Aeterna Zentaris Inc.
Form 20-F
March 30, 2016

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

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FORM 20-F

¨Registration Statement Pursuant to Section 12(b) or 12(g) of The Securities Exchange Act of 1934

OR

ý Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the fiscal year ended December 31, 2015

OR

¨Transition Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

OR

¨Shell Company Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Commission file number 0-30752

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

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

Canada
(Jurisdiction of Incorporation)

c/o Norton Rose Fulbright Canada LLP
1 Place Ville Marie, Suite 2500
Montréal, Quebec
Canada H3B 1R1
(Address of Principal Executive Offices)

Philip Theodore
Telephone: 843-900-3211
E-mail: ptheodore@aezsinc.com
315 Sigma Drive, Suite 302D
Summerville, South Carolina
29483
(Name, Telephone, E-mail and Address of Company Contact Person)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Shares	NASDAQ Capital Market Toronto Stock Exchange

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

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

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as at the close of the period covered by the annual report: 9,928,697 Common Shares as at December 31, 2015.

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

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

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

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

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

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ý

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

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

If "other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ¨ Item 18 ¨

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

Basis of Presentation

General

Except where the context otherwise requires, all references in this Annual Report on Form 20-F to the "Company", "Aeterna Zentaris Inc.", "we", "us", "our" or similar words or phrases are to Aeterna Zentaris Inc. and its subsidiaries, taken together. In this Annual Report on Form 20-F, references to "$" and "US$" are to United States dollars, references to "CAN$" are to Canadian dollars and references to "EUR" are to euros. Unless otherwise indicated, the statistical and financial data contained in this Annual Report on Form 20-F are presented as at December 31, 2015. All share, option and share purchase warrant as well as per share, option and share purchase warrant information presented in this Annual Report on Form 20-F has been adjusted, including proportionate adjustments being made to each option and share purchase warrant exercise price, to reflect and to give effect to a share consolidation (or reverse split), on November 17, 2015, of our issued and outstanding common shares on a 100-to-1 basis (the "Share Consolidation"). The Share Consolidation affected all shareholders, optionholders and warrantholders uniformly and thus did not materially affect any securityholder's percentage of ownership interest.

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

Forward-Looking Statements

This Annual Report on Form 20-F contains forward-looking statements made pursuant to the safe harbor provisions of the U.S. Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "intend," "believe," "designed to," "vision," "aimed at," "expect," "may," "should," "would," "will" and similar references. Such statements include, but are not limited to, statements about the progress of our research, development and clinical trials and the timing of, and prospects for, regulatory approval and commercialization of our product candidates, the timing of expected results of our studies and the anticipated results of these studies, statements about the status of our efforts to establish a commercial operation and to obtain the right to promote or sell products that we did not develop, and estimates regarding our capital requirements and our needs for, and our ability to obtain, additional financing. Forward-looking statements involve known and unknown risks and uncertainties, which could cause the Company's actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue our research and development ("R&D") projects, the successful and timely completion of clinical studies, the risk that safety and efficacy data from any of our Phase 3 trials may not coincide with the data analysis from previously reported Phase 1 and/or Phase 2 clinical trials, the rejection or non-acceptance of any new drug application by one or more regulatory authorities and, more generally, uncertainties related to the regulatory process, the ability of the Company to efficiently commercialize one or more of our products or product candidates, the degree of market acceptance once our products are approved for commercialization, the ability of the Company to take advantage of business opportunities in the pharmaceutical industry, the ability of the Company to protect its intellectual property and general changes in economic conditions. Investors should consult the Company's quarterly and annual filings with the Canadian and United States ("U.S.") securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake to update these forward-looking statements and disclaims any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except if required to do so by a governmental authority or applicable law.

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PART I

Item 1. Identity of Directors, Senior Management and Advisers

A. Directors and senior management

Not applicable.

B. Advisers

Not applicable.

C. Auditors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

A. Offer statistics

Not applicable.

B. Method and expected timetable

Not applicable.

Item 3. Key Information

A. Selected financial data

The consolidated statement of comprehensive (loss) income data set forth in this Item 3.A with respect to the years ended December 31, 2015, 2014 and 2013 and the consolidated statement of financial position data as at December 31, 2015 and 2014 have been derived from the audited consolidated financial statements set forth in Item 18, which have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The consolidated statement of comprehensive (loss) income information with respect to the years ended December 31, 2012 and 2011 and the consolidated statement of financial position information as at December 31, 2013, 2012 and 2011 set forth in this Item 3.A. have been derived from our previous consolidated financial statements not included herein, and have also been prepared in accordance with IFRS, as issued by the IASB. The selected financial data should be read in conjunction with our audited consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 20-F, as well as "Item 5. – Operating and Financial Review and Prospects" of this Annual Report on Form 20-F.

Consolidated Statements of Comprehensive (Loss) Income Information
(in thousands of US dollars, except share and per share data)
Derived from consolidated financial statements prepared in accordance with IFRS, as issued by the IASB

	Years ended December 31,				
	2015	2014	2013	2012	2011
	$	$	$	$	$
Revenues					
Sales commission and other	297	—	96	834	250
License fees	248	11	6,079	1,219	4,455
	545	11	6,175	2,053	4,705
Operating expenses					
Cost of sales	—	—	51	591	212
Research and development costs	17,234	23,716	21,284	20,592	24,245
General and administrative expenses	11,308	9,840	11,091	9,226	10,046
Selling expenses	6,887	3,850	1,225	1,380	1,909
	35,429	37,406	33,651	31,789	36,412
Loss from operations	(34,884)	(37,395)	(27,476)	(29,736)	(31,707)
Finance income	305	20,319	1,748	6,974	6,239
Finance costs	(15,649)	—	(1,512)	(382)	(8)
Net finance (costs) income	(15,344)	20,319	236	6,592	6,231
Loss before income taxes	(50,228)	(17,076)	(27,240)	(23,144)	(25,476)
Income tax expense	—	(111)	—	—	(1,104)
Net loss from continuing operations	(50,228)	(17,187)	(27,240)	(23,144)	(26,580)
Net income from discontinued operations	85	623	34,055	2,732	(487)
Net (loss) income	(50,143)	(16,564)	6,815	(20,412)	(27,067)
Other comprehensive (loss) income:					
Items that may be reclassified subsequently to profit or loss:					
Foreign currency translation adjustments	1,509	(1,158)	1,073	(504)	(789)
Items that will not be reclassified to profit or loss:					
Actuarial gain (loss) on defined benefit plans	844	(1,833)	2,346	(3,705)	(1,335)
Comprehensive (loss) income	(47,790)	(19,555)	10,234	(24,621)	(29,191)
Net loss per share (basic and diluted) from continuing operations[1]	(18.17)	(29.12)	(92.41)	(117.04)	(168.75)
Net income per share (basic and diluted) from discontinued operations[1]	0.03	1.06	115.53	13.79	(3.09)
Net (loss) income per share (basic and diluted)[1]	(18.14)	(28.06)	23.12	(103.22)	(171.84)
Weighted average number of shares outstanding:[1]					
Basic	2,763,603	590,247	294,765	197,751	157,513
Diluted	3,424,336	590,247	294,765	198,067	157,513

[1] Adjusted to reflect the November 17, 2015 100-to-1 Share Consolidation

Consolidated Statement of Financial Position Information
(in thousands of US dollars)
Derived from consolidated financial statements prepared in accordance with IFRS, as issued by the IASB

	As at December 31,				
	2015	2014	2013	2012	2011
	$	$	$	$	$
Cash and cash equivalents	41,450	34,931	43,202	39,521	46,881
Restricted cash equivalents	255	760	865	826	806
Total assets	51,498	47,435	59,196	67,665	75,369
Warrant liability (current and non-current portion)	10,891	8,225	18,010	6,176	9,162
Share capital	204,596	150,544	134,101	122,791	101,884
Shareholders' equity (deficiency)	21,615	14,484	17,064	(6,695)	(4,546)

B. Capitalization and indebtedness

Not applicable.

C. Reasons for the offer and use of proceeds

Not applicable.

D. Risk factors

Risks Relating to Us and Our Business

Investments in biopharmaceutical companies are generally considered to be speculative.

The prospects for companies operating in the biopharmaceutical industry 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 in each of the last several years. As at December 31, 2015, we had an accumulated deficit of approximately $271.6 million. Our operating losses have adversely impacted, and will continue to adversely impact, our working capital, total assets, operating cash flow and shareholders' equity. 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 Common Shares or other securities could result in a significant or total loss.

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 or the value of our Common Shares or other 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 or the value of our other securities 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 securities class action litigation pending against us that is described elsewhere in this Annual Report on Form 20-F;
- foreign currency fluctuations;

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- 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 quarters or years, our revenues and expenses will be above or below the expectations of securities analysts or investors. In this case, the price of our Common Shares and/or the value of our other securities could fluctuate significantly or decline.

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

We are currently developing our product candidates based on R&D activities, preclinical testing and clinical trials conducted to date, and we may not be successful in developing or introducing to the market these or any other new products or technology. If we fail to develop and deploy new products successfully and on a timely basis, we may become non-competitive and unable to 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 Common Shares and/or a decline in the value of our other 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 US 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 (i) meet the requirements of these authorities; (ii) meet the requirements for informed consent; and (iii) 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 US 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 21 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 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

- 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, co-promotional or marketing 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 and/or detail 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 that 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 would 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 cash and cash equivalents as at December 31, 2015 will be sufficient to fund our commercial operations, development programs, clinical trials and other operating expenses at least through December 31, 2016. 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;
- the potential addition of commercialized products to our portfolio;
- lower sales commission than expected;
- the outcome of litigation, including the securities class action litigation pending against us that is described elsewhere in this Annual Report on Form 20-F; 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 incurred 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 could also 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, the demands 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 clinical experience with a drug expands after approval because the drug is used by a greater number and more diverse group of patients than during clinical trials, side effects or other problems may be observed after approval that were not observed or anticipated during pre-approval clinical trials. In such a case, a regulatory authority could restrict the indications for which the product may be sold or revoke the product's regulatory approval.
We and our contract manufacturers will be required to comply with applicable current Good Manufacturing Practice regulations for the manufacture of our products. These regulations include requirements relating to quality assurance, as well as the corresponding maintenance of rigorous records and documentation. Manufacturing facilities must be approved before we can use them in the commercial manufacturing of our products and are subject to subsequent periodic inspection by regulatory authorities. In addition, material changes in the methods of manufacturing or changes in the suppliers of raw materials are subject to further regulatory review and approval.
If we, or 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 US 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 U.S. Food and Drug Administration ("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 US 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 US or internationally, the reimportation of drugs into the US 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.

Regardless of the impact of the ACA on us, the US 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 US 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" to such physician owners and their immediate family members. Manufacturers are required to report such data to the government by the 90th 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.

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 Common Shares and/or a decline in the value of our other 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™ (zoptarelin doxorubicin) and Macrilen™ (macimorelin), 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 Common Shares and/or the value of our other 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 US, in Canada and in many other countries, pricing and/or profitability of some or all prescription pharmaceuticals and biopharmaceuticals are subject to government control.

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

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

The 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 US, 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 US 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 US 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 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 US post-grant proceedings as well as in opposition or nullity proceedings in certain countries outside the US. 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 US 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 US 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 US 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 US patent position.

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 US government and may be subject to the rights of the US 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.

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.

Some of our patents have expired or will be expiring in 2016.

The product development timeline for our products is lengthy and it is possible that our issued patents covering our product candidates in the US and other jurisdictions may expire prior to commercial launch of the products. The patent that covers Zoptrex™ 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 US 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 US patent. As a result, our ability to protect this compound from competition will be based on the protections provided in the US 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 US, 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 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 US 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 US. 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 US 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.

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.

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 Common Shares and/or a decline in the value of our other securities.

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.

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 US 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™, 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 filed a motion to dismiss the Second Amended Complaint on November 11, 2015, because we believe that the Second Amended Complaint also fails to state a claim. The hearing of the motion to dismiss the Second Amended Complaint occurred on January 19, 2016.

On March 2, 2016, the Court issued an order granting our motion to dismiss the complaint in part and denying it in part. The Court dismissed certain of our current and former officers from the lawsuit. The Court allowed the claim that we omitted material facts from our public statements during the Class Period to proceed against us and our former CEO who departed in 2013, while dismissing such claims against other current and former officers. The Court also

allowed a claim for “controlling person” liability to proceed against certain current and former officers. We disagree with the Court's decision and we filed a motion for reconsideration on March 16, 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™ and Macrilen™ on human participants in our clinical trials subjects us to the risk of liability to such participants, who may suffer unintended consequences. If Zoptrex™ and/or Macrilen™ 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.

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 Common Shares to participate in those assets, are subject to the prior claims of such subsidiary's creditors. To the extent that we may be a creditor with recognized claims against any such subsidiary, our claims would still be subject to the prior claims of our subsidiary's creditors to the extent that they are secured or senior to those held by us.

Holders of our Common Shares are not creditors of our subsidiaries. Claims to the assets of our subsidiaries will derive from our own ownership interest in those operating subsidiaries. Claims of our subsidiaries' creditors will generally have priority as to the assets of such subsidiaries over our own ownership interest claims and will therefore have priority over the holders of our Common Shares. Our subsidiaries' creditors may from time to time include

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

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

Our subsidiaries may incur additional indebtedness and other liabilities.

It may be difficult for US 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 US, and all or a substantial portion of their assets, and a substantial portion of our assets, are located outside the US. Consequently, although we have appointed an agent for service of process in the US, it may be difficult for investors in the US to bring an action against such directors, officers or experts or to enforce against those persons or us a judgment obtained in a US court predicated upon the civil liability provisions of federal securities laws or other laws of the US. Investors should not assume that foreign courts (1) would enforce judgments of US courts obtained in actions against us or such directors, officers or experts predicated upon the civil liability provisions of the US federal securities laws or the securities or "blue sky" laws of any state within the US or (2) would enforce, in original actions, liabilities against us or such directors, officers or experts predicated upon the US federal securities laws or any such state securities or "blue sky" laws. In addition, we have been advised by our Canadian counsel that in normal circumstances, only civil judgments and not other rights arising from US 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 US.

We are subject to various internal control reporting requirements under applicable Canadian securities laws and the Sarbanes-Oxley Act in the US. 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 US 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 (US) 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.

We believe we were a passive foreign investment company for the 2015 taxable year and we may be a passive foreign investment company for the 2016 taxable year, which could result in adverse tax consequences to US investors.

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

We believe we were a PFIC for the 2015 taxable year. The PFIC determination depends on the application of complex US 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.

Since we believe we were a PFIC in 2015, US Holders may suffer adverse US federal income tax consequences. In particular, absent certain elections, a US Holder would generally be subject to US federal income tax at ordinary income tax rates, plus a possible interest charge, in respect of a gain derived from a disposition of our Common

Shares, as well as certain distributions by us. A US Holder may be able to minimize the adverse tax consequences by making an election to "mark to market" Common Shares each taxable year and recognize ordinary income pursuant to such election based upon increases in the value of the Common Shares. In addition, US Holders may mitigate the adverse tax consequences of the PFIC rules by making a "qualified electing fund" ("QEF") election. We will endeavor to satisfy the record keeping requirements that apply to a QEF and to supply requesting US Holders with the information that such US Holders are required to report under the QEF rules. However, there can be no assurance that we will satisfy the record keeping requirements or provide the information required to be reported by US Holders.

In addition, if we are a PFIC, US 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 US federal income tax or information returns) relating to their ownership of Common Shares.

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

We may incur losses associated with foreign currency fluctuations.

Our operations are in many instances conducted in currencies other than 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 US dollar, the euro, the Canadian dollar and other currencies.

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, could result in a material disruption of our clinical activities and business operations and could expose us to third-party legal claims. Furthermore, we could be required to make substantial expenditures of resources to remedy the cause of cyber attacks or break-ins. 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.

Risks Relating to our Common Shares

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. There can be no assurance that the market price of our Common Shares will not fall below $1.00 in the future or that, if it does, we will regain compliance with the minimum bid price requirement. 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, (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 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 (collectively, the "Additional Listing Standards"). If we fail to

meet at least one of the Additional Listing Standards, our securities may be subject to delisting after the expiration of the period of time, if any, that we are allowed for regaining compliance.

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 US, 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 January 1, 2015 and December 31, 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. Our share price may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. The stock market generally, and the biopharmaceutical sector in particular, are vulnerable to abrupt changes in investor sentiment. Prices of shares and trading volume of companies in the biopharmaceutical industry can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, operating performance. Our share price and trading volume may fluctuate based on a number of factors including, but not limited to:

- clinical and regulatory developments regarding our product candidates;
- delays in our anticipated development or commercialization timelines;
- developments regarding current or future third-party collaborators;
- 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 US, 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 US, 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 Common Shares will depend upon any future appreciation in value. There is no guarantee that our Common Shares or any of our other securities will appreciate in value or even maintain the price at which shareholders have purchased them.

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

Any additional or future issuance of Common Shares or Convertible Securities, including the issuance of Common Shares upon the exercise of stock options and upon the exercise of warrants, could dilute the interests of our existing shareholders, and could substantially decrease the trading price of our Common Shares. We may issue equity securities in the future for a number of reasons, including to finance our operations and business strategy, to satisfy our obligations upon the exercise of options or warrants or for other reasons. Our Stock Option Plan generally permits us to have outstanding, at any given time, stock options that are exercisable for a maximum number of Common Shares equal to 11.4% of all then issued and outstanding Common Shares. As at March 29, 2016, there were:

- 9,928,697 Common Shares issued and outstanding;
- no issued and outstanding Preferred Shares;
- 2,842,309 Common Shares issuable upon exercise of outstanding warrants (excluding any exercises of Series B Warrants under the alternate cashless exercise feature of such warrants); and
- 275,041 stock options outstanding.

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

trading price of our Common Shares.

We believe that there is a reasonable likelihood that we may lose our foreign private issuer status as of June 30, 2016, which would require us to comply with the Exchange Act's domestic reporting regime and cause us to incur additional legal, accounting and other expenses.

In order to maintain our current status as a foreign private issuer, either (1) a majority of our common shares must not be either directly or indirectly owned of record by residents of the US or (2) (a) a majority of our executive officers and of our directors must not be US citizens or residents, (b) more than 50 percent of our assets cannot be located in the US and (c) our business must

be administered principally outside the US. We believe that there is a reasonable likelihood that we may lose our foreign private issuer status when it is next reassessed as of June 30, 2016. If we lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to US domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC rules and NASDAQ listing standards. The regulatory and compliance costs to us of complying with the reporting requirements applicable to a US domestic issuer under US securities laws may be higher than the cost we have historically incurred as a foreign private issuer. In addition, if we lose our foreign private issuer status, we would no longer qualify under the Canada-US multijurisdictional disclosure system to benefit from being able to file registration statements on Form F-10, which could make it longer and more difficult to register our securities and raise funds by way of public, registered offerings in the US, and we would become subject to "baby shelf" rules that place limitations on our ability to issue an amount of securities above a certain threshold depending on our market capitalization and public float at a given point in time. As a result, we expect that a loss of foreign private issuer status may increase our legal and financial compliance costs, and it is difficult at this time to estimate by how much our legal and financial compliance costs may increase.

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

Our articles of incorporation, as amended, authorize the issuance of an unlimited number of "blank check" Preferred Shares, which could be issued by our board of directors without shareholder approval and 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 brought before an annual meeting of our shareholders, including proposed nominations of persons for election to our board of directors. These provisions, among others, whether alone or together, could delay or impede hostile takeovers and changes in control or changes in our management. Any provision of our constating documents that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their Common Shares and could also affect the price that some investors are willing to pay for our Common Shares.

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.

Item 4. Information on the Company

A. History and development of the Company

We are a specialty biopharmaceutical company engaged in developing and commercializing novel treatments in oncology, endocrinology and women's health.

We were incorporated on September 12, 1990 under the Canada Business Corporations Act (the "CBCA") and continue to be governed by the CBCA. Our registered address is located at 1 Place Ville Marie, Suite 2500, Montréal, Quebec, Canada H3B 1R1, c/o Norton Rose Fulbright Canada LLP. Our executive offices are located at 315 Sigma Drive, Suite 302D, Summerville, South Carolina 29483; our telephone number is (843) 900-3223 and our website is www.aezsinc.com. None of the documents or information found on our website shall be deemed to be included in or incorporated by reference into this Annual Report on Form 20-F, unless such document is specifically incorporated herein by reference.

On December 30, 2002, we acquired Zentaris AG, a biopharmaceutical company based in Frankfurt, Germany. Zentaris was a spin-off of Asta Medica GmbH, a former pharmaceutical company affiliated with Degussa AG. In May 2004, we changed our name to Aeterna Zentaris Inc. and on May 11, 2007, Zentaris GmbH was renamed Aeterna Zentaris GmbH. Aeterna Zentaris GmbH conducts our drug development efforts. In September 2007, we incorporated Aeterna Zentaris, Inc. under the laws of Delaware. This wholly-owned subsidiary, which is based in the Charleston, South Carolina area, conducts our commercial operations.

On October 1, 2013, we announced the completion of our previously announced agreements with various partners and licensees
with respect to the manufacturing rights and obligations for our Cetrotide® product. The principal outcome of such agreements was the transfer of all manufacturing rights and the grant of a license to a subsidiary of Merck KGaA of Darmstadt, Germany for the manufacture, testing, assembling, packaging, storage and release of Cetrotide® in all territories (the "Cetrotide® Business"). Following this transfer, the Cetrotide® Business has been presented in our consolidated financial statements as a discontinued operation. Except for this discontinued operation, we have not made any material divestitures or capital expenditures from 2013 to present.
On November 17, 2015, we effected a 100-to-1 Share Consolidation (reverse stock split). Our Common Shares commenced trading on a consolidated and adjusted basis on both NASDAQ and TSX on November 20, 2015.
We currently have three wholly-owned direct and indirect subsidiaries, AEZS GmbH, 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 with an office in the Charleston, South Carolina area in the United States.

Aeterna Zentaris Inc.
(Canada)

100%

100%

Aeterna Zentaris GmbH
(Germany)

Aeterna Zentaris, Inc.
(Delaware)

100%

Zentaris IVF GmbH
(Germany)

Our Common Shares are listed for trading on the TSX under the trading symbol "AEZ" and on NASDAQ under the trading symbol "AEZS".
Our agent for service of process and SEC matters in the United States is our wholly-owned subsidiary, Aeterna Zentaris, Inc., located at 315 Sigma Drive, Suite 302D, Summerville, South Carolina 29483.
There have been no public takeover offers by third parties with respect to us or by us in respect of other companies' shares during the last or current fiscal year.
Recent Developments
For a complete description of our recent corporate and pipeline developments, refer to "Item 5. - Operating and Financial Review and Prospects - Key Developments".
B. Business overview
We are engaged in drug development activities and in the promotion of products for others. We are now conducting Phase 3 studies of two internally developed compounds. The focus of our business development efforts is the acquisition or license of products that are relevant to our therapeutic areas of focus. We also intend 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 and by 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.

Our Business Strategy

Our primary business strategy is to pursue the development of our principal product candidates -- Zoptrex™ (zoptarelin doxorubicin) and Macrilen™ (macimorelin) in oncology and endocrinology, respectively -- and to commercialize oncology, endocrinology and women's health products that we may acquire, in-license or promote. Our vision is to become a growth-oriented specialty biopharmaceutical company.

Overview of our Drug Development Efforts

Our product pipeline

(1) Phase 2 in ovarian cancer completed.

(2) Investigator-driven and sponsored Phase 2 trial in castration and taxane resistant prostate cancer completed.

(3) Potential oral prostate cancer vaccine available for co-development/out-licensing, subject to an option granted to a third party.

(4) Available for co-development/out-licensing.

(5) Compound library transferred to Medical University of South Carolina. Aeterna Zentaris has access to future potential development candidates.

Our drug development efforts are focused currently on two compounds, Zoptrex™ and Macrilen™, which are in Phase 3 clinical development, and on a LHRH-disorazol Z conjugate (AEZS-138), which is in pre-clinical development in oncology and is available for partnering. We made the decision to focus our efforts in pre-clinical development on one compound following a review of our portfolio, during which we concluded that we lack the resources to pursue other earlier-stage opportunities. As a result of this decision, we discontinued drug discovery efforts, including basic research activities in medicinal chemistry and biology and our high-throughput-screening operations, which resulted in a reduction of our research and development staff by approximately 29 personnel during 2014.

Zoptrex™

Overview

Zoptrex™ represents a new targeting concept in oncology using a hybrid molecule composed of a synthetic peptide carrier, zoptarelin, and a well-known chemotherapy agent, doxorubicin, resulting in a cytotoxic conjugate. Most chemotherapeutic agents, including doxorubicin, are toxic to normally growing, healthy cells as well as to tumor cells that grow uncontrolled. Therefore, a method for targeting such drugs specifically to cancerous tissue offers a potential benefit for patients with tumors, and particularly with advanced or metastatic tumors.

The illustration above depicts the believed mode of action of our hybrid cytotoxic compound Zoptrex™. The LHRH receptor targeting part of the hybrid is believed to transport doxorubicin to a cancer cell presenting the LHRH receptor, which leads to the death of this cancer cell.

Zoptrex™ is the first intravenous drug in advanced clinical development that is considered to direct the chemotherapy agent specifically to LHRH-receptor expressing tumors, which then could result in a more targeted treatment with less damage to healthy tissue. This design is believed to allow 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 and a more favorable safety profile with lower incidence and severity of side effects as compared to doxorubicin. In addition, the targeted approach may enable treatment of LHRH receptor-positive cancers that have become resistant to doxorubicin.

We are conducting a pivotal Phase 3 clinical study of Zoptrex™ in women with locally advanced, recurrent or metastatic endometrial cancer who have progressed and who have received one chemotherapeutic regimen with platinum and taxane (either as adjuvant or first-line treatment). The clinical study is known as the "ZoptEC" study (zoptarelin doxorubicin in endometrial cancer). ZoptEC is a fully-recruited (over 500 patients), open-label, randomized-controlled study, comparing the efficacy and safety of Zoptrex™ to doxorubicin alone. Patients are centrally randomized in a 1:1 ratio and receive either Zoptrex™ (267 mg/m^2) or doxorubicin (60 mg/m^2) intravenously, every three weeks and for up to nine cycles. Response is being evaluated every three cycles during treatment and thereafter every 12 weeks until progression.

We are conducting ZoptEC under a Special Protocol Assessment ("SPA") with the FDA. The SPA agreement states that the proposed trial protocol design, clinical endpoints and planned analyzes are acceptable to the FDA to support a regulatory submission. Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in ZoptEC. The primary efficacy endpoint of the ZoptEC trial is improvement in median Overall Survival ("OS"). Secondary endpoints include progression-free survival, objective response rate and clinical benefit rate.

On October 13, 2015, we announced that the independent Data and Safety Monitoring Board ("DSMB") appointed to monitor ZoptEC recommended that ZoptEC continue as planned to completion. The DSMB's decision followed completion of its pre- specified second interim analysis on efficacy and safety for ZoptEC at approximately 192 events. In April 2015, the DSMB made the same recommendation following its first pre-specified analysis on safety and futility at approximately 124 events. A final analysis of the data is expected at approximately 384 events.

ZoptEC is being conducted by Ergomed plc, a contract clinical development organization with which we have entered into a co-development and profit-sharing agreement. Under the terms of the agreement, Ergomed has agreed to assume 30% (up to $10 million) of the clinical and regulatory costs for ZoptEC, which are estimated at approximately $32.5 million. Ergomed will receive

its return on investment based on an agreed single-digit percentage of any net income or net proceeds from licensing activity we receive for Zoptrex™ in this indication, up to a specified maximum amount.

We are attempting to commercialize Zoptrex™ as a treatment for endometrial cancer because, according to the American Cancer Society, endometrial cancer is the most common invasive gynecologic cancer in women in the United States, with approximately 50,000 new cases annually. This disease primarily affects postmenopausal women at an average age of 60 years at diagnosis. In the United States, it is estimated that approximately 8,000 women will die of endometrial cancer annually. To the best of our knowledge, there is also no systemic therapy approved in either the United States or Europe (except Germany, where doxorubicin is approved for this indication) for treating advanced or recurrent endometrial cancer.

We expect to complete the ZoptEC trial in the third quarter of 2016 and, if the results of the trial warrant doing so, to file a new drug application ("NDA") in the United States for Zoptrex™ in 2017. We are now moving forward with our planning to commercialize Zoptrex™, looking toward commercial launch of the product in 2018, assuming positive Phase 3 results and that the NDA is granted.

Development History

The following is a summary of the history of our development of Zoptrex™ in ovarian and endometrial cancer:

- In 2007, a Phase 2 open-label, non-comparative, multicenter two-indication trial stratified with two stages Simon Design was prepared. The study was planned to involve up to 82 patients, with up to 41 patients each with a diagnosis of platinum-resistant ovarian cancer (stratum A) or disseminated endometrial cancer (stratum B). Under coordination by Prof. Günter Emons, M.D., Chairman of the Department of Obstetrics & Gynecology at the University of Göttingen, Germany, this open-label, multicenter and multinational Phase 2 study “AGO-GYN 5” was conducted by the German AGO Study Group (Arbeitsgemeinschaft Gynäkologische Onkologie / Gynaecological Oncology Working Group), in cooperation with clinical sites in Europe. An intravenous infusion of Zoptrex™ (267 mg/m^2) was administered on every first day of a 21-day (three-week) cycle. The proposed duration of the study treatment was six cycles. The study was performed with 14 centers of the German Gynaecological Oncology Working Group, in cooperation with three clinical sites in Europe. The primary efficacy endpoint was a response rate with a success criterion at the end of Stage II defined as five or more patients with partial or complete tumor responses according to Response Evaluation Criteria in Solid Tumors (“RECIST”) and/or Gynaecologic Cancer Intergroup (“GCIG”) guidelines. Secondary endpoints included time to progression (“TTP”), survival and toxicity, as well as adverse effects. In October 2008, we announced that we had entered the second stage of patient recruitment for the Phase 2 trial in the platinum-resistant ovarian cancer indication. This decision was taken following the report of two partial responses (“PR”) among patients with ovarian cancer. The second stage of patient recruitment for the endometrial cancer indication was reached in November 2008 and was based on the report of one complete response (“CR”) and two PR among 14 patients with endometrial cancer.
- On June 7, 2010, Prof. Emons initially presented positive efficacy and safety data for Zoptrex™ in ovarian cancer at the American Society of Clinical Oncology’s (“ASCO”) Annual Meeting, now published in an article entitled "Phase 2 study of AEZS-108, a targeted cytotoxic LHRH analog, in patients with LHRH receptor-positive platinum resistant ovarian cancer" in the journal Gynecologic Oncology (Gynecol.Oncol. (2014) 133:427). Efficacy included PR in six patients (14.3%) and stable disease for more than twelve weeks in 16 patients (38%). Based on those data, a clinical benefit rate (“CBR”) of 52% was estimated. Median TTP and OS were evaluated at 2.8 months (12 weeks) and 12.2 months (53 weeks), respectively. Prof. Emons concluded that (i) Zoptrex™ was efficacious and well tolerated in patients with heavily pre-treated platinum- and taxane-resistant ovarian cancer; (ii) the safety profile confirmed the dose of 267 mg/m^2; (iii) hematological toxicity was rapidly reversible; (iv) non-hematological toxicities were usually limited to lower severity; (v) tolerability and CBR compared with topotecan and liposomal doxorubicin; (vi) no cardiotoxic events were observed; and (vii) overall survival was encouraging as all patients treated with Zoptrex™ had platinum-resistant disease.
- On September 14, 2011, Prof. Emons presented positive final Phase 2 efficacy and safety data for zoptarelin doxorubicin in advanced endometrial cancer at the European Society of Gynecological Oncology in Milan, Italy. The results of the study were published in an article by Prof. Emons, et al. in the journal Gynecologic Oncology (Gynecol.Oncol. (2014) 24:260). The study involved 43 patients with LHRH positive advanced or recurrent

endometrial cancer. Patients received Zoptrex™ at a dose of 267 mg/m^2 by intravenous infusion, with retreatment every three weeks, for up to six courses. Response rate per RECIST was defined as the primary endpoint. Secondary endpoints were safety, TTP and OS. The responses, as confirmed by independent review, included two patients with complete response (5%), eight patients with PR (18%) and 20 patients with stable disease ("SD") (47%). Based on such data, the estimated overall response rate ("ORR") (ORR=CR+PR) was 23% and the CBR was 70%. Responses were also achieved in patients with prior chemotherapy - two PR and three SD in eight of the patients pre-treated with platinum/taxane regimens. Median TTP and OS were seven months (30 weeks) and 14.9 months (62 weeks), respectively. Prof. Emons concluded as follows: (i) Zoptrex™ was efficacious and well tolerated in patients with advanced endometrial cancer; (ii) the safety profile confirmed the dose of 267 mg/m^2; (iii) hematological toxicity was rapidly reversible; (iv) non-hematological toxicities were usually not severe, causing few deviations from scheduled treatment; (v) no cardiotoxic events were observed; (vi)

the ORR of 23% compares well with those of single-agent platinum or taxane treatment; (vii) responders included patients pre-treated with platinum/taxane combination; (viii) in addition, the rate of SD was 47%, resulting in a CBR of 70%; and (ix) the OS after single agent Zoptrex™ was similar to that reported for modern triple combination chemotherapy, but was achieved with lower toxicity.

Competition

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

Drug	Co-administered drugs & comparator arm	Target	Indication	Clinical Trial/ Approval Status	Innovator	Primary Endpoint	Com Clin Hist Com Hist
Ixabepilone (Ixempra; BMS-247550)	Doxorubicin, paclitaxel	Tubulin-micro-tubules; epothilone B analog	Second-line endometrial cancer	IXAMPLE2; Phase III (not in Bristol-Myers Squibb's pipe-line, did not meet OS primary endpoint)	BMS	Overall survival (OS)	500- trial impr at in anal Q4/1
Ixabepilone (Ixempra; BMS- 247550)	Paclitaxel, carboplatin, temsirolimus, bevacizumab (Avastin)	As above	Stage III/IV, recurrent endometrial cancer	Phase III	US NCI	PFS out to five years (RECIST)	330- trial data expe 2016
Lenvatinib (E7080)	Monotherapy	Tyrosine kinase VEGFR2 inhibitor, multi-targeted	Second-line endometrial cancer	Phase II, open-label single-arm (still active, but not recruiting patients)	Eisai	Objective response rate to six months	167- trial resp data expe H2/1
MK-2206	Monotherapy	Serine/ threonine kinase Akt inhibitor	Recurrent, advanced endometrial cancer	Phase II, two-arm, only patients with PIK3CA mutation	US NCI (Astra--Zeneca-Merck partnered drug)	Objective response, PFS	90-p trial PFS resp data
Buparlisib (BKM120)	Monotherapy	Phosphatidyl inositol-3-kinase (PI3K)-Akt-mTOR pathway inhibitor	Second-line endometrial cancer	Phase II (ENDOPIK)	Novartis	ORR/PFS out to six months	56-p trial PFS resp data H2/1
BMN 673 (BioMarin)	Monotherapy	Poly-ADP ribose polymerase inhibitor	Inoperable, advanced endometrial cancer	Phase II (PANDA trial)	BioMarin, University College London	PFS at six months, time-to-recurrence	100- trial in Ju 2015 prob H1/1

GSK 2141795	Mekinist (trametinib, MEK inhibitor)	Akt inhibitor	Recurrent, persistent endometrial cancer	Phase II, control arm is Mekinist alone	US NCI (is GSK drug, but GSK not identified as sponsor)	PFS, up to five years, impact of Kras status on response	148- inter data H1/

Virexxa (Cridanimod sodium)	Progesterone	Carboxymethyl -acridinone; elevates PrR expression	Recurrent, persistent endometrial cancer (PrR-negative)	Phase II	Pharmsynthez (Estonia), AS Kevelt	ORR at one year, PFS at two years	58-patients, first enrolled in Jan/15; data in H2/18
Cabozantinib s-malate (Exelixis' Comitriq)	Monotherapy	Multi-kinase inhibitor, already approved in thyroid cancer	Recurrent, metastatic endometrial cancer	Phase II	US NCI (Exelixis not identified as partner)	ORR/PFS out to three months	72-patient, PFS data expected by Q3/16
LY3023414	Monotherapy	PI3K-mTOR dual inhibitor	Recurrent endometrial cancer	Phase II (multiple cancer forms)	MSKC, Eli Lilly	Three-month CBR, one-year O/S	25-patient, single-arm, clinical benefit rate data by Q4/16
IMMU-132	Monotherapy	TROP-2-targeted mAb linked to SN38 (metabolite of irinotecan)	Endometrial cancer	Phase I/II (multiple epithelial cancers being tested simultane-ously)	Immuno medics	Safety, tumor response	250-patient, three- month response rate data in H2/16
KPT-330 (Selinexor)	Monotherapy	XPO1 (nuclear export protein) antagonist	Advanced gynecologic cancers	Phase II	Karyopharm Therapeutics	Safety, survival, QoL	105-patient, two-year survival data in H2/17
HuMax-TF-ADC	Monotherapy	Tissue factor-targeted mAb lined to auristatin	Solid tumors, including endometrial cancer	Phase I/II	Genmab	Safety, PK, response rate	80-patient, adverse event rate & response rate data in H2/17

Source: D. Loe, “Aeterna Zentaris: Recalibrating Valuation Following Capital Structure De-construction, But Still Positive on Zoptarelin Prospects” (Euro Pacific Canada) December 11, 2015 (quoting NIH data)

Additional Indications

We believe that Zoptrex™ may be useful in treating other cancers, including breast cancer, bladder cancer and prostate cancer. We terminated early clinical trials of the compound as a treatment for triple-negative breast cancer and bladder cancer as part of our ongoing review of our development activities to ensure the most effective use of our resources. We assisted Dr. Jacek Pinski, Associate Professor of Medicine at the Norris Comprehensive Cancer Center of the University of Southern California, to conduct a Phase 1/2 study in refractory prostate cancer with Zoptrex™. Dr. Pinski received a $1.6 million grant from The National Institutes of Health (“NIH”) to conduct the study. The study, entitled “A Phase I/II Trial of AN-152 [AEZS-108] in Castration-and Taxane-Resistant Prostate Cancer”, was conducted in two portions: an abbreviated dose-escalation study followed by a single arm, Simon Optimum two-stage design Phase 2 study, using the dose selected in the Phase 1 portion.

The following is a summary of Dr. Pinski's study:

- On December 14, 2010, we announced the initiation of the Phase 1/2 trial.
- On February 3, 2012, we reported updated results for the Phase 1 portion of the study. The results were based on 13 patients who had been previously treated with androgen-deprivation therapy (LHRH agonist) and at least one taxane-based chemotherapy regimen, who were treated on three dose levels of Zoptrex™: three at 160 mg/m^2, three at 210 mg/m^2, and seven at 267 mg/m^2. Overall, Zoptrex™ was well tolerated among this group of heavily pretreated older patients. There were two dose-limiting toxicities, each of which having been a case of asymptomatic Grade 4 neutropenia at the 267 mg/m^2 dose level and both patients fully recovered. The Grade 3 and 4 toxicities were primarily hematologic. There was minimal non-hematologic toxicity, most frequently fatigue and alopecia. Despite the low doses of Zoptrex™ in the first cohorts, there was some evidence of antitumor activity. One patient received eight cycles (at 210 mg/m^2) due to continued benefit. Among the five evaluable patients with measurable disease, four achieved stable disease. At the time of submission of the abstract, a decrease in PSA was noted in six patients. Six of 13 (46%) treated patients received at least five cycles of therapy with no evidence of disease progression at twelve weeks. Correlative studies on CTC demonstrated the uptake of zoptarelin doxorubicin into the targeted tumor.
- On November 12, 2012, we announced the initiation of the Phase 2 portion of Dr. Pinski's Phase 1/2 study of Zoptrex™ in prostate cancer. This was a single-arm Simon Optimum design Phase 2 study of Zoptrex™ in 25 patients with CRPC. Patients received Zoptrex™ (210 mg/m^2) intravenously over two hours, every three weeks. The primary endpoint was CB, defined as remaining progression-free by RECIST and PSA after treatment for 12+ weeks. Secondary endpoints were progression free survival ("PFS"), best overall response, toxicity, pain and OS.
- On June 3, 2013, we announced that final data for the Phase 1 portion of Dr. Pinski's Phase 1/2 trial with Zoptrex™ in prostate cancer demonstrated the compound's promising anti-tumor activity. Results were presented by Dr. Pinski during a poster session at the ASCO Annual Meeting in Chicago. The results of the study were published in an article by Liu et al in the journal Clinical Cancer Research (Clin. Cancer Res. (2014) 20:6277). Eighteen men were treated at three dose levels: (160 mg/m^2; (ii) 210 mg/m^2; and (iii) 267 mg/m^2). Overall Zoptrex™ was well tolerated among this group of heavily pretreated patients. There were two dose-limiting toxicities (grade four neutropenia and grade three febrile neutropenia), prompting de-escalation to 210 mg/m^2 and establishing it as the Maximum Tolerated Dose. Among the 15 evaluable patients with measurable disease, ten achieved SD, and a drop in PAS was noted in three patients.
- On September 28, 2015, Dr. Pinski announced during a poster session at the 18th ECCO - 40th ESMO European Cancer Congress in Vienna, Austria, that among the 25 patients in the Phase 2 portion of the trial, 11 patients experienced clinical benefit as the primary endpoint and 13 patients achieved SD. Maximal PSA response was stable in 20 patients. Pain assessment improved for 11 patients. Zoptrex™ was well tolerated in this heavily pretreated patient population with hematological toxicities, usually limited to grade three, as the most common adverse events. Dr. Pinski concluded that Zoptrex™ was well tolerated and met the primary efficacy endpoint in castration- and taxane-resistant prostate cancer patients.

We believe that immuno-modulatory and targeted therapies have been key areas of innovation in oncology over the last few years. Zoptrex™ is a targeted cytotoxic therapy using a peptide as the targeting agent and is therefore part of the ongoing innovation in the treatment of cancer. Furthermore, we believe that Zoptrex™ is ahead of many of the immuno-oncology products that are in development. Due to our lack of resources, we intend to pursue the development of Zoptrex™ for indications other than endometrial cancer by seeking development partners to assist with the effort. In this regard, on December 1, 2014, we entered into an exclusive license and technology transfer agreement with Sinopharm A-Think Pharmaceuticals Co., Ltd. for the compound, for the initial indication of endometrial cancer and for all other human indications, in the territories of China, Hong Kong and Macau. We are currently seeking to sublicense the compound to others for development in additional markets.

Macrilen™

Macrilen™ 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"). If approved by the FDA, Macrilen™ would be the first orally administered drug indicated

for the evaluation of adult growth hormone deficiency (“AGHD”). Competitors for Macrilen™ as a product for the evaluation of AGHD are principally the diagnostic tests currently performed by endocrinologists, although none of these tests are approved by the FDA for this purpose. The most commonly used diagnostic tests for GHD are:

- Measurement of blood levels of Insulin Growth Factor (“IGF”)-1, which is typically used as the first test when GHD is suspected. However, this test is not used to definitively diagnose GHD because many growth hormone deficient patients show normal IGF-1 levels.
- The insulin tolerance test (“ITT”), which is considered the historical gold standard for the evaluation of AGHD because of its high sensitivity and specificity. However, the ITT is inconvenient to both patients and physicians and contra-indicated in certain patients, such as patients with coronary heart disease or seizure disorder, because it requires the patient

to experience hypoglycemia to obtain a result. Some physicians will not induce full hypoglycemia, intentionally compromising accuracy to increase safety and comfort for the patient. Furthermore, administration of the ITT is expensive because the patient must be constantly monitored by a physician for the two- to four-hour duration of the test and the test must be administered in a setting where emergency equipment is available and where the patient may be quickly hospitalized. The ITT is not used for patients with co-morbidities, such as cardiovascular disease, seizure disorder or a history of brain cancer or for patients who are elderly and frail, due to safety concerns.

- The Glucagon test, which is simple to perform and is considered relatively safe by endocrinologists. The mechanism of action for this test is unclear. Also, this test takes up to three to four hours. It produces side effects in up to one-third of the patients. This test is administered intramuscularly.
- The GHRH + ARG test, which is an easier test to perform in an office setting and has a good safety profile but is considered to be costly to administer compared to ITT and Glucagon. GHRH + ARG is approved in the EU and has been proposed to be the best alternative to ITT, but GHRH is no longer available in the United States. This test is administered intravenously.

Oral administration of Macrilen™ offers more convenience and simplicity over the current GHD tests used, all of which require either intravenous or intramuscular administration. Additionally, Macrilen™ may demonstrate a more favorable safety profile than existing diagnostic tests, some of which may be inappropriate for certain patient populations, e.g. diabetes mellitus or coronary heart disease, and have demonstrated a variety of side effects, which Macrilen™ has not thus far. These factors may be limiting the use of GHD testing and may potentially enable Macrilen™ to become the product of choice in evaluating AGHD. We believe that Macrilen™, if it is approved, is likely to rapidly displace the ITT as the preferred means of evaluating AGHD for the following reasons:

- it is safer than the ITT because it does not require the patient to become hypoglycemic;
- Macrilen™ is administered orally, while the ITT requires an intravenous injection of insulin;
- the evaluation of AGHD using Macrilen™ is much less time consuming and labor intensive than the ITT and, therefore, it is less expensive to conduct; and
- the evaluation can be conducted in the physician's office rather than in a hospital-like setting.

There are approximately 36,000 AGHD tests performed annually in the U.S. Based on published information from the U.S. Centers for Disease Control and Prevention, different scientific publications and by Navigant Research, we estimate that the total potential U.S. market for AGHD evaluation is approximately 158,000 tests per year, including the evaluation of patients who have suffered traumatic brain injury (“TBI”). In patients with TBI, GHD is frequent and may contribute to cognitive sequel and reduction in quality of life. GHD develops in approximately 19% of both severe and moderate hospitalized TBI victims.

The following is a summary of the history of our development of Macrilen™:

- We out-licensed the development compound macimorelin acetate to Ardana Bioscience in 2004. Ardana Bioscience subsequently initiated the clinical development program of macimorelin acetate as an orally active compound intended to be used in the diagnosis of adult growth hormone deficiency. Following agreement with the FDA on the study design, Ardana Bioscience initiated a pivotal Phase 3 study in 2007, which tested the compound compared to a test of growth hormone-releasing hormone (“GHRH”) + L-Arginine (“ARG”), using a competitor's compound. The study was discontinued in 2008 due to Ardana Bioscience's bankruptcy. We terminated Ardana Bioscience's license to the compound due to its bankruptcy.
- On October 19, 2009, we announced that we had initiated activities intended to complete the clinical development of Macrilen™ for use in evaluating AGHD. We had already assumed the sponsorship of the IND from Ardana Bioscience and discussed with the FDA the best way to complete the ongoing Phase 3 clinical trial and subsequently to file an NDA for approval of Macrilen™ for use in evaluating AGHD. The pivotal Phase 3 trial was designed to investigate the safety and efficacy of the oral administration of Macrilen™ as a growth hormone stimulator for use in evaluating AGHD. It was accepted by the FDA that for the ongoing part of the study, Macrilen™ would not be compared to the GHRH + ARG test because the competitor's compound had been removed from the market.
- On December 20, 2010, we announced we had reached agreement with the FDA on a SPA for Macrilen™, enabling us to complete the ongoing registration study required to gain approval for use in evaluating AGHD. The first part of the study, conducted by our former licensee, Ardana, was a two-way cross-over study and included 42 patients with

confirmed AGHD or multiple pituitary hormone deficiencies and a low IGF-1. A control group of ten subjects without AGHD was matched to patients for age, gender, body mass index and (for females) estrogen status.

- On July 26, 2011, we announced the completion of the Phase 3 study of Macrilen™ as a first oral product for use in evaluating AGHD and the decision to meet with the FDA for the future filing of an NDA for the registration of Macrilen™ in the United States.
- On June 26, 2012, we announced that the final results from a Phase 3 trial for Macrilen™ showed that the drug is safe and effective in evaluating AGHD. Jose M. Garcia, MD, PhD, then of the Baylor College of Medicine and the Michael E. DeBakey VA Medical Center, disclosed these data during an oral presentation at the 94th ENDO Annual Meeting and

Expo in Houston, Texas. The study had originally been designed as a cross-over trial of Macrilen™ compared to the GHRH + ARG test in AGHD patients and in controls matched for body mass index (“BMI”), estrogen status, gender and age. After 43 AGHD patients and ten controls had been tested, the GHRH + ARG test became unavailable because the competitor's compound was withdrawn from the market. The study was completed by testing ten more AGHD patients and 38 controls with Macrilen™ alone. Of the 53 AGHD subjects enrolled, 52 received Macrilen™, and 50 who had confirmed AGHD prior to study entry were included in this analysis, along with 48 controls. Two AGHD subjects could not be matched due to the combination of young age, high BMI and estrogen use. The objective of this clinical trial was to determine the efficacy and safety of Macrilen™ in the evaluation of AGHD. Mean peak growth hormone ("GH") levels in AGHD patients and controls following Macrilen™ administration were 2.36ng/mL (range 0.03-33) and 17.71ng/mL (range 10.5-94), respectively. The ROC plot analysis yielded an optimal GH cut-point of 2.7ng/mL, with 82% sensitivity, 92% specificity and a 13% misclassification rate. Obesity (BMI>30) was present in 58% of cases and controls, and peak GH levels were inversely associated with BMI in controls. Adverse events ("AE") were seen in 37% of AGHD patients and in 21% of controls following Macrilen™. In contrast, 61% of AGHD subjects and 30% of controls experienced AEs with L ARG+GHRH. The most common AEs after Macrilen™ were unpleasant taste (19.2%) and diarrhea (3.8%) for the AGHD patients and unpleasant taste (4.2%) and diarrhea (4.2%) for the matched controls. No clinically meaningful changes from baseline in ECG results during the study for AGHD patients were observed; however, one control subject had an ECG change (T wave abnormality and QTc interval prolongation) one hour after treatment with Macrilen™ that was considered a serious treatment-related adverse event and resolved spontaneously within 24 hours. The subject had been pre-treated with citalopram, a drug that was later reported by the FDA to be associated with QT prolongation, although the patient had stopped this medication seven days prior to dosing. In an expert statement of January 9, 2015, Prof. Dr. W. Haverkamp, Centrum Herz-, Kreislauf- und Gefäßmedizin, Charité, Berlin, considered the observed QT prolongation to be not related to Macrilen™. Overall, this study demonstrated that Macrilen™ is safe and effective for use in evaluating AGHD.

- In November 2013, we filed an NDA for Macrilen™ for the evaluation of AGHD by evaluating the pituitary gland secretion of growth hormone in response to an oral dose of the product. The FDA accepted the NDA for substantive review in January 2014. On November 6, 2014, the FDA informed us, by issuing a Complete Response Letter (“CRL”), that it had determined that our NDA could not be approved in its then present form. The CRL stated that the planned analysis of our pivotal trial did not meet its stated primary efficacy objective as agreed to in the SPA. The CRL further mentioned issues related to the lack of complete and verifiable source data for determining whether patients were accurately diagnosed with AGHD. The FDA concluded that, “in light of the failed primary analysis and data deficiencies noted, the clinical trial does not by itself support the indication.” To address the deficiencies identified above, the CRL stated that we needed to demonstrate the efficacy of Macrilen™ as a diagnostic test for GHD in a new, confirmatory clinical study. The CRL also stated that a serious event of electrocardiogram QT interval prolongation occurred for which attribution to drug could not be excluded. Therefore, a dedicated thorough QT study to evaluate the effect of macimorelin on the QT interval would be necessary.
- Following receipt of the CRL, we assembled a panel of experts in the field of growth-hormone deficiency, including experts in the field from both the United States of America and the EU. The panel met on January 8, 2015, during which we discussed our conclusions from the CRL, as well as the potential design of a new pivotal study. The panel advised us to continue to seek approval for Macrilen™ because of their confidence in its efficacy and because there currently is no FDA-approved diagnostic test for AGHD. In parallel, we collected information on timelines and costs for such a study.
- During an end-of-review meeting with the FDA on March 6, 2015, we agreed with the FDA on the general design of the confirmatory study Phase 3 study of Macrilen™ for the evaluation of AGHD, as well as evaluation criteria. We agreed with the FDA that the confirmatory study will be conducted as a two-way crossover with the ITT as the benchmark comparator.
- On April 13, 2015, we announced plans to conduct a new, confirmatory Phase 3 clinical study to demonstrate the efficacy of Macrilen™ for the evaluation of AGHD, as well as a dedicated thorough QT study to evaluate the effect of Macrilen™ on myocardial repolarization. The confirmatory Phase 3 clinical study of Macrilen™, entitled “Confirmatory validation of oral macimorelin as a growth hormone (GH) stimulation test (ST) for the diagnosis of adult growth

hormone deficiency (AGHD) in comparison with the insulin tolerance test (ITT)", is designed as a two-way crossover study with the ITT as the benchmark comparator and will involve some 30 sites in the United States and Europe. The study population will consist of approximately 110 subjects (at least 55 ITT-positive and 55 ITT-negative) with a medical history documenting risk factors for AGHD, and will include a spectrum of subjects from those with a low risk of having AGHD to those with a high risk of having the condition. The primary endpoint is validation of a single oral dose of Macrilen™ for the diagnosis of AGHD, using the ITT as a comparator.

On May 26, 2015, we announced that we had received written scientific advice from the European Medicines Agency ("EMA") regarding the further development plan, including the study design, for the new confirmatory Phase 3 clinical study of Macrilen™ for use in evaluating AGHD. As a result of the advice, we believe that the confirmatory Phase 3

study that was agreed with the FDA meets the EMA's study-design expectations as well, allowing for US and European approval, if the study is successful.

- On November 19, 2015, we announced the enrollment of the first patient in the confirmatory Phase 3 clinical study of Macrilen™. Based on the current rate of enrollment, we expect the confirmatory Phase 3 clinical study of Macrilen™ to be concluded in the third quarter of 2016. Furthermore, we expect to be able to submit an NDA for Macrilen™ to the FDA by mid-year 2017 and, if the study is successful in meeting its primary endpoint, to obtain approval of the drug by year-end 2017.

LHRH-Disorazol Z (AEZS-138)

In search of new antitumor agents, we found that disorazol Z, a compound that was isolated from the myxobacterium Sorangium cellulosum, possesses cytotoxic activity in the picomolar range in a panel of different tumor cell lines. Inhibition of tubulin polymerization, cell cycle arrest and efficient induction of apoptosis have been identified as modes of action. AEZS-138 is a cytotoxic conjugate of disorazol Z and a synthetic peptide carrier that targets the LHRH receptor. It is, therefore, an outgrowth of our research that lead to our formulation of Zoptrex™. The following is a summary of our development efforts with respect to AEZS-138:

- On March 24, 2011, we were awarded a $1.5 million grant from the German Ministry of Education and Research to develop, up to the clinical stage, cytotoxic conjugates of the proprietary cytotoxic compound disorazol Z and peptides targeting G-protein coupled receptors, including the LHRH receptors. The compounds combine the targeting principle being studied in Phase 3 with zoptarelin doxorubicin with the novel cytotoxic disorazol Z. The grant was payable as a partial reimbursement of qualifying expenditures over a three-year period, until January 31, 2014. The qualified project was performed with Morphisto GmbH and the Helmholtz Institute in Saarbrücken, Germany, which received additional funding of approximately US$0.7 million. Researchers from the departments of Gynecology and Obstetrics at both the University of Göttingen and the University of Würzburg, Germany, were also part of the collaboration.
- On November 16, 2011, we announced the presentation of a poster at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on encouraging preclinical data for disorazol Z. The data showed that disorazol Z possesses cytotoxicity in a highly diverse panel of 60 different tumor cell lines, and also underlined the identification of important aspects of this novel natural compound's mechanism of action. Disorazol Z has been identified as a tubulin binding agent with highly potent antitumor properties. Cell cycle analysis revealed that disorazol Z arrested cells in the G2/M cell cycle phase and subsequently induced apoptosis with remarkable potency, as shown by sub-nanomolar EC50 values. To expand our zoptarelin doxorubicin technology platform, we aim to evaluate the utility of disorazol Z as a cytotoxic component in a drug-targeting approach utilizing GPCR ligands as the targeting moieties for the treatment of GPCR over-expressing cancers.
- On April 10, 2013, we announced at the American Association for Cancer Research's ("AACR") annual meeting encouraging updated proof-of-concept results for disorazol Z cytotoxic conjugates, such as AEZS-138, in human ovarian and endometrial cancer xenograft models. Data demonstrated that conjugates of D-Lys6-LHRH and disorazol Z retained strong binding to the LHRH receptor and showed potent inhibition of tubulin polymerization. Cellular cytotoxicity of the conjugates was in the low nanomolar EC50 range. Increased cytotoxicity in cells over-expressing the LHRH receptor, support receptor targeting as a mechanism of action. The LHRH receptor-dependent efficacies of disorazol Z - D-Lys6-LHRH conjugates in vitro and in mouse xenograft models that were presented support the principle of tumor targeting by the LHRH receptor as considered to be employed by zoptarelin doxorubicin.
- On February 11, 2014, at the 11th International Symposium on GnRH in Salzburg, Austria, we presented further data on the mechanism of action and proof of concept of the disorazol Z cytotoxic conjugate, AEZS-138, which had led to the initiation of its preclinical development during the second quarter of 2013.

Overview of our Commercial Operations

Our commercial operations consist of a full-time sales force and a sales-management staff. We currently have 21 sales representatives in the United States, who provide services solely for us pursuant to our agreement with inVentiv Commercial Services, LLC, an affiliate of inVentiv Health, Inc. (“inVentiv”), a contract-sales organization. Our sales force is managed by two Regional Sales Managers, a National Sales Director and led by our Senior Vice President and Chief Commercial Officer. Our sales force currently promotes EstroGel®, Saizen® and APIFINY®.

Our agreement with inVentiv provides that the inVentiv personnel who provide services to us are independent contractors and not our employees. Furthermore, inVentiv is solely responsible for the human-resource and performance-management functions of all such personnel. It is also responsible for paying the compensation, benefits, payroll-related or withholding taxes and any governmental charges or benefits, including unemployment and disability insurance contributions or benefits and workers compensation contributions with respect to such personnel and for reimbursing them for their expenses. We pay a fixed monthly fee to inVentiv for the services of the sales representatives it provides for us, which is subject to adjustment if the assumptions

regarding the annual salaries paid to the sales representatives prove to be too high or too low, and we also reimburse inVentiv for certain expenses that it incurs as a result of providing sales representatives to us.

Our agreement with inVentiv has a two-year term that started in November 2014. The term may be extended for additional periods of one year, if we reach a written agreement with inVentiv regarding the terms of the extension not less than 60 days before the end of the expiring term. The agreement is subject to customary termination provisions for non-payment of amounts due, material breach and bankruptcy or insolvency. In addition, we may terminate the agreement without cause by giving inVentiv at least 90 days' prior written notice.

We promote EstroGel®, a leading non-patch transdermal hormone replacement therapy product, pursuant to a co-promotion agreement (the "Ascend Agreement") with ASCEND Therapeutics US LLC ("ASCEND"), which we entered into in August 2014. The Ascend Agreement provides that we will promote EstroGel® in specific agreed-upon U.S. territories in exchange for a sales commission that is based upon incremental sales volumes of the product that are generated over pre-established baselines.

The Ascend Agreement has a two-year term that commenced in November 2014. It is subject to extension for successive periods of two years each upon our agreement with ASCEND. The Ascend Agreement has customary termination provisions and, in addition, is subject to termination for convenience by either party upon the provision of not less than six months' written notice to the other party. During the term of the Ascend Agreement, either party may offer other products that it acquires to the other party for inclusion in the co-promotion arrangement established by the Ascend Agreement.

Saizen® [somatropin (rDNA origin) for injection] is a prescription medicine indicated for the treatment of growth hormone deficiency in children and adults. We promote Saizen® pursuant to our co-promotion agreement (the "EMD Serono Agreement") with EMD Serono Inc. ("EMD Serono"), which we entered into in May 2015. The EMD Serono Agreement provides that we will promote Saizen® in specific agreed-upon U.S. territories in exchange for a sales commission that is based upon incremental new patient starts of the product that are generated over pre-established baselines.

The EMD Serono Agreement has a five-year term that began in May 2015, which is not subject to an agreed extension period, and is subject to customary termination provisions. EMD Serono has the right to terminate the EMD Serono Agreement for convenience at any time by giving us three months' advance written notice. EMD Serono has certain payment obligations to us that will arise if it terminates the EMD Serono Agreement for convenience, the type and amount of which will depend on the date that EMD exercises its right to terminate. We may terminate the EMD Serono Agreement for convenience at any time after the second anniversary of its date by giving EMD Serono three month's advance written notice.

APIFINY®, is the only cancer-specific, non-PSA blood test for the evaluation of the risk of prostate cancer. The test was developed by Armune BioScience, Inc. ("Armune"), a medical diagnostics company that develops and commercializes unique proprietary technology exclusively licensed from the University of Michigan for diagnostic and prognostic tests for cancer. We entered into a co-marketing agreement with Armune in November 2015 (the "Armune Agreement"), pursuant to which we have the right to promote APIFINY® to designated medical professionals in our 21 U.S. territories. We receive a commission for each test performed resulting from our targeted promotion without regard to a baseline. The Armune Agreement has a one-year term that renews automatically for successive one-year periods, unless either party terminates it by giving not less than 60 days' advance written notice to the other, which either party may do at any time with or without cause.

A description of the principal geographic areas in which we compete, including a geographical and categorical breakdown of our revenues in the past three years is presented in note 27 (Segment information) to our consolidated financial statements included in this Annual Report on Form 20-F at Item 18.

Raw Materials

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

Regulation of Drug Development

Generally. Governmental authorities in the United States, Canada, Europe and other countries extensively regulate the preclinical and clinical testing, manufacturing, labeling, storage, record keeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceuticals. Under the laws of the United States, the countries of the EU, and other countries, we and the institutions at which we sponsor research are subject to obligations to ensure that our clinical trials are conducted in accordance with Good Clinical Practices ("GCP") guidelines and the investigational plan and protocols contained in an IND application, or comparable foreign regulatory submission. The Japanese regulatory process for approval of new drugs is similar to the FDA approval process described below except that Japanese regulatory authorities request bridging studies to verify that foreign clinical data are applicable to Japanese patients and also require the tests to determine appropriate dosages for Japanese patients to be

conducted on Japanese patient volunteers. Due to these requirements, delays of two to three years in introducing a drug developed outside of Japan to the Japanese market are customary. Set forth below is a brief summary of the material governmental regulations affecting us in the major markets in which we intend to market our products and/or promote products that we acquire or in-license or to which we obtain promotional rights.

The United States. In the United States, the FDA under the United States Food, Drug and Cosmetic Act of 1938, as amended (the "FDA Act"), the Public Health Service Act and other federal statutes and regulations, subjects pharmaceutical products to rigorous review. In order to obtain approval of a new product from the FDA, we must, among other requirements, submit proof of safety and efficacy as well as detailed information on the manufacture and composition of the product. In most cases, this proof entails extensive preclinical, clinical, and laboratory tests. Before approving a new drug or marketing application, the FDA also typically conducts pre-approval inspections of the company, its CROs and/or its clinical trial sites to ensure that clinical, safety, quality control, and other regulated activities are compliant with GCP, or Good Laboratory Practices ("GLP"), for specific non-clinical toxicology studies. Manufacturing facilities used to produce a product are also subject to ongoing inspection by the FDA. The FDA may also require confirmatory trials, post-marketing testing, and extra surveillance to monitor the effects of approved products, or place conditions on any approvals that could restrict the commercial applications of these products. Once approved, the labeling, advertising, promotion, marketing, and distribution of a drug or biologic product must be in compliance with FDA regulatory requirements.

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

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

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

Orphan-drug designation is granted by the FDA Office of Orphan Drug Products to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity if the drug is the first of its type approved for the

specified indication or if it demonstrates superior safety, efficacy or a major contribution to patient care versus another drug of its type previously granted the designation for the same indication. We have been granted orphan drug designations for Zoptrex™ for the treatment of advanced ovarian cancer and for Macrilen™ for the evaluation of growth hormone deficiency.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), newly-approved drugs and indications may benefit from a statutory period of non-patent data exclusivity. The Hatch-Waxman Act provides five-year data exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active pharmaceutical ingredient, or active moiety. Although protection under the Hatch-Waxman Act will not prevent the submission or approval of another full NDA, such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness.

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

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

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

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

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

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. The application will be reviewed by a selected Reference Member State ("RMS"). The Marketing Authorization granted by the RMS will then be recognized by the other Member States involved in this procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Regulation of Commercial Operations

The marketing, promotional, and pricing practices of human pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers and prescribers, are subject to various U.S. federal and state laws, including the federal anti-kickback statute and the False Claims Act and state laws governing kickbacks, false claims, unfair trade practices, and consumer protection, and to similar laws in other countries. In the United States, these laws are administered by, among others, the Department of Justice (DOJ), the Office of Inspector General of the Department of Health and Human Services, the Federal Trade Commission, the Office of Personnel Management, and state attorneys general. Over the past several years, the FDA, the DOJ, and many other agencies have increased their enforcement activities with respect to pharmaceutical companies and increased the inter-agency coordination of enforcement activities.

In the United States, biopharmaceutical and medical device manufacturers are required to record any transfers of value made to licensed physicians and teaching hospitals and to disclose such data to the Department of Health and Human Services (“HHS”). In addition to civil penalties for failure to report transfers of value to physicians or teaching hospitals, there will be criminal penalties if a manufacturer intentionally makes false statements or excludes information in such reports. The payment data across biopharmaceutical and medical device companies is posted by HHS on a publicly available website. Increased access to such data by fraud and abuse investigators, industry critics and media will draw attention to our collaborations with reported entities and will importantly provide opportunities to underscore the critical nature of our collaborations for developing new medicines and exchanging scientific information. This national payment transparency effort coupled with industry commitment to uphold voluntary codes of conduct (such as the PhRMA Code on Interactions with Healthcare Professionals and PhRMA Guiding

Principles Direct to Consumer Advertisements About Prescription Medicines) and rigorous internal training and compliance efforts will complement existing laws and regulations to help ensure ethical collaboration and truthful product communications.

The Canadian association of Research-Based Pharmaceutical Companies ("Rx & D") has adopted "Guidelines for Transparency in Stakeholder Funding" that require member companies to regularly disclose, by means of the web sites and annual reports, a list of all stakeholders to which they provide direct funding. The term "stakeholder" is defined in Rx & D's Code of Ethical Practices to include "Health Care Professionals". In the EU, the disclosure code of transfers of value to healthcare professionals and organizations adopted by the European Federation of Pharmaceutical Industries and Associations ("EFPIA") requires all members of EFPIA to disclose transfers of value to healthcare professionals and healthcare organizations beginning in 2016, covering the relevant transfers in 2015. Each member company will be required to document and disclose: (i) the names of healthcare professionals and associations that have received payments or other transfers of value and (ii) the amounts or value transferred, and the type of relationship.

For more information about the regulatory risks associated with our business operations, see "Item 3. - Key Information - Risk Factors".

Intellectual Property - Patents

We seek to protect our compounds, manufacturing processes, compositions and methods of medical use for our lead drugs and drug candidates through a combination of patents, trade secrets and know-how. Our patent portfolio consists of approximately 13 owned and in-licensed patent families (issued, granted or pending in the United States, Europe and other jurisdictions). The patent positions of companies in the biotechnology and pharmaceutical industries are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims, if any, that may be allowed under any of our patent applications, or the enforceability of any of our allowed patents. See "Item 3D. Risk Factors - We may not obtain adequate protection for our products through our intellectual property."

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent, in which the patentee may file an application for yearly interim extensions within five years if the patent will expire and the FDA has not yet approved the NDA. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended.

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

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

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

Our drug development efforts are currently focused on two compounds, zoptarelin doxorubicin (Zoptrex™) and macimorelin (Macrilen™), which are in clinical development, and on an LHRH-disorazol Z conjugate (AEZS-138), which is in pre-clinical development. The following is a description of our intellectual property rights with respect to these compounds.

Zoptrex™:

We license intellectual property and associated rights relating to LHRH agonists and LH-RH antagonists carrying various cytotoxic radicals (including zoptarelin doxorubicin) from the Administrators of the Tulane Educational Fund ("Tulane") pursuant to a License Agreement dated September 17, 2002 between Tulane, as licensor, and AEZS Gmbh, as licensee (the "Tulane Agreement"). The Tulane Agreement grants to us an exclusive worldwide license for all therapeutic uses of LH-RH agonists and LH-RH antagonists carrying various cytotoxic radicals, to the extent covered by one of the patents listed below. The term of the Tulane Agreement continues for ten years after the first commercial sale of a product based on the licensed intellectual property (a "Licensed Product") or until the expiration of the last to expire of the patents listed below, whichever is longer, on a country-by-country basis.

Pursuant to the Tulane Agreement, we are required to pay Tulane the following amounts: (i) US$400,000 upon the first grant of regulatory approval for a Licensed Product in the United States, Canada, the European Union or Japan; (ii) 10% of all consideration received by us from a sublicensee for authorization to use the licensed intellectual property to develop, manufacture, market, distribute and sell a Licensed Product; (iii) 5% of our net sales of Licensed Products; and (iv) 50% of any royalties that we receive from a sublicensee with respect to its net sales of Licensed Products; provided, however, that the payment with respect to royalties received from a sublicensee shall not be less than 3.5% nor more than 5% of the sublicensee's net sales of the Licensed Product.

The following patents are covered by the Tulane Agreement:

- US patent 5,843,903 covers zoptarelin doxorubicin and other related targeted cytotoxic anthracycline analogs, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This patent expired in November 2015.
- European patent 0 863 917 B1 covers zoptarelin doxorubicin and other related targeted cytotoxic anthracycline analogs, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This patent expires in November 2016.
- Japanese patent 3 987 575 covers zoptarelin doxorubicin and other related targeted cytotoxic anthracycline analogs, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This patent expires in November 2016.
- Chinese patent ZL96198605.0 covers zoptarelin doxorubicin and other related targeted cytotoxic anthracycline analogs, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This patent expires in November 2016.
- Hong Kong patent 1017363 covers zoptarelin doxorubicin and other related targeted cytotoxic anthracycline analogs, pharmaceutical compositions comprising the compounds as well as their medical use for the treatment of tumors. This patent expires in November 2016.

In early 2015, we filed a European patent application directed to a novel method of manufacturing Zoptrex™. Within the 12 months priority period, we also filed an international patent application for the manufacturing process, as well as national patent applications in selected countries, including the US, China, and Taiwan, Japan and India. We decided to file patent applications in additional territories after the European Patent Office issued a search report for the European patent application that we consider to be favorable. The claimed manufacturing process is expected to result in a significant reduction in our cost of manufacturing Zoptrex™, providing us with what should be a stronger competitive position and discouraging competition from generic manufacturers after our five-year period of data exclusivity expires.

Macrilen™:

We hold the worldwide rights to macimorelin pursuant to an exclusive license agreement with The French Centre National de la Recherche Scientifique, as licensor, and AEZS GmbH, as licensee.

The following patents relate to Macrilen™:

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U.S. patent 6,861,409 covers Macrilen™ and U.S. patent 7,297,681 covers other related growth hormone secretagogue compounds, each also covering pharmaceutical compositions comprising the compounds as well as their medical use for elevating the plasma level of growth hormone. U.S. patent 6,861,409 and U.S. patent 7,297,681 both expire in August 2022.

- European patent 1 289 951 covers Macrilen™ and European patent 1 344 773 covers other related growth hormone secretagogue compounds, pharmaceutical compositions comprising the compounds as well as their medical use for elevating the plasma level of growth hormone. EP patent 1 289 951 and EP patent 1 344 773 both expire in June 2021.
- Japanese patent 3 522 265 covers Macrilen™ and pharmaceutical compositions comprising the compounds as well as their medical use for elevating the plasma level of growth hormone. This patent expires in June 2021.

- Canadian patent 2,407,659 covers Macrilen™ and pharmaceutical compositions comprising the compounds as well as their medical use for elevating the plasma level of growth hormone. This patent expires in June 2021.
- U.S. patent 8,192,719 covers a method of assessing pituitary-related growth hormone deficiency in a human or animal subject comprising an oral administration of the compound Macrilen™ and determination of the level of growth hormone in the sample and assessing whether the level of growth hormone in the sample is indicative of growth hormone deficiency. This patent expires in October 2027.
- European patent 1 984 744 covers a method of assessing pituitary-related growth hormone deficiency by oral administration of Macrilen™. This patent expires in February 2027.
- Japanese patent 4 852 728 covers a method of assessing pituitary-related growth hormone deficiency by oral administration of Macrilen™. This patent expires in February 2027.

Disorazol Z - LHRH conjugates (AEZS-138):

We own a number of patents that relate to our Disorazol Z - LHRH conjugates, as follows:

- U.S. patent 7,741,277 covers AEZS-138 (disorazol Z - LHRH conjugate). This patent will expire in January 2028 (including PTA).
- U.S. patent 8,470,776 covers methods of treatment for compound AEZS-138 (disorazol Z - LHRH conjugate). This patent will expire in February 2029 (including PTA).
- European patent application 2,066,679 covers AEZS-138 (disorazol Z - LHRH conjugate) as well as methods of treatment for this compound. If granted, this patent will expire in September 2027.
- Japanese patent 5,340,155 covers AEZS-138 (disorazol Z - LHRH conjugate) as well as methods of treatment for this compound. This patent will expire in September 2027.

C. Organizational structure

Our corporate structure, the jurisdiction of incorporation of our direct and indirect subsidiaries and the percentage of shares that we held in those subsidiaries as at December 31, 2015 is depicted in the chart set forth under the caption "Item 4-A. History and development of the Company".

D. Property, plants and equipment

Our corporate head office is located in Summerville, South Carolina, which is a suburb of Charleston, South Carolina. The following table sets forth information with respect to our main facilities as at December 31, 2015.

Location	Use of space	Square Footage	Type of interest
315 Sigma Drive, Suite 302D, Summerville SC 29483	Partially occupied for management, administration, commercial operations and business development	4,623	Leasehold
Weismüllerstr. 50 D-60314 Frankfurt-am-Main, Germany	Occupied for management, R&D, business development and administration	36,168	Leasehold

Item 4A Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

Key Developments

Zoptrex™

Zoptrex™ is a complex molecule that combines a synthetic peptide carrier with doxorubicin, a well-known chemotherapy agent. The synthetic peptide carrier is a luteinizing hormone-releasing hormone ("LHRH") agonist, a modified natural hormone with affinity for the LHRH receptor. 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 a better efficacy and a more favorable safety profile with lower incidence and severity of side effects as compared to doxorubicin alone.

We believe that Zoptrex™ has the potential to become the first FDA-approved medical therapy for advanced, recurrent endometrial cancer, potentially resulting in the compound's rapid adoption as a novel core therapy for patient treatment and management, representing a significant potential market opportunity for us. Moving forward, we will continue to develop our commercialization plans regarding Zoptrex™ in this indication. In addition, contingent on the success of the ZoptEC (Zoptarelin Doxorubicin in Endometrial Cancer) pivotal Phase 3 clinical trial in women with advanced, recurrent or metastatic endometrial cancer, we have additional areas of interest for further therapeutic development for zoptarelin doxorubicin, including ovarian, prostate, breast cancer and potentially bladder cancer.

On April 16, 2015, we announced that we had filed an application for a European patent on a novel method of manufacturing Zoptrex™. Because this compound is a complex molecule, it is expensive to synthesize, and the requested patent, if granted, may make it difficult for generic manufacturers to produce Zoptrex™ on a financially feasible basis once our composition of matter patent on the compound expires. Further, the claimed manufacturing process is expected to result in a significant reduction in cost of goods sold, which should place us in a stronger competitive position.

On April 27, 2015, we announced that an independent Data and Safety Monitoring Board ("DSMB") for the pivotal Phase 3 Zoptrex™ clinical trial with zoptarelin doxorubicin in women with advanced, recurrent or metastatic endometrial cancer had completed a pre-specified first interim futility analysis at approximately 128 events, and on June 30, 2015, we announced that we had reached our goal of completing enrollment of 500 patients for this clinical trial.

On September 28, 2015, we announced that Zoptrex™ had met the primary end point of the investigator-driven and sponsored Phase 2 clinical trial in castration and taxane resistant prostate cancer ("CRPC") and demonstrated good tolerability. This was a single-arm Simon Optimum design Phase 2 study in 25 patients with CRPC.

On October 13, 2015, we announced that the independent DSMB had recommended that the pivotal Phase 3 ZoptEC study continue as planned. The DSMB's decision followed completion of its pre-specified second interim analysis on efficacy and safety at approximately 192 events. A final analysis of the data is expected at approximately 384 events.

Macrilen™

On April 13, 2015, we announced plans to conduct a new confirmatory Phase 3 clinical trial to demonstrate the efficacy of Macrilen™ for the evaluation of AGHD, as well as a dedicated thorough QT study to evaluate the effect of Macrilen™ on myocardial repolarization. During an end-of-review meeting with the FDA on March 6, 2015, we and the FDA agreed on the general design of the confirmatory Phase 3 clinical trial of Macrilen™, as well as on evaluation criteria.

On May 26, 2015, we announced that we had received written scientific advice from the European Medicines Agency (the "EMA") regarding the further development plan, including the study design, for the new confirmatory Phase 3 clinical trial of Macrilen™ for use in evaluating AGHD, following a Scientific Advice Meeting that had been held earlier that month. As a result of the advice, we believe that the confirmatory Phase 3 clinical trial that was agreed with the FDA meets the EMA's study-design expectations allowing for US and European approval if the study is successful.

On June 25, 2015, we announced that we had entered into an agreement with Ergomed PLC (formerly Ergomed Clinical Research Limited, hereafter referred to as "Ergomed"), pursuant to which Ergomed will manage the new confirmatory Phase 3 clinical trial of Macrilen™. Ergomed is already the clinical research organization supporting our pivotal Phase 3 ZoptEC clinical trial.

On November 19, 2015, we announced the first patient enrolled for confirmatory Phase 3 trial of Macrilen™ for the evaluation of AGHD. The confirmatory Phase 3 clinical study of Macrilen™ is designed as a two-way crossover study with the insulin tolerance test ("ITT") as the benchmark comparator and will involve some 30 sites in the US and Europe. The study population will consist of approximately 110 subjects (at least 55 ITT-positive and 55 ITT-negative) with a medical history documenting risk factors for AGHD, and will include a spectrum of subjects from those with a low risk of having AGHD to those with a high risk

of having the condition. The primary endpoint is validation of a single oral dose of macimorelin for the diagnosis of AGHD, using the ITT as a comparator.

Pre-clinical developments

On March 31, 2015, we announced the transfer of our discovery library of roughly 100,000 unique compounds to the South Carolina Center for Therapeutic Discovery and Development (the "Center") which is part of The Medical University of South Carolina ("MUSC"). Our material transfer agreement with the Center will result in the continued use of the library for the discovery of drug development candidates for the Company in the areas of oncology, neurology, endocrinology and women's health. The Center may make the library available to all investigators in the University of South Carolina system without restriction on its use and will own any therapeutic compounds discovered outside our areas of therapeutic interest.

The Center has agreed to conduct screening and pre-clinical activities with respect to the library with a view toward submitting to us at least one development candidate per year in our areas of therapeutic interest over a ten-year period beginning in 2018. We also have a right of first refusal to in-license any submitted development candidates. Should we decide to further develop a development candidate submitted by the Center, MUSC will license the compound candidate to us and be entitled to a royalty on the net sales of all commercialized products developed from the development candidate. However, should we decide not to further develop the development candidate submitted by the Center, MUSC is required to pay us a royalty on net sales of all commercialized products developed from the development candidate.

On July 28, 2015, we announced that we had granted to German life sciences entrepreneurs with a proven track-record of funding the development and commercialization of biotechnology (the "Optionee"), an option to license our live recombinant allogenic oral cancer vaccine technology (the "Technology"), including AEZS-120, the most advanced product candidate for prostate cancer which is ready to enter into a Phase 1 clinical trial. This option was granted to the Optionee worldwide, for a period of twelve months, in exchange for an upfront fee. Pursuant to the option agreement, the Optionee has the right to obtain a worldwide exclusive license to develop, use and sell products relating to the Technology and AEZS-120, in exchange for milestone payments and royalties on net sales of any product developed from the Technology and an equity interest in the company formed to develop the Technology. At the present time, we hold worldwide rights to the Technology, including AEZS-120.

On July 29, 2015, we announced that we had selected an optimized Erk inhibitor molecule, AEZS-140 and back-up candidates, for development. We have since decided to suspend our efforts on internally developing this class of potential cancer therapies to conserve our resources for other projects. Therefore, we are seeking proposals from parties who are interested in either co-developing or licensing the compounds.

On January 13, 2016, during our participation in the annual J.P. Morgan Healthcare conference, we announced that, in addition to our focus on Zoptrex™, we are also focusing on Disorazol Z, because it is an ideal compound for the formation of cytotoxic conjugates with peptides, proteins and antibodies to selectively target cancer cells. We have one cytotoxic conjugate, AEZS-138, in preclinical development. It is a conjugate based on Disorazol Z and the LHRH receptor agonist that is utilized in Zoptrex™. We believe that the peptide directs the compound specifically to LHRH receptor expressing tumor cells, and mediates binding and uptake via endocytosis. Within the cancer cell, the conjugates are cleaved and Disorazol Z can deploy its potent anti-proliferative activity. We have patented the cytotoxic agent Disorazol Z in 35 countries, including the US, Japan, Europe, China, Russia, Korea and Taiwan. This patent protection expires in 2026. The conjugate of Disorazol Z and the LHRH receptor agonist as a targeted cytotoxic agent is patented in 15 countries, including the US, Japan, China, Russia, Korea and Taiwan. This patent protection expires in 2027. We expect the European patent to be granted in the near future.

Commercial Operations

Our commercial operations consist of 21 full-time sales representatives and a sales-management staff. The sales representatives provide services pursuant to our agreement with a contract sales organization. The structuring and implementation of our commercial operations organization is felt to provide direct value through our existing co-promotion commercial activities, discussed below, as well as in support of our efforts to in-license and/or acquire

products into our portfolio.

EstroGel®

During 2015, we ramped up selling efforts related to our co-promotion agreement with Ascend, which we entered into in August 2014, for EstroGel®, a leading non-patch transdermal hormone replacement therapy product, in specific agreed-upon US territories in exchange for a sales commission that is based upon incremental sales volumes of the product that are generated over pre-established baselines.

Detailing efforts associated with EstroGel® commenced in earnest early in the first quarter of 2015, following the completion of sales force training and other knowledge-transfer activities that had been underway since late 2014. During 2015, we began exceeding pre-established unit sales baseline thresholds on a total nation basis.

Saizen®

On May 8, 2015, we announced that we had entered into a promotional services agreement with EMD Serono, allowing us to promote Saizen® [somatropin (rDNA origin) for injection] to designated medical professionals in specified US territories. Saizen® is a recombinant human growth hormone registered in the US for the treatment of growth hormone deficiency in children and adults. Under this agreement, we are detailing Saizen® to designated medical professionals, representing an important incremental field promotion activity in support of EMD Serono's product. Payment to Aeterna Zentaris is based on new, eligible patient starts on Saizen® above an agreed-upon baseline.

We are currently promoting Saizen® in 21 US territories, with efforts having commenced during the third quarter of 2015.

APIFINY®

On December 1, 2015, we announced the finalization of a co-marketing agreement that allows us to promote Armune's APIFINY®, the only cancer specific, non-PSA blood test for the detection of prostate cancer. Pursuant to this co-marketing agreement, we promote APIFINY to designated medical professionals in 20 US territories and are entitled to receive a commission for each test performed resulting from our targeted promotion.

Corporate Activities

Share consolidation

On November 18, 2015, we announced the details and implementation of the consolidation of our issued and outstanding common shares approved by shareholders at a special meeting held on November 16, 2015, which occurred at a consolidation ratio of 100-to-1 and became legally effective on November 17 2015. Our common shares began trading on a consolidated basis on each of the NASDAQ and the TSX at the opening of markets on November 20, 2015 under our current NASDAQ and TSX trading symbols, “AEZS” and “AEZ”, respectively. All common share and warrant data presented in the MD&A and pertaining to pre-share consolidation events or transactions have been retroactively adjusted to reflect this share consolidation.

On December 8, 2015, we announced that the NASDAQ had notified the Company that we regained compliance with Rule 5450(a)(1), which requires a minimum bid price of $1.00 for continued listing on the NASDAQ.

Public offerings and related events

On March 11, 2015, we completed a public offering of 596,775 units (the "Units"), generating net proceeds of approximately $34.4 million, with each Unit consisting of either one common share or one pre-funded warrant to purchase one common share ("Series C Warrant"), 0.75 of a warrant to purchase one common share ("Series A Warrant") and 0.50 of a warrant to purchase one common share ("Series B Warrant"), at a purchase price of $62.00 per Unit (the "March 2015 Offering"). The Series A Warrants are exercisable during a five-year term at an initial exercise price of $81.00 per share, and the Series B Warrants are exercisable during an 18-month term at an initial exercise price of $81.00 per share. Both the Series A and Series B warrants are subject to certain anti-dilution provisions. The Series C Warrants were exercisable for a period of five years at an exercise price of $62.00 per share. Total gross proceeds payable to us in connection with the exercise of the Series C Warrants were pre-paid by investors at the closing of the March 2015 Offering and therefore are included in the aforementioned proceeds. Between March 23, 2015 and June 16, 2015, all of the pre-funded Series C Warrants were exercised, resulting in the issuance of a total of 346,294 common shares.

Both the Series A and Series B Warrants may at any time be exercised on a standard cashless basis. In addition, the Series B Warrants may be exercised on an alternate net cashless basis. The exercise of Series B Warrants performed

on an alternate net cashless basis results in the issuance of a substantially larger number of the Company's common shares than otherwise would be issued following a standard cash or cashless exercise. Specifically, between May 26, 2015 and December 31, 2015, 290,318 Series B Warrants were exercised on an alternate net cashless basis, resulting in the issuance of approximately 5.7 million common shares. The remaining 8,064 Series B Warrants expire on September 12, 2016.

In connection with the March 2015 Offering, the holders of 211,230 of the 219,000 outstanding warrants issued in connection with previous public offerings completed in November 2013 and January 2014 each entered into an amendment agreement that caused such previously issued warrants to expire and terminate in consideration for a cash payment made by us in the aggregate amount of approximately $5.7 million out of the proceeds of the March 2015 Offering.

On November 2, 2015, we announced that the holders (the "Participating Holders") of substantially all of the remaining outstanding Series B Warrants at that time had agreed to exercise all of the Series B Warrants held by them, as promptly as practicable, 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. Following the exercise of Series B Warrants by the Participating Holders in accordance with the terms of the agreements, 8,064 Series B Warrants, with an expiry date of September 12, 2016, remain outstanding, representing approximately 2.7% of the originally issued number of Series B Warrants. A total of $2.9 million in cash was paid to the Participating Holders pursuant to the aforementioned agreements.

On December 14, 2015, we completed an underwritten public offering (the “December 2015 Offering”) of 3.0 million common shares and warrants to acquire 2.1 million common shares with 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. In addition, the Company 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. Prior to closing, the underwriter exercised its over-allotment option with respect to the warrants to acquire an additional 231,000 common shares, resulting in an issuance of warrants to acquire an aggregate of approximately 2.3 million common shares at closing.

The warrants are exercisable immediately and expire five years following issuance at an exercise price of $7.10 per share. The warrants do not contain any price or other adjustment provision, except for customary adjustment provisions that apply in the event of certain corporate events or transactions that affect all outstanding common shares. The warrants may at any time be exercised on a standard cashless basis in accordance with a customary formula but do not contain an alternate cashless exercise feature contained in our previously issued Series B common shares purchase warrants. The warrants are not listed on any stock exchange.

On December 30, 2015, we announced that we had filed a preliminary short form base shelf prospectus (the “Shelf Prospectus”) with the securities regulatory authorities in each of the provinces of Canada, and a corresponding shelf registration statement on Form F-10 with the SEC under the US/Canada Multijurisdictional Disclosure System. The Shelf Prospectus and corresponding shelf registration statement, which became effective subsequent to year-end on January 13, 2016, will allow us to offer up to $150 million of common shares, preferred shares, debt securities, subscription receipts, warrants or units comprised of one or more of such securities during the 25-month period that the Shelf Prospectus is effective.

Class action lawsuit

The Company and certain of its current and former officers are defendants in a putative class-action lawsuit brought on behalf of shareholders of the Company. The pending lawsuit is the result of the consolidation of several lawsuits, the first of which was filed on November 11, 2014. The plaintiffs filed their amended consolidated complaint on April 10, 2015. The amended complaint alleged violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by the defendants between August 30, 2011 and November 6, 2014 (the "Class Period"), regarding the safety and efficacy of Macrilen™ and the prospects for the approval of the Company's new drug application for the product by the FDA. The plaintiffs seek to represent a class comprised of purchasers of the Company's common shares during the Class Period and seek unspecified damages, costs and expenses and such other relief as determined by the court.

On September 14, 2015, the Court dismissed the lawsuit, but granted the plaintiffs leave to amend. In dismissing the lawsuit, the court affirmed that the plaintiffs had failed to state a claim. On October 14, 2015, the plaintiffs filed a second amended complaint. We subsequently filed a motion to dismiss, because we believe that the second amended complaint also fails to state a claim. The hearing of the motion to dismiss the Second Amended Complaint occurred on January 19, 2016. On March 2, 2016, the Court issued an order granting our motion to dismiss the complaint in part and denying it in part. The Court dismissed certain of our current and former officers from the lawsuit. The Court allowed the claim that we omitted material facts from our public statements during the Class Period to proceed against us and our former CEO who departed in 2013, while dismissing such claims against other current and former officers. The Court also allowed a claim for “controlling person” liability to proceed against certain current and former officers. We disagree with the Court's decision and we filed a motion for reconsideration on March 16, 2016.

Restructuring

On October 12, 2015, we announced that our Board of Directors had approved a plan to restructure our finance and accounting operations and to close our Quebec City office (the “Corporate Restructuring”). We transferred all functions performed by the five employees in our Quebec City office to other personnel and we intend to add new finance and accounting personnel, including a new Chief Financial Officer, in our Summerville, South Carolina, office. We estimate that the Corporate Restructuring will be completed by September 2016.

Consolidated Statements of Comprehensive (Loss) Income Information

(in thousands, except share and per share data)	Three-month periods ended December 31,		Years ended December 31,		
	2015	2014	2015	2014	2013
	$	$	$	$	$
Revenues					
Sales commission and other	41	—	297	—	96
License fees	61	11	248	11	6,079
	102	11	545	11	6,175
Operating expenses					
Cost of sales	—	—	—	—	51
R&D costs	4,243	6,282	17,234	23,716	21,284
General and administrative expenses	3,953	2,633	11,308	9,840	11,091
Selling expenses	1,764	2,043	6,887	3,850	1,225
	9,960	10,958	35,429	37,406	33,651
Loss from operations	(9,858)	(10,947)	(34,884)	(37,395)	(27,476)
Finance income	26	15,053	305	20,319	1,748
Finance costs	(211)	—	(15,649)	—	(1,512)
Net finance (costs) income	(185)	15,053	(15,344)	20,319	236
(Loss) income before income taxes	(10,043)	4,106	(50,228)	(17,076)	(27,240)
Income tax expense	—	(111)	—	(111)	—
Net (loss) income from continuing operations	(10,043)	3,995	(50,228)	(17,187)	(27,240)
Net income from discontinued operations	25	158	85	623	34,055
Net (loss) income	(10,018)	4,153	(50,143)	(16,564)	6,815
Other comprehensive (loss) income:					
Items that may be reclassified subsequently to profit or loss:					
Foreign currency translation adjustments	249	(677)	1,509	(1,158)	1,073
Items that will not be reclassified to profit or loss:					
Actuarial (loss) gain on defined benefit plans	(116)	1,336	844	(1,833)	2,346
Comprehensive (loss) income	(9,885)	4,812	(47,790)	(19,555)	10,234
Net (loss) income per share (basic and diluted) from continuing operations[1]	(1.46)	6.11	(18.17)	(29.12)	(92.41)
Net income per share (basic and diluted) from discontinued operations[1]	—	0.24	0.03	1.06	115.53
Net (loss) income per share (basic and diluted)[1]	(1.46)	6.35	(18.14)	(28.06)	23.12
Weighted average number of shares outstanding:[1]					
Basic	6,874,460	653,833	2,763,603	590,247	294,765
Diluted	7,302,816	653,833	3,424,336	590,247	294,765

[1] Adjusted to reflect the November 17, 2015 100-to-1 Share Consolidation

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A. Operating Results

Our operating and financial review and prospects should be read in conjunction with our consolidated financial statements, accompanying notes and other information appearing in this Annual Report.

2015 compared to 2014

Revenues

Revenues were $0.1 million and $0.5 million for the three-month period and the year ended December 31, 2015, respectively, compared to $0.0 million and $6.2 million for the same periods in 2014.

The revenues recorded during the year ended December 31, 2015 resulted primarily from the amortization of a one-time, non-refundable payment made to us in December 2014 in connection with a master collaboration agreement, a technology transfer and technical assistance agreement and a license agreement that we entered into with Sinopharm A-Think Pharmaceuticals Co., Ltd. ("Sinopharm") related to Zoptrex™. We deferred this non-refundable payment and we amortize it on a straightline basis over a four-year period. In addition, we started to generate sales commission in connection with our co-promotion efforts related to EstroGel®, pursuant to the co-promotion services agreement entered into with Ascend.

We expect revenues during the year ended December 31, 2016 to be higher than those recorded during the year ended December 31, 2015 due to the recording of expected higher sales commissions associated with our promotional efforts related to EstroGel® and as we begin to generate sales commissions related to Saizen®, provided that we are able to begin to exceed the pre-established baselines outlined in the related co-marketing agreement, as well as sales commissions related to APIFINY®.

Operating Expenses

R&D costs were $4.2 million and $17.2 million for the three-month period and the year ended December 31, 2015, respectively, compared to $6.3 million and $23.7 million for the same periods in 2014.

The decrease for the three-month period ended December 31, 2015, as compared to the same period in 2014, is attributable to lower comparative third-party costs, as described below, lower employee compensation and benefits costs and lower facilities rent and maintenance costs. A substantial portion of this decrease is due to the realization of cost savings in connection with our effort to streamline our R&D activities and to increase our commercial operations and flexibility by reducing our R&D staff, which was started in 2014 (the "Resource Optimization Program"), for which a provision had been recorded in the third quarter of 2014. In addition, the decrease is also due to the weakening, in 2015, of the EUR against the US dollar, which has appreciated quarter-over-quarter on average by approximately 12.0% from the quarter ended December 31, 2014 to the same period in 2015.

The decrease for the year ended December 31, 2015, as compared to the same period in 2014, is attributable to lower comparative employee compensation and benefits costs, facilities rent and maintenance costs as well as other costs. A substantial portion of this decrease is due to the realization of cost savings in connection with our Resource Optimization Program rolled out in the third quarter of 2014, as well as to the weakening, in 2015, of the EUR against the US dollar, which has appreciated on average by approximately 16.5% from the year ended December 31, 2014 to the same period in 2015. The decrease for the year ended December 31, 2015 was partly offset by higher third-party costs, as described below.

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

	Three-month periods ended December 31,		Years ended December 31,		
(in thousands)	2015	2014	2015	2014	2013
	$	$	$	$	$
Third-party costs	2,899	3,967	11,891	11,356	10,049
Employee compensation and benefits	905	1,231	3,699	8,430 *	7,864
Facilities rent and maintenance	224	887	940	2,160	1,758
Other costs**	231	197	727	1,901	2,130
R&D tax credits and grants	(16)	—	(23)	(131)	(517)
	4,243	6,282	17,234	23,716	21,284

* Includes a provision for restructuring in the amount of $2.2 million.
** Includes depreciation, amortization, impairment charges, loss (gain) on disposal of property, plant and equipment and onerous lease provision recognized.

The following table summarizes primary third-party R&D costs, by product candidate, incurred by the Company during the three-month periods ended December 31, 2015 and 2014.

(in thousands, except percentages)	Three-month periods ended December 31,			
Product Candidate	2015		2014	
	$	%	$	%
Zoptrex™ (zoptarelin doxorubicin)	1,488	51.3	3,609	91.0
Macrilen™ (macimorelin)	977	33.7	192	4.8
Erk inhibitors	71	2.5	112	2.8
LHRH - Disorazol Z	73	2.5	54	1.4
Other	290	10.0	—	—
	2,899	100.0	3,967	100.0

The following table summarizes primary third-party R&D costs, by product candidate, incurred by the Company during the years ended December 31, 2015, 2014 and 2013.

(in thousands, except percentages)	Years ended December 31,					
Product Candidate	2015		2014		2013	
	$	%	$	%	$	%
Zoptrex™ (zoptarelin doxorubicin)	8,635	72.6	9,668	85.1	4,934	49.1
Macrilen™ (macimorelin)	1,555	13.1	404	3.6	1,238	12.3
Erk inhibitors	1,081	9.1	488	4.3	1,128	11.2
LHRH - Disorazol Z	212	1.8	257	2.3	659	6.6
Perifosine	29	0.2	196	1.7	1,134	11.3
Other	379	3.2	343	3.0	956	9.5
	11,891	100.0	11,356	100.0	10,049	100.0

As shown above, a substantial portion of the quarter-to-date and year-to-date third-party R&D costs relates to development initiatives associated with Zoptrex™, and in particular with our pivotal Phase 3 ZoptEC clinical trial initiated in 2013 with Ergomed. Excluding the impact of the foreign exchange rate fluctuations, third-party costs attributable to Zoptrex™ increased slightly during the year ended December 31, 2015, as compared to the same period in 2014, mainly due to a higher comparative number of patients enrolled in the clinical trial, which is now fully enrolled. However, the quarter-over-quarter decrease is explained by the fact that the number of patients in active treatment in the clinical trial was lower in 2015 as compared to the same period in 2014.

During the year ended December 31, 2015, ongoing services provided by Ergomed included the conducting of monitoring visits at various clinical sites, screening and enrollment initiatives, investigation-related management and analysis as well as regulatory and quality assurance support. ZoptEC-related efforts are progressing in accordance with pre-established timelines. As we continue to closely monitor all initiatives supported by Ergomed, we may decide to revise some of the trial's parameters or expand the scope of work performed by Ergomed and, consequently, total estimated costs in connection with the co-development and revenue sharing agreement may be adjusted. To date, our arrangement with Ergomed has been revised following our decision to open additional clinical sites and to perform additional sub-studies, resulting in overall, cumulative cost increases of approximately $2.4 million, as compared to our original expectations. We currently estimate that we will incur approximately $6 million pursuant to our agreement with Ergomed over the next 12 months as we proceed with and complete our ZoptEC trial.

In addition, during the year 2015, we started the new confirmatory Phase 3 clinical trial of Macrilen™, which explains the increase in costs for this product candidate.

Excluding the impact of foreign exchange rate fluctuations, we expect R&D costs for 2016 to increase, as compared to 2015, with the recent initiation of our confirmatory Phase 3 clinical trial for Macrilen™. Based on currently available information and taking into account our more detailed forecasts for the Macrilen™ trial, and excluding the impact of foreign exchange rate fluctuations, we expect that we will incur overall R&D costs of between $19 million and $20 million for the year ended December 31, 2016.

General and administrative ("G&A") expenses were $4.0 million and $11.3 million for the three-month period and the year ended December 31, 2015, respectively, as compared to $2.6 million and $9.8 million for the same periods in 2014. The increase is mainly attributable to the recording of a provision related to our Corporate Restructuring in the fourth quarter of 2015, as well as to the recording of certain transaction costs associated with the completion of the March 2015 Offering and the December 2015 Offering, discussed above.

During 2016, excluding the impact of foreign exchange rate fluctuations and the recording of transaction costs related to potential financing activities (not currently known or estimable), we expect G&A expenses to be lower as compared to 2015, ranging between $6 million and $7 million, because we do not expect to record any restructuring charges in 2016 as we had in 2015.

Selling expenses were $1.8 million and $6.9 million for the three months and the year ended December 31, 2015, respectively, as compared to $2.0 million and $3.9 million for the same periods in 2014.

The decrease in selling expenses for the three-month period ended December 31, 2015 is explained by the start-up costs related to the deployment of our contracted sales force related to the co-promotion activities, which were launched during the fourth quarter of 2014.

The increase in selling expenses for the year ended December 31, 2015 as compared to the same period in 2014 is attributable to the fact that 2014 was not a full year of sales activity. During the third quarter of 2015, we also expanded the size of our contracted sales force from 19 to 21 sales representatives in order to support our promotional efforts associated with Saizen®. This sales force expense will also cover the recently initiated selling in support of APIFINY®.

During 2016, we expect selling expenses to increase slightly to reach a range of between $7 million and $8 million.

Net finance (costs) income are comprised predominantly of the change in fair value of warrant liability and of gains and losses recorded due to changes in foreign currency exchange rates, as presented below.

	Three-month periods ended December 31,		Years ended December 31,		
	2015	2014	2015	2014	2013
	$	$	$	$	$
Finance income					
Change in fair value of warrant liability	3,030	14,079	—	18,272	1,563
Gain associated with the extinguishment of warrant liability	—	—	162	—	—
Gains due to changes in foreign currency exchange rates	—	924	—	1,879	—
Interest income	26	50	143	168	185
	3,056	15,053	305	20,319	1,748
Finance costs					
Change in fair value of warrant liability	—	—	(10,956)	—	—
Warrant exercise inducement fee *	(2,926)	—	(2,926)	—	—
Losses due to changes in foreign currency exchange rates	(315)	—	(1,767)	—	(1,512)
	(3,241)	—	(15,649)	—	(1,512)
	(185)	15,053	(15,344)	20,319	236

*Recorded in connection with the agreement with the Participating Holders, as discussed above.

The change in fair value of our warrant liability results from the periodic "mark-to-market" revaluation, via the application of the intrinsic valuation and the Black-Scholes option pricing model, of currently outstanding share purchase warrants. The "mark-to-market" warrant valuation has been most notably impacted by the issuance of 3.1 million additional share purchase warrants and by the closing price of our common shares, which, on the NASDAQ, has fluctuated from $4.00 to $84.20 during the year ended December 31, 2015, from $52.00 to $150.00 for the same period in 2014 and from $103.00 to $323.00 for the same period in 2013.

With specific reference to 2014, we recorded substantial fair value gains on our warrant liability, resulting from the significant reduction in our share price following our announcement, in November, that the FDA had issued a complete response letter ("CRL") in connection with our new drug application ("NDA") for Macrilen™. The lower closing price of our shares following our announcement of the CRL has resulted in a lower Black-Scholes valuation of our outstanding share purchase warrants during the fourth quarter of 2014.

In 2015, the change in fair value of warrant liability was significantly impacted by the issuance of the Series B Warrants. More than 97% of the Series B Warrants were exercised before the end of the year.

Net (loss) income for the three-month period and the year ended December 31, 2015 was ($10.0) million and ($50.1) million, or ($1.46) and ($(18.14) per basic and diluted share, respectively, compared to $4.2 million and ($16.6) million, or $6.35 and ($28.06) per basic and diluted share for the same periods in 2014.

The increase in our net loss from continuing operations for the three-month period and for the year ended December 31, 2015, as compared to the same period in 2014, is due to the higher comparative G&A and selling expenses and net finance costs, partly offset by lower comparative R&D costs, as presented above.

2014 compared to 2013

Revenues

Revenues recorded during the year ended December 31, 2013 resulted predominantly from the non-recurring, accelerated recognition of remaining unamortized deferred revenue associated with an upfront payment received from a licensee following the termination of related R&D activities.

Operating Expenses

R&D costs were $23.7 million for the year ended December 31, 2014, compared to $21.3 million for the same period in 2013.

The increase for the year ended December 31, 2014, as compared to the same period in 2013, is attributable to higher comparative employee compensation and benefits costs, which in turn are mainly due to the recording of R&D restructuring costs. Following the approval of our aforementioned Resource Optimization Program, we recorded a provision for restructuring costs, amounting to approximately $2.5 million, for severance payments, onerous lease provisions and other directly related costs associated with the Resource Optimization Program. This increase was partly offset by lower comparative salaries and short-term employee benefits and share-based compensation costs.

A substantial portion of the increase in 2013-to-2014 third-party R&D costs relates to development initiatives associated with Zoptrex™, and in particular with our Phase 3 ZoptEC trial initiated in 2013 with Ergomed. This increase was partially offset by the lower comparative development costs associated with most of our other product candidates.

General and administrative ("G&A") expenses were $9.8 million for the year ended December 31, 2014, compared to $11.1 million for the same period in 2013.

For the year ended December 31, 2014, the decrease in G&A expenses, as compared to the same period in 2013, is mainly related to recognition in the second quarter of 2013 of non-recurring termination benefits paid to our former Chief Executive Officer and to the recording of related non-cash based compensation costs, partially offset by the recording of restructuring costs related to administrative staff redundancies resulting from the Resource Optimization Program.

Selling Expenses were $3.9 million for the year ended December 31, 2014 compared to $1.2 million for the same period in 2013.

For the year ended December 31, 2014, the increase in selling expenses, as compared to the same period in 2013, mainly relates to the ramping up of our pre-commercialization activities and the deployment of our contracted sales force related to our co-promotion activities.

Net finance income (costs) are comprised predominantly of the change in fair value of warrant liability and of gains and losses recorded due to changes in foreign currency exchange rates.

The change in fair value of our warrant liability results from the periodic "mark-to-market" revaluation, via the application of the Black-Scholes option pricing model, of currently outstanding share purchase warrants. The Black-Scholes "mark-to-market" warrant valuation most notably has been impacted by the issuance of 8.8 million additional share purchase warrants and by the closing price of our common shares, which, on the NASDAQ, fluctuated from $52.00 to $150.00 during the year ended December 31, 2014 and from $103.00 to $323.00 for the same period in 2013.

With specific reference to 2014, we recorded substantial fair value gains on our warrant liability, resulting from the significant reduction in our share price following our announcement, in November, that the FDA had issued a CRL in connection with our NDA for Macrilen™. The lower closing price of our shares following our announcement of the CRL has resulted in a lower Black-Scholes valuation of our outstanding share purchase warrants during the fourth quarter of 2014.

Gains or losses due to changes in foreign currency exchange rates are mainly related to the US dollar, which strengthened against the EUR by approximately 12.2%, during the twelve-month period ended December 31, 2014. During the twelve-month period ended December 31, 2013, however, the US dollar weakened against the EUR by approximately 4.5%.

Net loss from continuing operations for the year ended December 31, 2014 was $(17.2) million, or $(29.12) per basic and diluted share, compared to $(27.2) million, or $(92.41) per basic and diluted share for the same period in 2013. The decrease in net loss from continuing operations for the year ended December 31, 2014, as compared to the same period in 2013, is due largely to higher comparative net finance income, partly offset by lower comparative license fee revenues and by higher comparative net R&D costs and G&A and selling expenses, as presented above.

Discontinued Operations

Following a strategic review of our risks and prospects with respect to the manufacturing of Cetrotide® and related activities (collectively, the "Cetrotide® Business") and, in particular, having taken into account, as discussed below, the previous monetization of the corresponding royalty stream, we decided to transfer all manufacturing rights of Cetrotide® and to discontinue our involvement with the Cetrotide® Business. On April 3, 2013 (the "Cetrotide® Effective Date"), we entered into a transfer and service agreement ("TSA") and concurrent agreements with various partners and licensees with respect to our manufacturing rights for Cetrotide®, marketed for therapeutic use as part of in vitro fertilization programs. The principal effect of these agreements was to transfer, effective October 1, 2013 (the "Cetrotide®Closing Date"), our manufacturing rights for Cetrotide® to Merck Serono in all territories. Also per the TSA, we agreed to provide certain transition services to Merck Serono over a period of 36 months from the Cetrotide® Effective Date in order to assist Merck Serono in managing overall responsibility for the Cetrotide® Business. Under the TSA, during the period commencing on the Cetrotide® Effective Date and ending on the Cetrotide® Closing Date (the "Cetrotide® Interim Period"), we were obligated to continue to conduct the Cetrotide® Business in the ordinary course in a manner consistent with past practices, subject to certain conditions. Per the TSA, we received a non-refundable, one-time payment of €2.5 million (approximately $3.3 million) in consideration for the transfer of our manufacturing rights referred to above, as well as other payments in exchange for the transfer, also on the Cetrotide® Closing Date, of certain assets, such as inventory and equipment used solely for the manufacture of Cetrotide®. We recognized the non-refundable, one-time payment on the Cetrotide® Closing Date, as we no longer had managerial involvement or effective control over the manufacturing of goods sold through the Cetrotide® Business. We provide the aforementioned transition services to Merck Serono in exchange for a monthly service fee. As a result of the transfer of substantially all of the risks and rewards associated with the Cetrotide® Business on the Cetrotide® Closing Date, the Cetrotide® Business has been classified as a discontinued operation in the consolidated financial statements. As such, relevant amounts in our consolidated statements of comprehensive (loss) income have been retroactively reclassified to reflect the Cetrotide® Business as a discontinued operation.

	Three-month periods ended December 31,		Years ended December 31,		
(in thousands)	2015	2014	2015	2014	2013
	$	$	$	$	$
Revenues					
Sales and royalties	—	—	—	—	63,755
License fees and other*	59	118	331	1,037	4,589
	59	118	331	1,037	68,344
Operating expenses					
Cost of sales	—	—	—	—	30,002
Research and development costs	2	8	31	25	8
General and administrative expenses	—	—	—	1	15
Selling Expenses	32	(48)	215	388	4,264
	34	(40)	246	414	34,289
Net income from discontinued operations	25	158	85	623	34,055

* Includes the non-refundable, one-time payment made by Merck Serono in exchange for the manufacturing rights for Cetrotide®and revenues from certain transition services provided pursuant to the aforementioned agreement.

The decrease in sales and royalties from discontinued operations, in cost of sales from discontinued operations and in selling expenses from discontinued operations during the year ended December 31, 2014, as compared to the same

period in 2013, reflects the fact that we recorded no sales of Cetrotide® and royalties during the year ended December 31, 2014, as compared to the corresponding period of 2013, given that the transfer of the Cetrotide® Business was effective on October 1, 2013.

Net (loss) income

Net (loss) income for the year ended December 31, 2014 was $(16.6) million or $(28.06) per basic and diluted share compared to $6.8 million, or $23.12 per basic and diluted share, for the same period in 2013. The decrease in net income for the year ended December 31, 2014, as compared to the same period in 2013, is due largely to higher loss from operations and to lower net income from discontinued operations, partially offset by higher comparative net finance income.

Quarterly Consolidated Results of Operations Information

(in thousands, except for per share data)	Three-month periods ended			
	December 31, 2015	September 30, 2015	June 30, 2015	March 31, 2015
	$	$	$	$
Revenues	102	173	197	73
Loss from operations	(9,858)	(7,501)	(7,989)	(9,536)
Net loss from continuing operations	(10,043)	(15,401)	(15,148)	(9,636)
Net loss	(10,018)	(15,290)	(15,099)	(9,736)
Net loss per share from continuing operations (basic and diluted)*	(1.46)	(6.71)	(13.69)	(13.45)
Net loss per share (basic and diluted)*	(1.46)	(6.66)	(13.65)	(13.59)

(in thousands, except for per share data)	Three-month periods ended			
	December 31, 2014	September 30, 2014	June 30, 2014	March 31, 2014
		$	$	$
Revenues	11	—	—	—
Loss from operations	(10,947)	(9,843)	(8,410)	(8,195)
Net income (loss) from continuing operations	3,995	(11,629)	(5,249)	(4,304)
Net income (loss)	4,153	(11,337)	(5,024)	(4,356)
Net income (loss) per share from continuing operations (basic and diluted)*	6.11	(19.66)	(9.29)	(7.84)
Net income (loss) per share (basic and diluted)*	6.35	(19.16)	(8.89)	(7.93)

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

Historical quarterly results of operations and net income (loss) from continuing operations cannot be taken as reflective of recurring revenue or expenditure patterns or of predictable trends, largely given the non-recurring nature of certain components of our historical revenues due most notably to the accelerated recognition of upfront payments and to unpredictable quarterly variations attributable to our net finance income (costs), which in turn are comprised of the impact of the periodic "mark-to-market" revaluation of our warrant liability and of foreign exchange gains and losses. Additionally, our net R&D costs historically have varied on a quarter-over-quarter basis due to the ramping up or winding down of potential product candidate activities, which in turn are dependent upon a number of factors that often do not occur on a linear or predictable basis.

Our selling expenses have increased on a quarter-over-quarter basis due to the ramping up of pre-commercialization activities associated with Macrilen™ (prior to the receipt in November 2014 of the CRL from the FDA) and to the deployment of our contracted sales force and managerial staff related to our co-promotion and other commercial activities.

In addition to the items referred to above, our net income (loss) also has been impacted by net variations attributable to the Cetrotide® Business, which, as discussed above, has been presented on a retrospective basis within discontinued

operations.

Consolidated Statement of Financial Position Information

(in thousands)	As at December 31, 2015	2014
	$	$
Cash and cash equivalents[1]	41,450	34,931
Trade and other receivables and other current assets	944	1,286
Restricted cash equivalents	255	760
Property, plant and equipment	256	797
Other non-current assets	8,593	9,661
Total assets	51,498	47,435
Payables and other current liabilities[2]	4,770	7,304
Current portion of deferred revenues	244	270
Warrant liability (current and non-current portions)	10,891	8,225
Non-financial non-current liabilities[3]	13,978	17,152
Total liabilities	29,883	32,951
Shareholders' equity	21,615	14,484
Total liabilities and shareholders' equity	51,498	47,435

[1] Of which approximately $1.5 million was denominated in EUR as of December 31, 2015 ($3.6 million as of December 31, 2014).

[2] Of which approximately $0.6 million is related to a provision for restructuring costs as of December 31, 2015 ($1.5 million as of December 31, 2014).

[3] Comprised mainly of employee future benefits, provisions for onerous contracts and non-current portion of deferred revenues.

The increase in cash and cash equivalents as at December 31, 2015, as compared to December 31, 2014, is due to the receipt of aggregate net proceeds of $49.4 million in connection with the March 2015 Offering and the December 2015 Offering, as well as of the proceeds from the disposal of property, plant and equipment and the decrease in restricted cash equivalents, both of which were related to our Resource Optimization Program. This increase was partially offset by the variations in components of our working capital and to net cash used in operating activities, as well as to the effect of exchange rate fluctuations. We also paid $8.6 million in connection with warrant amendment agreements and a warrant exercise inducement fee, as discussed above.

The decrease in trade and other receivables and other current assets as at December 31, 2015, as compared to December 31, 2014, is mainly due to lower accounts receivable related to Canadian sites for our ZoptEC trial.

The decrease in other non-current assets, which consist mainly of goodwill, as at December 31, 2015, as compared to December 31, 2014, is primarily due to the lower comparative exchange rate of the EUR against the US dollar, which weakened from December 31, 2014 to December 31, 2015.

The decrease in payables and other current liabilities as at December 31, 2015, as compared to December 31, 2014, is due to the recording of a provision for restructuring costs related to the Resource Optimization Program in Q3-2014, discussed above.

Our warrant liability increased from December 31, 2014 to December 31, 2015. The increase is due to net fair value revaluation losses of $11.0 million, which were recorded pursuant to our periodic "mark-to-market" revaluation of the underlying outstanding share purchase warrants, as discussed above and by the issuance of 3.1 million additional share purchase warrants in connection with the March and December 2015 Offerings, which initially had increased our warrant liability by $28.7 million. Those increases were partly offset by the derecognition of part of the warrant liability due to early expiry as well as to the exercise of warrants for a total of $37.0 million.

Non-financial non-current liabilities decreased largely as a result of a change in discount rate underlying the calculation of the employee future benefit obligation.

The decrease in shareholders' equity as at December 31, 2015, as compared to December 31, 2014, is mainly attributable to the increase in our deficit due to the recording of net loss, partly offset by the increase in our share

capital following the issuance of common shares and warrants discussed above.

Outstanding Share Data

As at March 29, 2016, we had 9,928,697 common shares issued and outstanding, as well as 275,041 stock options outstanding. Warrants outstanding as at March 29, 2016 represented a total of 2,842,309 equivalent common shares (excluding any exercises of Series B Warrants under the alternate cashless exercise feature of such warrants).

Recent Accounting Pronouncements

Not yet adopted

Annual improvements to IFRS (2012-2014) cycle: On September 25, 2014 the IASB issued narrow-scope amendments to a total of four standards as part of its annual improvements process. The amendments will apply for annual periods beginning on or after January 1, 2016. Amendments were made to clarify the following in their respective standards:

- Changes in method for disposal under IFRS 5, Non-current Assets Held for Sale and Discontinued Operations ("IFRS 5");
- Continuing involvement for servicing contracts and offsetting disclosures in condensed interim financial statements under IFRS 7, Financial Instruments: Disclosures (“IFRS 7”);
- Discount rate in a regional market sharing the same currency under International Accounting Standard ("IAS") 19, Employee Benefits;
- Disclosure of information "elsewhere in the interim financial reports" under IAS 34, Interim Financial Reporting;

We are currently assessing the impact that these amendments may have on our consolidated financial statements.

The final version of IFRS 9, Financial Instruments ("IFRS 9"), was issued by the IASB in July 2014 and will replace IAS 39, Financial Instruments: Recognition and Measurement ("IAS 39"). IFRS 9 introduces a model for classification and measurement, a single, forward-looking expected loss impairment model and a substantially reformed approach to hedge accounting. The new single, principle-based approach for determining the classification of financial assets is driven by cash flow characteristics and the business model in which an asset is held. The new model also results in a single impairment model being applied to all financial instruments, which will require more timely recognition of expected credit losses. It also includes changes in respect of an entity's own credit risk in measuring liabilities elected to be measured at fair value, so that gains caused by the deterioration of an entity's own credit risk on such liabilities are no longer recognized in profit or loss. IFRS 9, which is to be applied retrospectively, is effective for annual periods beginning on or after January 1, 2018 and is available for early adoption. In addition, an entity's own credit risk changes can be applied early in isolation without otherwise changing the accounting for financial instruments. In addition, there are amendments to IFRS 7 which require additional disclosures on transition from IAS 39 to IFRS 9. These amendments are effective upon adoption of IFRS 9. We are currently assessing the impact, if any, that these new standards will have on our consolidated financial statements.

In May 2014, the IASB issued IFRS 15, Revenue from Contracts with Customers ("IFRS 15"). The objective of this new standard is to provide a single, comprehensive revenue recognition framework for all contracts with customers to improve comparability of financial statements of companies globally. This new standard contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to receive in exchange for those goods or services. This new standard is effective for annual periods beginning on or after January 1, 2018, with early adoption permitted. We are currently assessing the impact that this new standard may have on our consolidated financial statements.

In January 2016, the IASB issued IFRS 16, Leases ("IFRS 16"), which supersedes IAS 17, Leases, and the related interpretations on leases: IFRIC 4, Determining Whether an Arrangement Contains a Lease; Standard Interpretations Committee ("SIC") 15, Operating Leases - Incentives; and SIC 27, Evaluating the Substance of Transactions in the Legal Form of a Lease. IFRS 16 is effective for annual periods beginning on or after January 1, 2019, with earlier adoption permitted for companies that also apply IFRS 15. We are currently assessing the impact that this new standard may have on our consolidated financial statements.

B. Liquidity and capital resources

Our operations and capital expenditures have been financed through certain transactions impacting our cash flows from operating activities, public equity offerings, as well as from the drawdowns under various ATM programs. Based on our assessment, which took into account current cash levels, as well as our strategic plan and corresponding budgets and forecasts, we believe that we have sufficient liquidity and financial resources to fund planned expenditures and other working

capital needs for at least, but not limited to, the 12-month period following the statement of financial position date of December 31, 2015.

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

The variations in our cash and cash equivalents by activity are explained below.

(in thousands)	Three-month periods ended December 31,		Years ended December 31,		
	2015 $	2014 $	2015 $	2014 $	2013 $
Cash and cash equivalents - Beginning of period	38,345	41,952	34,931	43,202	39,521
Cash flows from operating activities:					
Cash used in operating activities from continuing operations	(8,419)	(8,676)	(33,929)	(30,787)	(30,131)
Cash provided by (used in) operating activities from discontinued operations	25	93	85	(295)	10,147
	(8,394)	(8,583)	(33,844)	(31,082)	(19,984)
Cash flows from financing activities:					
Net proceeds from issuance of common shares and warrants	14,987	2,075	49,427	24,358	23,708
Payment pursuant to warrant amendment agreements and Series B Warrant exercise inducement fee	(2,926)	—	(8,629)	—	—
	12,061	2,075	40,798	24,358	23,708
Cash flows from investing activities:					
Net cash (used in) provided by investing activities from continuing operations	(6)	(4)	913	(61)	(85)
Net cash provided by investing activities from discontinued operations	—	—	—	—	113
	(6)	(4)	913	(61)	28
Effect of exchange rate changes on cash and cash equivalents	(556)	(509)	(1,348)	(1,486)	(71)
Cash and cash equivalents - End of period	41,450	34,931	41,450	34,931	43,202

Operating Activities

2015 compared to 2014

Cash flows used in operating activities were $8.4 million and $33.8 million for the three-month period and the year ended December 31, 2015, respectively, compared to $8.6 million and $31.1 million for the same periods in 2014. The increase in cash used in operating activities for the year ended December 31, 2015, as compared to the same period in 2014, is mainly due to higher trade accounts payable settlements and higher payments in connection with the aforementioned restructuring programs.

We expect net cash used in operating activities to range from $30 million to $32 million for the year ended December 31, 2016, mainly as we continue to invest in our Zoptrex™ and Macrilen™ Phase 3 programs and related sub-studies and as we generate higher revenues in connection with the promotion of Estrogel®, Saizen® and APIFINY®. This guidance may vary significantly in future periods, most notably as we monitor our progress with regard to our co-promotion activities and in light of ongoing business development initiatives, as discussed further below.

2014 compared to 2013

Cash flows used in operating activities were $31.1 million and $20.0 million for the years ended December 31, 2014 and 2013, respectively. The significant increase in cash used in operating activities for the year ended December 31, 2014 as compared to the same period in 2013 is mainly due to the variations associated with our discontinued operations, following the transfer of the Cetrotide® Business in the fourth quarter of 2013, as discussed above.

Financing Activities

2015 compared to 2014

Cash flows provided by financing activities were $12.1 million and $40.8 million for the three-month period and the year ended December 31, 2015, respectively, compared to $2.1 million and $24.4 million for the same periods in 2014. The increase for the three-month period and year ended December 31, 2015, as compared to the same period in 2014 is mainly due to higher net proceeds received from the issuance of common shares and warrants.

Critical Accounting Policies, Estimates and Judgments

Our consolidated financial statements as at December 31, 2015 and December 31, 2014 and for the years ended December 31, 2015, 2014 and 2013 have been prepared in accordance with IFRS as issued by the IASB.

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

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

A summary of those critical accounting estimates and assumptions, as well as critical judgments used in applying accounting policies in the preparation of our consolidated financial statements, can be found in note 3 to our consolidated financial statements as at December 31, 2015 and December 31, 2014 and for the years ended December 31, 2015, 2014 and 2013.

Capital Disclosures

Our objective in managing capital, consisting of shareholders' equity, with cash and cash equivalents and restricted cash equivalents being its primary components, is to ensure sufficient liquidity to fund R&D costs, selling expenses, general and administrative expenses, working capital and capital expenditures.

Over the past several years, we have increasingly raised capital via public equity offerings and drawdowns under various ATM sales programs as our primary source of liquidity.

Our capital management objective remains the same as that in previous periods. The policy on dividends is to retain cash to keep funds available to finance the activities required to advance our product development portfolio and to pursue appropriate commercial opportunities as they may arise. We are not subject to any capital requirements imposed by any regulators or by any other external source.

C. Research and development, patents and licenses, etc.

For a description of our R&D policies for the last three years, see "Item 4B. Business Overview" and "Recent Developments" at the beginning of this Item 5.

D. Trend Information

Outlook for 2016

Clinical Activities

Zoptrex™

With the recent DSMB recommendation that the pivotal Phase 3 ZoptEC study in women with advanced, recurrent, or metastatic endometrial cancer continue as planned, we are expanding our commercialization planning for Zoptrex™. Our commercialization efforts will focus on the development of a scientific platform, the identification of key opinion leaders and the expansion of market research initiatives. We expect to complete the ZoptEC trial during the third quarter of 2016 and, if the results of the trial warrant doing so, to file the NDA for Zoptrex™ in 2017, looking toward commercial launch of the product in 2018, assuming positive Phase 3 results and that our NDA is granted.

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Macrilen™
We will focus on patient recruitment for the confirmatory Phase 3 trial in AGHD. We also initiated the QT study. We currently estimate that the trials will be completed in Q3 of 2016, with a combined expected expenditure of approximately $5 million over the remaining trial period. This would permit us to submit a NDA by mid-year 2017. If the study is successful in meeting its primary endpoint, we anticipate FDA approval of Macrilen™ by year-end 2017.
Commercial Operations

EstroGel®

Our promotional efforts in support of EstroGel® continue to demonstrate positive promotional response, and ongoing activities by our contract sales force are expected to continue to result in exceeding pre-established baseline thresholds for unit sales in our US territories. We expect steady incremental growth of EstroGel prescriptions by competitively targeting high-volume transdermal prescriber's, expanding our total prescriber base and increasing usage with our current high prescriber's. For the remainder of 2016, we anticipate continued year-over-year growth of new and total prescriptions.

Saizen®

During the third quarter of 2015, we initiated promotional efforts in support of Saizen®. We recognize the value of direct promotion in the category of growth hormone treatments, and our objective is to exceed pre-established baselines on a total nation basis by significantly increasing the share-of-voice in support of this product in territories not previously covered by EMD Serono. There are now 21 representatives actively promoting Saizen® in conjunction with our promotion of EstroGel®.

APIFINY®

During the fourth quarter of 2015, we signed a co-marketing agreement with Armune. We already started promotional efforts using our existing contracted sales force, and we expect to commence generating commission revenues in the first quarter of 2016.

Summary of key expectations for revenues, operating expenditures and cash flows
As noted above, we expect to continue to record commissions revenue in connection with our co-promotion agreement for EstroGel® and to begin to record commissions revenues in relation to our promotional services agreement for Saizen® and with our co-marketing agreement with Armune. As for license fee revenues, we will continue to recognize the amortization of deferred revenues related to the agreements we entered into with Sinopharm in 2014, as mentioned above.
As noted above, our main focus for R&D efforts will be on Zoptrex™, with the ongoing pivotal Phase 3 ZoptEC clinical trial, as well as on Macrilen™ with the initiated confirmatory Phase 3 clinical trial and the QT study, where we continue to anticipate substantial investment to fund ongoing development initiatives. More specifically, we currently estimate that we will incur approximately $11 million pursuant to our agreements with Ergomed over the next 12 months as we complete our QT study and our confirmatory Phase 3 clinical trial for Macrilen™ and as we proceed with and complete our ZoptEC trial.
As discussed above, excluding the impact of foreign exchange rate fluctuations, we expect that we will incur R&D costs of between $19 million and $20 million for the year ended December 31, 2016.
We expect that selling expenses will slightly increase for the year ended December 31, 2016, as compared to the year ended December 31, 2015, mainly due to our increased promotional activities associated with Saizen® and APIFINY®.
Excluding the impact of foreign exchange rate fluctuations, we expect that our G&A expenses will be lower for the year ended December 31, 2016, as compared to the year ended December 31, 2015, mainly due to the aforementioned

recording of transaction costs in connection with our public offerings completed in March and December 2015 and to the recording of a provision for restructuring in connection to the closure of our Quebec City office during the fourth quarter of 2015.

Excluding any foreign exchange impacts, as well as income from new business development initiatives, we expect that our overall use of cash for operations in 2016 will range from $30 million to $32 million as we continue to fund ongoing operating activities and working capital requirements.

The preceding summary with regard to our revenue, operating expenditure and cash flow expectations excludes any consideration of any potential strategic commercial initiatives that may be consummated in connection with our efforts to expand our commercial operations in the US or elsewhere. In addition, these expectations may be materially impacted by our expected growth in sales

commission. As such, the guidance presented in this MD&A is subject to revision based on new information that is not currently known or available.

Financial Risk Factors and Other Instruments

Fair value risk

As noted above, the change in our warrant liability, which is measured at fair value through profit or loss, results from the periodic "mark-to-market" revaluation, via the application of the intrinsic valuation and the Black-Scholes option pricing model, of currently outstanding share purchase warrants. These valuation models are impacted, among other inputs, by the market price of our common shares. As a result, the change in fair value of the warrant liability, which is reported as finance income (cost) in our consolidated statements of comprehensive income (loss), has been and may continue in future periods to be materially affected by changes in our common share closing price, which has ranged from $4.00 to $84.20 on the NASDAQ during the year ended December 31, 2015.

If variations in the market price of our common shares of -10% and +10% were to occur, the impact on our net loss for the warrant liability held at December 31, 2015 would be as follows:

(in thousands)	Carrying amount	-10%	+10%
	$	$	$
Warrant liability	10,891	1,059	(1,067)
Total impact on net loss – decrease / (increase)		1,059	(1,067)

Liquidity risk

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

We believe that we have sufficient funds to pay our ongoing general and administrative expenses, to pursue our R&D activities and to meet our obligations and existing commitments as they fall due at least through December 31, 2016. In making this assessment, we took into account all available information about the future, which is at least, but not limited to, twelve months from the end of the most recent reporting period. We expect to continue to incur operating losses and may require significant capital to fulfill our future obligations. Our ability to continue future operations beyond December 31, 2016 and to fund our activities is dependent on our ability to secure additional funding, which may be completed in a number of ways, including but not limited to licensing arrangements, partnerships, share and other security issuances and other financing activities. We will pursue such additional sources of financing when required, and while we have been successful in securing financing in the past, there can be no assurance we will be able to do so in the future or that these sources of funding or initiatives will be available for the Company or that they will be available on terms which are acceptable to us.

Credit risk

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

As at December 31, 2015, trade accounts receivable for an amount of approximately $122,000 were with two counterparties and no trade accounts receivable were past due or impaired.

Generally, we do not require collateral or other security from customers for trade accounts receivable; however, credit is extended following an evaluation of creditworthiness. In addition, we perform ongoing credit reviews of all our

customers and establish an allowance for doubtful accounts when accounts are determined to be uncollectible.

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

E. Off-Balance sheet arrangements

As at December 31, 2015, we did not have any interests in special purpose entities or any other off-balance sheet arrangements.

F. Tabular disclosure of contractual obligations

Financial Liabilities, Obligations and Commitments

We have certain contractual lease obligation commitments as well as other long-term obligations related to unfunded pension plan benefits and unfunded post-employment benefit plans. The following tables summarize future cash requirements with respect to these obligations.

Expected future minimum lease payments which also include future payments in connection with utility service agreements and future minimum sublease receipts under non-cancellable operating leases (subleases), as well as future payments in connection with service and manufacturing agreements, as at December 31, 2015 are as follows:

(in thousands)	Minimum lease payments	Minimum sublease receipts	Service and manufacturing
	$	$	$
Less than 1 year	1,367	(385)	639
1 - 3 years	2,394	(487)	370
4 - 5 years	1,837	(23)	—
More than 5 years	286	—	—
Total	5,884	(895)	1,009

During the third quarter of 2015, our lease agreement in Germany for laboratory, office, and storage space was terminated, and we entered into a new lease agreement for the rental of less space on the same premises as compared to our former arrangement. The new lease expires on April 30, 2021 and is subject to renewal upon notice by us for two additional four-year periods. Under the terms of the arrangement, the minimum lease payment may be increased or decreased in accordance with the fluctuations in the German consumer price index up to 5% on a cumulative basis.

In accordance with the assumptions used in our employee future benefit obligation calculation as at December 31, 2015, undiscounted benefits expected to be paid are as follows:

(in thousands)	$
Less than 1 year	453
1 – 3 years	944
4 – 5 years	1,016
More than 5 years	17,439
Total	19,852

Item 6. Directors, Senior Management and Employees

A. Directors and senior management

The following table sets forth information about our directors and our senior corporate officers as at March 29, 2016:

Name and Place of Residence	Position with Aeterna Zentaris
Cardiff, Michael Ontario, Canada	Director
Dinges, Jude Georgia, United States	Senior Vice President and Chief Commercial Officer
Dodd, David A. South Carolina, United States	Chairman, President and Chief Executive Officer
Egbert, Carolyn Texas, United States	Director
Ernst, Juergen North Rhine-Westphalia, Germany	Lead Independent Director
Guenther, Eckhard Hessen, Germany	Vice President, Business Development
Lapalme, Pierre Quebec, Canada	Director
Lemaire, Geneviève Quebec, Canada	Vice President, Finance and Chief Accounting Officer
Limoges, Gérard Quebec, Canada	Director
Newport, Ken Ontario, Canada	Director
Sachse, Richard Baden-Württemberg, Germany	Senior Vice President, Chief Scientific Officer/Chief Medical Officer
Teifel, Michael Hessen, Germany	Vice President, Pre-Clinical Development
Theodore, Philip A. South Carolina, United States	Senior Vice President, Chief Administrative Officer, General Counsel and Corporate Secretary

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

Michael Cardiff was appointed to our Board of Directors on January 29, 2016. He was most recently Global Senior Vice President for the Office of the CFO Business Unit at INFOR, a $3 billion revenue software company. His business unit included software for financials, payroll, human resources, performance management, business improvement, planning and forecasting, compliance and risk management. Prior to holding that position, Mr. Cardiff held numerous senior positions in a number of technology companies, including large multinationals such as EDS, SAP and IBM, as well as startup companies such as Fincentric, Convergent Technologies, Tandem, and Stratus Computer. Mr. Cardiff is currently a director of Hydrogenics Corporation (NASDAQ: HYGS; TSX: HYG), and Startech.Com. Mr. Cardiff has also served as a director of other publicly traded companies, including Husky Injection Molding, Descartes Systems Group, Visible Genetics and Burntsand Inc. He has also been a director of private companies, including Solcorp, Spectra Security Software and Visible Decisions and not-for-profot organizations such as The Toronto Film Festival, Roy Thomson Hall and Medic Alert Foundation. Mr. Cardiff is a member of, and holds the ICD.D designation from, the Institute of Corporate Directors.

Jude Dinges was appointed our Senior Vice President and Chief Commercial Officer in November 2013. He began his career nearly 30 years ago as a professional sales representative at Bristol Laboratories and later at Merck & Co., where he was promoted to positions with increased responsibilities in training, sales, management, marketing and market development. While at Merck, Mr. Dinges won multiple awards, including the President's Achievement Award in 2001, awarded to one of 32 Business Directors each year. He received the Change Agent Award for his market development prelaunch business planning and contributions to sales force execution, while launching the blockbuster brands Cozaar®, Fosamax®, Singulair®, Maxalt®, Vioxx®, and Vytorin®. He was recognized with a Career Achievement Award for his consistent top performance as a Senior/Executive Business Director. Mr. Dinges joined Novartis Pharmaceuticals in 2006 and led his region to top performance in the launch of Tekturna® while balancing a broad antihypertensive portfolio across several Novartis divisions. His region also led the nation in market share for Exelon® and Exelon Patch®. In 2008, Mr. Dinges became the Respiratory & Infectious Disease Specialty Medicines Director. In 2009, Mr. Dinges joined Amgen Inc. as Executive Director of Region Sales, Bone Health Business Unit. Mr. Dinges led his region team to a highly successful launch of monoclonal antibody, Prolia®, across the southeastern United States and Puerto Rico.

David A. Dodd was appointed our President and Chief Executive Officer in April 2013 and then assumed the position of Chairman of the Board in May 2014. Mr. Dodd's executive management experience in the pharmaceutical and biotechnology industries spans more than 35 years. Prior to joining Aeterna Zentaris, Mr. Dodd was President and CEO of Solvay Pharmaceuticals, Inc. During his six-year tenure as President, CEO and director of Serologicals Corporation, the market value of the company increased from $85 million in June 2000 to an all-cash sale to Millipore Corporation in July 2006 for $1.5 billion. He was also President, CEO and Chairman of BioReliance Corporation, a leading provider of biological safety and related testing services. Prior to that, Mr. Dodd held various senior management positions at Wyeth-Ayerst Laboratories, the Mead Johnson Laboratories Division at Bristol-Myers Squibb, and Abbott Laboratories. Mr. Dodd holds a Master of Science degree from Georgia State University, and he has completed the Harvard Business School Advanced Management Program.

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

Georgetown University Medical School at Washington, D.C. and Northwestern University Medical School at Chicago, Illinois. She remains an active member of both the Michigan State Bar and the District of Columbia Bar, Washington, D.C.

Juergen Ernst has served as a director on our Board since 2005. As the former General Manager of the Pharmaceutical Sector of Solvay S.A. (international chemical and pharmaceutical group), Mr. Ernst has had extensive senior management experience, where, among other functions, he oversaw the human resources department. Mr. Ernst is also a member of the Board of Directors of Pharming Group N.V., a publicly traded biotechnology company based in the Netherlands.

Eckhard Günther was appointed as our Vice President, Business Development in October 2014. He serves as one of our executive officers. From 2008 through 2014, he was our Vice President, Alliance Management and Intellectual Property and from 2006 through 2008, he was our Vice President, Head of Drug Discovery and Preclinical Development. Dr. Günther, who is based in the Frankfurt, Germany, office of our German subsidiary, began his career in the pharmaceutical industry in 1985. He joined ASTA Medica AG, a predecessor of our Company, in 1990, assuming roles of increasing responsibility in areas of medicinal

chemistry and drug discovery during his career. He possesses numerous scientific and business skills and has a long record of successful innovation and alliance building and management. Dr. Günther obtained a diploma in Chemistry from the Martin-Luther-University of Halle-Wittenberg in 1979 and was awarded his doctorate diploma in synthetic organic chemistry by the University of Halle-Wittenberg in 1985.

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

Geneviève Lemaire was appointed our interim Corporate Controller in August 2015 and subsequently our Vice President, Finance and Chief Accountant Officer in February 2016. Ms. Lemaire, who is based in Quebec City, Canada is serving us on a contract basis. She has worked in various accounting and audit functions for Ernst & Young in Canada and Switzerland from 1997 until 2012 and in senior finance and accounting functions at Atrium Innovations from 2012 until 2014. Since then, Ms. Lemaire serves as an independent consultant. Ms. Lemaire is a chartered professional accountant in Canada and Certified Public Accountant, registered in the State of Illinois, and holds a Bachelor's degree in Accountancy from the University of Sherbrooke.

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

Ken Newport was appointed to our Board of Directors on January 29, 2016. He is a chartered accountant, entrepreneur and life-sciences business executive and served as Senior Vice-President and Executive Committee member at PRA International Inc. for three years until his retirement in 2005. He was co-founder and President of CroMedica Inc., a clinical trials contract research organization, which was sold to PRA International in 2002. Mr. Newport was also a founding member of Global Biomedical Capital Corporation, Zelos Therapeutics Inc., Prime Trials Inc. and other life sciences organizations. He has served or serves on the corporate Boards of Nordion Inc., Opmedic Group Inc., Jennerex Inc. and Medgenesis Therapeutics Inc. He sits on several non-profit boards, including his role as Chair of the BioCanRx, the National Centre of Excellence for Biotherapeutics cancer research.

Richard Sachse was appointed our Senior Vice President and Chief Scientific Officer in January 2014. In March 2014, he was also appointed Chief Medical Officer. Dr. Sachse holds a degree in medicine from the Friedrich-Alexander-University Erlangen, in Germany, and a board certification in Clinical Pharmacology. With more than 20 years' experience as a physician and scientist, he has extensive expertise in a variety of different therapeutic areas, including endocrinology and oncology. In addition to registration studies, he is especially experienced in the design and implementation of translational programs to bridge research programs to the clinic, as well as in the design and implementation of clinical pharmacology programs, including all required profiling studies and activities, enabling successful registration of products at the international level. From 1996 to 2000, he was International Project Leader at the Bayer AG Institute for Clinical Pharmacology, and Principal Investigator at the Bayer Clinical Pharmacology Unit, implementing innovative exploratory development tools, including biomarkers to demonstrate early Proof of Concept. From 2001 to 2006, Dr. Sachse held a variety of different management positions within early and late phase clinical

development programs, including responsibilities for completed Phase 3 programs leading to successful NDA/MAA submissions. In 2007, after a merger, he became Senior Director, Head of Experimental Medicine, at UCB in Belgium, where he managed the implementation of novel biomarkers in clinical development to provide data supporting identification of appropriate target indication and target population. In 2010, Dr. Sachse became Vice President, Head of Global Translational Medicine at Boehringer Ingelheim.

Michael Teifel became our Vice President, Non-Clinical Sciences in October 2014. He joined our German subsidiary, which is based in Frankfurt, in 2004, where he has been involved in a number of roles focused on the design and implementation of non-clinical development programs for small molecule drugs, targeted therapies and biologics. He serves as one of our executive officers. Prior to joining us, Dr. Teifel co-founded Munich Biotech AG, which developed anti-tumor diagnostics and therapeutics, from 1998 through August 2004. Prior to founding Munich Biotech AG, Dr. Teifel was employed by Boehringer Mannheim GmbH/Roche Diagnostics GmbH where his focus was on gene therapy. He received his diploma in biology from the Technical University Darmstadt in 1992 and his doctorate from the same institution in 1996.

Philip A. Theodore was appointed our Senior Vice President, Chief Administrative Officer and General Counsel and Corporate Secretary in October 2014. Prior to joining us, he was the Vice President, General Counsel and Corporate Secretary of Zep Inc., a consumable chemical packaged goods company based in Atlanta, Georgia, from July 2010 through September 2014; the Vice President of Corporate Development, Compliance, and Legal for BioReliance, Inc., a provider of biologics-safety-testing services based in Rockville, Maryland, from September 2008 to April 2009; the Senior Vice President and General Counsel of John H. Harland Company, a financial services company based in Atlanta, Georgia, from September 2006 to September 2007; and the Vice President, General Counsel and Corporate Secretary of Serologicals Corporation, a life-sciences tools company based in Atlanta, Georgia, from 2004 through August 2006. Mr. Theodore also served as a partner in the corporate practice of King & Spalding, LLP, an Atlanta-based law firm, from 1986 through 2003.

B. Compensation

Our directors and executive officers are generally paid in their home country's currency. Unless otherwise indicated, all directors' and executive's compensation information included in this document is presented in US dollars and, to the extent a director or officer has been paid in a currency other than US dollars (i.e. Canadian dollars or euros), the amounts have been converted from such person's home country currency to US dollars based on the following average exchange rates: for the financial year ended December 31, 2015: €1.000 = US$1.110 and CAN$1.000 = US$0.783; for the financial year ended December 31, 2014: €1.000 = US$1.329 and CAN$1.000 = US$0.905; and for the financial year ended December 31, 2013: €1.000 = US$1.329 and CAN$1.000 = US$0.971.

1. Compensation of Outside Directors

The compensation paid to members of our Board of Directors who are not our employees (our "Outside Directors") is designed to (i) attract and retain the most qualified people to serve on the Board and its committees, (ii) align the interests of the Outside Directors with those of our shareholders, and (iii) provide appropriate compensation for the risks and responsibilities related to being an effective Outside Director. This compensation is recommended to the Board by the Nominating, Governance and Compensation Committee (the "Compensation Committee") of the Board. The Compensation Committee is composed of three Outside Directors, each of whom is independent, namely Ms. Carolyn Egbert (Chair), Mr. Gérard Limoges and Mr. Pierre Lapalme.

Annual Retainers and Attendance Fees

Our Outside Directors are paid an annual retainer, the amount of which depends on the position held on the Board, and attendance fees. Annual retainers and attendance fees are paid on a quarterly basis to our Outside Directors on the following basis:

Type of Compensation	Annual Compensation for the year 2015 (in units of home country currency)
Lead Director Retainer	65,000
Board Member Retainer	15,000

Board Meeting Attendance Fees	1,000 per meeting
Audit Committee Chair Retainer	15,000
Audit Committee Member Retainer	4,000
Audit Committee Meeting Attendance Fees	1,000 per meeting
Compensation Committee Chair Retainer	12,000
Compensation Committee Member Retainer	2,000
Compensation Committee Meeting Attendance Fees	1,000 per meeting

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

Outstanding Option-Based Awards and Share-Based Awards

The following table shows all awards outstanding to each Outside Director up to the end of the financial year ending and as at December 31, 2015:

	Option-based Awards					Share-based Awards		
Name	Issuance Date	Number of Securities Underlying Unexercised Options[1]	Option Exercise Price	Option Expiration Date	Value of Unexercised In-the-money Options[2]	Issuance Date	Number of Shares or Units of Shares that have Not Vested	Market or Payout Value of Share-based Awards that have Not Vested
	(mm-dd-yyyy)	(#)	(CAN$ or $)	(mm-dd-yyyy)	(CAN$ or $)	(mm-dd-yyyy)	(#)	($)
Egbert, Carolyn	12/06/2012	75	$217.00	12/05/2022	—	—	—	—
	05/08/2013	50	$186.00	05/07/2023	—	—	—	—
	11/27/2013	250	$112.00	11/26/2023	—	—	—	—
	05/09/2014	600	$107.00	05/08/2021	—	—	—	—
	05/08/2015	600	$52.50	05/07/2022	—	—	—	—
Ernst, Juergen	01/04/2007	8	CAN$2,790.00	01/03/2017	—	—	—	—
	12/11/2007	41	CAN$1,092.00	12/10/2017	—	—	—	—
	11/14/2008	166	CAN$390.00	11/13/2018	—	—	—	—
	12/08/2008	25	CAN$330.00	12/08/2018	—	—	—	—
	12/09/2009	33	CAN$570.00	12/08/2019	—	—	—	—
	12/08/2010	50	CAN$912.00	12/07/2020	—	—	—	—
	12/07/2011	83	$1,044.00	12/06/2021	—	—	—	—
	05/09/2012	100	$354.00	05/08/2022	—	—	—	—
	05/08/2013	50	$186.00	05/07/2023	—	—	—	—
	11/27/2013	250	$112.00	11/26/2023	—	—	—	—
	05/09/2014	600	$107.00	05/08/2021	—	—	—	—
	05/08/2015	600	$52.50	05/07/2022	—	—	—	—
Lapalme, Pierre	12/09/2009	33	CAN$570.00	12/08/2019	—	—	—	—
	12/08/2010	50	CAN$912.00	12/07/2020	—	—	—	—
	12/07/2011	83	$1,044.00	12/06/2021	—	—	—	—
	05/09/2012	100	$354.00	05/08/2022	—	—	—	—
	05/08/2013	50	$186.00	05/07/2023	—	—	—	—
	11/27/2013	250	$112.00	11/26/2023	—	—	—	—
	05/09/2014	600	$107.00	05/08/2021	—	—	—	—
	05/08/2015	600	$52.50	05/07/2022	—	—	—	—
Limoges, Gérard	01/04/2007	8	CAN$2,790.00	01/03/2017	—	—	—	—
	12/11/2007	41	CAN$1,092.00	12/10/2017	—	—	—	—
	12/08/2008	25	CAN$330.00	12/08/2018	—	—	—	—
	12/09/2009	33	CAN$570.00	12/08/2019	—	—	—	—
	12/08/2010	50	CAN$912.00	12/07/2020	—	—	—	—
	12/07/2011	83	$1,044.00	12/06/2021	—	—	—	—
	05/09/2012	100	$354.00	05/08/2022	—	—	—	—

05/08/2013	50	$186.00	05/07/2023	—	—	—	—
11/27/2013	250	$112.00	11/26/2023	—	—	—	—
05/09/2014	600	$107.00	05/08/2021	—	—	—	—
05/08/2015	600	$52.50	05/07/2022	—	—	—	—

(1) The number of securities underlying unexercised options represents all awards outstanding as at December 31, 2015. Awards that were issued before November 17, 2015 have been adjusted to reflect and give effect to the 100-for-1 reverse stock split (or share consolidation) that occurred on that date.

(2) "Value of unexercised in-the-money options" at financial year-end is calculated based on the difference between the closing prices of the Common Shares on the NASDAQ or the TSX, as applicable, on the last trading day of the fiscal year (December 31, 2015) of $4.48 and CAN$6.19, respectively, and the exercise price of the options, multiplied by the number of unexercised options.

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

Total Compensation of Outside Directors

The table below summarizes the total compensation paid to our Outside Directors during the financial year ended December 31, 2015 (all amounts are in US dollars). Our Outside Directors are paid in their home currency, which is the Canadian dollar for all Outside Directors other than Ms. Egbert, who is paid in US dollars, and Mr. Ernst, who is paid in euros.

Name	Fees earned ($)		Share-based Awards	Option-based Awards[1]	Non-Equity Incentive Plan Compensation	Pension Value	All Other Compensation[2]	Total
	Retainer	Attendance	($)	($)	($)	($)	($)	($)
Aubut, Marcel[3]	8,809	3,915	—	25,200	—	—	—	37,924
Dorais, José[4]	5,827	4,307	—	—	—	—	—	10,134
Egbert, Carolyn	29,593	14,500	—	25,200	—	—	1,000	70,293
Ernst, Juergen	63,473	12,205	—	25,200	—	—	51,862	152,740
Lapalme, Pierre	15,892	12,528	—	25,200	—	—	—	53,620
Limoges, Gérard	24,505	11,354	—	25,200	—	—	—	61,059

(1) The value of stock options represents the closing price of the Common Shares on the NASDAQ on the last trading day preceding the date of grant ($52.50 for options granted on May 8, 2015) multiplied by the Black-Scholes factor as at such date (80.00% for options granted on May 8, 2015) and the number of stock options granted on such date. The number of shares subject to the options granted in 2015 and the corresponding exercise price have been adjusted to reflect and give effect to the 100-for-1 reverse stock split (or share consolidation) that occurred on November 17, 2015.

(2) The amounts paid to Ms. Egbert was for special tasks she performed for us. The amount paid to Mr. Ernst was a recognition payment for his past service as both Chairman and interim President/CEO between April and August 2008.

(3) Mr. Aubut ceased to be a director effective November 16, 2015.

(4) Mr. Dorais did not stand for election at the Company's annual and special meeting of shareholders held on May 8, 2015.

During the financial year ended December 31, 2015, we paid an aggregate amount of $259,770 to all of our Outside Directors for services rendered in their capacity as directors, excluding reimbursement of out-of-pocket expenses and the value of stock options issued in 2015.

2. Compensation of Executive Officers

The following is disclosure of information related to the compensation that we paid to our "Named Executive Officers" during 2015. Our "Named Executive Officers" were

- Mr. David A. Dodd, who served as our Chief Executive Officer during all of 2015;
- Mr. Dennis Turpin, who served as our Chief Financial Officer from January 1, 2015 through October 9, 2015;
- Mr. Keith Santorelli, who served as our Vice President, Finance throughout 2015 as well as Chief Accounting Officer and as our interim principal financial officer from October 9, 2015 up to and including December 31, 2015; and
- Messrs. Philip A. Theodore, our Senior Vice President, Chief Administrative Officer and General Counsel and Jude Dinges, our Senior Vice President and Chief Commercial Officer; and Dr. Richard Sachse, our Senior Vice President and Chief Scientific and Medical Officer, who were our three most highly compensated

executive officers (other than our Chief Executive Officer, our former Chief Financial Officer and our former Chief Accounting Officer and interim principal financial officer) during 2015.

Compensation Discussion & Analysis

Compensation Philosophy and Objectives

Our Board of Directors, through the Compensation Committee, establishes our executive compensation program that is market-based and at a competitive percentile grouping for both total cash and total direct compensation. The Compensation Committee has established a compensation program that is designed to attract, motivate and retain high-performing senior executives, encourage and reward superior performance and align the executives' interests with those of our shareholders by:

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

Compensation Elements

Our executive compensation is targeted at the 50th percentile for small cap biopharma companies within both the local and national market and is comprised of both fixed and variable components. The variable components include equity and non-equity incentive plans. Each compensation component is intended to serve a different function, but all elements are intended to work in concert to maximize both corporate and individual performance by establishing specific, competitive operational and corporate goals and by providing financial incentives to employees based on their level of attainment of these goals.

Our current executive compensation program is comprised of the following four basic components: (i) base salary; (ii) an annual bonus linked to both individual and corporate performance; (iii) equity incentives, consisting solely of stock options granted under our stock option plan established for the benefit of our directors, certain executive officers and other participants as may be designated from time to time by either the Board or the Compensation Committee (the "Stock Option Plan"); and (iv) other elements of compensation, consisting of benefits, perquisites and retirement benefits.

Base Salary. Base salaries are intended to provide a steady income to the executive officers regardless of share price. In determining individual base salaries, the Compensation Committee takes into consideration individual circumstances that may include the scope of an executive's position, the executive's relevant competencies or experience and retention risk. The Compensation Committee also takes into consideration the fulfillment of our corporate objectives, as well as the individual performance of the executive.

Short-Term, Non-Equity Incentive Compensation. Our short-term, non-equity incentive compensation plan sets a target cash bonus for each executive officer, expressed as a percentage of the executive officer’s base salary. The amount of cash bonus paid to an executive officer depends on the extent to which he or she contributed to the achievement of the annual performance objectives established by the Board for the year. The annual performance objectives are specific operational, clinical, regulatory, financial, commercial and corporate goals that are intended to advance our product pipeline, to promote the success of our commercial efforts and to enhance our financial position. The annual performance objectives are set at the end of each financial year as part of the annual review of corporate strategies. The performance objectives are not established for individual executive officers but rather by functional area(s), many of which are carried out by or fall within the responsibility of our President and Chief Executive Officer, Chief Financial Officer (or principal financial officer) and our other executive officers, including our Named Executive Officers. The award of a cash bonus requires the approval of both the Compensation Committee and the Board and is based upon an assessment of each individual's performance, as well as our overall performance at a corporate level. The determination of individual performance does not involve quantitative measures using a mathematical calculation in which each individual performance objective is given a numerical weight. Instead, the Compensation Committee's determination of individual performance is a subjective determination as to whether a particular executive officer substantially achieved the stated objectives or over-performed or under-performed with respect to corporate objectives that were deemed to be important to our success.

Long-Term Equity Compensation Plan of Executive Officers. The long-term component of the compensation of our executive officers is based exclusively on the Stock Option Plan, which permits the award of a number of options based on the contribution of the officers and their responsibilities. To encourage retention and focus management on developing and successfully implementing our continuing growth strategy, stock options vest over a period of three years, with the first third vesting on the first anniversary of the date of grant. Stock options are usually granted to executive officers in December of each year.

Other Forms of Compensation. Our executive employee benefits program also includes life, medical, dental and disability insurance to the same extent and in the same manner as all other employees. Several of our executive officers also receive a car allowance as a perquisite. These benefits and perquisites are designed to be competitive overall with equivalent positions in comparable North American organizations in the life sciences industry. We also contribute to our North American employees' retirement plans to the extent of 50% of the employee's contribution up to an annual maximum amount of $9,000 for employees in the United States, and up to a maximum of $12,000 for employees and executive officers over 50 years old in the United States. The contribution amounts for our United States employees are subject to limitations imposed by the United States Internal Revenue Service on contributions to

our most highly compensated employees. Employees based in Frankfurt, Germany also benefit from certain employer contributions into the employees' pension funds. Our executive officers, including the Named Executive Officers, are eligible to participate in such employer-contribution plans to the same extent and in the same manner as all other employees.

Positioning

The Compensation Committee is authorized to engage its own independent consultant to advise it with respect to executive compensation matters. While the Compensation Committee may rely on external information and advice, all of the decisions with respect to executive compensation are made by the Board upon the recommendation of the Compensation Committee and may reflect factors and considerations other than, or that may differ from, the information and recommendations provided by any external compensation consultants that may be retained from time to time.

In 2013, the Compensation Committee retained a compensation consultant to benchmark our executive compensation plan in an effort to determine whether we were achieving our objective of providing market competitive compensation opportunities. The compensation consultant gathered compensation data from companies that it concluded were of comparable size and/or stage of

development as us and from other companies with which we compete for executive talent and advised the Compensation Committee that our executive compensation should be generally aligned with the 50th percentile, or the mid-point, of the companies surveyed by the consultant. Furthermore, the consultant advised the Compensation Committee that the total cash target payment (base salary and, if applicable or awarded in cash, annual bonus) for our executive officers in 2013 generally fell around the 50th percentile of the companies surveyed. The base salaries of our Chairman, President and Chief Executive Officer and our Senior Vice President and their target bonuses were not increased in 2014 or 2015. Therefore, the Compensation Committee did not repeat or update the benchmarking process in 2014 or 2015 because it concluded that doing so would not provide additional meaningful data, considering the expense of the process. However, the Compensation Committee, as a matter of good governance, will review and assess the current compensation program and make appropriate adjustments, if any, during 2016.

Risk Assessment of Executive Compensation Program

The Board, through the Compensation Committee, oversees the implementation of compensation methods that tie a portion of executive compensation to our short-term and longer-term performance and that of each executive officer and that take into account the advantages and risks associated with such compensation methods. In addition, the Board oversees the creation of compensation policies that are intended to reward the creation of shareholder value while reflecting a balance between our short-term and longer-term performance and that of each executive officer. The Compensation Committee has considered in general terms the concept of risk as it relates to our executive compensation program.

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

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

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

While we have not formally adopted a policy prohibiting or restricting our executive officers and directors from purchasing financial instruments, including, for greater certainty, pre-paid variable forward contracts, equity swaps, collars, or units of exchange funds, which are designed to hedge or offset a decrease in market value of our equity securities granted as executive compensation or directors' remuneration, our executive officers and directors have not

historically engaged in such financial instruments or transactions. In addition, our disclosure and trading policy requires that all "reporting insiders", including executive officers and directors, pre-clear with our Corporate Secretary each trade in our securities, which would include the entering into of any such financial instrument or transaction, hedge, swap or forward contract.

2015 Compensation

Base Salary. The base salaries of our Chairman, President and Chief Executive Officer and our Senior Vice Presidents were not increased in 2015 because the Compensation Committee determined that the financial position of the Company did not justify an increase in base salaries.

Short-Term, Non-Equity Incentive Compensation. The Board of Directors, based on the Compensation Committee's recommendation, adopted the following performance objectives for 2015:

Objectives for 2015		Result
Financing	Secure a minimum of $10 million during the first half of 2015 End 2015 with a minimum of two years of cash	$37 million raised in March 2015 financing, but issuance of highly dilutive Series B Warrants precluded additional fund raising until December 2015. Ended year with $41.45 million of cash. Unable to build cash reserve to two years due to impact of Series B Warrants. Inability to achieve funding goal was offset by achievement of a meaningful reduction in use of cash for operating activities during the year.
EstroGel®	Achieve minimum of $5 million in annual revenue in AEZS territories	Growth in market share of total prescriptions from 31.2% in Q1 to 36.8% in Q4, resulting in a 17.4% increase in total prescriptions in our territories, but revenues far below target.
ZoptEC Phase 3 trial	Issue first interim results If trial continues, issue second interim results Conduct clinical quality assessment of trial	The first interim results were successful and were issued on April 27, 2015. The second interim results were successful and were issued on October 9, 2015. The quality assessment was conducted.
Macrilen™	Decide whether to continue with clinical development If the decision is to continue, clarify protocol issues with the FDA If the decision is to continue, initiate the clinical program	We decided to continue with clinical development in the first quarter of 2015. We clarified the protocol issues with the FDA in the second quarter of 2015 and initiated the clinical program ahead of schedule, also in the second quarter of 2015.
Erk Inhibitors	Determine a development candidate	During the second quarter of 2015, we selected AEZS-140 as the lead development candidate. Two back-up candidates were also identified.
Business Development	Complete in-license, acquisition or promotion agreements with a minimum annual revenue or commission potential of $10 million	The Saizen® co-promotion agreement was signed on May 7 and selling was launched on July 27. Apifiny® co-marketing agreement was signed on November 30 and selling was launched on December 1.

The Chief Executive Officer recommended to the Compensation Committee that we award cash bonuses to two of our Named Executive Officers with respect to 2015. The Compensation Committee concurred with the Chief Executive

Officer's recommendation as did the full Board of Directors. Mr. Philip A. Theodore, our Senior Vice President, Chief Administrative Officer, General Counsel and Corporate Secretary, was awarded a cash bonus with respect to 2015 in the amount of $35,000, which represented approximately 25% of his target bonus. Dr. Richard Sachse, our Senior Vice President, Chief Medical Officer and Chief Scientific Officer, was awarded a cash bonus with respect to 2015 in the amount of €100,000, which represented 100% of his target bonus. Both bonuses were recommended by the Chief Executive Officer based on performance he deemed significant.

Long-Term Equity Compensation

The Compensation Committee approved significant option awards to our Named Executive Officers in 2015 because, as a result of the Share Consolidation and the significant decrease in our stock price following the dilution attributable to the issuance of Common Shares upon the exercise of the Series B Warrants, all previous option awards became extremely out-of-the-money and, therefore, ceased to provide a long-term equity incentive. Mr. Dodd was awarded 85,000 stock options and Messrs. Dinges, Sachse and Theodore were each awarded 40,000 stock options. The stock options have an exercise price of $4.58 and vest in three annual installments, commencing on December 21, 2016.

Summary of the Stock Option Plan

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

The Stock Option Plan provides that the sole persons eligible to receive grants under the Stock Option Plan (each, a "Participant") shall be: (i) our most senior executive officers, including the persons occupying the positions of Chief Executive Officer, Chief Financial Officer, Chief Scientific Officer, Chief Commercial Officer, Chief Administrative Officer and Chief Compliance Officer; (ii) such other of our executive officers or executive officers of our subsidiaries that may, from time to time, report directly to the Chief Executive Officer; (iii) the non-employee, independent members of the Board; and (iv) such other of our officers or employees or the officers or employees of any of our subsidiaries, as the case may be, or suppliers of ongoing services, as may be expressly designated by resolution of the Board or the Compensation Committee.

The maximum number of Common Shares issuable under the Stock Option Plan is fixed at 11.4% of the issued and outstanding Common Shares at any given time, which, as of March 29, 2016, represented 1,131,871 Common Shares. There were 275,041 options outstanding under the Stock Option Plan, representing approximately 2.8% of all issued and outstanding Common Shares, on March 29, 2016.

Under the Stock Option Plan, (i) the number of securities issuable to insiders, at any time, or issued within any one-year period, under all of our security-based compensation arrangements, cannot exceed 10% of our issued and outstanding securities and (ii) no single Participant may hold options to purchase, from time to time, more than 5% of our issued and outstanding Common Shares. In addition: (i) the aggregate fair value of options granted under all of our security-based compensation arrangements to any one of our Outside Directors entitled to receive a benefit under the Stock Option Plan, within any one-year period, cannot exceed $100,000 valued on a Black-Scholes basis and as determined by the Compensation Committee; and (ii) the aggregate number of securities issuable to all of our Outside Directors entitled to receive a benefit under the Stock Option Plan, within any one-year period, under all of our security-based compensation arrangements, cannot exceed 1% of its issued and outstanding securities.

Options granted under the Stock Option Plan may be exercised at any time within a maximum period of seven or ten years following the date of their grant (the "Outside Expiry Date"), depending on the date of grant. The Board or the Compensation Committee, as the case may be, designates, at its discretion, the specific Participants to whom stock options are granted under the Stock Option Plan and determines the number of Common Shares covered by each of such option grants, the grant date, the exercise price of each option, the Outside Expiry Date and any other matter relating thereto, in each case in accordance with the applicable rules and regulations of the regulatory authorities. The price at which the Common Shares may be purchased may not be lower than the greater of the closing prices of the Common Shares on the NASDAQ or the TSX, as applicable, on the last trading day preceding the date of grant of the option. Options granted under the Stock Option Plan shall vest in equal tranches over a three-year period (one-third each year, starting on the first anniversary of the grant date) or as otherwise determined by the Board or the Compensation Committee, as the case may be.

Unless the Board or the Compensation Committee decides otherwise, Participants cease to be entitled to exercise their options under the Stock Option Plan: (i) immediately, in the event a Participant who is an officer or employee resigns or voluntarily leaves his or her employment or his or her employment is terminated with cause and, in the case of a

Participant who is a non-employee director of us or one of our subsidiaries, the date on which such Participant ceases to be a member of the relevant Board of Directors; (ii) six months following the date on which employment is terminated as a result of the death of a Participant who is an officer or employee and, in the case of a Participant who is an Outside Director, six months following the date on which such Participant ceases to be a member of the Board of Directors by reason of death; (iii) 90 days following the date on which a Participant's employment is terminated for a reason other than those mentioned in (i) or (ii) above including, without limitation, upon the disability, long-term illness, retirement or early retirement of the Participant; and (iv) where the Participant is a service supplier, 30 days following the date on which such Participant ceases to act as such, for any cause or reason (each, an "Early Expiry Date").

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

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

If (i) we accept an offer to amalgamate, merge or consolidate with any other entity (other than one of our wholly-owned subsidiaries) or to sell or license all or substantially all of our assets to any other entity (other than one of our wholly-owned subsidiaries); (ii) we sign a support agreement in customary form pursuant to which the Board agrees to support a takeover bid and recommends that our shareholders tender their Common Shares to such takeover bid; or (iii) holders of greater than 50% of our then outstanding Common Shares tender all of their Common Shares to a takeover bid made to all of the holders of the Common Shares to purchase all of the then issued and outstanding Common Shares, then, in each case, all of the outstanding options shall, without any further action required to be taken by us, immediately vest. Each Participant shall thereafter be entitled to exercise all of such options at any time up to and including, but not after the close of business on that date which is ten days following the Closing Date (as defined below). Upon the expiration of such ten-day period, all rights of the Participant to such options or to the exercise of same (to the extent not already exercised) shall automatically terminate and have no further force or effect whatsoever. "Closing Date" is defined to mean (x) the closing date of the amalgamation, merger, consolidation, sale or license transaction in the case of clause (i) above; (y) the first expiry date of the takeover bid on which each of the offeror's conditions are either satisfied or waived in the case of clause (ii) above; or (z) the date on which it is publicly announced that holders of greater than 50% of our then outstanding Common Shares have tendered their Common Shares to a takeover bid in the case of clause (iii) above.

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

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

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

- amendments of a "housekeeping" or clerical nature or to clarify the provisions of the Stock Option Plan;
- amendments regarding any vesting period of an option;
- amendments regarding the extension of an option beyond an Early Expiry Date in respect of any Participant, or the extension of an option beyond the Outside Expiry Date in respect of any Participant who is a "non-insider";
- adjustments to the number of issuable Common Shares underlying, or the exercise price of, outstanding options resulting from a split or a consolidation of the Common Shares, a reclassification, the payment of a stock dividend,
- the payment of a special cash or non-cash distribution to our shareholders on a pro rata basis provided such distribution is approved by

our shareholders in accordance with applicable law, a recapitalization, a reorganization or any other event which necessitates an equitable adjustment to the outstanding options in proportion with corresponding adjustments made to all outstanding Common Shares;

- discontinuing or terminating the Stock Option Plan; and
- any other amendment which does not require shareholder approval under the terms of the Stock Option Plan.

Outstanding Option-Based Awards and Share-Based Awards

The following table shows all awards outstanding to our Named Executive Officers as of December 31, 2015. The number of shares subject to the stock options and the corresponding exercise prices have been adjusted to reflect and give effect to the 100-for-1 reverse stock split (or share consolidation) that occurred on November 17, 2015.

	Option-based Awards					Share-based Awards		
Name	Issuance Date	Number of Securities Underlying Unexercised Options[1]	Option Exercise Price	Option Expiration Date	Value of Unexercised In-the-money Options[2]	Issuance Date	Number of Shares or Units of shares that have Not Vested	Market or Payout Value of Share-based Awards that have Not Vested (3)
	(mm-dd-yyyy)	(#)	(CAN$ or $)	(mm-dd-yyyy)	(CAN$ or $)		(#)	
Dodd, David A.	04/15/2013	3,000 [3]	$198.00	04/14/2023	—	—	—	—
	12/04/2014	4,750	$76.00	12/04/2021	—	—	—	—
	12/21/2015	85,000	$4.58	12/20/2022	—	—	—	
Santorelli, Keith	05/09/2014	750	$107.00	05/08/2021	—	—	—	—
	12/04/2014	300	$76.00	12/04/2021	—	—	—	—
Turpin, Dennis[4]	01/04/2007	83	CAN$2,790.00	01/08/2016	—	—	—	—
	12/11/2007	83	CAN$1,092.00	01/08/2016	—	—	—	—
	12/09/2009	191	CAN$570.00	01/08/2016	—	—	—	—
	12/08/2010	94	CAN$912.00	01/08/2016	—	—	—	—
	12/07/2011	172	$1,044.00	01/08/2016	—	—	—	—
	12/06/2012	840	$217.00	01/08/2016	—	—	—	—
Sachse, Richard	01/16/2014	1,500 [5]	$129.00	01/15/2021	—	—	—	—
	12/04/2014	1,300	$76.00	12/04/2021	—	—	—	—
	12/21/2015	40,000	$4.58	12/20/2022	—	—	—	—
Dinges, Jude	11/27/2013	1,500 [6]	$112.00	11/26/2023	—	—	—	—
	12/04/2014	1,660	$76.00	12/04/2021	—	—	—	—
	12/21/2015	40,000	$4.58	12/20/2022	—	—	—	—
Theodore, Philip A	10/06/2014	1,500 [7]	$134.00	10/05/2021	—	—	—	—
	12/04/2014	500	$76.00	12/04/2021	—	—	—	—
	12/21/2015	40,000	$4.58	12/20/2022	—	—	—	—

(1) The number of securities underlying unexercised options represents all awards outstanding at December 31, 2015.

(2) "Value of unexercised in-the-money options" at financial year-end is calculated based on the difference between the closing prices of the Common Shares on the NASDAQ or the TSX, as applicable, on the last trading day of the year (December 31, 2015) of $4.48 and CAN$6.19, respectively, and the exercise price of the options, multiplied by the number of unexercised options.

(3) David A. Dodd was appointed President and Chief Executive Officer effective April 15, 2013 and was granted 3,000 stock options in connection with such appointment.

(4) The vested stock options issued to Mr. Turpin expired without being exercised 90 days following the termination of his employment on October 9, 2015 in accordance with the terms of the Stock Option Plan.

(5) Richard Sachse was appointed Senior Vice President and Chief Scientific Officer effective January 1, 2014 and was granted 1,500 stock options in connection with such appointment.

(6) Jude Dinges was appointed Senior Vice President and Chief Commercial Officer effective November 1, 2013 and was granted 1,500 stock options in connection with such appointment.

(7) Philip A. Theodore was appointed Senior Vice President, Chief Administrative Officer and General Counsel effective October 6, 2014 and was granted 1,500 stock options in connection with such appointment.

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

Incentive Plan Awards - Value Vested or Earned During the Year

The following table shows the incentive plan awards value vested or earned for each Named Executive Officer for the financial year ended December 31, 2015.

Name	Option-based awards - Value vested during the year[1] ($)	Share-based awards - Value vested during the year ($)	Non-equity incentive plan compensation - Value earned during the year ($)
Dodd, David A.	—	—	—
Santorelli, Keith	—	—	—
Turpin, Dennis	—	—	—
Sachse, Richard	—	—	111,000
Dinges, Jude	—	—	—
Theodore, Philip A.	—	—	35,000

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

Summary Compensation Table

The Summary Compensation Table set forth below shows compensation information for each of the Named Executive Officers for services rendered in all capacities during each of the financial years ended December 31, 2015, 2014 and 2013. All amounts in the table below are in US dollars. All cash amounts paid to Messrs. Dodd, Santorelli, Dinges and Theodore were paid in US dollars, while Mr. Turpin's cash payments were made in Canadian dollars and Dr. Sachse's cash payments were made in euros.

SUMMARY COMPENSATION TABLE

Name and principal position	Years	Salary ($)	Share based awards ($)	Option based awards[1] ($)	Non-equity incentive plan compensation Annual incentive plan ($)	Non-equity incentive plan compensation Long-term incentive plans ($)	Pension Value ($)	All other compensation[2] ($)	Total compensation ($)
Dodd, David A.	2015	475,000	—	358,690	—	—	—	—	833,690
Chairman,	2014	475,000	—	291,914	100,000	—	—	—	866,914
President and Chief Executive Officer	2013	328,846 [3]	414,048 [4]	474,606	50,000	—	—	—	1,267,500
Santorelli, Keith	2015	244,800	—	—	—	—	—	—	244,800
Former Vice	2014	240,000	—	82,554	—	—		—	322,554
President, Finance and Chief Accounting Officer and Interim Principal Financial Officer	2013	27,692 [5]	—	—	—	—	—	—	27,692
Turpin, Dennis	2015	206,590 [6]	—	—	—	—	—	481,569 [7]	688,159
Former Senior Vice	2014	309,299	—	107,547	22,013	—	—	—	438,859
President and Chief Financial Officer	2013	331,652	—	—	66,677	—	—	—	398,329

Sachse, Richard	2015	221,900	—	168,795	111,000	—	47,349 (8)	—	549,044
Senior Vice	2014	265,752	—	235,017	62,463	—	27,239	—	590,471
President, Chief Scientific Officer and Chief Medical Officer	2013	—	—	—	—	—	—	—	—
Dinges, Jude	2015	320,000		168,795	—	—	—	—	488,795
Senior Vice	2014	320,000	—	102,016	25,000	—	—	—	447,016
President and Chief Commercial Officer	2013	121,988 (9)	—	135,542	—	—	—	—	257,530
Theodore, Philip A	2015	320,000	—	168,795	35,000	—	—	—	523,795
Senior Vice	2014	67, 692 (10)	—	189,433	—	—	—	—	257,125
President, Chief Administrative Officer and General Counsel	2013	—	—	—	—	—	—	—	—

(1) The value of option-based awards represents the closing price of the Common Shares on the NASDAQ on the last trading day preceding the date of grant ($198.00 for options granted on April 15, 2013, $112.00 for options granted on November 27, 2013, $129.00 for options granted on January 16, 2014, $107.00 for options granted on May 9, 2014, $134.00 for options granted on October 6, 2014, $76.00 for options granted on December 4, 2014 and $4.58 for options granted on December 21, 2015) multiplied by the Black-Scholes factor as at such date (79.96% for options granted on April 15, 2013, 80.68% for options granted on November 27, 2013, 80.17% for options granted on January 16, 2014, 79.90% for options granted on May 9, 2014, 78.96% for options granted on October 6, 2014, 80.86% for options granted on December 4, 2014 and 92.14% for options granted on December 21, 2015) and the number of stock options granted on such date.

(2) "All Other Compensation" represents perquisites and other personal benefits which, in the aggregate, amount to $50,000 or more, or are equivalent to 10% or more of a Named Executive Officer's total salary for the financial year ended December 31, 2015. The type and amount of each perquisite, the value of which exceeds 25% of the total value of perquisites, is separately disclosed for each Named Executive Officer, if applicable.

(3) Represents the salary earned by and paid to Mr. Dodd following his appointment as President and Chief Executive Officer on April 15, 2013.

(4) The value of Mr. Dodd's share-based awards represents the closing price of the Common Shares on the NASDAQ on the last trading day preceding the date of grant ($1.98 for share appreciation rights ("SARs") granted on April 15, 2013) multiplied by the Black-Scholes factor as at such date (175,000 SARs at a factor of 54% and 200,000 SARs at a factor of 58%) and the number of SARs granted on such date. The SARs expired on December 31, 2015 without being exercised.

(5) Represents the salary earned by and paid to Mr. Santorelli following his appointment as Vice President, Finance on November 11, 2013.

(6) Mr. Turpin served as Chief Financial Officer through October 9, 2015. The indicated salary amount represents salary earned and paid to Mr. Turpin up until the date of his departure.

(7) Represents severance payment, perquisites and other personal benefits paid to Mr. Turpin in 2015, of which $468,736 was paid in the form of a termination payment.

(8) We maintain a reinsured benevolent fund (Rückgedeckte Unterstützungskasse), which is a type of private defined contribution pension plan, for Dr. Sachse. We contribute to a private pension provider an amount equal to 2.4% of Dr. Sachse's salary, up to a monthly salary limit of €6,050, plus an additional contribution of 18% of the amount of Dr. Sachse's salary that exceeds the monthly limit. Dr. Sachse also contributes a percentage of his salary to the plan. We are liable to Dr. Sachse for the pension benefits that have been promised, if the private pension provider does not, or cannot, pay the promised pension payments. We obtained reinsurance against the insolvency or liquidation of the private pension provider. The table below sets forth additional information regarding Dr. Sachse's pension plan. The difference between (i) the sum of the Accumulated Value at Start of Year column plus the Compensatory column and (ii) the Accumulated Value at End of Year column is attributable to Dr. Sachse's contributions to the pension plan during the year ended December 31, 2015, as well as changes in foreign exchange rate, his contributions being made in euros.

Accumulated value at start of year	Compensatory	Accumulated value at year end
$28,187	$47,349	$73,729

(9) Represents consultant fees paid to Mr. Dinges between May 12, 2013 and October 31, 2013 combined with the salary paid to him following his appointment as Senior Vice President and Chief Commercial Officer on November 1, 2013.

(10) Represents the salary earned by and paid to Mr. Theodore following his appointment as Senior Vice President, Chief Administrative Officer, General Counsel and Corporate Secretary on October 6, 2014.

Compensation of the Chief Executive Officer

The compensation of our Chairman, President and Chief Executive Officer is governed by our executive compensation policy described in the section titled "Compensation of Executive Officers", and the Chairman,

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

Mr. Dodd's total earned salary during the financial year ended December 31, 2015 was $475,000. Mr. Dodd was not awarded an annual incentive bonus with respect to 2015.

For the financial year ended December 31, 2015, the Compensation Committee recommended that 85,000 stock options be granted to Mr. Dodd under the long-term equity compensation plan. The grant to Mr. Dodd is included in the table above captioned "Grants of Plan Based Awards".

See "Long-Term Equity Compensation Plan of Executive Officers - Summary of the Stock Option Plan", for a complete description of the Stock Option Plan.

C. Board Practices

Our Articles provide that our Board shall be composed of a minimum of five and a maximum of 15 directors. Directors are elected annually by our shareholders, but the directors may from time to time appoint one or more directors, provided that the total number of directors so appointed does not exceed one-third of the number of directors elected at the last annual meeting of shareholders. Each elected director will remain in office until termination of the next annual meeting of the shareholders or until his or her successor is duly elected or appointed, unless his or her post is vacated earlier. We do not have service agreements with our independent directors.

See Item 6A. for information about the period of service of each of our directors and senior corporate officers.

Committees of the Board of Directors

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

Audit Committee

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

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

The current members of the Audit Committee are Carolyn Egbert, Pierre Lapalme and Gérard Limoges (Chair).

Compensation Committee

The Compensation Committee is responsible for, among other matters, (i) assisting the Board in developing our approach to corporate governance issues, (ii) proposing new Board nominees, (iii) overseeing the assessment of the effectiveness of the Board and its committees, their respective chairs and individual directors and (iv) making recommendations to the Board with respect to directors' compensation and generally playing a leadership role in our corporate governance practices. It is also responsible for taking all reasonable measures to ensure that appropriate human resources systems and procedures, such as hiring policies, competency profiles, training policies and compensation structures, are in place so that we can attract, motivate and retain the quality of personnel required to meet our business objectives. The Compensation Committee also assists the Board in discharging its responsibilities relating to executive and other human resources hiring, assessment, compensation and succession planning matters. Thus, the Compensation Committee recommends the appointment of senior officers, including the terms and conditions of their appointment and termination, and reviews the evaluation of the performance of our senior officers, including recommending their compensation and overseeing risk identification and management in relation to executive compensation policies and practices. The Board, which includes the members of the Compensation Committee, reviews the Chief Executive Officer's corporate goals and objectives and evaluates his or her performance and compensation in light of such goals and objectives.

The Compensation Committee recognizes that the industry, regulatory and competitive environment in which we operate requires a balanced level of risk-taking to promote and achieve the performance expectations of executives of a specialty biopharmaceutical company that is also seeking to acquire or in-license new commercial products. The Compensation Committee is of the view that our executive compensation program should not encourage senior executives to take excessive risk. In this regard, the Compensation Committee recommends the implementation of compensation methods that tie a portion of senior executive compensation to our short-term and longer-term performance, as well as that of each individual executive officer and that take into account the advantages and risks associated with such compensation methods. The Compensation Committee is also responsible for creating compensation policies that are intended to reward the creation of shareholder value while reflecting a balance between our short-term and longer-term performance and that of each executive officer.

The current members of the Compensation Committee are Carolyn Egbert (Chair), Pierre Lapalme and Gérard Limoges.

D. Employees

As at December 31, 2015, we had a total of 46 active employees, of which 36 are based in Frankfurt, Germany. The remaining 10 employees are based in the United States. Our employees are engaged in the following activities: (i) 29 are engaged in research and development, regulatory affairs and quality assurance; (ii) eight are involved in commercial operations and business development; and (iii) nine are involved in various administrative functions, including finance and accounting. We do not employ any sales representatives. We have agreements with our

employees covering confidentiality, loyalty, non-competition and assignment of all intellectual property rights developed during the employment period. From August 17, 2014 to December 31, 2015, we conducted a resource optimization program that resulted in the termination of 28 employees.

E. Share ownership

The information in the table below is provided as at December 31, 2015:

Name	No. of Common Shares owned or held	Percent[1]	No. of stock options held[2]	No. of currently exercisable options
Dinges, Jude	6,533	*	43,160	1,554
Dodd, David A.	19,003	*	92,750	3,584
Egbert, Carolyn	1,920	*	1,575	476
Ernst, Juergen	1,348	*	2,006	907
Guenther, Eckhard	—	—	5,597	464
Lapalme, Pierre	—	—	1,766	667
Limoges, Gérard	14	*	1,840	741
Sachse, Richard	—	—	42,800	934
Santorelli, Keith	—	—	1,050	350
Teifel, Michael	—	—	10,526	393
Theodore, Philip A.	10,894	*	42,000	667
Total	39,712		245,070	10,737

* Less than 1%

(1) Based on 9,928,697 Common Shares outstanding as at December 31, 2015.

(2) For information regarding option expiration dates and exercise price refer to the tables included under the caption "Outstanding Option-Based Awards and Share-Based Awards".

Item 7. Major Shareholders and Related Party Transactions

A. Major shareholders

We are not directly or indirectly owned or controlled by another corporation or by any foreign government. Based on filings with the SEC and the Canadian securities regulatory authorities, as at March 29, 2016, the only entity that beneficially owned, directly or indirectly, or exercised control or direction over our Common Shares carrying more than 5% of the voting rights attached to all our Common Shares were Sabby Healthcare Master Fund, Ltd., Sabby Volatility Warrant Master Fund, Ltd., Sabby Management, LLC and Hal Mintz, who together beneficially owned 534,145 of our Common shares, representing approximately 5.38% of our outstanding Common Shares, as further described in their Schedule 13G/A filed with the SEC on January 14, 2016.

United States Shareholders

As at February 29, 2016, there were 10 holders of record of our Common Shares, of which one was registered with an address in the United States holding in the aggregate approximately 99.69% of our outstanding Common Shares. We believe that the number of beneficial owners of our Common Shares is substantially greater than the number of record holders, because the overwhelming majority of our Common Shares are held in broker "street names".

B. Related party transactions

In addition to recurring payments made to members of our key management team, during the years ended December 31, 2015 and 2014, we incurred nil and $38,000, respectively, in professional fees for services rendered by one of the members of the Company's Board of Directors in connection with special tasks mandated by our Compensation Committee.

C. Interests of experts and counsel

Not applicable.

Item 8. Financial Information

A. Consolidated statements and other financial information

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

B. Significant changes

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

Item 9. The Offering and Listing

A. Offer and listing details

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

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

	NASDAQ (US$)		TSX (CAN$)	
	High	Low	High	Low
2015	84.20	4.00	104.00	5.39
2014	150.00	52.00	166.00	57.00
2013	323.00	103.00	327.00	108.00
2012	1,290.00	187.00	1,284.00	187.00
2011	1,548.00	858.00	1,506.00	846.00
2016				
First quarter[(1)]	4.40	2.67	6.08	3.85
2015				
Fourth quarter	11.43	4.00	15.41	5.39
Third quarter	27.50	5.02	35.00	7.00
Second quarter	64.10	27.00	78.00	32.50
First quarter	84.20	51.00	104.00	64.00
2014				
Fourth quarter	134.00	52.00	151.00	57.00
Third quarter	150.00	114.00	164.00	123.00
Second quarter	123.00	105.00	135.00	113.00
First quarter	149.00	117.00	166.00	129.00
Most recent 6 months				
February 2016	3.18	2.81	4.37	3.92
January 2016	4.40	2.67	6.08	3.85
December 2015	9.95	4.42	13.27	6.06
November 2015	11.43	4.00	15.41	5.39
October 2015	9.30	4.25	12.50	5.50
September 2015	11.85	5.02	16.00	7.00

(1) Up to and including March 28, 2016

B. Plan of distribution

Not applicable.

C. Markets

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

D. Selling shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the issue

Not applicable.

Item 10. Additional Information

A. Share capital

Not applicable.

B. Memorandum and articles of association

We are governed by our restated articles of incorporation (the "Restated Articles of Incorporation") under the CBCA and by articles of amendment dated October 2, 2012 and November 16, 2015 (together with the Restated Articles of Incorporation, the "Articles") and by our bylaws (the "bylaws"). Our Articles are on file with the Corporations Directorate of Industry Canada under Corporation Number 264271-9. The Articles do not include a stated purpose and do not place any restrictions on the business that we may carry on.

Inspection Rights of Shareholders

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

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

Directors

The minimum number of directors we must have is five and the maximum number is 15. In accordance with the CBCA, at least 25% of our directors must be residents of Canada. In order to serve as a director, a person must be a natural person at least 18 years of age, of sound mind, not bankrupt, and must not be prohibited by any court from holding the office of director. None of the Articles, the bylaws and the CBCA imposes any mandatory retirement requirements for directors.

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

There is no provision in our bylaws or Articles that requires that a director must be a shareholder.

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

The CBCA provides that a director who is a party to, or who is a director or officer of, or has a material interest in, any person who is a party to a material contract or transaction or proposed material contract or transaction with us must disclose to us the nature and extent of his or her interest at the time and in the manner provided by the CBCA, or request that same be entered in the minutes of the meetings of the Board, even if such contract, in connection with our normal business activity, does not require the approval of either the directors or the shareholders. At the request of the president or any director, the director placed in a situation of conflict of interest must leave the meeting while the Board discusses the matter. The CBCA prohibits such a director from voting on any resolution to approve the contract or transaction unless the contract or transaction:

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

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

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

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

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

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

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

Subject to the limitations provided by the CBCA, our bylaws provide that we shall, to the full extent provided by law, indemnify a director or an officer, a former director or officer or a person who acts or acted at our request as a director or officer of a body corporate of which we are or were a shareholder or creditor, and his or her heirs and legal representatives, against all costs, losses, charges and expenses, including an amount paid to settle an action or satisfy a judgment, reasonably incurred by him or her in respect of any civil, criminal or administrative action or proceeding to

which he or she is made a party by reason of having been our director or officer or such body corporate, provided:

(a) he or she acted in good faith in our best interests; and

(b) in the case of a criminal or an administrative action or proceeding that is enforced by a monetary penalty, he or she had reasonable grounds to believe that his or her conduct was lawful.

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

Share Capitalization

Our authorized share capital structure consists of an unlimited number of shares of the following classes (all classes are without nominal or par value): Common Shares; and first preferred shares (the "First Preferred Shares") and second preferred shares (the "Second Preferred Shares" and, together with the First Preferred Shares, the "Preferred Shares"), both issuable in series. As at March 29, 2016, there were 9,928,697 Common Shares outstanding. No Preferred Shares have been issued to date. We have also issued warrants to acquire Common Shares in connection with certain equity financings.

Common Shares

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

Preferred Shares

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

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

Shareholder Actions

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

Shareholder Rights Plan

Our Board of Directors adopted a shareholder rights plan on March 29, 2016 (the "Rights Plan"). Under the rules of the TSX, shareholder rights plans must be ratified by shareholders of a listed company within six months of their adoption. Our shareholders will be asked to confirm and ratify the Rights Plan at our 2016 Annual Meeting, which will be held on May 10, 2016. If our shareholders do not confirm and ratify the Rights Plan at such meeting, the

Rights Plan and the rights issued thereunder will terminate at the close of the Annual Meeting. The Rights Plan replaces a similar plan that was adopted by our Board of Directors and confirmed and ratified by our shareholders in 2010 and reconfirmed by our shareholders in 2013.

Objectives and Background of the Shareholder Rights Plan

The fundamental objectives of the Rights Plan are to provide adequate time for our Board and shareholders to assess an unsolicited

take-over bid for us, to provide the Board with sufficient time to explore and develop alternatives for maximizing shareholder value if a take-over bid is made, and to provide shareholders with an equal opportunity to participate in a take-over bid.

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

Summary of the Rights Plan

The following is a summary of the principal terms of the Rights Plan, which summary is qualified in its entirety by reference to the terms thereof. Capitalized terms not otherwise defined in this summary shall have the meaning ascribed to such terms in the Shareholder Rights Plan Agreement which sets forth the Rights Plan. The Rights Plan is filed as an exhibit to this Annual Report on Form 20-F. In preparing this summary we reviewed the amendments to the regulatory framework governing take-over bids published by the Canadian Securities Administrators that are scheduled to generally come into effect on May 9, 2016 (the “Amendments”).

In particular, the Amendments will require that all “non-exempt” take-over bids remain open for a minimum of 105 days, subject to the ability of a target issuer’s board of directors to shorten, in a non-discriminatory manner with respect to any potential other bids, the minimum period to a period of no less than 35 days by issuing a news release to such effect. We will continue to monitor the regulatory and governance landscape in Canada regarding the interaction of the Amendments and shareholder rights plans generally.

For the purposes of this summary and as set out in the Rights Plan, the term “MI 62-104” refers to Multilateral Instrument 62-104-Take-Over Bids and Issuer Bids adopted by certain of the Canadian securities regulatory authorities, as now in effect or as the same may from time to time be amended, re-enacted or replaced and including for greater certainty any successor instrument thereto (including, without limitation, National Instrument 62-104-Take-Over Bids and Issuer Bids of the Canadian Securities Administrators proposed to come into force on or about May 9, 2016).

Operation of the Rights Plan

Pursuant to the terms of the Rights Plan, we issued one right in respect of each common share outstanding at 5:01 p.m. on March 29, 2016 (the "Record Time"). In addition, we will issue one right for each additional Common Share issued after the Record Time and prior to the earlier of the Separation Time (as defined below) and the Expiration Time (as defined below). The rights have an initial exercise price equal to the Market Price (as defined below) of the Common Shares as determined at the Separation Time, multiplied by five, subject to certain anti-dilution adjustments (the "Exercise Price"), and they are not exercisable until the Separation Time. Upon the occurrence of a Flip-in Event (as defined below), each right will entitle the holder thereof, other than an Acquiring Person or any other person whose rights are or become void pursuant to the provisions of the Rights Plan, to purchase from us, effective at the close of business on the eighth trading day after the Stock Acquisition Date (as defined below), upon payment to us of the Exercise Price, Common Shares having an aggregate Market Price equal to twice the Exercise Price on the date of consummation or occurrence of such Flip-in Event, subject to certain anti-dilution adjustments.

Definition of Market Price

Market Price is generally defined in the Rights Plan, on any given day on which a determination must be made, as the volume weighted average trading price of the Common Shares for the five consecutive trading days (i.e. days on which the TSX or another stock exchange or national securities quotation system on which the Common Shares are traded (including for greater certainty, each of the Nasdaq Global Select Market, the Nasdaq Global Market and the Nasdaq Capital Market) is open for the transaction of business, subject to certain exceptions), through and including the trading day immediately preceding such date of determination, subject to certain exceptions.

Trading of Rights

Until the Separation Time (or the earlier termination or expiration of the rights), the rights trade together with the Common Shares and are represented by the same share certificates as the Common Shares or an entry in our securities

register in respect of any outstanding Common Shares. From and after the Separation Time and prior to the Expiration Time, the rights are evidenced by rights certificates and trade separately from the Common Shares. The rights do not carry any of the rights attaching to the Common Shares such as voting or dividend rights.

Separation Time

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

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

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

From and after the Separation Time and prior to the Expiration Time, each right entitles the holder thereof to purchase one Common Share upon payment of the Exercise Price to us.

Flip-in Event

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

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

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

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

The Rights Plan requires that any Lock-up Agreement be made available to us and the public. The definition of Lock-up Agreement also provides that under a Lock-up Agreement, no "break up" fees, "topping" fees, penalties, expenses or other amounts that exceed in aggregate the greater of (i) 2.5% of the price or value of the aggregate consideration payable under the Lock-up Bid, and (ii) 50% of the amount by which the price or value of the consideration received by a Locked-up Person under another take-over bid or transaction exceeds what such Locked-up Person would have received under the Lock-up Bid, can be payable by such Locked-up Person if the

Locked-up Person fails to deposit or tender Common Shares to the Lock-up Bid or withdraws Common Shares previously tendered thereto in order to deposit such Common Shares to another take-over bid or support another transaction.

Permitted Bid Requirements

The requirements of a Permitted Bid include the following:

1. the take-over bid must be made by means of a take-over bid circular;
2. the take-over bid must be made to all holders of Common Shares wherever resident, on identical terms and conditions, other than the bidder;
3. the take-over bid must not permit Common Shares tendered pursuant to the bid to be taken up or paid for:
   a) prior to the close of business on a date that is not less than 105 days following the date of the relevant take-over bid or such shorter minimum period that a take-over bid (that is not exempt from any of the requirements of Division 5 (Bid Mechanics of MI 62-104) must remain open for deposits of securities thereunder, in the applicable circumstances at such time, pursuant to MI 62-104;
   b) then only if at the close of business on the date Common Shares (and/or "Convertible Securities", as defined in the Rights Plan) are first taken up or paid for under such take-over bid, outstanding Common Shares and Convertible Securities held by shareholders other than any other Acquiring Person, the bidder, the bidder's affiliates or associates, persons acting jointly or in concert with the bidder and any employee benefit plan, deferred profit-sharing plan, stock participation plan or trust for the benefit of our employees or the employees of any of our subsidiaries, unless the beneficiaries of such plan or trust direct the manner in which the Common Shares are to be voted or direct whether the Common Shares are to be tendered to a take-over bid (collectively, "Independent Shareholders") that represent more than 50% of the aggregate of (I) then outstanding Common Shares and (II) Common Shares issuable upon the exercise of Convertible Securities, have been deposited or tendered pursuant to the take-over bid and not withdrawn;
4. the take-over bid must allow Common Shares and/or Convertible Securities to be deposited or tendered pursuant to such take-over bid, unless such take-over bid is withdrawn, at any time prior to the close of business on the date Common Shares and/or Convertible Securities are first taken up or paid for under the take-over bid;
5. the take-over bid must allow Common Shares and/or Convertible Securities to be withdrawn until taken up and paid for; and
6. in the event the requirement set forth in clause 3.b. above is satisfied, the bidder must make a public announcement of that fact and the take-over bid must remain open for deposits and tenders of Common Shares for not less than ten days from the date of such public announcement.

A Permitted Bid need not be a bid for all outstanding Common Shares not held by the bidder, i.e., a Permitted Bid may be a partial bid. The Rights Plan also allows a competing Permitted Bid (a "Competing Permitted Bid") to be made while a Permitted Bid is in existence. A Competing Permitted Bid must satisfy all the requirements of a Permitted Bid other than the requirement set out in clause 3.a above and must not permit Common Shares tendered or deposited pursuant to the bid to be taken up or paid for prior to the close of business on the last day of the minimum initial deposit period that such take-over bid must remain open for deposits of securities thereunder pursuant to MI 62-104 after the date of the take-over bid constituting the Competing Permitted Bid; provided, however, that a take-over bid that has qualified as a Competing Permitted Bid shall cease to be a Competing Permitted Bid at any time and as soon as such time as when such take-over bid ceases to meet any or all of the foregoing provisions of the definition of "Competing Permitted Bid" and any acquisition of Common Shares and/or Convertible Securities made pursuant to such take-over bid that qualified as a Competing Permitted Bid, including any acquisition of Common Shares and/or Convertible Securities made before such take-over bid ceased to be a Competing Permitted Bid, will not be a "Permitted Bid Acquisition" (as defined in the Rights Plan).

Waiver and Redemption

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

The Board may, with the approval of a majority of Independent Shareholders (or, after the Separation Time has occurred, holders of rights, other than rights which are void pursuant to the provisions of the Rights Plan or which,

prior to the Separation Time, are held otherwise than by Independent Shareholders), at any time prior to the occurrence of a Flip-in Event which has not been waived, elect to redeem all, but not less than all, of the then outstanding rights at a price of CAN$0.00001 each, appropriately adjusted as provided in the Rights Plan (the "Redemption Price").

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

Amendment to the Rights Plan

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

Protection Against Dilution

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

Fiduciary Duty of Board

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

Exemptions for Investment Advisors

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

Term

The Rights Plan will expire (the "Expiration Time") at the close of business on the date on which the first annual meeting of our shareholders following March 29, 2019 (being the third anniversary of the Record Time) is held; provided, however, that if our Independent Shareholders approve a resolution confirming the Rights Plan at or prior to the 2019 annual meeting of our shareholders, Expiration Time shall mean the close of business on the date on which the first annual meeting of our shareholders following March 29, 2022 (being the sixth anniversary of the Record Time) is held.

Action Necessary to Change Rights of Shareholders

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

Disclosure of Share Ownership

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

ownership of, or control or direction over, securities of the reporting issuer.
Additionally, securities regulation in Canada provides for the filing of a report by an insider of a reporting issuer whose holdings change, which report must be filed within five days from the day on which the change takes place.
Section 13 of the United States Securities Exchange Act of 1934 (the "Exchange Act") imposes reporting requirements on persons

who acquire beneficial ownership (as such term is defined in the Rule 13d-3 under the Exchange Act) of more than five percent of a class of an equity security registered under Section 12 of the Exchange Act. Our Common Shares are so registered. In general, such persons must file, within ten days after such acquisition, a report of beneficial ownership with the SEC containing the information prescribed by the regulations under Section 13 of the Exchange Act. This information is also required to be sent to the issuer of the securities and to each exchange where the securities are traded.

Meeting of Shareholders

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

The CBCA provides that the holders of not less than 5% of our outstanding voting shares may requisition our directors to call a meeting of shareholders for the purpose stated in the requisition. Except in limited circumstances, including where a meeting of shareholders has already been called and a notice of meeting already given or where it is clear that the primary purpose of the requisition is to redress a personal grievance against us or our directors, officers or shareholders, our directors, on receipt of such requisition, must call a meeting of shareholders. If the directors fail to call a meeting of shareholders within twenty-one days after receiving the requisition, any shareholder who signed the requisition may call the meeting of shareholders and, unless the shareholders resolve otherwise at the meeting, we shall reimburse the shareholders for the expenses reasonably incurred by them in requisitioning, calling and holding the meeting of shareholders.

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

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

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

On March 21, 2013, the Board of Directors approved an amendment to our bylaws in order to include an advance notice provision (the "Advance Notice Requirement") and concurrently approved an amendment to and restatement of our bylaws giving effect to the Advance Notice Requirement (the "Amended and Restated Bylaws"). The Amended and Restated Bylaws giving effect to the Advance Notice Requirement were subsequently ratified and approved by our shareholders on May 8, 2013. The Advance Notice Requirement applies in certain circumstances where nominations of persons for election to the Board of Directors are made by our shareholders other than pursuant to: (a) a requisition of a meeting made pursuant to the provisions of the CBCA; or (b) a shareholder proposal made pursuant

to the provisions of the CBCA.

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

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

Limitations on Right to Own Securities

Neither Canadian law nor our Restated Articles of Incorporation, our articles of amendment or bylaws limit the right of a non-resident to hold or vote our Common Shares, other than as provided in the Investment Canada Act (the "Investment Act").

The Investment Act requires any person that is a “non-Canadian” (as defined in the Investment Act) who acquires “control” (as defined in the Investment Act) of an existing Canadian business to file either a pre-closing application for review or a post-closing notification with Industry Canada.

On March 25, 2015, the Canadian government announced new Investment Act regulations that changed the thresholds for determining when an acquisition of control of a Canadian business is a reviewable transaction (from an asset value-based test to an enterprise value-based test, in most cases). As of April 24, 2015, when amendments to the Investment Act and the regulations come into force, the threshold for review of a direct acquisition of control of a non-cultural Canadian business by a World Trade Organization member country investor is an enterprise value of assets that exceeds CAN$600 million. The enterprise value review threshold will remain at CAN$600 million for two years, before increasing to CAN$800 million for the following two years, and then to CAN$1 billion. For purposes of a publicly traded company, the “enterprise value” of the assets of the Canadian business is equal to the market capitalization of the entity, plus its liabilities (excluding its operating liabilities), minus its cash and cash equivalents. As such, under the Investment Act, the acquisition of control of us (either through the acquisition of our Common Shares or all or substantially all our assets) by a non-Canadian who is a World Trade Organization member country investor, including a U.S. investor, would be reviewable only if the enterprise value of our assets exceeds the specified threshold for review.

Where the acquisition of control is a reviewable transaction, the Investment Act generally prohibits the implementation of the reviewable transaction unless, after review, the relevant Minister is satisfied or deemed to be satisfied that the acquisition is likely to be of net benefit to Canada.

The acquisition of a majority of the voting interests of an entity is deemed to be acquisition of “control” of that entity. The acquisition of less than a majority but one-third or more of the total number of votes attached to all of the voting shares of a corporation or of an equivalent undivided ownership interest in the total number of votes attached to all of the voting shares of the corporation is presumed to be an acquisition of control of that corporation unless it can be established that, on the acquisition, the corporation is not controlled in fact by the acquiror through the ownership of voting shares. The acquisition of less than one-third of the total number of votes attached to all of the voting shares of a corporation is deemed not to be acquisition of control of that corporation subject to certain discretionary rights relative to investments involving state owned enterprises. Other than in connection with a "national security" review, discussed below, certain transactions in relation to our Common Shares would be exempt from the Investment Act including:

- the acquisition of our Common Shares by a person in the ordinary course of that person's business as a trader or dealer in securities;
- the acquisition or control of us in connection with the realization of security granted for a loan or other financial assistance and not for any purpose related to the provisions of the Investment Act; and
- the acquisition or control of us by reason of an amalgamation, merger, consolidation or corporate reorganization following which the ultimate direct or indirect control in fact of us, through the ownership of our voting interests, remains unchanged.

Under the national security regime in the Investment Act, review on a discretionary basis may also be undertaken by the federal government in respect of a much broader range of investments by a non-Canadian to "acquire, in whole or in part, or to establish an entity carrying on all or any part of its operations in Canada". The relevant test is whether such an investment by a non-Canadian could be "injurious to national security". The Minister of Innovation, Science and Economic Development has broad discretion to determine whether an investor is a non-Canadian and therefore

may be subject to national security review. Review on national security grounds is at the discretion of the federal government and may occur on a pre or post-closing basis.

There is no law, governmental decree or regulation in Canada that restricts the export or import of capital, or which would affect the remittance of dividends or other payments by us to non-resident holders of our Common Shares, other than withholding tax requirements.

C. Material contracts

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

Sinopharm Agreements

On December 1, 2014, we entered into an exclusive Master Collaboration Agreement, a Technology Transfer and Technical Assistance Agreement ("Tech Transfer Agreement") and a License Agreement ("License Agreement") with Sinopharm A-Think Pharmaceuticals Co., Ltd. ("Sinopharm") for the development, manufacture and commercialization of Zoptrex™ in all human uses, in the People's Republic of China, including Hong Kong and Macau (collectively, the "Territory"). Under the terms of the Tech Transfer Agreement, Sinopharm made a one-time, non-refundable payment of $1,101,000 ("Transfer Fee") to us for the transfer of technical documentation and materials, know-how and technical assistance services. We will be entitled to receive additional consideration upon achieving certain milestones, including the occurrence of certain regulatory and commercial events in the Territory. Furthermore, we will be entitled to royalties on future net sales of Zoptrex™ in the Territory. Sinopharm will be responsible for the development, production, registration and commercialization of Zoptrex™ in the Territory.

Sinopharm is required to use commercially reasonable efforts to develop, manufacture and commercialize Zoptrex™ in the Territory, in order to maximize the net sales derived from Zoptrex™ during the royalty term of the License Agreement. In particular, Sinopharm is required to use commercially reasonable efforts to: (i) develop Zoptrex™ for the indication of endometrial cancer in the Territory in accordance with an agreed development plan and not to terminate, suspend, halt or delay development, unless there are substantial safety, efficacy, commercial or regulatory reasons for doing so; (ii) apply for and obtain all required regulatory approvals in the Territory following successful completion of all appropriate clinical studies; (iii) make the first commercial sale of Zoptrex™ in the Territory within a specified period of time following the approval of Zoptrex™ for endometrial cancer; (iv) maintain an adequate sales force and provide for relevant staff to manage the pre- and post-launch activities required to commercialize Zoptrex™ in the Territory; and (v) seek to maximize sales of Zoptrex™ in the Territory. Sinopharm's failure to use commercially reasonable efforts to develop, manufacture and commercialize Zoptrex™ would be a material breach of the License Agreement.

The License Agreement imposes on Sinopharm the responsibility for marketing, promoting and selling Zoptrex™ in the Territory after all regulatory approvals for commercial sale have been obtained, including pre-launch and post-launch marketing, promoting, conducting market research, distributing, offering to commercially sell and commercially selling Zoptrex™, importing, exporting or transporting Zoptrex™ for commercial sale, conducting medical education activities, conducting clinical studies that are not required to obtain or maintain regulatory approval of Zoptrex™ for an indication, which may include epidemiological studies, modeling and pharmacoeconomic studies, conducting post-marketing surveillance studies, conducting investigator sponsored studies and health economics studies and regulatory affairs.

The License Agreement will expire at the end of a defined royalty period, at which time the license that we granted to Sinopharm will become a fully paid-up, perpetual license. Sinopharm has the right to terminate the License Agreement if there are material safety, efficacy, commercial or regulatory reasons for doing so; if we commit a material breach of any term of the License Agreement that we fail to cure within 90 days after receiving written notice of the breach; if we file or institute bankruptcy, reorganization, liquidation or receivership proceedings; or if we assign a substantial portion of our assets for the benefit of our creditors. If Sinopharm has the right to terminate because a third party institutes involuntary bankruptcy proceedings against us, we will have 90 days to obtain the dismissal of the proceedings, during which time, Sinopharm may not terminate the Agreement.

We have the right to terminate the License Agreement if Sinopharm commits a material breach of any term of the License Agreement that it fails to cure within 90 days after receiving written notice of the breach; if it files or institutes bankruptcy, reorganization, liquidation or receivership proceedings, or if it assigns a substantial portion of its assets for the benefit of its creditors. If we have the right to terminate because a third-party institutes involuntary bankruptcy proceedings against Sinopharm, it will have 90 days to obtain the dismissal of the proceedings, during which time, we may not terminate the Agreement.

The License Agreement contains customary provisions related to, among other things, our oversight of Sinopharm's commercialization efforts, intellectual property, pharmacovigilance, confidentiality and non-disclosure, representations and warranties, indemnity and dispute resolution. The License Agreement is governed by the laws of Hong Kong.

The Master Collaboration Agreement, the License Agreement and the Tech Transfer Agreement are incorporated by reference as Exhibits 4.11, 4.12 and 4.13 to this Annual Report on Form 20-F.

Employment Agreements

We have, or one of our subsidiaries has, entered into an employment agreement or a service contract (collectively, the "Employment Agreements") with each of the Named Executive Officers who remain in our employment, except for Mr. Philip A. Theodore, our Senior Vice President, Chief Administrative Officer, General Counsel and Secretary. The Employment Agreements provide that we will pay the executive a base salary and an annual bonus, if our economic results justify payment of a bonus and subject to the determination and approval of the Governance Committee and our Board, and that such executives will be eligible to receive long-term incentive grants in the form of stock options, which will be reviewed annually in accordance with our policies. The Employment Agreements have an indefinite term; provided, however, that Dr. Sachse's Employment Agreement will end without the need to give notice not later than the expiry of the month during which Dr. Sachse attains the minimum age of legal retirement in Germany.

The Employment Agreements of Messrs. Dodd, Dinges and Santorelli provide that (i) if we terminate their employment without “Cause”, (ii) in the case of Mr. Dinges, there is a “separation from service” within the meaning of Section 409A of the U.S. Internal Revenue Code of 1986, as amended (a “Separation from Service”) or (iii) if they resign for “Good Reason”, then the executive will be entitled to receive, in the case of Mr. Dodd, a lump-sum payment (less applicable tax withholdings) in an amount equal to twice the sum of his then base salary, his then annual bonus, the amount of his then car allowance, plus any earned retention bonus and eighteen months of the value of the other benefits to which he is entitled (through the purchase by us of eighteen months of the coverage required under the Consolidated Omnibus Budget Reconciliation Act of 1986 ("COBRA")). In the case of Messrs. Dinges and Santorelli, the executive is entitled to receive a lump-sum payment (less applicable tax withholdings) in an amount equal to one times the sum of his then base salary, his then annual bonus, pro-rated as applicable, any earned retention bonus, if applicable, the amount of his then car allowance, if applicable, and eighteen months of the value of the other benefits to which he is entitled (through our purchase of eighteen months of the coverage required under COBRA). In addition, in the case of Messrs. Dodd, Dinges and Santorelli, if the executive has a Separation of Service, then the executive's right to exercise all then outstanding stock options granted to him shall fully and immediately vest on the effective date of the Separation from Service.

In connection with the closure of our Quebec City office and the restructuring of our finance and accounting staff, on October 9, 2015, we entered into a transition agreement with Mr. Santorelli pursuant to which we agreed to pay him the sum of $336,600 and to maintain coverage under our health insurance plan until August 31, 2016, and to permit all stock options issued to him to immediately vest in exchange for his provision of certain transition services to us. We also agreed to waive the non-competition covenant contained in his employment agreement. Mr. Santorelli’s employment with us terminated on February 18, 2016 after he fulfilled his obligations to us pursuant to the transition agreement.

Dr. Sachse's Employment Agreement provides that we are entitled to terminate his agreement without cause by giving him six months' prior notice effective to the end of any calendar month. During the six-month notice period, Dr. Sachse is entitled only to his salary and he has no right to receive a cash bonus or any other form of remuneration. Furthermore, Messrs. Dodd and Dinges shall not, for a period equal to one year following such executive's termination of employment with us, directly or indirectly, compete with us; solicit any of our clients or do anything whatsoever to induce or to lead any person to end, in whole or in part, its business relations with us; induce, attempt to induce or otherwise interfere in the relations which we have with our distributors, suppliers, representatives, agents and other parties with whom we deal; or induce, attempt to induce or otherwise solicit our personnel to leave their employment with us or hire our personnel for any enterprise in which the executive has an interest. The foregoing agreement applies in each territory in which we had “actively exploited” (as defined in each executive's employment agreement) a product during the two years preceding the date of such executive's termination of employment.

Dr. Sachse's Employment Agreement also contains a non-competition provision. Dr. Sachse is prohibited from competing with us, or any of our subsidiaries, during the term of his Employment Agreement and for a period of one year following the date of termination of his Employment Agreement. The non-competition provision prohibits Dr. Sachse from participating in any capacity whatsoever, and from having any interest whatsoever, in a business that would directly or indirectly compete with us, or with any of our subsidiaries, including a business involved in the development and commercialization of the specific endocrine therapies and oncology treatments that we, or any of our subsidiaries, are actively developing. The territory covered by Dr. Sachse's non-competition provision is the geographical areas in which a specific product had been actively exploited by us or one of our subsidiaries during the two years preceding the date of termination of his employment. The non-competition provision prohibits Dr. Sachse from performing duties for the competing business that are identical or substantially similar to those duties he performed or carried on for us during the 24 months preceding the termination of his Employment Agreement. If Dr. Sachse is unable to find a new employment because of the existence of the non-competition provision, we will pay him his base salary during a period ending on the first to occur of (i) the date on which he starts a new employment and (ii) the date on which the non-competition provision expires.

Pursuant to his Employment Agreement, Mr. Dodd is also entitled to receive certain payments (the "Change of Control Payments") in the event (i) a "Change of Control" occurs and (ii) during the twelve-month period following

the Change of Control, either we terminate his employment without "Cause", or he terminates his employment for "Good Reason" during such period. The Change of Control Payment will equal the sum of the following amounts: (i) the equivalent of thirty-six months of his then annual base salary, (ii) an amount equivalent to twice the annual bonus, if any, which he would have been entitled to receive in the year during which the Change of Control occurred, (iii) any earned retention bonus, and (iv) an amount equivalent to 12 months of the then annual cost to provide the other benefits to which he is entitled, or our cost to purchase coverage under COBRA for such benefits, whichever is applicable. The Change of Control Payment is subject to applicable statutory withholdings. Any outstanding stock options held by Mr. Dodd shall, in such circumstances, fully and immediately vest on the date of his Separation from Service.

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

- a "Change of Control" shall be deemed to have occurred in any of the following circumstances: (i) subject to certain exceptions, upon the acquisition by a person (or one or more persons who are affiliates of one another or who are acting jointly or in concert) of a beneficial interest in our securities representing in any circumstance 50% or more of the voting rights attaching to our then outstanding securities; (ii) upon a sale or other disposition of all or substantially all of our assets; (iii) upon a plan of liquidation or dissolution of us; or (iv) if, for any reason, including our amalgamation, merger or consolidation with or into another company, the individuals who, as at the date of the relevant Employment Agreement, constituted the Board (and any new directors whose appointment by the Board or whose nomination for election by our shareholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors as at the date of the relevant Employment Agreement or whose appointment or nomination for election was previously so approved) cease to constitute a majority of the members of the Board;
- termination of employment for "Cause" includes (but is not limited to) (i) if the executive commits any fraud, theft, embezzlement or other criminal act of a similar nature, and (ii) if the executive is guilty of serious misconduct or willful negligence in the performance of his duties; and
- termination of employment by the executive officer for "Good Reason" means,

in the case of Mr. Dodd, the occurrence, without his express written consent, of any of the following acts: (i) a material reduction of his total compensation (including annual base salary plus annual bonus, benefits and number of stock options) as in effect on the date of his Employment Agreement or as same may be increased from time to time, provided such reduction is not warranted and due to our performance; (ii) any change in his direct reporting relationship to the Board; (iii) any reduction in his duties and responsibilities as our President and Chief Executive Officer; or (iv) a physical change of one hundred miles of more in his principal place of business; and

in the case of Mr. Dinges, the occurrence, without his express written consent, of any of the following acts: (i) a more than 25% reduction of his base annual salary as in effect on the date of his Employment Agreement or as the same may be increased from time to time, provided such reduction is not warranted and due to either our performance or failure of Mr. Dinges to achieve performance standards or objectives as determined by our President in his sole and absolute discretion and judgment; or (ii) a material reduction in his duties and responsibilities as our Chief Commercial Officer.

D. Exchange controls

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

E. Taxation

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

Material Canadian Income Tax Considerations

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

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

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

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

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

Holders Not Resident in Canada

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

Disposition of Common Shares

A Non-Resident holder generally will not be subject to tax under the Tax Act in respect of any capital gain realized by such Non- Resident holder on a disposition or deemed disposition of Common Shares unless such shares constitute "taxable Canadian property" (as defined in the Tax Act) of the Non-Resident holder at the time of disposition and the gain is not exempt from tax pursuant to the terms of an applicable income tax treaty or convention. As long as the Common Shares are listed on a designated stock exchange (which currently includes NASDAQ and the TSX) at the time of their disposition, the Common Shares generally will not constitute taxable Canadian property of a Non-Resident holder, unless (a) at any time during the 60-month period immediately preceding the disposition (i) one or any combination of (A) the Non-Resident holder, (B) persons with whom the Non-Resident holder did not deal at arm's length, and (C) partnerships in which the Non-Resident holder or a person described in (B) holds a membership interest directly or indirectly through one or more partnerships, owned 25% or more of the issued shares of any class or series of shares of the Company; and (ii) more than 50% of the fair market value of the shares of the Company was derived directly or indirectly from one or any combination of real or immovable property situated in Canada, "Canadian resource properties" (as defined in the Tax Act), "timber resource properties" (as defined in the Tax Act) or options in respect of, or interests in, or for civil law rights in, any such property whether or not such property exists or (b) our Common Shares are otherwise deemed to be taxable Canadian property to the Non-Resident holder.

A Non-Resident holder's capital gain (or capital loss) in respect of Common Shares that constitute or are deemed to constitute taxable Canadian property (and are not "treaty-protected property" as defined in the Tax Act) will generally be computed in the manner described below under the heading "Holders Resident in Canada - Disposition of Common Shares". If the Common Shares were to cease being listed on NASDAQ, the TSX or another "recognized stock exchange" (as defined in the Tax Act), a Non-Resident holder who disposes of Common Shares that are taxable Canadian property may be required to fulfill the requirements of section 116 of the Tax Act, unless the Common Shares are "treaty-protected property" (as defined in the Tax Act) of the disposing Non-Resident holder.

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

Taxation of Dividends on Common Shares

Dividends paid or credited or deemed to be paid or credited to a Non-Resident holder by the Company are subject to Canadian withholding tax at the rate of 25% unless reduced by the terms of an applicable tax treaty or convention. Under the Canada - United States Tax Convention (1980) (the "Convention") as amended, the rate of withholding tax on dividends paid or credited to a Non-

Resident holder who is the beneficial owner of the dividends, is resident in the US for purposes of the Convention and entitled to the benefits of the Convention (a "US holder") is generally limited to 15% of the gross amount of the dividend (or 5% in the case of a US holder that is a company beneficially owning at least 10% of the Company's voting shares). Non-Resident holders should consult their own tax advisors.

Holders Resident in Canada

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

Taxation of Dividends on Common Shares

Dividends received or deemed to have been received on the Common Shares will be included in a Canadian holder's income for purposes of the Tax Act. Such dividends received or deemed to have been received by a Canadian holder that is an individual (other than certain trusts) will be subject to the gross-up and dividend tax credit rules generally applicable under the Tax Act in respect of dividends received on shares of taxable Canadian corporations. Generally, a dividend will be eligible for the enhanced gross-up and dividend tax credit if the Company designates the dividend as an "eligible dividend" (within the meaning of the Tax Act) in accordance with the provisions of the Tax Act. There may be limitations on the ability of the Company to designate dividends as eligible dividends. A Canadian holder that is a corporation will be required to include such dividends in computing its income and will generally be entitled to deduct the amount of such dividends in computing its taxable income. A Canadian holder that is a "private corporation" or a "subject corporation" (as such terms are defined in the Tax Act), may be liable under Part IV of the Tax Act to pay a refundable tax of 38 1/3% on dividends received or deemed to have been received on the Common Shares to the extent such dividends are deductible in computing the holder's taxable income.

Disposition of Common Shares

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

Additional Refundable Tax

A Canadian holder that is a "Canadian-controlled private corporation" (as such term is defined in the Tax Act) may be liable to pay an additional refundable tax of 10 2/3% on certain investment income including amounts in respect of "Taxable Capital Gains", as defined below.

Taxation of Capital Gains and Capital Losses

In general, one half of any capital gain (a "Taxable Capital Gain") realized by a Canadian holder in a taxation year will be included in the holder's income in the year. Subject to and in accordance with the provisions of the Tax Act, one half of any capital loss (an "Allowable Capital Loss") realized by a Canadian holder in a taxation year must be deducted from Taxable Capital Gains realized by the holder in the year and Allowable Capital Losses in excess of Taxable Capital Gains may be carried back and deducted in any of the three preceding taxation years or carried forward and deducted in any subsequent taxation year against net Taxable Capital Gains realized in such years. The

amount of any capital loss realized by a Canadian holder that is a corporation on the disposition or deemed disposition of a Common Share may be reduced by the amount of dividends received or deemed to have been received by it on such Common Share (or on a share for which the Common Share has been substituted) to the extent and under the circumstances prescribed by the Tax Act. Similar rules may apply where a corporation is a member of a partnership or a beneficiary of a trust that owns Common Shares, directly or indirectly, through a partnership or a trust.

Alternative Minimum Tax

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

Certain Material US Federal Income Tax Considerations

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

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

- dealers in stocks, securities or currencies;
- securities traders that use a mark-to-market accounting method;
- banks and financial institutions;
- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- tax-exempt organizations;
- retirement plans, individual plans, individual retirement accounts and tax-deferred accounts;
- partnerships or other pass-through entities for US federal income tax purposes and their partners or members;
- persons holding Common Shares as part of a hedging or conversion transaction straddle or other integrated or risk reduction transaction;
- persons who or that are, or may become, subject to the expatriation provisions of the Code;
- persons whose functional currency is not the US dollar; and
- direct, indirect or constructive owners of 10% or more of the total combined voting power of all classes of our voting stock.

This summary also does not address the tax consequences of holding, exercising or disposing of warrants in the Company. If the Company is a PFIC, as described below, US Holders of its warrants will be subject to adverse tax rules and will not be able to make the mark-to-market or the QEF election described below with respect to such warrants. We believe that we were a PFIC for the 2015 taxable year. US Holders of warrants should consult their tax advisors with regard to the US federal income tax consequences of holding, exercising or disposing of warrants in the

Company, including in the situation in which the Company is classified as a PFIC.

This summary also does not discuss any aspect of state, local or foreign law, or estate or gift tax law as applicable to US Holders. In addition, this discussion is limited to US Holders holding Common Shares as capital assets. For purposes of this summary, "US Holder" means a beneficial holder of Common Shares who or that for US federal income tax purposes is:

- an individual citizen or resident of the United States;
- a corporation or other entity classified as a corporation for US federal income tax purposes created or organized in or under the laws of the United States, any state thereof or the District of Columbia;

- an estate, the income of which is subject to US federal income taxation regardless of its source; or
- a trust, if (a) a court within the United States is able to exercise primary supervision over the administration of such trust and one or more "US persons" (within the meaning of the Code) have the authority to control all substantial decisions of the trust, or (b) a valid election is in effect to be treated as a US person for US federal income tax purposes.

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

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

Tax Consequences if we are a Passive Foreign Investment Company ("PFIC")

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

The Company believes it was a PFIC for the 2015 taxable year. However, the fair market value of the Company's assets may be determined in large part by the market price of the Common Shares, which is likely to fluctuate, and the composition of the Company's income and assets will be affected by how, and how quickly, the Company spends any cash that is raised in any financing transaction. Thus, no assurance can be provided that the Company will not be classified as a PFIC for any future taxable year. US Holders should consult their tax advisors regarding the Company's PFIC status.

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

Under these adverse rules (a) the excess distribution or gain will be allocated ratably over the US Holder's holding period, (b) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which the Company is classified as a PFIC will be taxed as ordinary income, and (c) the amount allocated to each of the other taxable years during which the Company was classified as a PFIC will be subject to tax at the highest rate of tax

in effect for the applicable category of taxpayer for that year and an interest charge will be imposed with respect to the resulting tax attributable to each such other taxable year. A US Holder that is not a corporation will be required to treat any such interest paid as "personal interest", which is not deductible.

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

A US Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year an amount equal to the excess, if any, of the fair market value of the US Holder's Common Shares at the close of the taxable year

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

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

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

In some cases, a shareholder of a PFIC can avoid the interest charge and the other adverse PFIC consequences described above by making a QEF election to be taxed currently on its share of the PFIC's undistributed income. We will endeavor to satisfy the record keeping requirements that apply to a QEF and to supply requesting US Holders with the information that such US 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 US Holders.

A US Holder that makes a timely and effective QEF election for the first tax year in which its holding period of its Common Shares begins generally will not be subject to the adverse PFIC consequences described above with respect to its Common Shares. Rather, a US Holder that makes a timely and effective QEF election will be subject to US federal income tax on such US Holder's pro rata share of (a) the Company's net capital gain, which will be taxed as long-term capital gain to such US Holder, and (b) the Company's ordinary earnings, which will be taxed as ordinary income to such US Holder, in each case regardless of which such amounts are actually distributed to the US Holder by the Company. Generally, "net capital gain" is the excess of (a) net long-term capital gain over (b) net short-term capital loss, and "ordinary earnings" are the excess of (a) "earnings and profits" over (b) net capital gain.

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

The QEF election is made on a shareholder-by-shareholder basis. Once made, a QEF election will apply to the tax year for which the QEF election is made and to all subsequent tax years, unless the QEF election is invalidated or terminated or the IRS consents to revocation of the QEF election. In addition, if a US Holder makes a QEF election,

the QEF election will remain in effect (although it will not be applicable) during those tax years in which the Company is not a PFIC.

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

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

In addition, if the Company is a PFIC, US Holders will generally be required to file an annual information return with the IRS (also on IRS Form 8621, which PFIC shareholders are required to file with their US federal income tax or information returns)

relating to their ownership of Common Shares. This new filing requirement is in addition to the preexisting reporting requirements described above that apply to a US Holder's interest in a PFIC (which this requirement does not affect).

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

Dividends

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

Dividends paid to non-corporate US Holders by the Company in a taxable year in which it is treated as a PFIC, or in the immediately following taxable year, will not be eligible for the special reduced rates normally applicable to long-term capital gains. In all other taxable years, dividends paid by the Company should be taxable to a non-corporate US Holder at the special reduced rates normally applicable to long-term capital gains, provided that certain conditions are satisfied. The Company believes it was a PFIC for the 2015 taxable year and, therefore, a US Holder will not be able to claim a reduced rate for dividends paid in 2016 (if any). See "Passive Foreign Investment Company Considerations" above.

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

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

Dividends paid in Canadian dollars will be included in the gross income of a US Holder in a US dollar amount calculated by reference to the exchange rate in effect on the date the US Holder (actually or constructively) receives the dividend, regardless of whether such Canadian dollars are actually converted into US dollars at that time. If the Canadian dollars received are not converted into US dollars on the date of receipt, a US Holder will have a tax basis in

the Canadian dollars equal to their US dollar value on the date of receipt. Gain or loss, if any, realized on a sale or other disposition of the Canadian dollars will generally be US source ordinary income or loss to a US Holder.

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

Sale, Exchange or Other Taxable Disposition of Common Shares

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

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

Information Reporting and Backup Withholding

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

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

Subject to certain exceptions and future guidance, US tax legislation generally requires a US Holder that is a specified individual or, to the extent provided in future guidance, a domestic entity, to report annually to the IRS on IRS Form 8938 such US Holder's interests in stock or securities issued by a non-US person (such as the Company). US Holders should consult their tax advisors regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of Common Shares.

F. Dividends and paying agents

Not applicable.

G. Statement by experts

Not applicable.

H. Documents on display

In addition to placing our audited consolidated annual financial statements before every annual meeting of shareholders as described above, we are subject to the information requirements of the Securities Exchange Act of 1934, as amended. In accordance with these requirements, we file and furnish reports and other information with the SEC. These materials, including this Annual Report on Form 20-F and the exhibits hereto, may be inspected and copied at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. The public may obtain information on the operation of the SEC's Public Reference Room by calling the SEC in the United States at 1-800-SEC-0330. The SEC also maintains a website at www.sec.gov that contains reports, proxy statements and other information regarding registrants that file electronically with the SEC. Our annual reports and some of the other information we submitted to the SEC may be accessed through this website. In addition, material we filed can be inspected on the Canadian Securities Administrators' electronic filing system, SEDAR, accessible at the website www.sedar.com. This material includes our Management Information Circular for our annual meeting of shareholders to be held on May 10, 2016 furnished to the SEC on Form 6-K, which provides information including directors' and officers' remuneration and indebtedness and principal holders of securities. Additional financial information is provided in our audited annual financial statements for the year ended December 31, 2015 and our MD&A relating to these statements included elsewhere in this Annual Report on Form 20-F. These documents are also accessible on SEDAR (www.sedar.com) and on EDGAR (www.sec.gov).

I. Subsidiary information

Our subsidiaries are set forth under "Item 4C. – Organizational Structure".

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Item 11. Quantitative and Qualitative Disclosures About Market Risk

Fair value

The Company classifies its financial instruments in the following categories: "Financial assets at fair value through profit or loss ("FVTPL")"; "Loans and receivables"; "Financial liabilities at FVTPL"; and "Other financial liabilities".

- The Company's loans and receivables are comprised of cash and cash equivalents, trade and other receivables and restricted cash equivalents.
- Financial liabilities at FVTPL are currently comprised of the Company's warrant liability.
- Other financial liabilities include trade accounts payable and accrued liabilities, provision for restructuring costs and other non-current liabilities.

The carrying values of all of the aforementioned financial instruments, excluding warrant liability which is stated at fair value, approximate their fair values due to their short-term maturity or to the prevailing interest rates of these instruments, which are comparable to those of the market.

Financial risk factors

The following provides disclosures relating to the nature and extent of the Company's exposure to risks arising from financial instruments, including credit risk, liquidity risk and market risk (share price risk and currency risk), and how the Company manages those risks.

(a) Credit risk

Credit risk is the risk of an unexpected loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. The Company regularly monitors credit risk exposure and takes steps to mitigate the likelihood of this exposure resulting in losses. The Company's exposure to credit risk currently relates to cash and cash equivalents, trade and other receivables and restricted cash equivalents. The Company holds its available cash in amounts that are readily convertible to known amounts of cash and deposits its cash balances with financial institutions that have an investment grade credit rating of at least "A" or the equivalent. This information is supplied by independent rating agencies where available and, if not available, the Company uses publicly available financial information to ensure that it invests its cash in creditworthy and reputable financial institutions.

As at December 31, 2015, trade accounts receivable for an amount of approximately $122,000 were with two counterparties, and no trade accounts receivable were past due or impaired.

Generally, the Company does not require collateral or other security from customers for trade accounts receivable; however, credit is extended following an evaluation of creditworthiness. In addition, the Company performs ongoing credit reviews of all its customers and establishes an allowance for doubtful accounts when accounts are determined to be uncollectible.

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

(b) Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they become due. As indicated in the capital disclosures section (see "Item 5 – Operating and Financial Review and Prospects") the Company manages this risk through the management of its capital structure. It also manages liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors reviews and approves the Company's operating and capital budgets, as well as any material transactions out of the ordinary course of business. The Company has adopted an investment policy in respect of the safety and preservation of its capital to ensure the Company's liquidity needs are met. The instruments are selected with regard to the expected timing of expenditures and prevailing interest rates.

The Company expects to continue to incur operating expenses and may require significant capital to fulfill its future obligations in absence of sufficient corresponding revenues. The Company's ability to continue future operations beyond December 31, 2016 and to fund its activities is dependent on its ability to secure additional financings, which may be completed in a number of ways, including but not limited to licensing arrangements, partnerships, promotional arrangements, the issuance of securities and other financing activities. Management will pursue such additional sources of financing when required, and while the Company has been successful in securing financing in the past, there can be no assurance it will be able to do so in the future or that these sources of funding or initiatives will be available or on terms acceptable to the Company.

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(c) Market risk

Share price risk

The change in fair value of the Company's warrant liability, which is measured at FVTPL, results from the periodic "mark-to-market" revaluation, via the application of the intrinsic valuation and the Black-Scholes option pricing model. These valuation models are impacted, among other inputs, by the market price of the Company's common shares. As a result, the change in fair value of the warrant liability, which is reported as finance income (costs) in the accompanying consolidated statements of comprehensive (loss) income, has been and may continue in future periods to be materially affected most notably by changes in the Company's common share closing price, which on the NASDAQ, has ranged from $4.00 to $84.20 during the year ended December 31, 2015.

If variations in the market price of our Common Shares of -10% and +10% were to occur, the impact on the Company's net (loss) income for warrant liability held at December 31, 2015 would be as follows:

(in thousands)	Carrying amount	-10%	+10%
	$	$	$
Warrant liability	10,891	1,059	(1,067)
Total impact on net income – decrease / (increase)		1,059	(1,067)

Foreign currency risk

We have not entered into any forward currency contracts or other financial derivatives to hedge foreign exchange risk. We are therefore subject to foreign currency transaction and translation gains and losses.

Item 12. Description of Securities Other than Equity Securities

A. Debt securities

Not applicable.

B. Warrants and rights

Not applicable.

C. Other securities

Not applicable.

D. American depositary shares

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

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

None.

Item 15. Controls and Procedures

Under the supervision of and with the participation of the Registrant's management, including the Chief Executive Officer and the Principal Financial Officer, we have conducted an evaluation pursuant to Rule 13a-15, promulgated under the Securities Exchange Act of 1934, as amended, of the effectiveness of our disclosure controls and procedures as at December 31, 2015. Based on that evaluation, the Chief Executive Officer and the Principal Financial Officer have concluded that these disclosure controls and procedures were effective as at December 31, 2015.

Management's Annual Report on Internal Control over Financial Reporting

The Registrant's management is responsible for establishing and maintaining adequate internal control over financial reporting. The Registrant's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS as issued by IASB.

The Registrant's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Registrant's assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS, and that receipts and expenditures of the Registrant are being made only in accordance with authorizations of the Registrant's management; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Registrant's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management conducted an evaluation of the effectiveness of the Registrant's internal control over financial reporting based on the criteria established in Internal Control - Integrated Framework: 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that the Registrant's internal control over financial reporting was effective as at December 31, 2015.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our Board has determined that we have at least one audit committee financial expert (as defined in paragraph (b) of Item 16A to Form 20-F). The name of the audit committee financial expert is Mr. Gérard Limoges, FCPA, FCA, the Audit Committee's Chairman. In accordance with Item 6A, paragraph (d) of Form 20-F, the designation of Mr. Limoges as our audit committee financial expert does not: (i) make Mr. Limoges an "expert" for any purpose, including without limitation for purposes of Section 11 of the Securities Act of 1933, as amended, as a result of this designation; (ii) impose any duties, obligations or liability on Mr. Limoges that are greater than those imposed on him as a member of the Audit Committee and the Board in the absence of such designation; or (iii) affect the duties, obligations or liability of any other member of the Audit Committee or the Board. The other members of the Audit Committee are Mr. Pierre Lapalme and Ms. Carolyn Egbert, each of whom, along with Mr. Limoges, is independent, as that term is defined in the NASDAQ listing standards. For a description of their respective education and experience, please refer to "Item 6. – Directors, Senior Management and Employees".

Item 16B. Code of Ethics

On March 29, 2004, the Board adopted a "Code of Ethical Conduct", which has been amended by the Board on November 3, 2004, December 13, 2005, March 2, 2007 and March 10, 2009. The December 13, 2005 amendment incorporates changes to the duty to report violations consistent with applicable laws. We selected an independent third party supplier to provide a confidential and anonymous communication channel for reporting concerns about possible violations to the our Code of Ethical Conduct as well as financial and/or accounting irregularities or fraud. A copy of the Code of Ethical Conduct, as amended, is included as Exhibit 11.1 to this Annual Report on Form 20-F and is also available on our Web site at www.aezsinc.com under the Investors - Governance tab. The Code of Ethical Conduct is

a "code of ethics" as defined in paragraph (b) of Item 16B to Form 20- F. The Code of Ethical Conduct applies to all of our employees, directors and officers, including our principal executive officer, principal financial officer, and principal accounting officer or controller, or persons performing similar functions, and includes specific

provisions dealing with integrity in accounting matters, conflicts of interest and compliance with applicable laws and regulations. On December 4, 2014, our Board of Directors adopted a "Code of Business Conduct and Ethics for Members of the Board of Directors", which is included as Exhibit 11.2 to this Annual Report on Form 20-F. We will provide these documents without charge to any person or company upon request to our Corporate Secretary, at our head office at 315 Sigma Drive, Suite 302D, Summerville, South Carolina 29483.

Item 16C. Principal Accountant Fees and Services

(All amounts are in US dollars)

(a) Audit Fees

During the financial years ended December 31, 2015 and 2014, the Registrant's principal accountant, PricewaterhouseCoopers LLP, billed $473,515 and $458,248, respectively, for the audit of the Registrant's annual consolidated financial statements and for services rendered in connection with the Registrant's statutory and regulatory filings.

(b) Audit-related Fees

During the financial years ended December 31, 2015 and 2014, the Registrant's principal accountant, PricewaterhouseCoopers LLP, billed $57,524 and $92,241, respectively, for audit or attest services not required by statute or regulation, for accounting consultations on proposed transactions, for the review of prospectuses and prospectus supplements, including the delivery of customary consent and comfort letters in connection therewith.

(c) Tax Fees

During the financial years ended December 31, 2015 and 2014, the Registrant's principal accountant, PricewaterhouseCoopers LLP, billed $24,269 and $27,661, respectively, for services related to tax compliance, tax planning and tax advice.

(d) All Other Fees

During the financial years ended December 31, 2015 and 2014, the Registrant's principal accountant, PricewaterhouseCoopers LLP, did not bill us for services not included in audit fees, audit-related fees and tax fees.

(e) Audit Committee Pre-Approval Policies and Procedures

Under applicable Canadian securities regulations, the Registrant is required to disclose whether its Audit Committee has adopted specific policies and procedures for the engagement of non-audit services and to prepare a summary of these policies and procedures. The Audit Committee Charter (included as Exhibit 11.3 to this Annual Report on Form 20-F, incorporated by reference to Exhibit 11.3 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2014 filed with the Commission on March 17, 2015) provides that it is such committee's responsibility to approve all audit engagement fees and terms as well as reviewing policies for the provision of non-audit services by the external auditors and, when required, the framework for pre-approval of such services. The Audit Committee delegates to its Chairman the pre-approval of such non-audit fees. The pre-approval by the Chairman is then presented to the Audit Committee at its first scheduled meeting following such pre-approval.

For each of the years ended December 31, 2015 and 2014, there were no non-audit services provided by the Registrant's external auditor that required the approval from the Audit Committee pursuant to the "de minimis exception" to the pre-approval requirement for non-audit services.

(f) Work performed by Full-time, Permanent Employees of Principal Accountant

During the financial year ended on December 31, 2015, no person other than the full-time, permanent employees of the Registrant's principal accountant, PricewaterhouseCoopers LLP, performed more than 50% of the audit work on the Registrant's financial statements.

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

None.

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

None.

Item 16F. Change in Registrant's Certifying Accountant

None.

Item 16G. Corporate Governance

We are generally in compliance with the corporate governance requirements of NASDAQ except as described below. We are not in compliance with the NASDAQ requirement that a quorum for a meeting of the holders of our Common Shares be no less than 33 1/3% of such outstanding shares. Our bylaws provide that a quorum for purposes of any meeting of our shareholders consists of at least 10% of the outstanding voting shares. We benefit from an exemption from NASDAQ from this quorum requirement because the quorum provided for in our bylaws complies with the requirements of the CBCA, our governing corporate statute, and with the rules of TSX, the home country exchange on which our voting shares are traded. In accordance with applicable current NASDAQ requirements, we have in the past, and upon request, provided to NASDAQ letters from outside counsel certifying that these practices are not prohibited by our home country law.

Item 16H. Mine Safety Disclosure

None.

PART III

Item 17 Financial Statements

We have elected to provide financial statements pursuant to Item 18.

Item 18. Financial Statements

The financial statements appear on pages 95 to 144.

Aeterna Zentaris Inc.

Consolidated Financial Statements
As at December 31, 2015 and December 31, 2014 and for the years ended
December 31, 2015, 2014 and 2013
(presented in thousands of US dollars)