions are satisfied. A U.S. Holder will not be able to claim a reduced rate if the Company is treated as a PFIC for the taxable year in which the dividend is paid or the preceding year. See *Taxation of U.S. Holders of Common Shares - Passive Foreign Investment Company Considerations* below.

Under current law, payments of dividends by the Company to beneficial owners who are not resident in Canada for purposes of the *Income Tax Act* (Canada) (the *Tax Act*) are generally subject to a 25% Canadian withholding tax. The rate of withholding tax applicable to U.S. Holders that are eligible for benefits under the Canada-United States Tax Convention (the *Convention*) is reduced to a maximum of 15%. This reduced rate of withholding will not apply if the dividends received by a U.S. Holder are effectively connected with a permanent establishment of the U.S. Holder in Canada. For U.S. federal income tax purposes, U.S. Holders will be treated as having received the amount of Canadian taxes withheld by the Company, and as then having paid over the withheld taxes to the Canadian taxing authorities. As a result of this rule, the amount of dividend income included in gross income for U.S. federal income tax purposes by a U.S. Holder with respect to a payment of dividends may be greater than the amount of cash actually received (or receivable) by the U.S. Holder from the Company with respect to the payment.



---

## **Table of Contents**

Subject to certain limitations, a U.S. Holder will generally be entitled, at the election of the U.S. Holder, to a credit against its U.S. federal income tax liability, or a deduction in computing its U.S. federal taxable income, for Canadian income taxes withheld by the Company. This election is made on a year-by-year basis and applies to all foreign taxes paid (whether directly or through withholding) by a U.S. Holder during a year. For purposes of the foreign tax credit limitation, dividends paid by the Company generally will constitute foreign source income in the passive category income basket. The foreign tax credit rules are complex and prospective purchasers should consult their tax advisors concerning the availability of the foreign tax credit in their particular circumstances.

Dividends paid in Canadian dollars will be included in the gross income of a U.S. Holder in a U.S. dollar amount calculated by reference to the exchange rate in effect on the date the U.S. Holder (actually or constructively) receives the dividend, regardless of whether such Canadian dollars are actually converted into U.S. dollars at that time. If the Canadian dollars received are not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a tax basis in the Canadian dollars equal to their U.S. dollar value on the date of receipt. Gain or loss, if any, realized on a sale or other disposition of the Canadian dollars will generally be U.S. source ordinary income or loss to a U.S. Holder.

The Company generally does not pay any dividends and does not anticipate paying any dividends in the foreseeable future.

### *Sale, Exchange or Other Taxable Disposition of Common Shares*

Subject to the PFIC rules discussed below, upon a sale, exchange or other taxable disposition of Common Shares, a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference, if any, between the amount realized on the sale, exchange or other taxable disposition and the U.S. Holder's adjusted tax basis in the Common Shares.

This capital gain or loss will be long-term capital gain or loss if the U.S. Holder's holding period in the Common Shares exceeds one year. The deductibility of capital losses is subject to limitations. Any gain or loss will generally be U.S. source for U.S. foreign tax credit purposes.

### *Passive Foreign Investment Company Considerations*

A foreign corporation will be classified as a PFIC for any taxable year in which, after taking into account the income and assets of the corporation and certain subsidiaries pursuant to applicable look-through rules, either (i) at least 75% of its gross income is passive income or (ii) at least 50% of the average value of its assets is attributable to assets which produce passive income or are held for the production of passive income. Passive income generally includes dividends, interest, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income.

The Company believes it was not a PFIC for the 2012 taxable year. However, the fair market value of the Company's assets may be determined in large part by the market price of the Common Shares, which is likely to fluctuate, and the composition of the Company's income and assets will be affected by how, and how quickly, the Company spends any cash that is raised in any financing transaction. Thus, no assurance can be provided that the Company will not be classified as a PFIC for the 2013 taxable year and for any future taxable year. Prospective purchasers should consult their tax advisors regarding the Company's PFIC status.

If the Company is classified as a PFIC for any taxable year during which a U.S. Holder owns Common Shares, the U.S. Holder, absent certain elections (including the mark-to-market and QEF elections described below), will generally be subject to adverse rules (regardless of whether the Company continues to be classified as a PFIC) with respect to (i) any excess distributions (generally, any distributions received by the U.S. Holder on the Common Shares in a taxable year that are greater than 125% of the average annual distributions received by the U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period for the Common Shares) and (ii) any gain realized on the sale or other disposition of the Common Shares.

---

**Table of Contents**

Under these adverse rules (a) the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period, (b) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which the Company is classified as a PFIC will be taxed as ordinary income, and (c) the amount allocated to each of the other taxable years during which the Company was classified as a PFIC will be subject to tax at the highest rate of tax in effect for the applicable category of taxpayer for that year and an interest charge will be imposed with respect to the resulting tax attributable to each such other taxable year. A U.S. Holder that is not a corporation will be required to treat any such interest paid as personal interest, which is not deductible.

U.S. Holders can avoid the adverse rules described above in part by making a mark-to-market election with respect to the Common Shares, provided that the Common Shares are marketable. Common Shares will be marketable if they are regularly traded on a qualified exchange or other market within the meaning of applicable U.S. Treasury regulations. For this purpose, Common Shares generally will be considered to be regularly traded during any calendar year during which they are traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. The Common Shares are currently listed on NASDAQ, which constitutes a qualified exchange; however, there can be no assurance that the Common Shares will be treated as regularly traded for purposes of the mark-to-market election on a qualified exchange. If the Common Shares were not regularly traded on NASDAQ or were delisted from the NASDAQ and were not traded on another qualified exchange for the requisite time period described above, the mark-to-market election would not be available.

A U.S. Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year an amount equal to the excess, if any, of the fair market value of the U.S. Holder's Common Shares at the close of the taxable year over the U.S. Holder's adjusted tax basis in the Common Shares. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted tax basis in the Common Shares over the fair market value of the Common Shares at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains previously included in income. A U.S. Holder that makes a mark-to-market election generally will adjust such U.S. Holder's tax basis in the Common Shares to reflect the amount included in gross income or allowed as a deduction because of such mark-to-market election. Gains from an actual sale or other disposition of the Common Shares will be treated as ordinary income, and any losses incurred on a sale or other disposition of the Common Shares will be treated as ordinary losses to the extent of any net mark-to-market gains previously included in income.

If the Company is classified as a PFIC for any taxable year in which a U.S. Holder owns Common Shares but before a mark-to-market election is made, the adverse PFIC rules described above will apply to any mark-to-market gain recognized in the year the election is made. Otherwise, a mark-to-market election will be effective for the taxable year for which the election is made and all subsequent taxable years. The election cannot be revoked without the consent of the IRS unless the Common Shares cease to be marketable, in which case the election is automatically terminated.

If the Company is classified as a PFIC, a U.S. Holder of Common Shares will generally be treated as owning stock owned by the Company in any direct or indirect subsidiaries that are also PFICs and will be subject to similar adverse rules with respect to distributions to the Company by, and dispositions by the Company of, the stock of such subsidiaries. A mark-to-market election is not permitted for the shares of any subsidiary of the Company that is also classified as a PFIC. Prospective purchasers should consult their tax advisors regarding the availability of, and procedure for making, a mark-to-market election.

In some cases, a shareholder of a PFIC can avoid the interest charge and the other adverse PFIC consequences described above by making a QEF election to be taxed currently on its share of the PFIC's undistributed income. The Company does not, however, expect to provide the information regarding its income that would be necessary in order for a U.S. Holder to make a QEF election with respect to Common Shares if the Company is classified as a PFIC.

A U.S. Holder that makes a timely and effective QEF election for the first tax year in which its holding period of its Common Shares begins generally will not be subject to the adverse PFIC consequences described above with respect to its Common Shares. Rather, a U.S. Holder that makes a timely and effective QEF election will be subject to U.S. federal income tax on such U.S. Holder's pro rata share of (a) the Company's net capital gain, which will be taxed

## **Table of Contents**

as long-term capital gain to such U.S. Holder, and (b) the Company's ordinary earnings, which will be taxed as ordinary income to such U.S. Holder, in each case regardless of which such amounts are actually distributed to the U.S. Holder by the Company. Generally, net capital gain is the excess of (a) net long-term capital gain over (b) net short-term capital loss, and ordinary earnings are the excess of (a) earnings and profits over (b) net capital gain.

A U.S. Holder that makes a timely and effective QEF election with respect to the Company generally (a) may receive a tax-free distribution from us to the extent that such distribution represents earnings and profits that were previously included in income by the U.S. Holder because of such QEF election and (b) will adjust such U.S. Holder's tax basis in the Common Shares to reflect the amount included in income or allowed as a tax-free distribution because of such QEF election. In addition, a U.S. Holder that makes a QEF election generally will recognize capital gain or loss on the sale or other taxable disposition of Common Shares.

The QEF election is made on a shareholder-by-shareholder basis. Once made, a QEF election will apply to the tax year for which the QEF election is made and to all subsequent tax years, unless the QEF election is invalidated or terminated or the IRS consents to revocation of the QEF election. In addition, if a U.S. Holder makes a QEF election, the QEF election will remain in effect (although it will not be applicable) during those tax years in which the Company is not a PFIC.

If the Company is classified as a PFIC and then ceases to be so classified, a U.S. Holder may make an election (a deemed sale election) to be treated for U.S. federal income tax purposes as having sold such U.S. Holder's Common Shares on the last day of the taxable year of the Company during which it was a PFIC. A U.S. Holder that made a deemed sale election would then cease to be treated as owning stock in a PFIC by reason of ownership of Common Shares in the Company. However, gain recognized as a result of making the deemed sale election would be subject to the adverse rules described above and loss would not be recognized.

If the Company is a PFIC in any year with respect to a U.S. Holder, the U.S. Holder will be required to file an annual information return on IRS Form 8621 regarding distributions received on Common Shares and any gain realized on the disposition of Common Shares.

In addition, under U.S. tax legislation and subject to future guidance, if the Company is a PFIC, U.S. Holders will be required to file an annual information return with the IRS (also on IRS Form 8621, which PFIC shareholders will be required to file with their U.S. federal income tax or information returns) relating to their ownership of Common Shares. The IRS has suspended this new filing requirement pending the issuance of additional guidance. This new filing requirement is in addition to the preexisting reporting requirements described above that apply to a U.S. Holder's interest in a PFIC (which the tax legislation does not affect).

Prospective purchasers should consult their tax advisors regarding the potential application of the PFIC regime and any reporting obligations to which they may be subject under that regime.

### *Information Reporting and Backup Withholding*

Payments made within the U.S., or by a U.S. payor or U.S. middleman, of dividends on, and proceeds arising from sales or other dispositions of Common Shares, generally will be reported to the IRS and to the U.S. Holder as required under applicable regulations. Backup withholding tax may apply to these payments if the U.S. Holder fails to timely provide in the appropriate manner an accurate taxpayer identification number or otherwise fails to comply with, or establish an exemption from, such backup withholding tax requirements. Certain U.S. Holders are not subject to the information reporting or backup withholding tax requirements described herein. U.S. Holders should consult their tax advisors as to their qualification for exemption from backup withholding tax and the procedure for establishing an exemption.

---

## Table of Contents

Backup withholding tax is not an additional tax. U.S. Holders generally will be allowed a refund or credit against their U.S. federal income tax liability for amounts withheld, provided the required information is timely furnished to the IRS.

Subject to certain exceptions and future guidance, U.S. tax legislation generally requires a U.S. Holder that is a specified individual or, to the extent provided in recently proposed and temporary U.S. Treasury regulations, a domestic entity, to report annually to the IRS on IRS Form 8938 such U.S. Holder's interests in stock or securities issued by a non-U.S. person (such as the Company). Pursuant to IRS Notice 2013-10, reporting under this legislation will not be required by domestic entities any earlier than taxable years beginning after December 31, 2012. U.S. Holders should consult their tax advisors regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of Common Shares.

### **Canadian Federal Income Tax Considerations for U.S. Shareholders**

The following is a general summary, as of the date hereof, of the principal Canadian federal income tax considerations generally applicable to the holding and disposition of Common Shares acquired pursuant to this prospectus supplement by a holder who, at all relevant times, (a) for the purposes of the Tax Act, (i) is not resident, or deemed to be resident, in Canada, (ii) deals at arm's length with the Company, and is not affiliated with the Company, (iii) beneficially owns Common Shares as capital property, (iv) does not use or hold the Common Shares in the course of carrying on, or otherwise in connection with, a business or a part of a business carried on or deemed to be carried on in Canada and (v) is not a registered non-resident insurer or authorized foreign bank within the meaning of the Tax Act, and (b) for the purposes of the Convention, is a resident of the U.S., has never been a resident of Canada, does not have and has not had, at any time, a permanent establishment or fixed base in Canada, and who is a qualifying person or otherwise qualifies for the full benefits of the Convention. Common Shares will generally be considered to be capital property to a holder unless such Common Shares are held in the course of carrying on a business of buying or selling securities, or an adventure or concern in the nature of trade. Our shares will generally not be capital property to holders that are financial institutions (as defined in subsection 142.2(1) of the Tax Act). Holders who meet all the criteria in clauses (a) and (b) are referred to herein as a U.S. Shareholder or U.S. Shareholders. This summary does not deal with special situations, such as the particular circumstances of traders or dealers, holders an interest in which is a tax shelter investment as defined in the Tax Act, tax exempt entities, insurers, financial institutions or holders who have made a functional currency reporting election under section 261 of the Tax Act. Such holders and other holders who do not meet the criteria in clauses (a) and (b) should consult their own tax advisors.

This summary is based upon the current provisions of the Tax Act and the regulations thereunder (the Regulations) and the Company's understanding of the current administrative policies and assessing practices of the Canada Revenue Agency (CRA) made publicly available prior to the date hereof. 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) prior to the date hereof, 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 take into account tax laws of any province or territory of Canada or of any other jurisdiction outside Canada.

For purposes of the Tax Act, all amounts, including dividends, adjusted cost base and proceeds of disposition, must generally be determined in Canadian dollars. Amounts denominated in U.S. dollars must be converted to Canadian currency using the Bank of Canada noon rate on the day on which the amount arose or such other rate of exchange that is acceptable to the Minister of National Revenue (Canada). The amount of any capital gain or any capital loss to a U.S. shareholder with respect to the Common Shares may be affected by fluctuations in Canadian dollar exchange rates.

**This 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 U.S. Shareholder and no representation with respect to the federal income tax consequences to any particular U.S. Shareholder or prospective U.S. Shareholder is made. The tax consequences to a U.S. Shareholder will depend on the holder's particular circumstances. Accordingly, U.S. Shareholders should consult with their own tax advisors for advice with respect to their own particular circumstances.**



---

## **Table of Contents**

The cost for Canadian tax purposes to a U.S. Shareholder of a Common Share must be averaged at the time such Common Share is acquired with the adjusted cost base of all other Common Shares held by such U.S. Shareholder as capital property at that time for purposes of calculating the adjusted cost base of such Common Shares.

### ***Dividends***

Amounts paid or credited or deemed to be paid or credited as, on account or in lieu of payment, or in satisfaction of, dividends on our Common Shares to a U.S. Shareholder will be subject to Canadian withholding tax. Under the Convention, the rate of Canadian withholding tax on dividends paid or credited by us to a U.S. Shareholder that beneficially owns such dividends is generally 15% unless the beneficial owner is a company that owns at least 10% of our voting stock at that time, in which case the rate of Canadian withholding tax is reduced to 5%.

### ***Dispositions***

A U.S. Shareholder will generally not be subject to tax under the Tax Act on any capital gain realized on a disposition of our Common Shares, unless the Common Shares constitute taxable Canadian property to the U.S. Shareholder at the time of disposition and the U.S. Shareholder is not entitled to relief under the Convention. Generally, our Common Shares will not constitute taxable Canadian property to a U.S. Shareholder provided our Common Shares are listed on a designated stock exchange (which includes NASDAQ and TSX) at the time of the disposition, unless (a) at any time during the 60-month period immediately preceding the disposition, the U.S. Shareholder, persons with whom the U.S. Shareholder does not deal at arm's length, or the U.S. Shareholder together with such persons, owned 25% or more of the issued shares of any series or class of our capital stock and more than 50% of the fair market value of our Common Shares was derived, directly or indirectly, from a combination of (i) real or immovable property situated in Canada, (ii) Canadian resource property (as defined in the Tax Act), (iii) timber resource property (as defined in the Tax Act), and (iv) options in respect of, interests in, or for civil law rights in any such properties whether or not the property exists, or (b) our Common Shares are otherwise deemed to be taxable Canadian property to the U.S. Shareholder.

If our Common Shares constitute taxable Canadian property to a particular U.S. Shareholder, any capital gain arising on their disposition may be exempt from Canadian tax under the Convention if, at the time of disposition, our Common Shares do not derive their value principally from real property situated in Canada as defined in the Convention.

As long as our Common Shares are listed at the time of their disposition on NASDAQ, TSX or another recognized stock exchange (as defined in the Tax Act), a U.S. Shareholder who disposes of our Common Shares that are taxable Canadian property will not be required to apply for and obtain a certificate of compliance and will not be subject to withholding by a purchaser under Section 116 of the Tax Act. An exemption from such obligations may also be available in respect of such a disposition if the Common Shares are treaty-protected property (as defined in the Tax Act) of the disposing U.S. shareholder.

## **LEGAL MATTERS**

Certain legal matters relating to the offering will be passed upon for us by Norton Rose Canada LLP with respect to matters of Canadian law and certain legal matters relating to the offering will be passed upon for us by Ropes & Gray LLP with respect to certain matters of U.S. law. MLV is being represented in connection with this offering by LeClairRyan, A Professional Corporation, with respect to matter of U.S. law. At the date of this prospectus supplement, the partners and associates of Norton Rose Canada LLP as a group, the partners and associates of Ropes & Gray LLP as a group and the members of LeClairRyan as a group, beneficially own, directly or indirectly, less than 1% of our outstanding securities.

---

**Table of Contents**

**EXPERTS**

The consolidated financial statements and management's assessment of the effectiveness of internal control over financial reporting (which is included in Management's Report on Internal Control over Financial Reporting) incorporated into this prospectus supplement by reference to the Annual Report on Form 20-F of Aeterna Zentaris Inc. for the financial year ended December 31, 2012, have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent auditors, given on the authority of said firm as experts in auditing and accounting.

**EXEMPTIVE RELIEF GRANTED BY THE AUTORITÉ DES MARCHÉS FINANCIERS**

Pursuant to a decision dated February 28, 2013 (the "Decision") issued by the Québec *Autorité des marchés financiers*: (a) an exemption has been granted from the requirement under applicable Canadian securities legislation to send a purchaser of Common Shares under this offering the latest prospectus and any amendment thereto and, as a result, the withdrawal right and the right of action for non-delivery of the accompanying prospectus, as supplemented by this prospectus supplement, will not apply to the offering; and (b) the Company is exempt from: (i) the requirement to include in the accompanying prospectus, as supplemented by this prospectus supplement, the form of certification for a base shelf prospectus prescribed by NI 44-102 provided that the certificate in the form set out in the Decision is included in this prospectus supplement; and (ii) the requirement to include in this prospectus supplement the statement respecting purchasers' statutory rights of withdrawal and remedies for rescission and damages prescribed by Form 44-101F1 under *Regulation 44-101 respecting Short Form Prospectus Distributions* ( *Regulation 44-101* ), provided that the disclosure set out under the heading "Purchasers' Statutory Rights" is included herein. Furthermore, pursuant to a decision dated June 21, 2012 issued by the Québec *Autorité des marchés financiers* the Company is exempt from: (i) the requirement to include in this prospectus supplement the form of certification of an underwriter for a base shelf prospectus prescribed by Regulation 44-101; and (ii) the requirement prescribed by the *Securities Act* (Québec) and by Regulation 44-101 to prepare a French version of this prospectus supplement, provided that all Common Shares issued in connection therewith shall be issued solely in the U.S.

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual reports on Form 20-F with the SEC, and we furnish other documents, such as quarterly and current reports, proxy statements and other information and documents that we file with the Canadian securities regulatory authorities, to the SEC, as required. You may read and copy any materials we file with or furnish to the SEC at the public reference room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements and other information regarding registrants who file electronically with the SEC. As we are a Canadian issuer, we also file continuous disclosure documents with the Canadian securities regulatory authorities, which documents are available on the SEDAR website maintained by the Canadian Securities administrators at [www.sedar.com](http://www.sedar.com).

This prospectus supplement and the accompanying prospectus form part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and our Common Shares, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the address listed above or electronically at [www.sec.gov/edgar/shtml](http://www.sec.gov/edgar/shtml).

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

This prospectus supplement and the accompanying prospectus are part of a base shelf prospectus forming part of a registration statement on Form F-10 filed by us with the SEC. This prospectus supplement and the accompanying prospectus do not contain all of the information set forth in the registration statement, certain parts of which are omitted in accordance with the rules and regulations of the SEC. Statements contained in this prospectus supplement,

## Table of Contents

the accompanying prospectus or the documents incorporated by reference into this prospectus supplement or the accompanying prospectus as to the contents of any contract or other document referred to are not necessarily complete and in each instance reference is made to the copy of that contract or other document filed with or furnished to the SEC. For further information about us and the securities offered by this prospectus supplement, we refer you to the registration statement and its exhibits and schedules which may be obtained as described herein.

The SEC and the Canadian securities regulatory authorities allow us to incorporate by reference the information contained in documents that we file with or furnish to it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus, and information in documents that we subsequently file with or furnish to the SEC and the Canadian securities regulatory authorities will automatically update and supersede information in this prospectus supplement and the accompanying prospectus. We incorporate by reference the documents listed below into this prospectus supplement, and any future filings made by us with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act until the offering of all the securities by this prospectus supplement is completed, including all filings made after the date of this prospectus supplement. We hereby incorporate by reference the documents listed below (File No. 000-30752):

our annual report on Form 20-F for the financial year ended December 31, 2012 (filed in Canada with the Canadian securities regulatory authorities in lieu of an annual information form), and which includes our consolidated statements of financial position as at December 31, 2012 and December 31, 2011 and our consolidated statements of changes in shareholders' equity, comprehensive loss and cash flows for the years ended December 31, 2012, 2011 and 2010 and management's annual report on internal control over financial reporting set out on page 100 of our 2012 annual report on Form 20-F, together with the auditors' report dated March 21, 2013 on our consolidated financial statements and effectiveness of internal control over financial reporting as at December 31, 2012; and our Management's Discussion and Analysis included as Item 5. Operating and Financial Review and Prospects in our annual report on Form 20-F;

our unaudited interim consolidated financial statements as at March 31, 2013 and for the three-month periods ended March 31, 2013 and 2012 and Management's Discussion and Analysis thereon, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on May 7, 2013;

our management information circular dated March 21, 2013 in connection with our annual meeting of shareholders held on May 8, 2013, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on March 21, 2012;

our material change report dated January 3, 2013 announcing our agreement with the FDA on a SPA for an upcoming Phase 3 registration trial in endometrial cancer with AEZS-108, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on January 8, 2013;

our material change report dated March 12, 2013 announcing that an independent Data Safety Monitoring Board has recommended discontinuing our ongoing Phase 3 trial of perifosine in multiple myeloma, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on March 12, 2013;

our material change report dated April 15, 2013 announcing that David A. Dodd was appointed as our President and Chief Executive Officer as well as to our Board of Directors, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on April 15, 2013, and

to the extent permitted by applicable securities law, any other documents which we elect to incorporate by reference into this prospectus supplement.

We will provide each person to whom this prospectus supplement is delivered a copy of all of the information that has been incorporated by reference in this prospectus supplement or the accompanying prospectus but not delivered with this prospectus supplement and the accompanying prospectus. You may obtain copies of these filings, at no cost, by writing or telephoning us at:

Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

Aeterna Zentaris Inc.

Attention: Investor Relations

1405 du Parc-Technologique Boulevard

Quebec City, Quebec

Canada, G1P 4P5

Tel. (418) 652-8525

S-38

---

**Table of Contents**

*No securities regulatory authority has expressed an opinion about these securities and it is an offence to claim otherwise.*

*This short form base shelf prospectus constitutes a public offering of securities only in those jurisdictions where such securities may be lawfully offered for sale and therein only by persons permitted to sell such securities and it is an offence to claim otherwise.*

*This short form base shelf prospectus has been filed under legislation in each of the provinces of Canada that permits certain information about these securities to be determined after this short form base shelf prospectus has become final and that permits the omission from this short form base shelf prospectus of that information. The legislation requires the delivery to purchasers of a prospectus supplement containing the omitted information within a specified period of time after agreeing to purchase any of these securities. **Information has been incorporated by reference in this short form base shelf prospectus from documents filed with securities commissions or similar authorities in Canada.** Copies of the documents incorporated herein by reference may be obtained on request without charge from the secretary of the issuer at 1405 du Parc-Technologique Blvd., Quebec City, Quebec, Canada G1P 4P5, tel. (418) 652-8525, and are also available electronically at [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml) or [www.sedar.com](http://www.sedar.com).*

New Issue

June 8, 2012

**SHORT FORM BASE SHELF PROSPECTUS**

**U.S.\$100,000,000**

**Common Shares**

**Warrants to Purchase Common Shares**

We may from time to time during the 25-month period that this short form base shelf prospectus (the Prospectus), including any amendments, remains valid, offer, sell, and issue under this Prospectus up to U.S.\$100,000,000 aggregate initial offering price of our common shares (the Common Shares) and/or warrants to purchase Common Shares (the Warrants), and, together with the Common Shares, the Securities). We may offer Securities from time to time in one or more transactions in such amounts and, in the case of the Warrants, with such terms, as we may determine in light of prevailing market conditions at the time of sale. We may sell and issue the Warrants under this Prospectus in one or more series.

The specific variable terms of any offering of Securities will be set out in the applicable supplement to this Prospectus (each, a Prospectus Supplement), including, where applicable: (i) in the case of the Common Shares, the number of Common Shares offered, the offering price, the currency in which the Common Shares will be issued and any other specific terms; and (ii) in the case of the Warrants, the designation of the particular series offered, the number of Warrants offered, the offering price, the currency in which the Warrants will be issued, the number of Common Shares that may be acquired upon exercise of the Warrants, the exercise price, dates and periods of exercise, adjustment procedures and any other specific terms applicable thereto.

A Prospectus Supplement may include specific terms pertaining to the Securities that are not within the alternatives and parameters described in this Prospectus. All shelf information permitted under applicable laws to be omitted from this Prospectus will be contained in one or more Prospectus Supplements that will be delivered to purchasers together with this Prospectus. Each Prospectus Supplement will be incorporated by reference into this Prospectus for the purposes of securities legislation as of the date of the Prospectus Supplement and only for the purposes of the distribution of the Securities to which the Prospectus Supplement pertains.

**We are a foreign private issuer under United States ( U.S. ) securities laws and are permitted, under a multi-jurisdictional disclosure system ( MJDS ) adopted by the U.S. and Canada, to prepare this Prospectus in accordance with Canadian disclosure requirements. Prospective investors should be aware that such**

## Table of Contents

requirements are different from those in the U.S. The financial statements included or incorporated by reference into this Prospectus have been prepared in accordance with International Financial Reporting Standards ( IFRS ) as issued by the International Accounting Standards Board. Our consolidated financial statements are subject to Canadian generally accepted auditing standards and auditor independence standards, in addition to the standards of the Public Company Accounting Oversight Board (United States) and the U.S. Securities and Exchange Commission ( SEC ) independence standards.

Prospective investors should be aware that the acquisition of the Securities described herein may have tax consequences both in Canada and in the U.S. Such consequences for investors who are resident in, or citizens of, the U.S. or Canada may not be described fully herein. Prospective investors should read the tax discussion in this Prospectus and any applicable Prospectus Supplement.

The enforcement of civil liabilities under U.S. federal securities laws may be affected adversely by the fact that we are incorporated under the laws of Canada, that many of our officers and directors and all of the experts named in this Prospectus are residents of Canada or elsewhere outside of the U.S., and that a substantial portion of our assets and the assets of such persons are located outside the U.S. See [Enforceability of Civil Liabilities](#) .

**NEITHER THE SEC NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENCE.**

Investing in the Securities involves risk. See [Risk Factors](#) .

Unless otherwise stated, currency amounts in this Prospectus are stated in U.S. dollars, or \$ or US\$ .

Our outstanding Common Shares are currently listed for trading on the NASDAQ Global Market ( NASDAQ ) under the trading symbol AEZS and on the Toronto Stock Exchange ( TSX ) under the trading symbol AEZ . On June 7, 2012, the last reported sale price of our Common Shares on NASDAQ was \$0.45 per share and the last reported sale price of our Common Shares on TSX was C\$0.46 per share. **There is currently no market through which the Warrants may be sold and purchasers may not be able to resell Warrants purchased under this Prospectus. This may affect the pricing of any Warrants in the secondary market, the transparency and availability of trading prices, the liquidity of the Warrants, and the extent of issuer regulation. See the [Risk Factors](#) section of the applicable Prospectus Supplement.**

We may sell Securities to or through underwriters or dealers or directly to investors or through agents. The Prospectus Supplement relating to a particular offering of Securities will identify each person who may be deemed to be an underwriter with respect to such offering and will set forth the terms of the offering of such Securities, including, to the extent applicable, the offering price, the proceeds that we will receive, the underwriting discounts or commissions and any other discounts or concessions to be allowed or reallocated to dealers. The managing underwriter or underwriters with respect to Securities sold to or through underwriters will be named in the related Prospectus Supplement. If offered on a non-fixed price basis, Securities may be offered at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at prices to be negotiated with purchasers at the time of sale, which prices may vary as between purchasers and during the period of distribution of the Securities. See [Plan of Distribution](#) .

**You should rely only on the information contained in this Prospectus. We have not authorized anyone to provide you with information different from that contained in this Prospectus. The information contained in this Prospectus is accurate only as of the date of this Prospectus, regardless of the time of delivery of this Prospectus or of any sale of our Securities.**

Our registered office is located at 1405 du Parc-Technologique Blvd., Quebec City, Quebec, Canada G1P 4P5.

**Table of Contents****TABLE OF CONTENTS**

<u>DOCUMENTS INCORPORATED BY REFERENCE</u>	3
<u>DOCUMENTS FILED AS PART OF THE REGISTRATION STATEMENT</u>	4
<u>CURRENCY AND EXCHANGE RATES</u>	5
<u>FORWARD-LOOKING STATEMENTS</u>	5
<u>ENFORCEABILITY OF CIVIL LIABILITIES</u>	6
<u>OUR BUSINESS</u>	6
<u>RISK FACTORS</u>	10
<u>CHANGES IN LOAN AND SHARE CAPITAL</u>	25
<u>DESCRIPTION OF SHARE CAPITAL</u>	25
<u>DESCRIPTION OF WARRANTS</u>	25
<u>PRICE RANGE AND TRADING VOLUME</u>	27
<u>PRIOR SALES</u>	27
<u>USE OF PROCEEDS</u>	27
<u>PLAN OF DISTRIBUTION</u>	27
<u>CERTAIN INCOME TAX CONSIDERATIONS</u>	28
<u>LEGAL MATTERS</u>	28
<u>AUDITORS</u>	29

**DOCUMENTS INCORPORATED BY REFERENCE**

The following documents have been filed with the various securities commissions or similar securities regulatory authorities in Canada and are specifically incorporated by reference into, and form an integral part of, this Prospectus:

- (a) our annual report on Form 20-F for the financial year ended December 31, 2011 (filed in Canada with the Canadian securities regulatory authorities in lieu of an annual information form), and which includes our consolidated statements of financial position as at December 31, 2011, December 31, 2010 and January 1, 2010 and our consolidated statement of comprehensive loss, changes in shareholders' equity and cash flows for the years ended December 31, 2011 and December 31, 2010 and management's annual report on internal control over financial reporting set out on page 140 of our 2011 annual report on Form 20-F, together with the auditors report dated March 27, 2012 on our consolidated financial statements and on the effectiveness of internal control over financial reporting as at December 31, 2011; and our Management's Discussion and Analysis included as Item 5. Operating and Financial Review and Prospects in our annual report on Form 20-F;
- (b) our unaudited interim consolidated financial statements as at March 31, 2012 and for the three-month periods ended March 31, 2012 and 2011 and Management's Discussion and Analysis thereon, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on May 9, 2012;
- (c) our material change report dated April 2, 2012, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on April 3, 2012;
- (d) our management information circular dated March 27, 2012 in connection with our annual meeting of shareholders held on May 9, 2012, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on March 29, 2012; and
- (e) to the extent permitted by applicable securities law, any other documents which we elect to incorporate by reference into this Prospectus.

Any documents of the type referred to in the preceding paragraph, or similar material, including any annual information form, annual report on Form 20-F, annual and interim financial statements and related management's discussion and analysis, material change report (excluding any



## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

confidential material change report, if any), business acquisition report and information circular of Aeterna Zentaris filed with the various securities commissions or similar securities regulatory authorities in Canada or filed with or furnished to the SEC after the date of this Prospectus and prior to the completion or withdrawal of any offering hereunder shall be deemed to be incorporated by reference into this Prospectus.

---

## **Table of Contents**

Information has been incorporated by reference into this Prospectus from documents filed with securities commissions or similar securities regulatory authorities in Canada. We will furnish without charge to each person to whom a copy of this prospectus is delivered, upon written or oral request, a copy of the information that has been incorporated into this prospectus by reference but not delivered with the prospectus. Copies of the documents incorporated herein by reference may be obtained on request without charge from the secretary of Aeterna Zentaris at 1405 du Parc-Technologique Blvd., Quebec City, Quebec, Canada G1P 4P5, tel. (418) 652-8525, or through the Internet on the Canadian System for Electronic Document Analysis and Retrieval ( SEDAR ) which can be accessed at [www.sedar.com](http://www.sedar.com).

In addition to our continuous disclosure obligations under the securities laws of the provinces of Canada, we are subject to the information requirements of the U.S. *Securities Exchange Act of 1934*, as amended (the Exchange Act ), and in accordance therewith we file with or furnish to the SEC reports and other information. Under the MJDS adopted by the U.S. and Canada, these reports and other information that we file with or furnish to the SEC may be prepared in accordance with the disclosure requirements of Canada, which differ in certain respects from those in the U.S. You may read and copy any document that we have filed with the SEC at the SEC 's public reference room at Room 1580, 100 F Street N.E., Washington, D.C., 20549. You may also obtain copies of the same documents from the public reference room of the SEC by paying a fee. You should call the SEC at 1-800-SEC-0330 or access its website at [www.sec.gov](http://www.sec.gov) for further information about the public reference rooms. The SEC 's EDGAR Internet site also contains reports and other information about us and any public documents that we file electronically with the SEC. The EDGAR site can be accessed at [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml).

Any statement contained in this Prospectus or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded, for the purposes of this Prospectus, to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. The modifying or superseding statement need not state that it has modified or superseded a prior statement or include any other information set forth in the document that it modifies or supersedes. The making of a modifying or superseding statement shall not be deemed an admission for any purposes that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of a material fact or an omission to state a material fact that is required to be stated or that is necessary to make a statement not misleading in light of the circumstances in which it was made. Any statement so modified or superseded shall not constitute a part of this Prospectus, except as so modified or superseded.

Upon a new annual information form or annual report on Form 20-F and the related audited annual consolidated financial statements together with the auditors ' report thereon and management 's discussion and analysis related thereto being filed by us with the applicable securities regulatory authorities during the currency of this Prospectus, the previous annual information form or annual report on Form 20-F, the previous audited annual consolidated financial statements and all interim financial statements, annual and quarterly management 's discussion and analyses, material change reports and business acquisition reports filed by us prior to the commencement of our financial year in which the new annual information form or annual report on Form 20-F was filed, no longer shall be deemed to be incorporated by reference into this Prospectus for the purpose of future offers and sales of Securities hereunder.

One or more Prospectus Supplements containing the specific variable terms of an offering of Securities and other information in relation to such Securities will be delivered to purchasers of such Securities together with this Prospectus and shall be deemed to be incorporated by reference into this Prospectus as of the date of such Prospectus Supplement solely for the purposes of the offering of the Securities covered by any such Prospectus Supplement.

A Prospectus Supplement containing any additional or updated information that we elect to include therein will be delivered with this Prospectus to purchasers of Securities who purchase such Securities after the filing of this Prospectus and shall be deemed to be incorporated into this Prospectus as of the date of such Prospectus Supplement.

In this Prospectus and in any Prospectus Supplement, unless otherwise indicated, references to we , us , our , Aeterna Zentaris or the Company to Aeterna Zentaris Inc., a Canadian corporation, and its consolidated subsidiaries, unless it is clear that such terms refer only to Aeterna Zentaris Inc. excluding its subsidiaries.

## **DOCUMENTS FILED AS PART OF THE REGISTRATION STATEMENT**

The following documents have been filed with the SEC as part of the registration statement of which this prospectus forms a part: (1) the documents listed under the heading Documents Incorporated by Reference ; (2) powers of attorney from our directors and officers; (3) the consent of PricewaterhouseCoopers LLP; and (4) the consent of Norton Rose Canada LLP.



**Table of Contents****CURRENCY AND EXCHANGE RATES**

The following table sets out the high and low exchange rates for one U.S. dollar expressed in Canadian dollars, for the period indicated and, the average of such exchange rates, and the exchange rate at the end of such period, in each case, based upon the noon rates as quoted by the Bank of Canada:

	Three-month period	Year ended December 31,		
	ended March 31,	2011	2010	2009
	2012			
High	1.0272	1.0604	1.0778	1.3000
Low	0.9849	0.9449	0.9946	1.0292
Rate at end of period	0.9991	1.0170	0.9946	1.0466
Average rate per period	1.0011	0.9891	1.0299	1.1420

On June 7, 2012, the exchange rate for one U.S. dollar expressed in Canadian dollars based upon the noon rate of the Bank of Canada was C\$1.0244.

**FORWARD-LOOKING STATEMENTS**

This Prospectus and the documents incorporated herein by reference contain forward-looking statements concerning the business, operations, financial performance and condition of Aeterna Zentaris. When used in this Prospectus, words such as may, will, should, could, expects, plans, seeks, anticipates, intends, believes, estimates, predicts, potential or continue or the negative of these terms and similar expressions are used to identify forward-looking statements, although not all forward-looking statements contain such words. These forward-looking statements are based on current expectations and are naturally subject to uncertainty and changes in circumstances that may cause actual results to differ materially from those expressed or implied by such forward-looking statements. Such statements, based as they are on the current expectations of management, inherently involve numerous risks and uncertainties, known and unknown, many of which are beyond our control. Such risks include but are not limited to:

investments in biopharmaceutical companies are generally considered to be speculative;

we may never achieve or maintain operating profitability;

our clinical trials may not yield results which will enable us to obtain regulatory approval for our products and we may suffer setbacks in any of our clinical trials;

we may not be able to successfully complete our clinical trial programs, or such clinical trials could take longer to complete than we project;

the impact of the stringent ongoing government regulation to which our product candidates are subject and future changes in such regulatory environment;

we may not be able to generate significant revenues if our products do not gain market acceptance;

we may require significant additional financing, and we may not have access to sufficient capital;

## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

we may cease to continue operating as we do if we are unsuccessful in increasing our revenues and/or raising additional funding;

failure to achieve our projected development goals in the time-frames we announce and expect;

the impact of any failure on our part to obtain acceptable prices or adequate reimbursement for our products on our ability to generate revenues;

competition in our targeted markets;

we may not obtain adequate protection for our products through our intellectual property;

we may infringe the intellectual property rights of others;

**Table of Contents**

we may incur liabilities from our involvement in any patent litigation;

we may not obtain trademark registrations in connection with our product candidates;

we may not be able to make adequate arrangements with third parties for the purpose of commercializing our product candidates;

the failure to perform satisfactorily by third parties upon which we rely to conduct, supervise and monitor our clinical trials;

the failure to perform satisfactorily by third parties upon which we rely to manufacture and supply products;

our ability to retain or attract key personnel;

our strategic partners' manufacturing capabilities may not be adequate to effectively commercialize our product candidates;

risks related to product liability claims;

the impact of legislative actions, new accounting pronouncements and higher insurance costs on our future financial position or results of operations;

fluctuations in currency exchange rates; and

stock market volatility and the possibility that our Common Shares may be delisted from the stock exchanges on which they currently trade.

More detailed information about these and other factors is included in this Prospectus under the section entitled "Risk Factors" as well as in other documents incorporated by reference into this Prospectus. Many of these factors are beyond our control. Future events may vary substantially from what we currently foresee. You should not place undue reliance, if any, on such forward-looking statements. Aeterna Zentaris disavows and is under no obligation to update or alter such forward-looking statements whether as a result of new information, future events or otherwise, other than as required by applicable securities legislation.

**ENFORCEABILITY OF CIVIL LIABILITIES**

We are a corporation incorporated under and governed by the *Canada Business Corporations Act*. Many of our officers and directors, and all of the experts named in this Prospectus, are residents of Canada or elsewhere outside of the U.S., and a substantial portion of our assets and the assets of such persons are located outside the U.S. As a result, it may be difficult for investors in the U.S. to effect service of process within the U.S. upon such directors, officers and representatives of experts who are not residents of the U.S. or to enforce against them judgments of a U.S. court predicated solely upon civil liability under U.S. federal securities laws or the securities laws of any state within the U.S. We have been advised by our legal counsel, Norton Rose Canada LLP, that a judgment of a U.S. court predicated solely upon civil liability under U.S. federal securities laws would probably be enforceable in Canada if the U.S. court in which the judgment was obtained has a basis for jurisdiction in the matter that would be recognized by a Canadian court for the same purposes. We have also been advised by Norton Rose Canada LLP, however, that there is substantial doubt as to whether an action could be brought in Canada in the first instance on the basis of liability predicated solely upon U.S. federal securities laws.

**OUR BUSINESS**

## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

We are an oncology and endocrinology drug development company currently investigating treatments for various unmet medical needs. Our pipeline encompasses compounds at all stages of development, from drug discovery through marketed products. We also benefit from our relationships with strategic collaborators and licensee partners to contribute to the development of our pipeline of product candidates and to establish commercial activities in specific territories.

Our highest priorities in oncology are the advancement of a Phase 3 study with perifosine, an oral AKT/PI3K inhibitor, in multiple myeloma ( MM ), as well as the initiation of a Phase 3 study in endometrial cancer with AEZS-108, a doxorubicin luteinizing hormone releasing hormone ( LHRH ) targeted conjugate compound, while advancing perifosine and AEZS-108 in other cancer indications. In endocrinology, a Phase 3 trial under a Special Protocol Assessment ( SPA ) obtained from the U.S. Food and Drug Administration ( FDA ) with AEZS-130, an oral ghrelin agonist, as a diagnostic test for adult growth hormone deficiency ( AGHD ) has been completed, and we are planning to file a New Drug Application ( NDA ) for its registration in the U.S.

**Table of Contents**

Aeterna Zentaris Inc. was incorporated on September 12, 1990 under the laws of Canada. Our registered office is located at 1405 du Parc-Technologique Blvd., Quebec City, Quebec, Canada G1P 4P5, our telephone number is (418) 652-8525 and our website is [www.aezsinc.com](http://www.aezsinc.com). None of the documents or information found on our website shall be deemed to be included in or incorporated into this Prospectus, unless such document is specifically incorporated herein by reference and enumerated as such under Documents Incorporated by Reference .

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

Our Common Shares are currently listed for trading on NASDAQ under the trading symbol AEZS and on TSX under the trading symbol AEZ .

The following table summarizes the development status of our principal products and product candidates:

**Status of our drug pipeline as at June 8, 2012**

Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial
~120,000	AEZS-120	AEZS-112 (oncology)	AEZS-108 Endometrial cancer	Perifosine	Cetrotide®
compound	Prostate cancer immunotherapy (vaccine)		Ovarian cancer CRPC	Multiple myeloma AEZS-130	( <i>in vitro</i> fertilization)
library	Phosphoinositide 3-kinase ( PI3K )/Erk inhibitors (oncology)		Refractory bladder cancer Triple- negative breast cancer	Diagnostic in AGHD (endocrinology)	
	AEZS-137 (Disorazol Z) (oncology)		Ozarelix Prostate cancer		
	AEZS-125 (LHRH- Disorazol Z) (oncology)		AEZS-130 Therapeutic in cancer cachexia		
<b>Partners</b>			Perifosine:	Perifosine:	Cetrotide®:
			<b>Handok</b>	<b>Handok</b>	<b>Merck Serono</b>
			Korea	Korea	(World except Japan)
			<b>Yakult</b>	<b>Yakult</b>	<b>Nippon Kayaku / Shionogi</b>
			Japan	Japan	
			<b>Hikma</b>	<b>Hikma</b>	Japan
			Middle East/North Africa	Middle East/North Africa	





**Table of Contents**

Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial
			Ozarelis:		
			<b>Spectrum</b>		
			World (ex-Japan for oncology indications, ex-Korea and ex-other Asian countries for BPH indication)		
			<b>Handok</b>		
			Korea and other Asian countries for BPH indication		
			<b>Nippon Kayaku</b>		
			Japan for oncology indications		

**Our Business Strategy**

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

***Oncology***

*Perifosine*

Perifosine is an orally active AKT/PI3K pathway inhibitor.

We are currently conducting a Phase 3 study in MM and advancing Phase 2 studies in other indications.

The FDA and the Committee for Orphan Medicinal Products of the EMA have granted orphan-drug status for perifosine in MM in the U.S. and Europe, respectively. The ongoing perifosine Phase 3 study in MM is conducted under a SPA in the U.S. and a positive scientific advice from the EMA in Europe.

We own the worldwide rights to perifosine ex-Japan, Korea and the Middle East and North Africa countries ( MENA ).

*AEZS-108*

AEZS-108 represents a targeting concept in oncology leading to personalized medicine using a cytotoxic peptide conjugate, which is a hybrid molecule composed of a synthetic peptide carrier and doxorubicin. The design of AEZS-108 allows for the specific binding and selective uptake of the cytotoxic conjugate by LHRH receptor-positive tumors.

We are planning to initiate a Phase 3 program in endometrial cancer, while advancing Phase 2 studies in Castration Refractory Prostate Cancer ( CRPC ) and refractory bladder cancer. We are also initiating a Phase 2 study in triple-negative breast cancer ( TNBC ).

We own the worldwide rights to AEZS-108 and also have a collaboration agreement in place with Ventana Medical Systems, Inc. ( Ventana ) to develop a companion diagnostic for the immunohistochemical determination of LHRH-receptor expression for AEZS-108.

*Endocrinology*

In endocrinology, in addition to Cetrotide®, we have completed a Phase 3 trial with AEZS-130, which would be the first oral diagnostic test for AGHD.

---

## **Table of Contents**

### *AEZS-130*

AEZS-130, a ghrelin agonist, is an orally available synthetic small molecule that stimulates the secretion of growth hormone.

We completed a Phase 3 trial under a SPA obtained from the FDA. Subject to the conclusion of a successful pre-NDA meeting with the FDA, we plan to file an NDA in the U.S.

AEZS-130 has been granted orphan-drug designation by the FDA in the U.S. as a diagnostic test for AGHD.

In addition to the diagnostic indication, we believe that AEZS-130 has potential application for the treatment of cachexia, a wasting and muscle loss condition frequently associated with severe chronic diseases such as cancer, chronic obstructive pulmonary disease and Acquired Immune Deficiency Syndrome. Furthermore, the FDA has agreed to allow for the initiation of a physician sponsored IND Phase 2A trial in cancer induced cachexia. The study is currently conducted under a Cooperative Research and Development Agreement ( CRADA ) with the Michael E. DeBakey Veterans Affairs Medical Center which will be funding the study.

We own the worldwide rights to AEZS-130.

### ***Clinical and Pre-clinical Programs***

AEZS-112, an oral anticancer agent which involves three mechanisms of action (tubulin, topoisomeras II and angiogenic inhibition) has completed a Phase 1 trial in advanced solid tumors and lymphoma. Additionally, several novel targeted potential anti-cancer candidates such as AEZS-120, a live recombinant oral tumor vaccine candidate, as well as our PI3K/Erk inhibitors, including AEZS-136, are currently in pre-clinical development.

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.

### **Recent Developments**

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

On May 7, 2012, we announced that we had agreed with Keryx to terminate our license agreement with respect to perifosine, as a result of which we regained in full the North American rights to perifosine, in all indications. Under the terms of the agreement to terminate, all intellectual property and development data, including orphan drug designations and Investigational New Drug applications on perifosine generated by Keryx, have been transferred to the corporation. In return, we have agreed to pay low single-digit royalties to Keryx on future net sales of perifosine in North America (U.S., Canada and Mexico).

On May 16, 2012, we announced that we had received a letter from the NASDAQ Listing Qualifications Department indicating that the minimum closing bid price of the Common Shares had fallen below U.S.\$1.00 for 30 consecutive trading days, and therefore, Aeterna Zentaris was not in compliance with NASDAQ Listing Rule 5450(a)(1). In accordance with NASDAQ Listing Rule 5810(C)(3)(a), we were provided a grace period of 180 calendar days, or until November 12, 2012, to regain compliance with this requirement. If we do not regain compliance within the initial 180-day period, but otherwise meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the NASDAQ Capital Market, except for the bid price requirement, and we provide NASDAQ with notice of our intention to cure the bid price deficiency, the NASDAQ rules may permit us to transfer to the NASDAQ Capital Market, which would give us an additional 180 calendar days to regain compliance.

---

**Table of Contents**

**RISK FACTORS**

The purchase of Securities offered under this Prospectus involves risks which prospective purchasers should take into consideration when making a decision to purchase such Securities. Investors should carefully consider the risks described below, together with all of the other information included in this Prospectus and the documents incorporated by reference into this Prospectus, before making an investment decision. Certain of these risk factors have been disclosed in our annual report on Form 20-F for the financial year ended December 31, 2011 (filed in Canada with the Canadian securities regulatory authorities in lieu of an annual information form) under the heading "Risks Factors" and in our management's discussion and analysis for the three-month period ended March 31, 2012 under the heading "Risks Factors and Uncertainties", which documents are incorporated by reference into this Prospectus. This discussion of risk factors will be updated from time to time in our subsequent filings with the Canadian securities regulatory authorities, including in subsequent annual and quarterly management's discussion and analysis and annual information forms. If any of the following risks actually occurs or materializes, our business, financial condition or results of operations could be adversely affected, even materially adversely affected. In such an event, the trading price of our Securities could decline and you may lose part or all of your investment. Any reference in this section to our "products" includes a reference to our product candidates and future products we may develop.

**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 disclosed in our unaudited interim consolidated financial statements as at and for the three-month periods ended March 31, 2012 and 2011, we had an accumulated deficit of U.S.\$200.4 million as at March 31, 2012. Our operating losses have adversely impacted, and will continue to adversely impact, our working capital, total assets and shareholders' deficiency. We do not expect to reach operating profitability in the immediate future, and our expenses are likely to increase as we continue to expand our 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.

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

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

None of our product candidates has to date received regulatory approval for its intended commercial sale. We cannot market a pharmaceutical product in any jurisdiction until it has completed rigorous pre-clinical 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. Pre-clinical testing and clinical development are long, expensive and uncertain

## Table of Contents

processes. Preparing, submitting and advancing applications for regulatory approval is complex, expensive and time-consuming and entails significant uncertainty. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. It may take us many years to complete the testing of our product candidates and failure can occur at any stage of this process. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval in the U.S., in Canada and abroad and, accordingly, may encounter unforeseen problems and delays in the approval process. Though we may engage a clinical research organization with experience in conducting regulatory trials, errors in the conduct, monitoring and/or auditing could invalidate the results from a regulatory perspective. Even if a product candidate is approved by the 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, pre-clinical testing and clinical trials conducted to date, and we may not be successful in developing or introducing to the market these or any other new products or technology. If we fail to develop and deploy new products successfully and on a timely basis, we may become non-competitive and unable to recoup the R&D and other expenses we incur to develop and test new products.

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

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

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

must meet the requirements of these authorities;

must meet requirements for informed consent; and

must meet requirements for good clinical practices.

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

In addition, we rely on third parties, including 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 the price of our Securities.



## **Table of Contents**

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

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

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

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

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

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

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



## **Table of Contents**

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

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

demonstration of clinical efficacy and safety;

the prevalence and severity of any adverse side effects;

limitations or warnings contained in the product's approved labeling;

availability of alternative treatments for the indications we target;

the advantages and disadvantages of our products relative to current or alternative treatments;

the availability of acceptable pricing and adequate third-party reimbursement; and

the effectiveness of marketing and distribution methods for the products.

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

Our ability to further penetrate our core markets and existing geographic markets in which we compete or to successfully expand our business into additional countries in Europe, Asia or elsewhere is subject to numerous factors, many of which are beyond our control. Our products, if successfully developed, may compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products may also compete with new products currently under development by others or with products which may be less expensive than our products. We cannot assure you that our efforts to increase market penetration in our core markets and existing geographic markets will be successful. Our failure to do so could have an adverse effect on our operating results and would likely cause a drop in the price of our Securities.

*We 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 Prospectus and the documents incorporated by reference herein, we do not anticipate generating significant revenues from operations in the near future and we currently have no committed sources of capital.

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

## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

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

the duration and results of our clinical trials for our various product candidates going forward;

unexpected delays or developments in seeking regulatory approvals;

the time and cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

other unexpected developments encountered in implementing our business development and commercialization strategies;

## **Table of Contents**

the outcome of litigation, if any; and

further arrangements, if any, with collaborators.

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

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

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

We have had sustained losses, accumulated deficits and negative cash flows from operations since our inception. We expect that this will continue throughout 2012.

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

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

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

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

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

The ability for us and/or our partners to successfully commercialize our products will depend significantly on our ability to obtain acceptable prices and the availability of reimbursement to the patient from third-party payers, such as governmental and private insurance plans. These third-party payers frequently require companies to provide predetermined discounts from list prices, and they are increasingly challenging the prices charged for pharmaceuticals

## **Table of Contents**

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 U.S., in Canada and in many other countries, pricing and/or profitability of some or all prescription pharmaceuticals and biopharmaceuticals are subject to government control.

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

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

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

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

We rely heavily on our proprietary information in developing and manufacturing our product candidates. Our success depends, in large part, on our ability to protect our competitive position through patents, trade secrets, trademarks and other intellectual property rights. The patent positions of pharmaceutical and biopharmaceutical firms, including Aeterna Zentaris, are uncertain and involve complex questions of law and fact for which important legal issues remain unresolved. Applications for patents and trademarks in Canada, the U.S. 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 U.S. 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 U.S. 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

## **Table of Contents**

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 U.S. 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 U.S. covering our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the United States Patent and Trademark Office to determine priority of invention in the U.S. The costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful, resulting in a loss of our U.S. patent position.

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

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

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 U.S. 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.

## **Table of Contents**

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

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

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

the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals to commercialize our product candidates;

the timing of regulatory submissions and approvals;

the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize our product candidates;

the revenue available from royalties derived from our strategic partners;

licensing fees revenues;

tax credits and grants (R&D);

the outcome of litigation, if any;

changes in foreign currency fluctuations;

the timing of achievement and the receipt of milestone payments from current or future collaborators; and

failure to enter into new or the expiration or termination of current agreements with collaborators.

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

## **Table of Contents**

*We may invest or spend the proceeds of any offering of Securities under this Prospectus in ways with which investors may not agree and in ways that may not earn a profit.*

Our management team will have broad discretion concerning the use of the proceeds of any offering of Securities under this Prospectus as well as the timing of their expenditure. As a result, investors will be relying on the judgment of management for the application of the proceeds of any offering of Securities under this Prospectus. We intend to use the proceeds from any offering primarily for general corporate purposes, which may include, but are not limited to, our current clinical development programs. Investors may not agree with the ways we decide to use these proceeds, and our use of the proceeds may not yield any results or profits.

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

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

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

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

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

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

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

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

not all of our strategic partners are contractually prohibited from developing or commercializing, either alone or with others, products and services that are similar to or competitive with our product candidates, and, with respect to our strategic partnership agreements that do contain such contractual prohibitions or restrictions, prohibitions or restrictions do not always apply to our partners' affiliates and they may elect to pursue the development of any additional product candidates and pursue technologies or products either on their own or in collaboration with other parties, including our competitors, whose technologies or products may be competitive with ours;

our strategic partners may under-fund or fail to commit sufficient resources to marketing, distribution or other development of our products;

we may not be able to renew such agreements;



## Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

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);

## **Table of Contents**

delays in, or failures to achieve, scale-up to commercial quantities, or changes to current raw material suppliers or product manufacturers (whether the change is attributable to us or the supplier or manufacturer) could delay clinical studies, regulatory submissions and commercialization of our product candidates; and

disputes may arise between us and our strategic partners that could result in the delay or termination of the development or commercialization of our product candidates, resulting in litigation or arbitration that could be time-consuming and expensive, or causing our strategic partners to act in their own self-interest and not in our interest or those of our shareholders or other stakeholders.

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

We have entered into important strategic partnership agreements relating to certain of our product candidates for various indications. Detailed information on our research and collaboration agreements is available in our various reports and disclosure documents filed with the Canadian securities regulatory authorities and filed with or furnished to the SEC, including the documents incorporated by reference into this Prospectus. See, for example, Note 5 to our audited consolidated financial statements as at December 31, 2011 and December 31, 2010 and for the years ended December 31, 2011 and December 31, 2010 included in our Annual Report on Form 20-F (filed in Canada with the Canadian securities regulatory authorities in lieu of an annual information form) and our Management's Discussion and Analysis of our financial and operating results for the three-month periods ended March 31, 2012 and 2011, which are incorporated by reference into this Prospectus.

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

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

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

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

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

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

## **Table of Contents**

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

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

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

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

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

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

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

The sale and use of our products, in particular our biopharmaceutical products, involve the risk of product liability claims and associated adverse publicity. Our risks relate to human participants in our clinical trials, who may suffer unintended consequences, as well as products on the market whereby claims might be made directly by patients, healthcare providers or pharmaceutical companies or others selling, buying or using our products. We manage our liability risks by means of insurance. We maintain liability insurance covering our liability for our pre-clinical 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 are subject to additional reporting requirements under applicable Canadian securities laws and the Sarbanes-Oxley Act in the U.S. We can provide no assurance that we will at all times in the future be able to report that our internal controls over financial reporting are effective.***

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

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

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

We believe that we were not a PFIC for the 2011 taxable year. However, the fair market value of our assets may be determined in large part by the market price of our Common Shares, which is likely to fluctuate, and the composition of our income and assets will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction, no assurance can be provided that we will not be classified as a PFIC for the 2012 taxable year and for any future taxable year.

PFIC characterization could result in adverse U.S. federal income tax consequences to U.S. Holders. In particular, absent certain elections, a U.S. Holder would be subject to U.S. federal income tax at ordinary income tax rates, plus a possible interest charge, in respect of a gain derived from a disposition of our Common Shares, as well as certain distributions by us. If we are treated as a PFIC for any taxable year, a U.S. Holder may be able to make an election to mark to market Common Shares each taxable year and recognize ordinary income pursuant to such election based upon increases in the value of the Common Shares. However, a mark-to-market election is not available to be made in respect of a warrant.

Under recently enacted U.S. tax legislation and subject to future guidance, if the Company is a PFIC, U.S. Holders will be required to file an annual information return with the Internal Revenue Service ( IRS ) (on IRS Form 8621, which PFIC shareholders will be required to file with their income tax or information returns) relating to their

---

## **Table of Contents**

ownership of Common Shares. Pursuant to Notice 2011-55, the IRS has suspended this new filing requirement for U.S. Holders that are not otherwise required to file the current version of the IRS Form 8621 until the IRS releases a subsequent revision of IRS Form 8621, modified to reflect the recently enacted U.S. tax legislation. Guidance has not yet been issued regarding the information required to be included on such form. This new filing requirement is in addition to any pre-existing reporting requirements that apply to a U.S. Holder's interest in a PFIC (which the recently enacted tax legislation and IRS Notice 2011-55 do not affect).

For a more detailed discussion of the potential tax impact of us being a PFIC, see Item 10.E Taxation Material U.S. Federal Income Tax Considerations in our annual report on Form 20-F.

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

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

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

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

## **Risks Related to the Securities**

### ***Our share price is volatile, which may result from factors outside of our control. If our Common Shares were to be delisted from NASDAQ or TSX, investors may have difficulty in disposing of our Common Shares held by them.***

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

During the year ended December 31, 2011, the closing price of our Common Shares ranged from \$1.43 to \$2.58 per share on NASDAQ and from C\$1.41 to C\$2.51 per share on TSX, during the three months ended March 31, 2012, the closing price of our Common Shares ranged from \$1.56 to \$2.15 per share on NASDAQ and from C\$1.57 to C\$2.14 per share on TSX and more recently our Common Shares have traded as low as \$0.41 on NASDAQ and C\$0.43 on TSX. See Price Range and Trading Volume. Our share price may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. The stock market generally, and the biopharmaceutical sector in particular, are vulnerable to abrupt changes in investor sentiment. Prices of shares and trading volume of companies in the biopharmaceutical industry can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, operating performance. Our share price and trading volume may fluctuate based on a number of factors including, but not limited to:

clinical and regulatory developments regarding our product candidates;

delays in our anticipated development or commercialization timelines;

developments regarding current or future third-party collaborators;

other announcements by us regarding technological, product development or other matters;

Edgar Filing: Aeterna Zentaris Inc. - Form SUPPL

arrivals or departures of key personnel;

governmental or regulatory action affecting our product candidates and our competitors' products in the U.S., Canada and other countries;

developments or disputes concerning patent or proprietary rights;

actual or anticipated fluctuations in our revenues or expenses;

---

**Table of Contents**

general market conditions and fluctuations for the emerging growth and biopharmaceutical market sectors; and

economic conditions in the U.S., Canada or abroad.

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

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

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

On May 16, 2012, we announced that we had received a letter from the NASDAQ Listing Qualifications Department indicating that the minimum closing bid price of the Common Shares had fallen below U.S.\$1.00 for 30 consecutive trading days, and therefore, Aeterna Zentaris was not in compliance with NASDAQ Listing Rule 5450(a)(1). In accordance with NASDAQ Listing Rule 5810(C)(3)(a), we were provided a grace period of 180 calendar days, or until November 12, 2012, to regain compliance with this requirement. If we do not regain compliance within the initial 180-day period, but otherwise meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the NASDAQ Capital Market, except for the bid price requirement, and we provide NASDAQ with notice of our intention to cure the bid price deficiency, the NASDAQ rules may permit us to transfer to the NASDAQ Capital Market, which would give us an additional 180 calendar days to regain compliance. If we are not eligible for an additional compliance period, NASDAQ will notify us that our securities are subject to delisting. At that time, we may appeal this determination to delist our securities to a Listing Qualifications Panel. There can be no assurance that we will meet the requirements for continued listing or whether an application to the NASDAQ Capital Market would be approved or that any appeal would be granted by the Listing Qualifications Panel.

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

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

To date, we have not declared or paid any dividends on our Common Shares. We currently intend to retain our future earnings, if any, to finance further research and the expansion of our business. As a result, the return on an investment in our Securities will, for the foreseeable future, depend upon any future appreciation in value. There is no guarantee that our Securities will appreciate in value or even maintain the price at which shareholders have purchased their Securities.

**Risks Related to the Issuance of Securities under this Prospectus**

*An active market may not develop for the Warrants, which may hinder your ability to liquidate your investment.*

Each issuance of Warrants will be a new issue of securities with no established trading market, and we do not currently intend to list them on any securities exchange. A dealer may intend to make a market in the Warrants after their issuance pursuant to this Prospectus; however, a dealer may not be obligated to do so and may discontinue such market-making at any time. As a result, we cannot assure you that an active trading market will develop for any series of the Warrants. In addition, subsequent to their initial issuance, the Warrants may trade at a discount to their initial offering price, depending upon the value of the underlying Common Shares and upon our prospects or the prospects for companies in our industry generally and other factors, including those described herein.

---

**Table of Contents**

*A large number of Common Shares may be issued and subsequently sold upon the exercise of the Warrants. The sale or availability for sale of these Warrants may depress the price of our Common Shares.*

The number of Common Shares that will be initially issuable upon the exercise of Warrants will be determined by the particular terms of each issue of Warrants and will be described in the relevant Prospectus Supplement. To the extent that purchasers of Warrants sell Common Shares issued upon the exercise of the Warrants, the market price of our Common Shares may decrease due to the additional selling pressure in the market. The risk of dilution from issuances of Common Shares underlying the Warrants may cause shareholders to sell their Common Shares, which could further contribute to any decline in the Common Share price.

*The sale of Common Shares issued upon exercise of the Warrants could encourage short sales by third parties which could further depress the price of the Common Shares.*

Any downward pressure on the price of Common Shares caused by the sale of Common Shares issued upon the exercise of the Warrants could encourage short sales by third parties. In a short sale, a prospective seller borrows Common Shares from a shareholder or broker and sells the borrowed Common Shares. The prospective seller hopes that the Common Share price will decline, at which time the seller can purchase Common Shares at a lower price for delivery back to the lender. The seller profits when the Common Share price declines because it is purchasing Common Shares at a price lower than the sale price of the borrowed Common Shares. Such sales could place downward pressure on the price of our Common Shares by increasing the number of Common Shares being sold, which could further contribute to any decline in the market price of our Common Shares.

*We cannot predict the actual number of Common Shares that we will issue upon the exercise of the Warrants. The number of Common Shares that we will issue under the Warrants may depend on the market price of our Common Shares.*

The actual number of Common Shares that we will issue upon the exercise of the Warrants is uncertain and will be determined, or made determinable, by the particular terms of each issue of Warrants and will be described in the relevant Prospectus Supplement. The number of Common Shares issuable upon the exercise of the Warrants may fluctuate based on the market price of our Common Shares. Holders of Warrants may receive more Common Shares if our Common Share price declines.

*Future issuances of securities and hedging activities may depress the trading price of our Common Shares.*

Any issuance of equity securities or securities convertible into or exchangeable for equity securities after the offering of Securities under this Prospectus, including the issuance of Common Shares upon the exercise of stock options and upon exercise of the Warrants, could dilute the interests of our existing shareholders, and could substantially decrease the trading price of our Common Shares. We may issue equity securities in the future for a number of reasons, including to finance our operations and business strategy, to satisfy our obligations upon the exercise of options or for other reasons. Our stock option plan generally permits us to have outstanding, at any given time, stock options that are exercisable for a maximum number of Common Shares equal to 11.4% of all then issued and outstanding Common Shares. As of June 7, 2012, there were:

111,392,181 Common Shares issued and outstanding;

no issued and outstanding Preferred Shares (as defined below);

8,752,868 Common Shares issuable upon exercise of outstanding warrants; and

8,552,634 stock options outstanding.

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





## **Table of Contents**

### **CHANGES IN LOAN AND SHARE CAPITAL**

Since March 31, 2012, there has been no material change in our loan and capital structure on a consolidated basis, except for the issuance of 2,604,815 Common Shares under our at-the-market offering implemented in January 2012, for aggregate gross proceeds of approximately \$1.9 million, less cash and previously deferred transaction costs totalling approximately \$83.9 thousand.

As at March 31, 2012, we had no outstanding long-term debt.

### **DESCRIPTION OF SHARE CAPITAL**

Our authorized share capital structure consists of an unlimited number of shares of the following classes (all classes are without nominal or par value): Common Shares; and first preferred shares (the First Preferred Shares ) and second preferred shares (the Second Preferred Shares and, together with the First Preferred Shares, the Preferred Shares ), both issuable in series. As at June 7, 2012, there were 111,392,181 Common Shares outstanding. No Preferred Shares of the Company have been issued to date.

#### **Common Shares**

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

#### **Preferred Shares**

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

Our Board of Directors may, from time to time, provide for additional series of Preferred Shares to be created and issued, but the issuance of any Preferred Shares is subject to the general duties of the directors under the Canada Business Corporations Act 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.

### **DESCRIPTION OF WARRANTS**

Warrants may be offered separately or together with Common Shares. Each series of Warrants will be issued under a separate warrant agreement or indenture to be entered into between us and one or more purchasers of such Warrants or with banks or trust companies acting as warrant agent. The applicable Prospectus Supplement will include details of the warrant agreements covering the Warrants being offered. The warrant agent will act solely as our agent and will not assume a relationship of agency with any holders of Warrant certificates or beneficial owners of Warrants.

**Table of Contents**

The particular terms of each issue or series of Warrants will be described in the related Prospectus Supplement. This description will include, where applicable:

the designation and aggregate number of Warrants offered;

the price at which the Warrants will be offered;

the currency or currency unit in which the Warrants are denominated;

the date on which the right to exercise the Warrants will commence and the date on which the right will expire;

the number of Common Shares that may be purchased upon exercise of each Warrant and the price at which and currency or currencies in which that amount of Common Shares may be purchased upon exercise of each Warrant;

if offered in conjunction with the Common Shares, the number of Warrants that will be offered with each Common Share;

the date or dates, if any, on or after which the Warrants and the related Common Shares will be transferable separately;

the minimum or maximum amount, if any, of Warrants that may be exercised at any one time;

whether the Warrants will be subject to redemption or call, and, if so, the terms of such redemption or call provisions; and

any other terms, conditions and rights (or limitations on such rights) of the Warrants.

We reserve the right to set forth in a Prospectus Supplement specific terms of the Warrants that are not within the options and parameters set forth in this Prospectus. In addition, to the extent that any particular terms of the Warrants described in a Prospectus Supplement differ from any of the terms described in this Prospectus, the description of such terms set forth in this Prospectus shall be deemed to have been superseded by the description of such differing terms set forth in such Prospectus Supplement with respect to such Warrants.

We will not offer Warrants or other convertible or exchangeable securities for sale separately (as opposed to as part of a unit offering) to any member of the public in Canada unless the offering is in connection with and forms part of the consideration for an acquisition or merger transaction or unless a Prospectus Supplement containing the specific terms of the Warrants or other convertible or exchangeable securities to be offered separately is first approved for filing by the *Autorité des marchés financiers* on behalf of the securities commissions or similar securities regulatory authorities in each of the provinces of Canada where the Warrants will be offered for sale.

**Table of Contents****PRICE RANGE AND TRADING VOLUME**

Our Common Shares are listed and posted for trading on NASDAQ under the symbol **AEZS** and on TSX under the symbol **AEZ**. The following table indicates the monthly range of high and low closing prices of a Common Share and the average daily volumes traded on NASDAQ and on TSX during the period beginning on May 1, 2011 and ending on June 7, 2012:

	NASDAQ (U.S.\$)			TSX (C\$)		
	High	Low	Volume	High	Low	Volume
<b>2011</b>						
May	2.54	2.11	2,520,089	2.47	2.04	141,533
June	2.58	2.12	1,922,137	2.51	2.07	64,491
July	2.35	1.98	1,580,762	2.26	1.89	54,812
August	2.03	1.43	1,948,541	1.99	1.41	93,486
September	1.99	1.48	1,279,012	1.98	1.54	68,453
October	1.75	1.43	1,799,307	1.72	1.47	50,225
November	1.76	1.46	1,152,395	1.80	1.50	51,863
December	1.78	1.51	1,180,521	1.80	1.54	63,146
<b>2012</b>						
January	1.71	1.56	737,107	1.78	1.57	47,205
February	1.83	1.58	995,972	1.84	1.58	67,305
March	2.15	1.69	2,617,809	2.14	1.67	171,664
April	0.80	0.61	3,759,831	0.80	0.60	270,255
May	0.63	0.43	1,012,802	0.62	0.46	41,518
June <sup>(1)</sup>	0.47	0.43	946,707	0.47	0.45	24,499

<sup>(1)</sup> Up to and including June 7, 2012.

**PRIOR SALES**

During the twelve months preceding the date of this Prospectus, we issued an aggregate of 15,670,285 Common Shares under our at-the-market issuance programs pursuant to various prospectus supplements at an average issuance price of US\$1.66 per share, for aggregate gross proceeds of approximately \$26.0 million, less cash and previously deferred transaction costs totalling approximately \$1.1 million. During the same period, we issued an aggregate of 364,300 Common Shares upon exercise of previously issued warrants at an average issuance price of \$1.37 per share and 172,300 Common Shares upon exercise of stock options granted under our Stock Option Plan at an average issuance price of C\$1.37 per share.

**USE OF PROCEEDS**

Unless otherwise specified in a Prospectus Supplement, the net proceeds resulting from the issuance of Securities will be used for the general corporate purposes of Aeterna Zentaris, which may include development costs of our product pipeline. All expenses relating to an offering of Securities and any compensation paid to underwriters, dealers or agents, as the case may be, will be paid out of our general funds or from the proceeds of any offering under this Prospectus or a Prospectus Supplement. The use of proceeds will be specified in the Prospectus Supplement relating to a particular offering of Securities, as required by applicable securities legislation. Depending on the results of our various product candidates currently in clinical and pre-clinical development, we would require significant new sources of capital in order to fund either the continued development of such product candidates or commercialize such product candidates. We could require the raising of up to U.S.\$100 million in new sources of capital within the 25-month period following the date of the receipt for this Prospectus depending on the possible outcomes of our ongoing clinical studies and trials.

**PLAN OF DISTRIBUTION**

We may offer and sell the Securities to or through underwriters or dealers purchasing as principals, and we may also sell the Securities to one or more purchasers directly or through agents. Securities may be sold from time to time in one or more transactions at a fixed price or prices, or at non-fixed prices.



---

**Table of Contents**

If offered on a non-fixed price basis, the Securities may be offered at prevailing market prices at the time of sale or at prices to be negotiated with purchasers, including sales in transactions that are deemed to be at the market distributions under applicable securities laws. The prices at which the Securities may be offered may vary as between purchasers and during the period of distribution. Consequently, any dealer's overall compensation will increase or decrease by the amount by which the aggregate price paid for the Securities by the purchasers exceeds or is less than the gross proceeds paid by the dealers, acting as principals, to us.

If, in connection with the offering of Securities at a fixed price or prices, the underwriters have made a bona fide effort to sell all of the Securities at the initial offering price fixed in the applicable Prospectus Supplement, the public offering price may be decreased and thereafter further changed, from time to time, to an amount not greater than the initial public offering price fixed in such Prospectus Supplement, in which case the compensation realized by the underwriters will be decreased by the amount that the aggregate price paid by purchasers for the Securities is less than the gross proceeds paid by the underwriters to us.

A Prospectus Supplement will identify each underwriter, dealer or agent engaged by us, as the case may be, in connection with the offering and sale of a particular issue of Securities, and will also set forth the terms of the offering, including the public offering price (or the manner of determination thereof if offered on a non-fixed price basis), the proceeds to us and any compensation payable to the underwriters, dealers or agents.

Under agreements which may be entered into by Aeterna Zentaris, underwriters, dealers and agents who participate in the distribution of the Securities may be entitled to indemnification by us against certain liabilities, including liabilities arising out of any misrepresentation in this Prospectus and the documents incorporated by reference herein, other than liabilities arising out of any misrepresentation made by underwriters, dealers or agents who participate in the offering of the Securities.

Each issue of Warrants will be a new issue of securities with no established trading market. In connection with any offering of Securities, the underwriters, dealers or agents, as the case may be, may over-allot or effect transactions which stabilize or maintain the market price of the Securities of such series or issue at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. Any underwriters, dealers or agents to or through whom Securities are sold by us for public offering and sale may make a market in the Securities, but such underwriters, dealers or agents will not be obligated to do so and may discontinue any market making at any time without notice. No assurance can be given that a trading market in the Securities of any series or issue will develop or as to the liquidity of any such trading market for the Securities.

**CERTAIN INCOME TAX CONSIDERATIONS**

The applicable Prospectus Supplement will describe certain Canadian federal income tax consequences to an investor of acquiring any Securities offered thereunder, including, for investors who are non-residents of Canada, whether the payments of dividends (or any other amounts) on the Securities, if any, will be subject to Canadian non-resident withholding tax.

The applicable Prospectus Supplement may also describe certain U.S. federal income tax consequences of the acquisition, ownership and disposition of any Securities offered thereunder by an initial investor who is a U.S. person (within the meaning of the U.S. Internal Revenue Code), including, to the extent applicable, any such consequences relating to Securities payable in a currency other than the U.S. dollar, issued at an original issue discount for U.S. federal income tax purposes or containing early redemption provisions or other special items.

**LEGAL MATTERS**

Unless otherwise specified in the Prospectus Supplement relating to any offering of Securities, certain legal matters relating to the offering of the Securities under this Prospectus will be passed upon for us by Norton Rose Canada LLP with respect to matters of Canadian law. In addition, certain legal matters in connection with any offering of Securities under this Prospectus will be passed upon for any underwriters, dealers or agents by counsel to be designated at the time of the offering by such underwriters, dealers or agents with respect to matters of applicable law.

At the date of this Prospectus, the partners and associates of Norton Rose Canada LLP beneficially own, directly or indirectly, less than 1% of our outstanding Common Shares.

**Table of Contents**

**AUDITORS**

Our auditors are PricewaterhouseCoopers LLP, who have issued an audit opinion dated March 27, 2012 in respect of our consolidated statements of financial position as at December 31, 2011, December 31, 2010 and January 1, 2010 and our consolidated statement of comprehensive loss, changes in shareholders' equity and cash flows for the years ended December 31, 2011 and December 31, 2010 and the effectiveness of our internal control over financial reporting as at December 31, 2011. PricewaterhouseCoopers LLP has advised that they are independent within the meaning of the Code of Ethics of the *Ordre des comptables professionnels agréés du Québec*.