

Aeterna Zentaris Inc.  
Form F-10  
December 30, 2015

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As filed with the Securities and Exchange Commission on December 30, 2015

Registration No. 333-

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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### FORM F-10

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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### Aeterna Zentaris Inc.

(Exact name of Registrant as specified in its charter)

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Not Applicable

(Translation of Registrant's name into English)

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Canada

(Province or other jurisdiction of  
incorporation or organization)

2834

(Primary Standard Industrial  
Classification Code Number)

c/o Norton Rose Fulbright Canada LLP  
1 Place Ville Marie, Suite 2500  
Montreal, Quebec  
Canada, H3B 1R1  
(514) 847-4747

(Address and telephone number of Registrant's principal executive offices)

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Not Applicable

(I.R.S. Employer  
Identification Number, if applicable)

Aeterna Zentaris, Inc.  
315 Sigma Drive, Suite 302D  
Summerville, South Carolina 29483  
(843) 900-3223

(Name, address (including zip code) and telephone number (including area code) of agent for service in the United States)

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Copies to:

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New York, New York 1010  
(212) 318-3388

Approximate date of commencement of proposed sale of the securities to the public:  
From time to time after the effective date of this Registration Statement.

Province of Quebec, Canada  
(Principal jurisdiction regulating this offering)

It is proposed that this filing shall become effective (check appropriate box):

- A. ☐ upon filing with the Commission, pursuant to Rule 467(a) (if in connection with an offering being made contemporaneously in the United States and Canada).
- B. ☐ at some future date (check the appropriate box below).
1. ☐ pursuant to Rule 467(b) on *(date)* at *(time)* (designate a time not sooner than 7 calendar days after filing).
  2. ☐ pursuant to Rule 467(b) on *(date)* at *(time)* (designate a time 7 calendar days or sooner after filing) because the securities regulatory authority in the review jurisdiction has issued a receipt or notification of clearance on *(date)*.
  3. ☐ pursuant to Rule 467(b) as soon as practicable after notification of the Commission by the Registrant or the Canadian securities regulatory authority of the review jurisdiction that a receipt or notification of clearance has been issued with respect hereto.
  4. ☐ after the filing of the next amendment to this Form (if preliminary material is being filed).

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to the home jurisdiction's shelf prospectus offering procedures, check the following box. ☐

## CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered <sup>(1)(2)</sup>	Proposed maximum offering price per security	Proposed maximum aggregate offering price	Amount of registration fee <sup>(3)</sup>
Common Shares				
Preferred Shares				
Debt Securities				
Subscription Receipts				
Warrants				
Units				

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Total	\$150,000,000	100%	\$150,000,000	\$15,105.00
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- (1) There are being registered under this Registration Statement such indeterminate number of (i) common shares (no par value), (2) preferred shares (no par value), (3) debentures, notes, bonds or other evidences of indebtedness of any kind, nature or description, (4) subscription receipts, (5) warrants to purchase common shares, and/or (6) units comprised of one or more of the securities listed above in any combination as shall have an aggregate initial offering price not to exceed \$150,000,000. The proposed maximum initial offering price per security will be determined, from time to time, by the Registrant in connection with the sale of the securities registered under this Registration Statement.
- (2) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").
- (3) Calculated in accordance with Rule 457(o).
- 

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registration Statement shall become effective as provided in Rule 467 under the Securities Act or on such date as the Commission, acting pursuant to Section 8(a) of the Securities Act, may determine.**

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**PART I**

**INFORMATION REQUIRED TO BE DELIVERED TO OFFEREEES OR PURCHASERS**

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*The information contained in this prospectus is not completed and may be changed. We may not sell these securities until the registration statement filed with the U.S. Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.*

New Issue and/or Secondary Offering

December 29, 2015

**SUBJECT TO COMPLETION**

**PRELIMINARY SHORT FORM BASE SHELF PROSPECTUS**

**US\$150,000,000**

**Common Shares  
Preferred Shares  
Debt Securities  
Subscription Receipts  
Warrants  
Units**

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Aeterna Zentaris Inc. ("Aeterna Zentaris", "we", "us" or the "Company") may from time to time during the 25-month period that this short form base shelf prospectus (the "Prospectus"), including any amendments hereto, remains valid, offer, sell, and issue under this Prospectus up to US\$150,000,000 aggregate initial offering price of: (i) common shares (the "Common Shares"); (ii) 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"); (iii) debentures, notes, bonds or other evidences of indebtedness of any kind, nature or description (the "Debt Securities"); (iv) subscription receipts (the "Subscription Receipts"); (v) warrants to purchase Common Shares (the "Warrants"); and/or (vi) units comprised of one or more securities described herein in any combination (the "Units" and, together with the Common Shares, Preferred Shares, Debt Securities, Subscription Receipts and Warrants, the "Securities").

Upon the issuance of a receipt by the Canadian securities regulatory authorities for the final Prospectus and the effectiveness of the corresponding registration statement on Form F-10 of which this document forms part, this Prospectus will supersede and replace our short form base shelf prospectus dated March 13, 2014.

**Unless otherwise stated, currency amounts in this Prospectus are presented in United States dollars, or "\$" or "US\$".**

We may offer Securities from time to time in one or more transactions in such amounts and, if applicable, with such terms, as we may determine in light of prevailing market conditions at the time of sale. 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, in addition to the currency in which any class, series or issue of Securities will be issued and paid for, where applicable: (i) in the case of Common Shares, the number of Common Shares offered, the offering price, and any other specific terms applicable thereto; (ii) in the case of Preferred Shares, the designation of the particular series, aggregate principal amount and liquidation preference, the number of Preferred Shares being offered, the issue price, any rights to receive dividends, the dividend rate, the dividend payment date, any terms of redemption at the option of Aeterna Zentaris or the holder, any exchange or conversion terms and any other specific terms applicable thereto; (iii) in the case of Debt Securities, the specific designation of the Debt Securities, the aggregate principal amount of the Debt Securities, the currency, the maturity date, the offering price (at par, at a discount or at a premium), whether the Debt Securities will bear interest, the interest rate or method of determining the interest rate, the interest payment date(s), any terms of redemption, any conversion or exchange rights and any

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other specific terms applicable thereto; (iv) in the case of Subscription Receipts, the number of Subscription Receipts offered, the issue price, the terms, conditions and procedures pursuant to which the holders thereof will become entitled to receive Securities and any other specific terms applicable thereto; (v) in the case of Warrants, the designation of the particular series offered, the number of Warrants offered, the offering price, the currency in which the Warrants are denominated, 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; and (vi) in the case of Units, the number of Units offered, the offering price, the Securities comprising the Units, 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 the securities laws of the United States ("U.S.") and are permitted, under a multi-jurisdictional disclosure system ("MJDS") adopted in the U.S. and Canada, to prepare this Prospectus in accordance with Canadian regulatory disclosure requirements. Prospective investors 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 have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"), and thus may not be comparable to financial statements of U.S. companies. 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 (U.S.) 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 the U.S. and Canada. 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 fully and consult with their own tax advisors.**

**The enforcement of civil liabilities under U.S. federal securities laws may be adversely affected by the fact that we are incorporated under the laws of Canada, a number of our officers and directors and some 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 of the U.S. See "Enforceability of Civil Liabilities".**

**David A. Dodd, our Chairman, President and Chief Executive Officer, and Keith Santorelli, our Vice President, Finance and Chief Accounting Officer, each of whom is signing the certificate of the Company at the end of this Prospectus, and certain of our independent directors, namely Juergen Ernst and Carolyn Egbert, reside outside of Canada. Each such person has appointed Norton Rose Fulbright Canada LLP, at 1 Place Ville Marie, Suite 2500, Montreal, Quebec, Canada, H3B 1R1, as his or her agent for service of process in Canada.**

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

**No underwriter has been involved in the preparation of this Prospectus or has performed any review of the contents of this Prospectus.**

**Investing in the Securities involves a high degree of risk. See "Risk Factors".**

Our Common Shares are listed on the NASDAQ Capital Market ("NASDAQ") under the symbol "AEZS" and on the Toronto Stock Exchange ("TSX") under the symbol "AEZ". On December 28, 2015, the last reported sales price of our Common Shares on NASDAQ was \$4.86 per share and on December 24, 2015, the last reported sales price of our Common Shares on TSX was C\$6.77 per share.

There is no market through which the Preferred Shares, the Debt Securities, the Subscription Receipts, the Warrants and the Units may be sold, and purchasers may not be able to resell such Securities purchased under this Prospectus. This may affect the pricing of such Securities in the secondary market, the transparency and availability of trading prices, the liquidity of such Securities, and the extent of issuer regulation. See the "Risk Factors" section of this Prospectus and the applicable Prospectus Supplement.

We may sell Securities to or through underwriters or dealers or directly to investors or through agents designated from time to time at amounts and prices and other terms determined by us or any selling



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securityholders. In connection with any underwritten offering of Securities, the underwriters may over-allot or effect transactions which stabilize or maintain the market price of the offered Securities. Such transactions, if commenced, may discontinue at any time. See "Plan of Distribution". The Prospectus Supplement will set out the names of any underwriters, dealers, agents or selling securityholders involved in the sale of our Securities, the amounts, if any, to be purchased by underwriters, the plan of distribution for such Securities, including the net proceeds we expect to receive from the sale of such Securities, if any, the amounts and prices at which such Securities are sold and the compensation of such underwriters, dealers or agents.

**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 address is located at 1 Place Ville Marie, Suite 2500, Montreal, Quebec, Canada, H3B 1R1, c/o Norton Rose Fulbright Canada LLP, our head office is located at 315 Sigma Drive, Suite 302D, Summerville, South Carolina, USA, 29483, and our telephone number is (843) 900-3223.

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**ABOUT THIS PROSPECTUS**

This Prospectus provides you with a general description of the Securities that we may offer. Each time we sell Securities, we will provide a Prospectus Supplement that will contain specific information about the terms of that offering. The Prospectus Supplement may also add, update or change information contained in this Prospectus. Before you invest, you should read both this Prospectus and any applicable Prospectus Supplement together with the additional information described under the heading "Where You Can Find More Information".

The financial statements included in or incorporated by reference into this Prospectus have been prepared in accordance with IFRS as issued by the IASB. 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 (U. S.) and the SEC independence standards.

Except as otherwise indicated, all historical share, warrant and option data, including number of securities issued and outstanding and applicable exercise prices, in this Prospectus have been retroactively adjusted to reflect and give effect to the Share Consolidation (as defined below) that we implemented in November 2015.

In this Prospectus and in any Prospectus Supplement, unless otherwise indicated, references to "we", "us", "our", "Aeterna Zentaris" or the "Company" are 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.

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, as well as the exchange rate at the end of such period, in each case, based upon the noon rates as quoted by the Bank of Canada:

	December 2015 <sup>(1)</sup>	Nine-month period ended September 30, 2015	Year ended December 31,		
			2014	2013	2012
High	1.3990	1.3413	1.1643	1.0697	1.0418
Low	1.3360	1.1728	1.0614	0.9839	0.9710
Rate at end of period	1.3845	1.3394	1.1601	1.0636	0.9949
Average rate per period	1.3679	1.2600	1.1045	1.0299	0.9996

(1)

Up to and including December 24, 2015.

On December 24, 2015, the exchange rate for one U.S. dollar expressed in Canadian dollars based upon the noon rate of the Bank of Canada was C\$1.3845.

**SPECIAL NOTE ON 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 the Company. When used in this Prospectus and the documents incorporated herein by reference, 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 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;

fluctuations in our revenues and expenses may disappoint securities analysts and investors, causing the price of our securities to decline;

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;

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

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

we may not be able to realize any profit from our commercial operation;

we may not be able to acquire, in-license or otherwise obtain the right to sell other products;

we may breach or fail to maintain a necessary license agreement;

the impact of the stringent ongoing government regulation to which our product candidates are subject;

the impact of restrictions on, or withdrawals of, any product approvals and changes in regulatory requirements;

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the impact of healthcare reform measures on the commercial success of our product candidates and on our business prospects or future financial condition;

the impact of healthcare fraud and abuse laws on our ability to market products;

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

we are pursuing later-stage clinical development projects because we lack the resources to pursue earlier-stage projects, which could have a greater likelihood of success or greater commercial potential;

the 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;

the impact of 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;

current and future collaborations for the research and development ("R&D") of our product candidates may not provide the benefits we expect;

we may not be able to obtain the ingredients or raw materials that we require at acceptable prices or at all;

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 expect to rely to manufacture and supply products;

our ability to retain or attract key personnel;

we use hazardous materials and are subject to environmental and occupational safety laws;

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the impact of securities class action litigation or other litigation on our cash flow, results of operations and financial position;

risks relating to product liability and other claims;

risks relating to our holding company structure;

it may be difficult for U.S. investors to obtain and enforce judgments against us;

we may not be able to maintain effective internal controls;

there is a reasonable likelihood that we may be a passive foreign investment company for the 2015 taxable year, which could result in adverse tax consequences for U.S. investors;

fluctuations in currency exchange rates;

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

security breaches may disrupt our operations and adversely affect our operating results;

the possibility that our Common Shares may be delisted from the stock exchanges on which they currently trade;

our share price is volatile;

we do not intend to pay dividends;

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future issuances of securities and hedging activities may depress the price of our securities;

we are permitted to issue "blank check" preferred shares; and

our business could be negatively affected as a result of the actions of activist shareholders.

More detailed information about these and other factors is included under "Risk Factors" in this 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 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.

## ENFORCEABILITY OF CIVIL LIABILITIES

We are a corporation incorporated under and governed by the *Canada Business Corporations Act*. A number of our officers and directors, and some 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 Fulbright 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 Fulbright 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

We are a specialty biopharmaceutical company engaged in developing and commercializing novel treatments in oncology, endocrinology and women's health. We are currently engaged in drug development activities and in the promotion of products for others. The focus of our business development efforts is the acquisition of licenses to products that are relevant to our therapeutic areas of focus. We are endeavouring to license out certain commercial rights of internally developed products to licensees in territories where such out-licensing would enable us to ensure development, registration and launch of our product candidates. Our goal is to become a growth oriented specialty biopharmaceutical company by pursuing successful development and commercialization of our product portfolio, achieving successful commercial presence and growth, while consistently delivering value to our shareholders, employees and the medical providers and patients who will benefit from our products.

**Drug Development.** Our drug development efforts are focused currently on two lead, clinical-stage development compounds: Zoptrex (zoptarelin doxorubicin), which has the potential to become the first U.S. Food and Drug Administration ("FDA")-approved medical therapy for advanced, recurrent endometrial cancer, and Macrilen (macimorelin), a novel orally-active ghrelin agonist for use in evaluating adult growth hormone deficiency ("AGHD"). Zoptrex and Macrilen are currently in Phase 3 clinical trials. Additionally, our luteinizing hormone releasing hormone ("LHRH")-Disorazol Z compounds, potential oncology-indication product candidates, are in pre-clinical development.

Zoptrex is a complex molecule that combines a synthetic peptide carrier with doxorubicin, a well-known chemotherapy agent. The synthetic peptide carrier is an LHRH agonist, a modified natural hormone with affinity for the LHRH receptor. We believe that the design of the compound allows for the specific binding and selective uptake of the cytotoxic conjugate by LHRH receptor-positive tumors. Potential benefits of this targeted approach include better efficacy with lower incidence and severity of side effects as compared to doxorubicin alone. Zoptrex is currently in a pivotal Phase 3 clinical trial in women with advanced, recurrent or metastatic endometrial cancer. In October 2015, we announced that the independent Data and Safety Monitoring Board

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("DSMB") had recommended that the pivotal Phase 3 ZoptEC (Zoptarelin Doxorubicin in Endometrial Cancer) study continue as planned. The DSMB's decision followed completion of its pre-specified final interim analysis on efficacy and safety at approximately 192 events. The ZoptEC study will conclude upon the occurrence of approximately 384 events, which we expect to occur by September 2016. After the conclusion of the study, the data obtained will be analyzed and we will make a decision regarding the likelihood that the FDA will approve the compound for its indication. If we conclude that there is a reasonable likelihood of approval, we will prepare and file a New Drug Application ("NDA") seeking approval of the compound for its indication. The FDA typically requires one year to make a decision on the approvability of an NDA.

Macrilen (macimorelin acetate) is a novel orally available peptidomimetic ghrelin receptor agonist that stimulates the secretion of growth hormone by binding to the ghrelin receptor (GHSR-1a) and that has potential uses in both endocrinology and oncology indications. Macrilen has been granted orphan-drug designation by the FDA for use in evaluating growth hormone deficiency ("GHD"). Macrilen is currently in a confirmatory Phase 3 clinical trial for use in evaluating AGHD. In November 2015, we announced that the first patient had been enrolled in the confirmatory Phase 3 clinical trial. We expect to complete the confirmatory Phase 3 clinical trial by the end of 2016. After the conclusion of the confirmatory Phase 3 clinical trial, the data obtained will be analyzed and we will make a decision regarding the likelihood that the FDA will approve the compound for its indication. If we conclude that there is a reasonable likelihood of approval, we will prepare and file an NDA seeking approval of the compound for its indication. Because the Phase 3 clinical trial of Macrilen is a confirmatory trial, the FDA will make a decision regarding the approvability of Macrilen within approximately six months of the date we file the NDA.

*Commercial Operations.* Our commercial operations consist of 23 full-time sales representatives, who provide services pursuant to our agreement with a contract sales organization, and a sales-management staff. Our sales representatives are currently promoting three products:

**EstroGel®:** During the third quarter of 2014, we entered into a promotional services agreement with ASCEND Therapeutics US LLC to detail EstroGel®, a leading non-patch transdermal hormone replacement therapy product, in specific agreed upon US territories in exchange for a commission based upon incremental sales of the product that are generated over pre-established baselines;

**Saizen®** (somatropin (rDNA origin) for injection): In May 2015, we entered into a promotional services agreement with EMD Serono, Inc. to detail Saizen®, a recombinant human growth hormone registered in the U.S. for the treatment of growth hormone deficiency in children and adults, to designated medical professionals across 23 specified U.S. territories in exchange for a commission based on new, eligible patient starts on Saizen® above an agreed upon baseline; and

**APIFINY®:** On December 1, 2015, we entered into a co-marketing agreement with Armune BioScience, Inc. ("Armune") that will allow us to promote Armune's APIFINY®, the only cancer specific, non-PSA (prostate-specific antigen) blood test for the detection of prostate cancer, in exchange for a commission for each test performed resulting from our targeted promotion of the product.

Our sales force will also be available for the launch of our own potential product candidates (i.e., Zoptrex and Macrilen) in the U.S., if the products are approved for sale in the U.S.

We also continue to pursue opportunities to in-license, acquire, promote or co-promote additional commercial products that are relevant to our therapeutic areas of focus. Our preference is to in-license or acquire additional commercial products because we wish to control all aspects of the commercialization of the products and to record the sales revenue from the products.

**Recent Developments**

*Share Consolidation*

On November 17, 2015, we effected a share consolidation (reverse stock split) on a 100-for-1 basis (the "Share Consolidation"). Our Common Shares commenced trading on a consolidated and adjusted basis on both NASDAQ and TSX on November 20, 2015.

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***Capital Structure, Warrant Adjustments and Related Events***

On November 2, 2015, we announced that the holders (the "Participating Holders") of substantially all of our then remaining and outstanding Series B Common Share Purchase Warrants (the "Series B Warrants") originally issued in connection with our offering of units for gross proceeds of \$37.0 million in March 2015 (the "March 2015 Offering") had agreed to exercise all of the approximately 41.2 thousand (or 4.1 million pre-Share Consolidation) Series B Warrants held by them, at a maximum exercise ratio of approximately 33.23 common shares per warrant in accordance with the alternate cashless exercise feature in such Series B Warrants. On November 24, 2015, we announced that all Participating Holders had exercised the Series B Warrants held by them. As of the date hereof, approximately 8.1 thousand Series B Warrants remain outstanding. Such Series B Warrants are not held by a Participating Holder.

***December 2015 Public Offering***

On December 14, 2015, we announced the closing of our previously announced underwritten public offering consisting of 3.0 million common shares and warrants to acquire 2.1 million common shares at a combined purchase price of \$5.55 for one common share together with a warrant to purchase 0.7 of a common share, generating net proceeds of approximately \$15.0 million (the "December 2015 Offering"). Each warrant issued in the December 2015 Offering is exercisable for a period of five years from its date of issuance at an exercise price of \$7.10 per share. In connection with the December 2015 Offering, we also granted the underwriter a 45-day option to purchase up to an additional 330,000 common shares and/or warrants to purchase up to an additional 231,000 common shares, to cover over-allotments, if any (the "Over-Allotment Option"). Prior to closing, the underwriter exercised the Over-Allotment Option with respect to the warrants to acquire an additional 231,000 common shares.

**Corporate Information**

Aeterna Zentaris Inc. was incorporated on September 12, 1990 under the laws of Canada. Our registered address is located at 1 Place Ville Marie, Suite 2500, Montreal, Quebec, Canada, H3B 1R1, c/o Norton Rose Fulbright Canada LLP, our head office is located at 315 Sigma Drive, Suite 302D, Summerville, South Carolina, USA, 29483, our telephone number is (843) 900-3223 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.

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., an entity incorporated in the State of Delaware based in Summerville, South Carolina in the U.S.

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



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**RISK FACTORS**

*Before making an investment decision, you should carefully consider the risks described in this Prospectus, together with all of the other information incorporated by reference into this Prospectus, including the risks 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 condensed interim consolidated financial statements and corresponding management's discussion and analysis. The risks mentioned below are presented as of the date of this Prospectus 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 Securities.*

*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 and the value of our other Securities could decline due to any of these risks, and you may lose part or all of your investment. This 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 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. 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.*

**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 are uncertain, given the very nature of the industry, and, accordingly, investments in biopharmaceutical companies should be considered to be speculative assets.

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

We have incurred, and expect to continue to incur, substantial expenses in our efforts to develop and market products. Consequently, we have incurred operating losses historically and, as disclosed in our unaudited condensed interim consolidated financial statements as at September 30, 2015 and for the three-month and nine-month periods ended September 30, 2015 and 2014, we had a deficit of approximately \$261.5 million as at September 30, 2015. Our operating losses have adversely impacted, and will continue to adversely impact, our working capital, total assets, operating cash flow and shareholders' equity (deficiency). We do not expect to reach operating profitability in the immediate future, and our operating expenses are likely to continue to represent a significant component of our overall cost profile as we continue our R&D and clinical study programs, seek regulatory approval for our product candidates and carry out commercial activities. Even if we succeed in developing, acquiring or in-licensing new commercial products, we could incur additional operating losses for at least the next several years. If we do not ultimately generate sufficient revenue from commercialized products to achieve or maintain operating profitability, an investment in our Securities could result in a significant or total loss.

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***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 may continue 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 nature and timing of licensing fee revenues;

the outcome of litigation, including the litigation pending against us that is described elsewhere in this Prospectus;

foreign currency fluctuations;

the timing of the 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.

***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. Preclinical testing and clinical development are inherently lengthy, complex, expensive and uncertain processes and have a high risk of failure. It typically takes many years to complete testing, and failure can occur at any stage of testing. Results attained in preclinical testing and early clinical studies, or trials, may not be indicative of results that are obtained in later studies. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval and, accordingly, may encounter unforeseen problems and delays in the approval process. Furthermore, errors in the conduct, monitoring and/or auditing of a clinical trial, whether made by us or by a contract research organization (a "CRO") that we retain could invalidate the results from a regulatory perspective.

None of our current product candidates has to date received regulatory approval for their 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 R&D and clinical studies are required to demonstrate the safety and efficacy of our product candidates before we can submit regulatory applications. Even if a product candidate is approved by the applicable regulatory authority, we may not obtain approval for an indication whose market is large enough to recover 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.

## Edgar Filing: Aeterna Zentaris Inc. - Form F-10

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

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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 recover 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 perform 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.

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

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

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

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

meet the requirements of these authorities;

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meet the requirements for informed consent; and

meet the 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.

Additionally, we have limited experience in filing an NDA or similar application for approval in the U.S. or in any other 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, some questions may not be answered in time to prevent the delay of acceptance of an NDA or the rejection of an NDA.

***We have incurred, and expect to continue to incur, substantial expenses, and we have made, and expect to continue to make, substantial financial commitments to establish a commercial operation. There can be no assurance how quickly, if ever, we will realize a profit from our commercial operation.***

Our business strategy is to become a specialty biopharmaceutical company with commercial operations to market and sell products that we may develop, acquire or in-license. To that end, our commercial operations consist of 23 full-time sales representatives, who provide services pursuant to our agreement with a contract sales organization, and our sales-management employees. We have to date incurred, and expect to continue to incur, substantial expenses, and we have made, and expect to continue to make, substantial financial commitments to build out our commercial operations. Establishing a commercial operation is expensive and time-consuming, and there can be no assurance how quickly, if ever, we will realize a profit from our commercial operations. Factors that may inhibit our efforts to realize a profit from our commercial operations, should we be successful in consummating transactions such as acquisitions, in-licensing, promotional or co-promotional arrangements with third parties, include:

our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel and representatives;

the inability of our sales personnel to obtain access to or to persuade adequate numbers of physicians to prescribe our products or the products that we in-license or co-promote;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating an independent sales and marketing organization.

***Our financial viability depends, in part, on our ability to acquire, in-license or otherwise obtain the right to sell other products. If we are unable to do so, our business, financial condition and results of operations may be materially adversely affected.***

In connection with our strategy to further transform the Company into a commercially operating specialty biopharmaceutical organization, we may enter into commercial arrangements with third parties, including but not limited to promotion, co-promotion, acquisition or in-licensing agreements, in efforts to establish and expand our commercial revenue base. These business activities entail numerous operational and financial risks, including:

the difficulty or inability to secure financing to acquire or in-license products;

the incurrence of substantial debt or dilutive issuances of securities to pay for the acquisition or in-licensing of new products;

the disruption of our business and diversion of our management's time and attention;

higher than expected development, acquisition or in-license and integration costs;

exposure to unknown liabilities; and

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the difficulty in locating products that are in our targeted therapeutic areas and that are compatible with other products in our portfolio.

We can provide no assurance that we will be able to identify potential product candidates or strategic commercial partners or, if we identify such product candidates or partners, that any related commercial arrangements will be consummated on terms that are favorable to us. To the extent that we are successful in entering into any strategic commercial arrangements, including promotional or co-promotional agreements, or acquisition or in-licensing agreements with third parties, we cannot provide any assurance that any resulting initiatives or activities will be successful. To the extent that any related investments in such arrangements do not yield the expected benefits, our business, financial condition and results of operations may be materially adversely affected.

We have limited resources to identify and execute the procurement of additional products and to integrate them into our current commercial operations. The failure to successfully integrate the personnel and operations of businesses that we may acquire or of products that we may in-license in the future with our existing operations, business and products could have a material adverse effect on our operations and results. We compete with larger pharmaceutical companies and other competitors in our efforts to acquire, in-license, and/or obtain the right to market new products. Our competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisition, in-licensing, promotion or co-promotion opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

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

We will require significant additional capital to fund our commercial operations and may require additional capital to pursue planned clinical trials and regulatory approvals, as well as further R&D and marketing efforts for our product candidates and potential products. 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 CROs or from other sources, including, without limitation, through at-the-market offerings and issuances of Common Shares. 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 or exercisable for equity securities (collectively, "Convertible Securities"), the issuance of those securities could result in dilution to our shareholders. Moreover, the incurrence of debt financing or the issuance of dividend-paying preferred shares, 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 or the payment of dividends on such preferred shares and could impose restrictions on our operations and on our ability to make certain expenditures and/or to incur additional indebtedness, which 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 Securities hereunder and under the relevant Prospectus Supplement and anticipated revenues will be sufficient to fund our commercial operations, 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 of, changes to 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;

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

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the potential addition of commercialized products to our portfolio;

the outcome of litigation, including the litigation pending against us that is described elsewhere in this Prospectus; 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 generating new revenues, increasing our revenues and/or raising additional funding, we may possibly cease to continue operating as we currently do.***

We have had sustained operating losses, deficits and negative cash flows from operating activities over the past several years, and we expect that we will continue to do so for an extended period.

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 and/or non-traditional sources of financing. 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 also could be material uncertainties related to certain adverse conditions and events that could impact our ability to remain a going concern. If the going concern assumptions were deemed no longer appropriate for our consolidated financial statements, adjustments to the carrying value of assets and liabilities, reported expenses and consolidated statement of financial position classifications would be necessary. Such adjustments could be material.

Additional funding may be in the form of debt or equity or a hybrid instrument depending on our needs, those of investors and market conditions. Depending on the prevailing global economic and credit market conditions, we may not be able to raise additional liquidity through these traditional sources of financing. Although we may also pursue non-traditional sources of financing with third parties, the global equity and 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 strategic alliances with third parties, 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.

***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.



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If we, or if 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.

***Even if we receive marketing approval for our product candidates, such product approvals could be subject to restrictions or withdrawals. Regulatory requirements are subject to change.***

Regulatory authorities generally approve products for particular indications. If an approval is for a limited indication, this limitation reduces the size of the potential market for that product. Product approvals, once granted, are subject to continual review and periodic inspections by regulatory authorities. Our operations and practices are subject to regulation and scrutiny by the U.S. government, as well as governments of any other countries in which we do business or conduct activities. Later discovery of previously unknown problems or safety issues and/or failure to comply with domestic or foreign laws, knowingly or unknowingly, can result in various adverse consequences, including, among other things, a possible delay in the approval or refusal to approve a product, warning letters, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the government to renew marketing applications, complete withdrawal of a marketing application, criminal prosecution, withdrawal of an approved product from the market and/or exclusion from government healthcare programs. Such regulatory enforcement could have a direct and negative impact on the product for which approval is granted, but also could have a negative impact on the approval of any pending applications for marketing approval of new drugs or supplements to approved applications.

Because we operate in a highly regulated industry, regulatory authorities could take enforcement action against us in connection with our, or our licensees' or collaborators', business and marketing activities for various reasons.

From time to time, new legislation is passed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA and other health authorities. Additionally, regulations and guidance are often revised or reinterpreted by health agencies in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted, or whether regulations, guidance, or interpretations will change, and what the impact of such changes, if any, may be.

***Healthcare reform measures could hinder or prevent the commercial success of our product candidates and 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 healthcare. In the U.S. and in other jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare 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.

The *Patient Protection and Affordable Care Act* and the *Healthcare and Education Affordability Reconciliation Act of 2010* (collectively, the "ACA") may have far-reaching consequences for most healthcare companies, including specialty biopharmaceutical companies like us. For example, if reimbursement for our product candidates is substantially less than we expect, our revenue prospects could be materially and adversely impacted.

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Regardless of the impact of the ACA on us, the U.S. government and other governments have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services, including our product candidates, in the U.S. and internationally, as well as the amount of reimbursement available from governmental agencies and other third-party payers.

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.

***If we market products in a manner that violates healthcare fraud and abuse laws, we may be subject to civil or criminal penalties, including exclusion from participation in government healthcare programs.***

As a pharmaceutical company, even though we do not provide healthcare services or receive payments directly from or bill directly to Medicare, Medicaid or other third-party payers for our products, certain federal and state healthcare laws and regulations pertaining to fraud and abuse are and will be applicable to our business. We are subject to healthcare fraud and abuse regulation by both the federal government and the states in which we conduct our business.

The laws that may affect our ability to operate include the federal healthcare program anti-kickback statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce, or in return for, the purchase, lease, order, or arrangement for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute applies to arrangements between pharmaceutical manufacturers and prescribers, purchasers and formulary managers. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Drug Rebate Program.

The *Health Insurance Portability and Accountability Act of 1996* also created prohibitions against healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians. The ACA imposed new requirements on manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value"

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to such physician owners and their immediate family members. Manufacturers are required to report such data to the government by the 90<sup>th</sup> calendar day of each year.

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals, as amended. Certain states also mandate the tracking and reporting of gifts, compensation, and other remuneration paid by us to physicians and other healthcare providers.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state laws may prove costly.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The ACA also made several important changes to the federal Anti-Kickback Statute, false claims laws, and healthcare fraud statute by weakening the intent requirement under the anti-kickback and healthcare fraud statutes that may make it easier for the government or whistleblowers to charge such fraud and abuse violations. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. In addition, the ACA increases penalties for fraud and abuse violations. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and negatively impact our financial results.

***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 who may not accept or utilize our products, our ability to generate significant revenues from our products would be limited, and our financial condition could be materially adversely affected. In addition, if we fail to further penetrate our core markets and existing geographic markets or to successfully expand our business into new markets, the growth in sales of our products, along with our operating results, could be negatively

impacted.

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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, therapies, products and tests 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 Securities.

***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 lead, clinical-stage development compounds, Zoptrex and Macrilen, and we are doing so 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 Zoptrex, Macrilen and any 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 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.***

Our ability 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 to sell our products on a competitive basis. It may not be possible to negotiate favorable reimbursement rates for our products. Adverse pricing and reimbursement conditions would also likely diminish our ability to induce third parties to co-promote 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 controls 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

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

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

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

The laws of some countries do not protect intellectual property rights to the same extent as the laws of the U.S. and Canada. Many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement.

Our patents and/or the patents that we license from others 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, methods of manufacture and/or 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

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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 U.S. post-grant proceedings as well as 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, we cannot be certain that we were the first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in the 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 deviation 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.

Furthermore, the product development timeline for our products is lengthy and it is possible that our issued patents covering our product candidates in the U.S. and other jurisdictions may expire prior to commercial launch of the products. The patent that covers Zoptrex (zoptarelin doxorubicin) and other related targeted cytotoxic anthracycline analogues, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of cancer expired in the U.S. in November 2015 and will expire in the European Union, Japan, China and Hong Kong in November 2016. We did not apply for patent term extension for this U.S. patent. As a result, our ability to protect this compound from competition will be based on the protections provided in the U.S. for new chemical entities and similar protections, if any, provided in other countries.

We cannot assure you that Zoptrex or any of our other drug candidates will obtain new chemical entity exclusivity or any other market exclusivity in the U.S., the European Union 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 one or more of our 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. Inventions claimed in certain in-licensed patents may have been made with funding from the U.S. government and may be subject to the rights of the U.S. government and we may be subject to additional requirements in the event we seek to commercialize or manufacture product candidates incorporating such in-licensed technology.

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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.

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.***

If we become involved in any patent litigation, interference, opposition or other administrative proceedings we will likely incur substantial expenses in connection therewith, 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 for our product candidates.***

We have filed applications for trademark registrations in connection with Zoptrex and Macrilen in various jurisdictions, including the U.S. We may file applications for other possible trademarks for our product candidates in the future. No assurance can be given that any of our trademarks 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.



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***We are currently dependent on certain strategic relationships with third parties and we may enter into future collaborations for the R&D of our product candidates.***

We are currently dependent on certain strategic relationships with third parties and may enter into future collaborations for the R&D of our product candidates. Our arrangements with these third parties 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, third parties to perform various functions related to our business, including, but not limited to, R&D with respect to 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 to issue our equity, voting or other securities to third parties. Any license or sublicense of our commercial rights may reduce our product revenue.

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

not all of the third parties 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 contracts that do contain such contractual prohibitions or restrictions, prohibitions or restrictions do not always apply to the affiliates of the third parties 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;

the third parties may under-fund or fail to commit sufficient resources to marketing, distribution or other development of our products;

the third parties may cease to conduct business for financial or other reasons;

we may not be able to renew such agreements;

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

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

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

disputes may arise between us and the third parties 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 the third parties to act in their own self-interest and not in our interest or those of our shareholders or other stakeholders.

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In addition, the third parties 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 third party with which to contract or abandon the product candidate, which would likely cause a drop in the price of our Securities.

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***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 to 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 licensees, 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 we pay for them, could have a material adverse effect on our business, financial condition, liquidity and operating results.

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

We expect to rely on third parties to manufacture and supply marketed products. We also have or may have certain supply obligations vis-à-vis our existing and potential licensees, who are or will be 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, there are a limited number of contract manufacturers or suppliers that are capable of manufacturing our product candidates or the materials used in their manufacture. If we are unable to do so ourselves or to arrange for third-party manufacturing or supply of these product candidates or materials, or to do so on commercially reasonable terms, we may not be able to complete development of these product candidates or commercialize them ourselves or through our licensees. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

***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. Reductions in our staffing levels have eliminated redundancies in key capabilities and skill sets among our full-time staff and required us to rely more heavily on outside consultants and third parties. We have been unable to increase the compensation of our associates to the extent required to remain fully competitive for their services, which increased our employee retention risk. The competition for qualified personnel in the biopharmaceutical field is intense, and if we are not able to continue to attract and retain qualified personnel and/or maintain positive relationships with our outside consultants, we may not be able to achieve our strategic and operational objectives.

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***We are currently subject to securities class action litigation and we may be subject to similar or other litigation in the future.***

We and certain of our current and former officers are defendants in a purported class-action lawsuit pending in the U.S. District Court for the District of New Jersey (the "Court"), brought on behalf of shareholders of the Company. The lawsuit alleges violations of the *Securities Exchange Act of 1934* (the "Exchange Act") in connection with allegedly false and misleading statements made by the defendants between April 2, 2012 and November 6, 2014, or the Class Period, regarding the safety and efficacy of Macrilen<sup>®</sup>, a product we developed for use in the diagnosis of AGHD, and the prospects for the approval of the Company's NDA for the product by the FDA. The plaintiffs seek to represent a class comprised of purchasers of our Common Shares during the Class Period and seek damages, costs and expenses and such other relief as determined by the Court. On September 14, 2015, the Court dismissed the lawsuit stating that the plaintiffs failed to state a claim, but granted the plaintiffs leave to amend. On October 14, 2015, the plaintiffs filed a Second Amended Complaint against us. We will seek to have the lawsuit dismissed again as we believe that the Second Amended Complaint also fails to state a claim. The Court will conduct a hearing on our motion to dismiss on January 19, 2016.

While we believe we have meritorious defenses and intend to continue to defend this lawsuit vigorously, we cannot predict the outcome. Furthermore, we may, from time to time, be parties to other litigation in the normal course of business. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, legal fees and costs incurred in connection with such activities may be significant and we could, in the future, be subject to judgments or enter into settlements of claims for significant monetary damages. A decision adverse to our interests could result in the payment of substantial damages and could have a material adverse effect on our cash flow, results of operations and financial position.

With respect to any litigation, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer in contesting and concluding such lawsuit. Substantial litigation costs or an adverse result in any litigation may adversely impact our business, operating results or financial condition. We believe that our directors' and officers' liability insurance will cover our potential liability with respect to the securities class-action lawsuit described above; however, the insurer has reserved its rights to contest the applicability of the insurance to such claim, the limits of the insurance may be insufficient to cover our eventual liability, and we will be required to satisfy a substantial self-insured retention before any insurance coverage applies to the claim.

***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 use of Zoptrex<sup>®</sup> and Macrilen<sup>®</sup> on human participants in our clinical trials subjects us to the risk of liability to such participants, who may suffer unintended consequences. If Zoptrex<sup>®</sup> and/or Macrilen<sup>®</sup> are approved for commercialization or if we acquire a marketed product from a third party, the sale and use of such products will involve the risk of product liability claims and associated adverse publicity. Product-liability claims might be made against us directly by patients, healthcare providers or pharmaceutical companies or others selling, buying or using our products. We attempt to manage our liability risks by means of insurance. We maintain insurance covering our liability for our preclinical and clinical studies. 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. We do not currently maintain product liability insurance because we do not currently market, sell, distribute or handle any products. We may not be able to obtain product liability insurance on reasonable terms, if at all, when we begin to market, sell, distribute or handle products.

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

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

Aeterna Zentaris Inc. is a holding company and a substantial portion of our non-cash 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 non-cash 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 Securities 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 Securities are not creditors of our subsidiaries. Claims to the assets of our subsidiaries will derive from our own ownership interest in those operating subsidiaries. Claims of our subsidiaries' creditors will generally have priority as to the assets of such subsidiaries over our own ownership interest claims and will therefore have priority over the holders of our Securities. Our subsidiaries' creditors may from time to time include general creditors, trade creditors, employees, secured creditors, taxing authorities, and creditors holding guarantees. Accordingly, in the event of any foreclosure, dissolution, winding-up, liquidation or reorganization, or a bankruptcy or insolvency proceeding relating to us or our property, or any subsidiary, there can be no assurance as to the value, if any, that would be available to holders of our Securities.

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.

***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. A number 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

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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.

***We are subject to various internal control 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 U.S. *Sarbanes-Oxley Act* ("Section 404") and National Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings*. 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 (U.S.) 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, similar Canadian requirements or if we 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.

***There is a reasonable likelihood that we may be a passive foreign investment company for the 2015 taxable year or any future taxable years, which could result in adverse tax consequences to U.S. investors.***

Adverse U.S. federal income tax rules apply to "U.S. Holders" (as defined in "Item 10.E Taxation Certain Material U.S. Federal Income Tax Considerations" in our annual report on Form 20-F) that directly or indirectly hold common shares, preferred shares, warrants or units, to the extent such units are comprised of common shares, preferred 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% 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.

There is a reasonable likelihood that we may be a PFIC for the 2015 taxable year. However, our PFIC status for the 2015 taxable year or any future taxable year cannot be determined until after the end of such taxable year. 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 any future taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder holds common shares, preferred shares, warrants or units, to the extent such units are comprised of common shares, preferred shares or warrants, we generally would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds such securities, even if we ceased to meet the threshold requirements for PFIC status. 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, Preferred Shares, Warrants or Units, to the extent such disposition of Units is treated as a disposition of Common Shares, Preferred Shares or Warrants that comprise all or a portion of such Units, 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 (including Common Shares comprising all or a portion

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of a Unit, if applicable) 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 Preferred Shares or Warrants. In addition, U.S. Holders may mitigate the adverse tax consequences of the PFIC rules by making a "qualified electing fund" ("QEF") election. If we determine that the Company is a PFIC we will endeavor to satisfy the record keeping requirements that apply to a QEF and to supply requesting U.S. Holders with the information that such U.S. Holders are required to report under the QEF rules. However, there can be no assurance that the Company will satisfy the record keeping requirements or provide the information required to be reported by U.S. Holders.

If we are a PFIC, U.S. Holders will generally 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, Preferred Shares and, potentially, Warrants (including Common Shares, Preferred Shares and, potentially, Warrants comprising all or a portion of a Unit, if applicable).

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

***Legislative actions, new accounting pronouncements and higher insurance costs may adversely 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.

***Security breaches may disrupt our operations and adversely affect our operating results.***

Our network security and data recovery measures and those of third parties with which we contract, may not be adequate to protect against computer viruses, cyber-attacks, break-ins, and similar disruptions from unauthorized tampering with our computer systems. The misappropriation, theft, sabotage or any other type of security breach with respect to any of our proprietary and confidential information that is electronically stored, including research or clinical data, could cause interruptions in our operations, and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. This disruption could have a material adverse impact on our business, operating results and financial condition. Additionally, any break-in or trespass of our facilities that results in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our R&D equipment and assets could have a material adverse impact on our business, operating results, and financial condition.

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**Risks Relating to the Securities**

***Our Common Shares may be delisted from NASDAQ or TSX, which could affect their market price and liquidity. If our Common Shares were to be delisted, investors may have difficulty in disposing of their shares.***

Our Common Shares are currently listed on NASDAQ under the symbol "AEZS" and on TSX under the symbol "AEZ". 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 December 19, 2014, we received a notice from The NASDAQ Listing Qualifications Department indicating that the minimum bid price for our Common Shares had fallen below \$1.00 for 30 consecutive business days, and that, therefore, we were no longer in compliance with NASDAQ Marketplace Rule 5450(a)(1) (the "NASDAQ Bid Price Rule"). On December 8, 2015, we announced that we had regained compliance with the NASDAQ Bid Price Rule.

There can be no assurance that the market price of our Common Shares will not fall below \$1.00 in the future or that we will regain compliance with the minimum bid price requirement. Further, there can be no assurance that the Share Consolidation alone will guarantee the continued listing of our Common Shares on NASDAQ or that our Common Shares will not be delisted due to a failure to meet other NASDAQ continued listing requirements. In addition, in the future, the market price of our Common Shares may not exceed or remain higher than the market price prior to the Share Consolidation and thus the total market capitalization of our Common Shares in the future may be lower than the total market capitalization before the Share Consolidation.

In addition to the minimum bid price requirement, the continued listing rules of NASDAQ require us to meet at least one of the following listing standards: (i) stockholders' equity of at least \$2.5 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 \$35 million (the "Market Value Standard") or (iii) net income from continuing operations (in the latest fiscal year or in two of the last three fiscal years) of at least \$500,000 (the "Net Income Standard"). If our total market capitalization decreases to an amount less than \$35 million for 30 consecutive trading days, it is possible that we could no longer meet any of these three listing standards. Similar to the process described above in the minimum bid price context, if we fail to meet the Market Value Standard for 30 consecutive trading days and do not otherwise meet the Equity Standard or the Net Income 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 \$35 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 or TSX. If we fail to meet any of NASDAQ's or TSX'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.

***Our share price is volatile, which may result from factors outside of our control.***

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 the Share Consolidation, between December 1, 2014 and December 28, 2015, the closing price of our Common Shares ranged from \$4.00 to \$84.20 per share on NASDAQ and from C\$5.39 to C\$104.00 per share on TSX. See the section titled "Price Range and Trading Volume" of this Prospectus. 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



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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;

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.

***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 overall commercial expansion of our business. As a result, the return on an investment in our Securities will 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 them.

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

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

There is no established trading market for the Preferred Shares, Debt Securities, Subscription Receipts, Warrants and Units, and unless specified in the applicable Prospectus Supplement, we currently do not intend to list them on any securities exchange. A dealer may intend to make a market in such Securities 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 of such Securities. In addition, subsequent to their initial issuance, the Preferred Shares, Debt Securities, Subscription Receipts, Warrants and Units may trade at a discount to their initial offering price, depending on the market for similar securities, prevailing interest rates, our prospects or the

prospects for companies in our industry generally and other factors, including those described herein.

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

The number of Common Shares that will be initially issuable upon the exercise of Warrants or other Convertible Securities will be determined by the particular terms of each issue of Warrants or other Convertible Securities and will be described in the relevant Prospectus Supplement. To the extent that purchasers of Warrants or other Convertible Securities sell Common Shares issued upon the exercise of the Warrants or other

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Convertible Securities, 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 or other Convertible Securities 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 Warrants or other Convertible Securities 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 Warrants or other Convertible Securities 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 any Warrants or other Convertible Securities. The number of Common Shares that we will issue under any Warrants or other Convertible Securities may depend on the market price of our Common Shares.***

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

***Management will have broad discretion as to the use of proceeds of any offering of Securities. We may invest or spend any proceeds of any offering of Securities 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 to continue to fund our ongoing drug development activities, for the potential addition of commercialized products to our portfolio and for general corporate purposes, working capital and to fund our negative cash flow. 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 issuance of equity securities or Convertible Securities after the offering of Securities under this Prospectus, including the issuance of Common Shares upon the exercise of stock options and upon the exercise of warrants or other Convertible Securities, as well as the issuance of Common Shares under potential at-the-market offerings, could dilute the interests of our existing shareholders, and could substantially decrease the trading price of our Common Shares. For example, the Company has in the past filed prospectus supplements to qualify for distribution to the public in the U.S. Common Shares under various "at-the-market" distribution programs and the Company may file additional prospectus supplements for one or more "at-the-market" distribution programs in the future, which would be further dilutive to our existing shareholders. Under the remainder of our shelf registration statement on Form F-3 with the SEC, we may file one or more prospectus supplements to qualify for distribution to the public in the U.S. Common Shares in an amount not to exceed an aggregate of \$35 million by way of one or more "at-the-market" distribution programs. We may also consider filing a new shelf registration statement on either Form F-3 or S-3 with the SEC in the future.

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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 September 30, 2015, there were:

4,924,738 Common Shares issued and outstanding (9,925,364 as of the date of this Prospectus);

no issued and outstanding Preferred Shares;

7,403 Common Shares issuable upon exercise of warrants that we previously issued in a registered direct offering in April 2010, which had a weighted average exercise price as of September 30, 2015 of \$900.00 per Common Share, all of which expired subsequent to September 30, 2015 but prior to the date of this Prospectus;

an aggregate of 55,671 Common Shares issuable upon exercise of warrants that we previously issued in a registered direct offering in July 2013 and in an underwritten public offering in October 2012, which had a weighted average exercise price of \$270.29 per Common Share;

3,333 Common Shares issuable upon exercise of warrants that we previously issued in an underwritten public offering in January 2014, which had an exercise price as of September 30, 2015 of \$14.00 per Common Share, adjusted to \$0.00 per Common Share in connection with and following the December 2015 Offering;

447,574 Common Shares issuable upon exercise of Series A warrants that we previously issued in the March 2015 Offering, which had an exercise price as of September 30, 2015 of \$81.00 per Common Share, adjusted to \$4.95 per Common Share in connection with and following the December 2015 Offering;

68,798 Common Shares issuable upon exercise of the Series B Warrants (excluding, however, any Common Shares issuable upon alternate cashless exercise of the Series B Warrants), which had an exercise price as of September 30, 2015 of \$81.00 per Common Share, adjusted to \$4.95 per Common Share in connection with and following the December 2015 Offering, of which 8,064 remain outstanding as of the date of this Prospectus;

36,705 Common Shares that underlie outstanding stock options granted under our stock option plan as at September 30, 2015, having a weighted average exercise price of \$176.00 per Common Share, and an additional 4,555 Common Shares that underlie outstanding stock options granted under our stock option plan as at September 30, 2015, having a weighted average exercise price of C\$1,009.00 per Common Share; and

an aggregate of 520,117 additional Common Shares available for future grants under our stock option plan, which provides that the maximum number of Common Shares issuable under the plan may equal 11.4% of the issued and outstanding Common Shares at any given time. Therefore, as of the date of this Prospectus and following the December 2015 Offering as well as a grant of 240,000 stock options to management and certain other Company employees on December 21, 2015, there are now 852,723 Common Shares available for future grants under our stock option plan.

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.

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

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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 which may contain liquidation, dividend and other rights equivalent or superior to our Common Shares. In addition, we have implemented in our constating documents an advance notice procedure for shareholder approvals to be

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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 constituting 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.

***Our business could be negatively affected as a result of the actions of activist shareholders.***

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to successfully respond to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest because:

responding to proxy contests and other actions by activist shareholders may be costly and time-consuming, and may disrupt our operations and divert the attention of management and our employees;

perceived uncertainties as to the potential outcome of any proxy contest may result in our inability to consummate potential acquisitions, collaborations or in-licensing opportunities and may make it more difficult to attract and retain qualified personnel and business partners; and

if individuals that have a specific agenda different from that of our management or other members of our board of directors are elected to our board as a result of any proxy contest, such an election may adversely affect our ability to effectively and timely implement our strategic plan and to create value for our shareholders.

**CONSOLIDATED CAPITALIZATION**

There has been no material change to our share and loan capital since September 30, 2015, except for: (i) the issuance of approximately 2.0 million Common Shares upon the alternate cashless exercise of our Series B Warrants; (ii) the implementation of the Share Consolidation on November 17, 2015; and (iii) the issuance of 3.0 million Common Shares and Warrants to acquire approximately 2.3 million Common Shares (which includes Warrants issued upon exercise of the Over-Allotment Option) in connection with the December 2015 Offering, for aggregate net proceeds of approximately \$15.0 million.

In addition, as at September 30, 2015, 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 and Second Preferred Shares; both issuable in series. As of the date of this Prospectus, there are 9,925,364 Common Shares issued and outstanding. No Preferred Shares 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 issued and outstanding shares are fully paid and non-assessable.

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**Preferred Shares**

The Preferred Shares are issuable in series with rights and privileges specific to each class. The holders of Preferred Shares are not entitled to receive notice of or to attend or vote at meetings of shareholders. 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.

The specific terms of any offerings of Preferred Shares, including the designation of the particular series, aggregate principal amount and liquidation preference, the number of Preferred Shares being offered, the issue price, any rights to receive dividends, the dividend rate, the dividend payment date, any terms for redemption at our option or the holder's option, any exchange or conversion terms and any other specific terms may be determined in the sole discretion of our board of directors without being required to seek or obtain shareholder approval and will be described in one or more Prospectus Supplements.

**DESCRIPTION OF DEBT SECURITIES**

Debt Securities may be offered separately or together with Common Shares and/or other Securities. The Debt Securities may be offered in an amount and on such terms as may be determined from time to time depending on market conditions and other factors. The Debt Securities may be issued under a trust indenture to be entered into between us and one or more trustees. The particular terms and provisions of Debt Securities offered by any Prospectus Supplement, and the extent to which the general terms and provisions described below may apply thereto, will be described in the Prospectus Supplement filed in respect of such Debt Securities. This description will include, where applicable:

the specific designation, aggregate principal amount and denominations of Debt Securities;

the price at which the Debt Securities will be issued or whether the Debt Securities will be issued on a non-fixed price basis;

the date or dates on which the Debt Securities will mature and the portion (if less than all of the principal amount) of the Debt Securities to be payable upon declaration of an acceleration of maturity;

the currency or currency unit in which the Debt Securities are being sold and in which the principal of (and premium, if any), and interest, if any, on, the Debt Securities will be payable, whether the holder of any the Debt Securities or we may elect the currency in which payments thereon are to be made and, if so, the manner of such election;

whether the Debt Securities are interest-bearing and, in the case of interest bearing Debt Securities, the rate or rates (which may be fixed or variable) per annum at which the Debt Securities will bear interest, if any;

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the date from which interest, if any, on the Debt Securities, whether payable in cash, in kind, or in shares, will accrue, the date or dates on which such interest will be payable and the date on which payment of such interest will commence;

the dates on which and the price or prices at which the Debt Securities will, pursuant to any required repayment provisions, or may, pursuant to any repurchase or redemption provisions, be repurchased, redeemed or repaid and the other terms and provisions of any such optional repurchase or redemption or required repayment;

any special provisions for the payment of additional interest with respect to the Debt Securities;

any additional covenants included for the benefit of holders of the Debt Securities;

the general terms or provisions, if any, pursuant to which the Debt Securities are to be guaranteed or secured;

any additional events of default provided with respect to the Debt Securities;

any securities exchange on which the Debt Securities will be listed;

terms for any conversion or exchange of the Debt Securities into other Securities;

the extent and manner, if any, to which payment on or in respect of the Debt Securities will be senior to, or will be subordinated to the prior payment of, other liabilities and obligations of the Company;

whether the Debt Securities will be issuable in registered form or bearer form or both, and, if issuable in bearer form, the restrictions as to the offer, sale and delivery of the Debt Securities in bearer form and as to exchanges between registered and bearer form;

whether the Debt Securities will be issuable in the form of one or more registered global debt securities ("Registered Global Debt Securities") and, if so, the identity of the depository for those Registered Global Debt Securities;

any index pursuant to which the amount of payments of principal of and any premium and interest on the Debt Securities will or may be determined;

any special tax implications of or any special tax provisions, or indemnities relating to the Debt Securities; and

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

We reserve the right to set forth in a Prospectus Supplement specific terms of the Debt Securities that are not within the options and parameters set forth in this Prospectus. In addition, to the extent that any particular terms of the Debt Securities 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 Debt Securities.



### **DESCRIPTION OF SUBSCRIPTION RECEIPTS**

Subscription Receipts may be offered separately or together with Common Shares and/or other Securities. The Subscription Receipts will be issued under one or more subscription receipt agreements to be entered into between us and an escrow agent at the time of issuance of the Subscription Receipts.

A Subscription Receipt will entitle the holder thereof to receive a Common Share and/or other Security upon the completion of a particular transaction or event, typically but not limited to an acquisition of the assets or securities of another entity by us or one or more of our subsidiaries. The subscription proceeds from an offering of Subscription Receipts will be held in escrow by an escrow agent pending the completion of the transaction or the termination time (the time at which the escrow terminates regardless of whether the transaction or event has occurred). Holders of Subscription Receipts are not our shareholders. Holders of Subscription Receipts will receive Common Shares and/or other Securities upon the completion of the particular transaction or event or, if the transaction or event does not occur by the termination time, a return of the subscription funds for their Subscription Receipts together with any interest or other income earned thereon.

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The particular terms and provisions of Subscriptions Receipts offered by any Prospectus Supplement, and the extent to which the general terms and provisions described below may apply thereto, will be described in the Prospectus Supplement filed in respect of such Subscription Receipts. This description will include, where applicable:

the number of Subscription Receipts;

the price at which the Subscription Receipts will be offered;

the currency or currency unit in which the Subscription Receipts are being sold;

the terms, conditions and procedures pursuant to which the holders of Subscription Receipts will become entitled to receive Common Shares and/or other Securities;

the number of Common Shares and/or other Securities that may be obtained upon exercise of each Subscription Receipt;

the designation and terms of any other Securities with which the Subscription Receipts will be offered, if any, and the number of Subscription Receipts that will be offered with each Security;

the terms applicable to the gross proceeds from the sale of the Subscription Receipts plus any interest earned thereon;

the material income tax consequences of owning, holding and disposing of the Subscription Receipts;

whether the Subscription Receipts will be issued in fully registered or global form; and

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

We reserve the right to set forth in a Prospectus Supplement specific terms of the Subscription Receipts that are not within the options and parameters set forth in this Prospectus. In addition, to the extent that any particular terms of the Subscription Receipts 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 Subscription Receipts.

**DESCRIPTION OF WARRANTS**

Warrants may be offered separately or together with Common Shares, and may be attached to or separate from any offered Securities. Each series of Warrants will be issued under a separate warrant certificate, 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. Any 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.

The particular terms and provisions of each issue or series of Warrants offered by any Prospectus Supplement, and the extent to which the general terms and provisions described below may apply thereto, will be described in the Prospectus Supplement filed in respect of such Warrants. This description will include, where applicable:

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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;

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the designation and terms of any Securities with which the Warrants will be offered, if any, and the number of Warrants that will be offered with each Security;

the date or dates, if any, on or after which the Warrants and the related Securities 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 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 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.

**DESCRIPTION OF UNITS**

We may issue Units comprised of one or more of the other Securities described herein in any combination. The Prospectus Supplement relating to the particular Units offered thereby will describe the particular terms and provisions of such Units and, as applicable, the particular terms and provisions of such other Securities. Each Unit will be issued so that the holder of the Unit is also the holder of each Security included in the Unit. Thus, the holder of a Unit will have the rights and obligations of a holder of each included Security. The Unit agreement under which a Unit is issued may provide that the Securities included in the Unit may not be held or transferred separately, at any time or at any time before a specified date. The description in the applicable Prospectus Supplement will include, where applicable:

the designation and aggregate number of Units offered;

the price at which the Units will be offered;

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

the designation and terms of the Units and of the Securities comprising the Units, including whether and under what circumstances those Securities may be held or transferred separately;

any provisions for the issuance, payment, settlement, transfer or exchange of the Units or of the Securities comprising the Units;

whether the Units will be issued in fully registered or global form; and

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

The preceding description and any description of Units in an applicable Prospectus Supplement does not purport to be complete and is subject to and is qualified in its entirety by reference to the Unit agreement and, if applicable, collateral arrangements and depositary arrangements relating to such Units. We reserve the right to set forth in a Prospectus Supplement specific terms of the Units that are not within the options and parameters set forth in this Prospectus. In addition, to the extent that any particular terms of the Units 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 Units.

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

Our Common Shares are listed 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 December 1, 2014 and ending on December 28, 2015, as adjusted to reflect and give effect to the Share Consolidation:

	NASDAQ (US\$) <sup>(1)</sup>			TSX (C\$) <sup>(1)</sup>		
	High	Low	Volume	High	Low	Volume
<b>2014</b>						
December	78.02	57.00	11,475	88.00	66.00	664
<b>2015</b>						
January	61.00	52.00	3,830	72.00	65.00	282
February	67.00	51.25	5,837	83.00	64.00	289
March	84.20	51.00	35,867	104.00	64.00	1,128
April	64.10	51.51	21,461	78.00	65.00	950
May	55.45	27.50	43,004	68.00	35.50	2,499
June	29.80	27.00	44,894	37.00	32.50	866
July	27.50	18.16	40,174	35.00	24.00	961
August	18.16	8.08	117,558	25.00	11.00	3,975
September	11.85	5.02	370,781	16.00	7.00	17,348
October	9.30	4.25	223,072	12.50	5.50	9,533
November	11.43	4.00	3,255,306	15.41	5.39	141,016
December <sup>(2)</sup>	9.95	4.42	1,595,240	13.27	6.06	71,314

(1) Between December 1, 2014 and November 20, 2015, the "high" and "low" prices have been multiplied by one hundred (100) to retroactively give effect to and reflect the Share Consolidation and, for the same period, the volume has been divided by one hundred (100).

(2) Up to and including December 28, 2015. As TSX was closed for trading on December 28, 2015, the high and low closing price for TSX and the average daily volume traded on TSX was actually calculated up to and including December 24, 2015.

**EARNINGS COVERAGE**

If we offer Debt Securities having a term to maturity in excess of one year or Preferred Shares under this Prospectus and any applicable Prospectus Supplement, the applicable Prospectus Supplement will include earnings coverage ratios giving effect to the issuance of such Securities.

**PRIOR SALES**

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

an aggregate of approximately 596.8 thousand Common Shares at an issuance price of \$62.00 per share issued in connection with the March 2015 Offering;

an aggregate of approximately 447.6 thousand Series A warrants to acquire Common Shares issued in connection with the March 2015 Offering, which have an adjusted exercise price of \$4.95 following the December 2015 Offering;

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an aggregate of approximately 298.4 thousand Series B Warrants, of which approximately 8.1 thousand remain outstanding as of the date of this Prospectus, which have an adjusted exercise price of \$4.95 following the December 2015 Offering;

an aggregate of approximately 5.7 million Common Shares upon the alternate cashless exercise of our Series B Warrants;

an aggregate of 3.0 million Common Shares and warrants to acquire 2.1 million Common Shares at a combined issuance price of \$5.55 per Common Share together with a warrant to purchase 0.7 of a

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common share in connection with the December 2015 Offering, as well as Warrants to acquire approximately 0.2 million common shares upon exercise of the Over-Allotment Option at an issuance price of \$0.01 per Warrant, with each Warrant having an exercise price of \$7.10 per share; and

243,000 stock options exercisable at a weighted average price of \$5.18 per share.

**SELLING SECURITY HOLDERS**

Securities may be sold under this Prospectus by way of secondary offering by certain holders or purchasers of the Securities. The Prospectus Supplement for or including any offering of Securities by selling securityholders will include the following information:

the names of the selling securityholders;

the number or amount of Securities owned, controlled or directed by each selling securityholder;

the number or amount of Securities being distributed for the account of each selling securityholder;

the number or amount of Securities to be owned by the selling securityholders after the distribution and the percentage that number or amount represents of the total number of our outstanding Securities;

whether the Securities are owned by the selling securityholders both of record and beneficially, of record only, or beneficially only;

the date or dates the selling securityholder acquired the Securities; and

if the selling securityholder acquired any Securities in the twelve months preceding the date of this Prospectus, the cost thereof to the securityholder in the aggregate and on an average cost-per-Security basis.

**USE OF PROCEEDS**

Unless otherwise specified in a Prospectus Supplement, the net proceeds resulting from the issuance of Securities will be used to continue to fund the Company's ongoing drug development activities, for the potential addition of commercialized products to its portfolio and for general corporate purposes, working capital and to fund its negative cash flow. 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.

**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.

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. The prices at which the Securities may be offered may vary as between purchasers and during the period of



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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.

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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 us, 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 Preferred Shares, Debt Securities, Subscription Receipts, Warrants and Units 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 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 of 1986, as amended).

### **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 Fulbright Canada LLP with respect to matters of Canadian law, and certain legal matters relating to the offering of the Securities under this Prospectus will be passed upon for us by Norton Rose Fulbright US LLP with respect to matters of U.S. 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.

The partners and associates of Norton Rose Fulbright Canada LLP as a group and the partners and associates of Norton Rose Fulbright US LLP as a group, each beneficially own, directly or indirectly, less than 1% of the outstanding securities of any class of securities issued by us.

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

Pursuant to a decision dated December 22, 2015 (the "Decision") issued by the *Autorité des marchés financiers*, the Company is exempt from the requirement prescribed by the *Securities Act* (Quebec) and by *Regulation 41-101 respecting General Prospectus Requirements* to prepare a French version of this Prospectus, any Prospectus Supplement, any amendment hereto or thereto and any document required to be incorporated by reference into this Prospectus (or any accompanying Prospectus Supplement) for any distribution of Securities made exclusively outside of Canada.

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**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 by reference to our Annual Report on Form 20-F for the financial year ended December 31, 2014, 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.

**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 System for Electronic Document Analysis and Retrieval ("SEDAR") website maintained by the Canadian Securities administrators at [www.sedar.com](http://www.sedar.com).

This Prospectus forms part of a registration statement that we filed with the SEC. The registration statement contains more information than this Prospectus regarding us and our Securities, 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).

**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:

our annual report on Form 20-F for the financial year ended December 31, 2014 (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, 2014 and December 31, 2013 and our consolidated statements of changes in shareholders' equity (deficiency), comprehensive income (loss) and cash flows for the years ended December 31, 2014, 2013 and 2012 and management's annual report on internal control over financial reporting set out on page 96 of our 2014 annual report on Form 20-F, together with the auditors' report dated March 17, 2015 on our consolidated financial statements and effectiveness of internal control over financial reporting as at December 31, 2014; and our Management's Discussion and Analysis included as "Item 5. Operating and Financial Review and Prospects" in our 2014 annual report on Form 20-F;

our unaudited condensed interim consolidated financial statements as at September 30, 2015 and for the three-month and nine-month periods ended September 30, 2015 and 2014 and Management's Discussion and Analysis thereon, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on November 5, 2015;

our management information circular dated March 17, 2015 in connection with our annual and special meeting of shareholders held on May 8, 2015, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on March 25, 2015;

our management information circular dated October 16, 2015 in connection with our special meeting of shareholders held on November 16, 2015, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on October 16, 2015;

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our material change report dated March 11, 2015 in connection with the March 2015 Offering, included as Exhibit 99.2 to our Report on Form 6-K furnished to the SEC on March 11, 2015;

our material change report dated October 13, 2015 describing the Restructuring, included as Exhibit 99.2 to our Report on Form 6-K furnished to the SEC on October 13, 2015;

our material change report dated November 18, 2015 describing the implementation of the Share Consolidation, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on November 18, 2015;

our material change report dated December 15, 2015 in connection with the December 2015 Offering, included as Exhibit 99.1 to our Report on Form 6-K furnished to the SEC on December 15, 2015; and

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 confidential material change report, if any), business acquisition report and information circular filed by us with the various securities commissions or similar securities regulatory authorities in Canada or filed by us 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.

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 (except exhibits, unless they are specifically incorporated into this Prospectus by reference). Copies of the documents incorporated herein by reference may be obtained on request without charge from our secretary at 315 Sigma Drive, Suite 302D, Summerville, South Carolina, USA, 29483, tel. (843) 900-3223, or through the Internet on 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 Exchange Act, as amended, 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 herein by reference 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 herein by reference 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.

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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.

**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 Fulbright Canada LLP.

## PART II

### INFORMATION NOT REQUIRED TO BE DELIVERED TO OFFEREEES OR PURCHASERS

#### Indemnification of Directors and Officers

Under Section 124 of the *Canada Business Corporations Act*, the Registrant may indemnify a present or former director or officer of the Registrant or another individual who acts or acted at the Registrant's request as a director or officer, or an individual acting in a similar capacity, of another entity, against all costs, charges and expenses, including an amount paid to settle an action or satisfy a judgment, reasonably incurred by the individual in respect of any civil, criminal, administrative, investigative or other proceeding in which the individual is involved because of that association with the Registrant or other entity. The Registrant may not indemnify an individual unless the individual (i) acted honestly and in good faith with a view to the best interests of the Registrant or, as the case may be, to the best interests of the other entity for which the individual acted as director or officer or in a similar capacity at the Registrant's request, and (ii) in the case of a criminal or administrative action or proceeding that is enforced by a monetary penalty, had reasonable grounds for believing that his or her conduct was lawful. Such indemnification may be made in connection with an action by or on behalf of the Registrant or other entity to procure a judgment in its favor only with court approval. A director or officer is entitled to indemnification from the Registrant as a matter of right if he or she was not judged by the Court or other competent authority to have committed any fault or omitted to do anything that he or she ought to have done and fulfilled the conditions set forth above. The Registrant may advance moneys to a director, officer or other individual for the costs, charges and expenses of a proceeding referred to above. The individual shall repay the moneys if he or she does not fulfill the *conditions* set forth above to qualify for indemnification.

In accordance with provisions of the *Canada Business Corporations Act* described above, the by-laws of the Registrant provide that the Registrant shall indemnify a director or officer of the Registrant, a former director or officer of the Registrant or a person who acts or acted at the Registrant's request as a director or officer of a body corporate of which the Registrant is or was a shareholder or creditor, and his or her heirs and legal representatives, against all costs, losses, charges and expenses, including an amount paid to settle an action or satisfy a judgment, reasonably incurred by such person in respect of any civil, criminal or administrative action or proceeding to which such person is made a party by reason of being or having been a director or officer of the Registrant or such body corporate, if: (a) the person acted honestly and in good faith with a view to the best interests of the Registrant and (b) in the case of criminal or administrative action or proceeding that is enforced by a monetary penalty, the person had reasonable grounds for believing that their conduct was lawful. The Registrant may indemnify from time to time any director or other person who has assumed or is about to assume in the normal course of business any liability for the Registrant or for any corporation controlled by the Registrant, and to secure such director or other person against any loss by the pledge of all or part of the movable or immovable property of the Registrant through the creation of a hypothec or any other real right in all or part of such property or in any other manner.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Securities Act") may be permitted to directors, officers or persons controlling the Registrant pursuant to the foregoing provisions, the Registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### Exhibits

See Exhibit Index following the signature pages of this Registration Statement.

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**PART III**

**UNDERTAKING AND CONSENT TO SERVICE OF PROCESS**

**Item 1. Undertaking**

The Registrant undertakes to make available, in person or by telephone, representatives to respond to inquiries made by the Commission staff, and to furnish promptly, when requested to do so by the Commission staff, information relating to the securities registered pursuant to Form F-10 or to transactions in said securities.

**Item 2. Consent to Service of Process**

At the time of filing of this Registration Statement on Form F-10, the Registrant filed with the Commission a written irrevocable consent and power of attorney on Form F-X.

Any change to the name or address of the agent for service of the Registrant shall be communicated promptly to the Commission by amendment to Form F-X referencing the file number of this Registration Statement.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing and has duly caused this Registration Statement on Form F-10 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, State of Massachusetts, United States, on December 30, 2015.

AETERNA ZENTARIS INC.

By: /s/ KEITH SANTORELLI

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Name: Keith Santorelli

Title: *Vice President, Finance and Chief Accounting Officer*

**POWER OF ATTORNEY**

Each person whose signature appears below hereby constitutes and appoints David Dodd and Keith Santorelli, either of whom may act without the joinder of the other, as the true and lawful attorney-in-fact and agent of the undersigned, with full power of substitution and resubstitution, to execute in the name, place and stead of the undersigned, in any and all such capacities, any and all amendments (including post-effective amendments) and supplements to this Registration Statement on Form F-10 (including any subsequent registration statement for the same offering which may be filed under the Securities Act of 1933), and all instruments necessary or in connection therewith, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the United States Securities and Exchange Commission, and hereby grants to such attorney-in-fact and agent, full power and authority to do and perform in the name and on behalf of the undersigned each and every act and thing whatsoever necessary or advisable to be done, as fully and to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

This Power of Attorney may be executed in multiple counterparts, each of which shall be deemed an original, but which taken together shall constitute one instrument.

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Pursuant to the requirements of the Securities Act, this Registration Statement on Form F-10 has been signed by the following persons in the capacities indicated below on December 30, 2015.

Signature	Title
<hr/> <div>/s/ DAVID A. DODD</div> <div>David A. Dodd</div>	Chairman, President and Chief Executive Officer <i>(Principal Executive Officer)</i>
<hr/> <div>/s/ KEITH SANTORELLI</div> <div>Keith Santorelli</div>	Vice President, Finance and Chief Accounting Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>
<hr/> <div>/s/ JUERGEN ERNST</div> <div>Juergen Ernst</div>	Lead Director
<hr/> <div>/s/ CAROLYN EGBERT</div> <div>Carolyn Egbert</div>	Director
<hr/> <div>/s/ PIERRE LAPALME</div> <div>Pierre Lapalme</div>	Director
<hr/> <div>/s/ GÉRARD LIMOGES</div> <div>Gérard Limoges</div>	Director

### AUTHORIZED REPRESENTATIVE

Pursuant to the requirements of Section 6(a) of the Securities Act of 1933, the undersigned has signed this Registration Statement on Form F-10, solely in the capacity of the duly authorized representative of Aeterna Zentaris Inc. in the United States on December 30, 2015.

AETERNA ZENTARIS, INC.

By: /s/ PHILIP A. THEODORE

Name: Philip A. Theodore

Title: Senior Vice President, Chief Administrative Officer  
and General Counsel

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
4.1	The Annual Report on Form 20-F for the financial year ended December 31, 2014, which includes Aeterna Zentaris Inc.'s audited consolidated statements of financial position of Aeterna Zentaris Inc. as at December 31, 2014 and December 31, 2013 and Aeterna Zentaris Inc.'s statements of changes in shareholders' equity (deficiency), comprehensive income and loss and cash flows the years ended December 31, 2014, 2013 and 2012 and management's annual report on internal control over financial reporting set out on page 96 thereof, together with the report of Aeterna Zentaris Inc.'s independent auditors, PricewaterhouseCoopers LLP, dated March 17, 2015, on Aeterna Zentaris Inc.'s consolidated financial statements and effectiveness of internal control over financial reporting as at December 31, 2014; and Aeterna Zentaris Inc.'s Management's Discussion and Analysis included as "Item 5. Operating and Financial Review and Prospects" thereof (filed in Canada with the Canadian securities regulatory authorities in lieu of an annual information form) (filed with the SEC on March 17, 2015).
4.2	The unaudited condensed interim consolidated financial statements of Aeterna Zentaris Inc. as at September 30, 2015 and for the three-month and nine-month periods ended September 30, 2015 and 2014 and Management's Discussion and Analysis thereon (included as Exhibit 99.1 to Aeterna Zentaris Inc.'s Report on Form 6-K furnished to the SEC on November 5, 2015).
4.3	The Management Information Circular dated March 17, 2015 in connection with Aeterna Zentaris Inc.'s annual meeting of shareholders held on May 8, 2015 (included as Exhibit 99.1 to Aeterna Zentaris Inc.'s Report on Form 6-K furnished to the SEC on March 25, 2015).
4.4	The Management Information Circular dated October 16, 2015 in connection with the special meeting of shareholders held on November 16, 2015 (included as Exhibit 99.1 to Aeterna Zentaris Inc.'s Report on Form 6-K furnished to the SEC on October 16, 2015).
4.5	The Material Change Report dated March 11, 2015 in connection with the March 2015 offering (included as Exhibit 99.2 to Aeterna Zentaris Inc.'s Report on Form 6-K furnished to the SEC on March 11, 2015).
4.6	The Material Change Report dated October 13, 2015 describing the restructuring (included as Exhibit 99.2 to Aeterna Zentaris Inc.'s Report on Form 6-K furnished to the SEC on October 13, 2015).
4.7	The Material Change Report dated November 18, 2015 describing the implementation of the share consolidation (included as Exhibit 99.1 to Aeterna Zentaris Inc.'s Report on Form 6-K furnished to the SEC on November 18, 2015).
4.8	The Material Change Report dated December 15, 2015 in connection with the December 2015 offering (included as Exhibit 99.1 to Aeterna Zentaris Inc.'s Report on Form 6-K furnished to the SEC on December 15, 2015).
5.1	Consent of PricewaterhouseCoopers LLP (to be filed by subsequent amendment).
5.2	Consent of Norton Rose Fulbright Canada LLP (to be filed by subsequent amendment).
6.1	Powers of Attorney (included on the signature pages to this Registration Statement).

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