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

FORM 20-F

	Registration Statement Pursuant to Section 12(b) or 12(g) of The Securities Exchange Act of 1934  OR
$\boxtimes$	Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the fiscal year ended December 31, 2016
	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) 315 Sigma Drive, Suite 302D
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	29486 (Name, Telephone, E-mail and Address of Company Contact Person)
Sec	urities registered or to be registered pursuant to Section 12(b) of the Act:
~~~	
	Title of Each Class  Name of Each Exchange on Which Registered  NASDAQ Capital Market
_	Toronto Stock Exchange
	urities registered or to be registered pursuant to Section 12(g) of the Act: <b>NONE</b> urities for which there is a reporting obligation pursuant to Section 15(d) of the ACT: <b>NONE</b>
Ind	cate 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: 12,917,995 nmon Shares as at December 31, 2016.
	cate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes $\square$ No $\boxtimes$
	is 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 of 1934. Yes $\square$ No $\boxtimes$
	cate 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 nonths (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
Ind pos	s. Yes $\square$ No $\square$ cate 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 red 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 post such files). Yes $\square$ No $\square$
Ind	cate 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 elerated filer" in Rule 12b-2 of the Exchange Act. (Check one):
Lar	ge accelerated filer   Accelerated filer   Non-accelerated filer
	cate 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 ☒
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.
Iter	n 17 □ Item 18 □
II th	is 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 $\square$ No $\boxtimes$

#### **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 ("US") 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, 2016.

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 have 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 stock 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 provision of the US Securities Litigation Reform Act of 1995, which reflect our current expectations regarding future events. Forward-looking statements may include, but are not limited to statements preceded by, followed by, or that include the words "expects," "believes," "intends," "anticipates," and similar terms that relate to future events, performance, or our results. Forward-looking statements involve known risks and uncertainties, which are discussed in this Annual Report on Form 20-F, under the caption "Key Information - Risk Factors" filed with the relevant Canadian securities regulatory authorities in lieu of an annual information form and with the US Securities and Exchange Commission ("SEC"). 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, 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. Known and unknown risks and uncertainties could cause our actual results to differ materially from those in forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue our research and development projects and clinical trials, 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 analyses 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 (including whether or not the regulatory authorities will accept the Company's conclusions regarding Macrilen<sup>TM</sup> following its comprehensive review of the Phase 3 study data described elsewhere in this Annual Report on Form 20-F), the ability of the Company to efficiently commercialize one or more of its products or product candidates, the degree of market acceptance once our products are approved for commercialization, our ability to take advantage of business opportunities in the pharmaceutical industry, our ability to protect our intellectual property, the potential of liability arising from shareholder lawsuits and general changes in economic conditions. Investors should consult the Company's quarterly and annual filings with the Canadian and US securities commissions for additional information on risks and uncertainties. Given these uncertainties and risk factors, readers are cautioned not to place undue reliance on these forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, unless required to do so by a governmental authority or applicable law.

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Exhibits

# 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, 2016, 2015 and 2014 and the consolidated statement of financial position data as at December 31, 2016 and 2015 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, 2013 and 2012 and the consolidated statement of financial position information as at December 31, 2014, 2013 and 2012 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

	December 31,				
	2016	2015	2014	2013	2012
	\$	\$	\$	\$	\$
Revenues					
Sales commission and other	414	297	_	96	834
License fees	497	248	11	6,079	1,219
	911	545	11	6,175	2,053
Operating expenses					
Cost of Sales	_	_	_	51	591
Research and development costs	16,495	17,234	23,716	21,284	20,592
General and administrative expenses	7,147	11,308	9,840	11,091	9,226
Selling expenses	6,745	6,887	3,850	1,225	1,380
	30,387	35,429	37,406	33,651	31,789
Loss from operations	(29,476)	(34,884)	(37,395)	(27,476)	(29,736)
(Loss) gain due to changes in foreign currency exchange rates	(70)	(1,767)	1,879	(1,512)	(382)
Change in fair value of warrant liability	4,437	(10,956)	18,272	1,563	6,746
Warrant exercise inducement fee	<u> </u>	(2,926)	_	_	_
Other finance income	150	305	168	185	228
Net finance (costs) income	4,517	(15,344)	20,319	236	6,592
Loss before income taxes	(24,959)	(50,228)	(17,076)	(27,240)	(23,144)
Income tax expense			(111)	_	
Net loss from continuing operations	(24,959)	(50,228)	(17,187)	(27,240)	(23,144)
Net income from discontinued operations	_	85	623	34,055	2,732
Net (loss) income	(24,959)	(50,143)	(16,564)	6,815	(20,412)
Other comprehensive (loss) income:	, , ,				
Items that may be reclassified subsequently to profit or loss:					
Foreign currency translation adjustments	569	1,509	(1,158)	1,073	(504)
Items that will not be reclassified to profit or loss:					
Actuarial (loss) gain on defined benefit plans	(1,479)	844	(1,833)	2,346	(3,705)
Comprehensive (loss) income	(25,869)	(47,790)	(19,555)	10,234	(24,621)
Net loss per share (basic and diluted) from continuing operations <sup>1</sup>	(2.41)	(18.17)	(29.12)	(92.41)	(117.04)
Net income per share (basic and diluted) from discontinued operations <sup>1</sup>		0.03	1.06	115.53	13.79
Net (loss) income per share (basic and diluted) <sup>1</sup>	(2.41)	(18.14)	(28.06)	23.12	(103.22)
Weighted average number of shares outstanding: <sup>1</sup>	<del></del>				
Basic	10,348,879	2,763,603	590,247	294,765	197,751
Diluted	10,665,149	3,424,336	590,247	294,765	198,067

<sup>&</sup>lt;sup>1</sup> 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

		A	As at December 31,		
	2016	2015	2014	2013	2012
	\$	\$	\$	\$	\$
Cash and cash equivalents	21,999	41,450	34,931	43,202	39,521
Restricted cash equivalents	496	255	760	865	826
Total assets	31,659	51,498	47,435	59,196	67,665
Warrant liability (current and non-current portion)	6,854	10,891	8,225	18,010	6,176
Share capital	213,980	204,596	150,544	134,101	122,791
Shareholders' equity (deficiency)	6,212	21,615	14,484	17,064	(6,695)

#### B. Capitalization and indebtedness

Not applicable.

# C. Reasons for the offer and use of proceeds

Not applicable.

# D. Risk factors

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this annual report, before making an investment decision. If any of the following risks actually occurs, our business, prospects, financial condition or results of operations could suffer. In that case, the trading price, if any, of our securities could decline, and you may lose all or part of your investment.

#### 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. In addition, if we are unsuccessful in generating new revenue, increasing our revenue and/or raising additional funding, we may not be able to continue as a going concern.

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, 2016, we had an accumulated deficit of approximately \$298 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 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 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. We did not have, as at December 31, 2016, sufficient liquidity and financial resources to fund planned expenditures and other working capital needs for the 12-month period following such date. Therefore, our audited consolidated financial statements as at December 31, 2016 include a footnote disclosing material uncertainties related to events and conditions that may cast significant doubt about our ability to continue as a going concern for at least twelve months from December 31, 2016.

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 cash 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 for 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.

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, the additional funding 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.

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;
- 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 periods, 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 our failure to obtain regulatory and marketing approval for our product candidates, the withdrawal of such 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 not 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.

By way of example, on February 13, 2017, we announced that, after reviewing the raw top-line data on which the confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup> were based, we had concluded that Macrilen<sup>TM</sup> had, despite not having attained one of its co-primary endpoints in the Phase 3 study, demonstrated performance supportive of achieving FDA registration and that we intended to pursue registration of Macrilen<sup>TM</sup> with the FDA and, to that end, the Company will meet with the FDA at the end of March 2017 to confirm this position. There can be no assurance, however, that the FDA will agree, in whole or in part, with our conclusions regarding Macrilen<sup>TM</sup>, particularly in light of the infrequency with which the FDA has in the past agreed to reassess portions of clinical trial data and elements of the design of a clinical trial following the conclusion of such trial.

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 our clinical trial of Zoptrex<sup>TM</sup>, which is the only clinical trial that we are conducting, is dependent in part upon the rate at which we are able to collect, clean, lock and analyze the clinical trial database. The ZoptEC (zoptarelin doxorubicin in endometrial cancer) trial was designed to continue until a pre-determined number of events occur to the patients enrolled. On January 30, 2107, we announced the occurrence of the requisite pre-determined number of events in the ZoptEC trial, representing the clinical endpoint of the study. We expect to lock the clinical database and to report top-line results in April 2017.

We have no plans to conduct another Phase 3 clinical trial but we may decide to do so in the future. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our future clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective or timely basis. In addition, conducting multi-national studies adds another level of complexity and risk as we are subject to events affecting countries other than the U.S. and Canada. Moreover, negative or inconclusive results from the clinical trials we conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time-frame, if at all. If we or our CRO have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing clinical trials.

Clinical trials are subject to continuing oversight by governmental regulatory authorities and institutional review boards and must meet requirements: (i) of such authorities; (ii) for informed consent; and (iii) for good clinical practices. We may not be able to comply with these requirements in respect of one or more of our product candidates.

Additionally, we have limited experience in filing an NDA or similar application for approval in the U.S. or in any other country for our current product candidates, which may result in a delay in, or the rejection of, our filing of an NDA or similar application. During the drug development process, regulatory agencies will typically ask questions of drug sponsors. While we endeavor to answer all such questions in a timely fashion, some questions may not be answered in time to prevent the delay of acceptance of an NDA or the rejection of an NDA.

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

Our business strategy is to become a specialty biopharmaceutical company with commercial operations to market and sell products that we may develop internally, acquire or in-license. To that end, our commercial operations consist of 13 full-time staff, who provide services pursuant to our agreement with a contract sales organization, and our sales-management staff. 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 maintain 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 inlicense 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 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.

Our future capital requirements are substantial and may increase beyond our current expectations depending on many factors, including:

- the results of our recently completed clinical trials;
- 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 revenues from 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.

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 product. 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 U.S. government, as well as governments of any other countries in which we do business or conduct activities. Later discovery of previously unknown problems or safety issues and/or failure to comply with domestic or foreign laws, knowingly or unknowingly, can result in various adverse consequences, including, among other things, a possible delay in the approval or refusal to approve a product, warning letters, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the government to renew marketing applications, complete withdrawal of a marketing application, criminal prosecution, withdrawal of an approved product from the market and/or exclusion from government healthcare programs. Such regulatory enforcement could have a direct and negative impact on the product for which approval is granted, but also could have a negative impact on the approval of any pending applications for marketing approval of new drugs or supplements to approved applications.

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

From time to time, new legislation is passed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the 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. The U.S. government and other governments have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services, including our product candidates, both in the U.S. and internationally, as well as the amount of reimbursement available from governmental agencies and other third-party payers. If reimbursement for our product candidates is substantially less than we expect, our revenue prospects could be materially and adversely impacted.

In the U.S. and in other jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system, such as proposals relating to the pricing of healthcare products and services in the U.S. or internationally, the reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price), and the amount of reimbursement available from governmental agencies or other third party payers. Furthermore, the pricing of pharmaceutical products, in general, and specialty drugs, in particular, has been a topic of concern in the U.S. Congress, where hearings on the topic have been held, and has been a topic of speeches given by political figures, including President Trump. There can be no assurance as to how this scrutiny on pricing of pharmaceutical products will impact future pricing of our products or orphan drugs or pharmaceutical products generally.

The Patient Protection and Affordable Care Act and the Healthcare and Education Affordability Reconciliation Act of 2010 (collectively, the "ACA") has had far-reaching consequences for most healthcare companies, including specialty biopharmaceutical companies like us. The future of the ACA is, however, uncertain. In January 2017, the U.S. Congress voted to adopt a budget resolution for fiscal year 2017, that while not law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an executive order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On March 6, 2017, members of the U.S. House of Representatives released proposed legislation intended to replace the ACA. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, the *Food and Drug Administration Amendments Act of 2007* gives 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 90<sup>th</sup> calendar day of each year.

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

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

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The ACA also made several important changes to the federal Anti-Kickback Statute, false claims laws, and healthcare fraud statute by weakening the intent requirement under the anti-kickback and healthcare fraud statutes that may make it easier for the government or whistleblowers to charge such fraud and abuse violations. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. 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<sup>TM</sup> (zoptarelin doxorubicin) and Macrilen<sup>TM</sup> (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<sup>TM</sup>, Macrilen<sup>TM</sup> 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 we will make regulatory submissions based on our recently completed clinical trials 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. For example, drug manufacturers are required to have a national rebate agreement with the U.S. Federal 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. 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. The pricing of pharmaceutical products, in general, and specialty drugs, in particular, has been a topic of concern in the U.S. Congress, where hearings on the topic have been held, and has been a topic of speeches given by political figures, including President Trump. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Further, third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. There can be no assurance as to how this scrutiny on pricing of pharmaceutical products will impact future pricing of our products or orphan drugs or pharmaceutical products generally. In addition, increasing emphasis on managed care will continue to put pressure on the pricing of pharmaceutical and biopharmaceutical products. Cost control initiatives could decrease the price that we or any current or potential collaborators could receive for any of our products and could adversely affect our profitability. In addition, in the U.S., in Canada and in many other countries, pricing and/or profitability of some or all prescription pharmaceuticals and biopharmaceuticals are subject to government control.

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

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

The 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 many countries. Pending patent applications may not result in the issuance of patents and we may not be able to obtain additional issued patents relating to our technology or products.

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

Our patents and/or the patents that we license from others may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. The patents issued or to be issued to us may not provide us with any competitive advantage or protect us against competitors with similar technology. In addition, it is possible that third parties with products that are very similar to ours will circumvent our patents by means of alternate designs or processes. We may have to rely on method-of-use, methods of manufacture and/or new-formulation protection for our compounds in development, and any resulting products, which may not confer the same protection as claims to compounds *per se*.

In addition, our patents may be challenged by third parties in patent litigation, which is becoming widespread in the biopharmaceutical industry. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There may also be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that our patents would, if challenged, be held by a court to be valid or enforceable or that a competitor's technology or product would be found by a court to infringe our patents. Our granted patents could also be challenged and revoked in U.S. post-grant proceedings as well as in opposition or nullity proceedings in certain countries outside the U.S. In addition, we may be required to disclaim part of the term of certain patents.

Patent applications relating to or affecting our business have been filed by a number of pharmaceutical and biopharmaceutical companies and academic institutions. A number of the technologies in these applications or patents may conflict with our technologies, patents or patent applications, and any such conflict could reduce the scope of patent protection that we could otherwise obtain. Because patent applications in the U.S. and many other jurisdictions are typically not published until eighteen months after their first effective filing date, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in the patent applications. If a third party has also filed a patent application in the U.S. covering our product candidates or a similar invention, we may have to participate in adversarial proceedings, such as interferences and deviation proceedings, before the United States Patent and Trademark Office to determine which party is entitled to a U.S. patent claiming the disputed invention. The costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful, resulting in a loss of our U.S. patent position.

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 that is conceived by the individual during the course of employment is our exclusive property. These agreements may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of our proprietary information. In addition, it is possible that third parties could independently develop proprietary information and techniques substantially similar to ours or otherwise gain access to our trade secrets. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products and technologies, which could adversely impact our business.

We currently have the right to use certain patents and technologies under license agreements with third parties. Our failure to comply with the requirements of one or more of our license agreements could result in the termination of such agreements, which could cause us to terminate the related development program and cause a complete loss of our investment in that program. Inventions claimed in certain in-licensed patents may have been made with funding from the U.S. government and may be subject to the rights of the U.S. government and we may be subject to additional requirements in the event we seek to commercialize or manufacture product candidates incorporating such in-licensed technology.

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 recently expired.

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

and similar protections, if any, provided in other countries. We cannot assure you that Zoptrex<sup>TM</sup> or any of our other drug candidates will obtain new chemical entity exclusivity or any other market exclusivity in the U.S., the European Union or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection.

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

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

If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business. Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be accused of infringing one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may subsequently be issued and to which we do not hold a license or other rights. Third parties may own or control these patents or patent applications in the U.S. and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

The biopharmaceutical industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. In the event of infringement or violation of another party's patent or other intellectual property rights, we may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us or our partners and collaborators.

# Patent litigation is costly and time consuming and may subject us to liabilities.

If we become involved in any patent litigation, interference, opposition or other administrative proceedings we will likely incur substantial expenses in connection therewith, and the efforts of our technical and management personnel will be significantly diverted. In addition, an adverse determination in litigation could subject us to significant liabilities.

# We may not obtain trademark registrations for our product candidates.

We have filed applications for trademark registrations in connection with Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup> in various jurisdictions, including the U.S. We may file applications for other possible trademarks for our product candidates in the future. No assurance can be given that any of our trademarks will be registered in the U.S. or elsewhere, or that the use of any registered or unregistered trademarks will confer a competitive advantage in the marketplace. Furthermore, even if we are successful in our trademark registrations, the FDA and regulatory authorities in other countries have their own process for drug nomenclature and their own views concerning appropriate proprietary names. The FDA and other regulatory authorities also have the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. No assurance can be given that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future. On December 16, 2016, we learned that the European Medicines Agency ("EMA") had rejected the "Macrilen<sup>TM</sup>" as the proposed invented name for macimorelin. We intend to appeal the EMA's determination. 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 development of our product candidates.

We are currently dependent on certain strategic relationships with third parties and may enter into future collaborations for the development 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, development of some of our product candidates. Our reliance on these relationships poses a number of risks. We may not realize the contemplated benefits of such agreements nor can we be certain that any of these parties will fulfill their obligations in a manner which maximizes our revenue. These arrangements may also require us to transfer certain material rights or 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 to 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 increases 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 U.S. District Court for the District of New Jersey (the "Court"), brought on behalf of shareholders of the Company. The lawsuit alleges violations of the *Securities Exchange Act of 1934* (the "Exchange Act") in connection with allegedly false and misleading statements made by the defendants between April 2, 2012 and November 6, 2014, or the Class Period, regarding the safety and efficacy of Macrilen<sup>TM</sup>, a product we developed for use in the diagnosis of AGHD, and the prospects for the approval of the Company's NDA for the product by the FDA. The plaintiffs seek to represent a class comprised of purchasers of our Common Shares during the Class Period and seek damages, costs and expenses and such other relief as determined by the Court. On September 14, 2015, the Court dismissed the lawsuit stating that the plaintiffs failed to state a claim, but granted the plaintiffs leave to amend. On October 14, 2015, the plaintiffs filed a Second Amended Complaint against us. We subsequently filed a motion to dismiss because we believed that the Second Amended Complaint also failed to state a claim.

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. On March 16, 2016, we filed a motion for reconsideration of the Court's March 2, 2016 order and on April 6, 2016 we filed an answer to the second amended complaint. On June 30, 2016, the Court issued an order denying our motion for reconsideration. As a result, the lawsuit will proceed to the class certification phase and the discovery process has commenced.

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 a party 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, including the substantial self-insured retention that we were required to satisfy before any insurance applied to the claim, 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 and the limits of the insurance may be insufficient to cover our eventual liability.

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

The use of Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup> on human participants in our clinical trials subjects us to the risk of liability to such participants, who may suffer unintended consequences. If Zoptrex<sup>TM</sup> and/or Macrilen<sup>TM</sup> are approved for commercialization or if we acquire a marketed product from a third party, the sale and use of such products will involve the risk of product liability claims and associated adverse publicity. Product liability claims might be made against us directly by patients, healthcare providers or pharmaceutical companies or others selling, buying or using our products. We attempt to manage our liability risks by means of insurance. We maintain insurance covering our liability for our preclinical and clinical studies. However, we may not have or be able to obtain or maintain sufficient and affordable insurance coverage, including coverage for potentially very significant legal expenses, and without sufficient coverage any claim brought against us could have a materially adverse effect on our business, financial condition or results of operations. We do not currently maintain product liability insurance because we do not currently market, sell, distribute or handle any products. We may not be able to obtain product liability insurance on reasonable terms, if at all, when we begin to market, sell, distribute or handle products.

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. In addition, we may be required to fund obligations of AEZS Germany under a Letter of Comfort provided by us to AEZS Germany.

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, which may incur additional or other liabilities and/or obligations. 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, insolvency or creditor protection 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.

At the present time, AEZS Germany does not generate any revenue and, therefore, it depends on cash advances or contributions from Aeterna Zentaris Inc. to finance its operations. For the reasons described in the following paragraph, we issued a written undertaking, called a "Letter of Comfort", to AEZS Germany. The Letter of Comfort provides that we will furnish to AEZS Germany the necessary funds to ensure that it will always be able to fulfill all of its financial and economic obligations to its third party creditors. Our advances to AEZS Germany are characterized by the Letter of Comfort as loans that are subordinated to all present and future creditors of AEZS Germany.

We provided the Letter of Comfort to AEZS Germany because German law imposes an obligation on the managing director of AEZS Germany to institute insolvency proceedings if the managing director concludes that AEZS Germany is insolvent because

it is either illiquid or "over-indebted". The purpose of the Letter of Comfort is to preclude the managing director from determining that AEZS Germany is illiquid or over-indebted. The Letter of Comfort will be sufficient for that purpose only as long as the managing director reasonably believes that we will be able to honor our obligations under the Letter of Comfort. If we fail to renew the Letter of Comfort or if the managing director concludes that we will be unable to honor our obligations under the Letter of Comfort, the managing director of AEZS Germany may determine that he or she is obligated to institute insolvency proceedings in Germany for AEZS Germany.

Because we are a holding company and because we have an obligation to advance funds to AEZS Germany to prevent it from becoming either illiquid or over-indebted, we may be required to use our cash to fund payments by AEZS Germany to its creditors. Therefore, in the event of any winding-up, liquidation or reorganization, or a bankruptcy or insolvency proceeding relating to us or our property, there can be no assurance as to the value or assets, if any, that would be available to holders of our Common Shares because we may be required to advance cash to AEZS Germany under the Letter of Comfort.

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

We are a company existing under the laws of Canada. A number of our directors and officers, and certain of the experts named herein, are residents of Canada or otherwise reside outside the U.S., and all or a substantial portion of their assets, and a substantial portion of our assets, are located outside the U.S. Consequently, although we have appointed an agent for service of process in the U.S., it may be difficult for investors in the U.S. to bring an action against such directors, officers or experts or to enforce against those persons or us a judgment obtained in a U.S. court predicated upon the civil liability provisions of federal securities laws or other laws of the U.S. Investors should not assume that foreign courts (1) would enforce judgments of U.S. courts obtained in actions against us or such directors, officers or experts predicated upon the civil liability provisions of the U.S. federal securities laws or the securities or "blue sky" laws of any state within the U.S. or (2) would enforce, in original actions, liabilities against us or such directors, officers or experts predicated upon the U.S. federal securities laws or any such state securities or "blue sky" laws.

In addition, we have been advised by our Canadian counsel that in normal circumstances, only civil judgments and not other rights arising from U.S. securities legislation (for example, penal or similar awards made by a court in a regulatory prosecution or proceeding) are enforceable in Canada and that the protections afforded by Canadian securities laws may not be available to investors in the U.S.

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

As a public company, we are required to comply with Section 404 of the U.S. Sarbanes-Oxley Act ("Section 404") and National Instrument 52-109 - Certification of Disclosure in Issuers' Annual and Interim Filings. In any given year, we cannot be certain as to the time of completion of our internal control evaluation, testing and remediation actions or of their impact on our operations. Upon completion of this process, we may identify control deficiencies of varying degrees of severity under applicable SEC and Public Company Accounting Oversight Board (U.S.) rules and regulations. As a public company, we are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal controls that, or that are reasonably likely to, materially affect internal controls over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our 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 or 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.

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

Adverse U.S. federal income tax rules apply to "U.S. Holders" (as defined in "Item 10.E - Taxation - Certain Material U.S. 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 U.S. federal income tax purposes for a taxable year if (i) at least 75% of our gross income is "passive income" or (ii) at least 50% of the average value of our assets, including goodwill (based on annual quarterly average), is attributable to assets which produce passive income or are held for the production of passive income.

We believe that we were not a PFIC for the 2016 taxable year. However, the PFIC determination depends on the application of complex U.S. federal income tax rules concerning the classification of our assets and income for this purpose, and these rules are

uncertain in some respects. In addition, the fair market value of our assets may be determined in large part by the market price of our Common Shares, which is likely to fluctuate, and the composition of our income and assets will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction. No assurance can be provided that we will not be classified as a PFIC for the 2017 taxable year and for any future taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder holds Common Shares, we generally would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds such Common Shares, even if we ceased to meet the threshold requirements for PFIC status. PFIC characterization could result in adverse U.S. federal income tax consequences to U.S. Holders. In particular, absent certain elections, a U.S. Holder would generally be subject to U.S. federal income tax at ordinary income tax rates, plus a possible interest charge, in respect of a gain derived from a disposition of our Common Shares, as well as certain distributions by us. If we are treated as a PFIC for any taxable year, a U.S. Holder may be able to make an election to "mark to market" Common Shares each taxable year and recognize ordinary income pursuant to such election based upon increases in the value of the Common Shares. In addition, U.S. Holders may mitigate the adverse tax consequences of the PFIC rules by making a "qualified electing fund" ("QEF") election; however, there can be no assurance that the Company will satisfy the record keeping requirements applicable to a QEF or that it will provide the information regarding its income that would be necessary for a U.S. Holder to make a QEF election.

If the Company is a PFIC, U.S. Holders will generally be required to file an annual information return with the Internal Revenue Service (the "IRS") (on IRS Form 8621, which PFIC shareholders will be required to file with their U.S. federal income tax or information returns) relating to their ownership of Common Shares. This filing requirement is in addition to any preexisting reporting requirements that apply to a U.S. Holder's interest in a PFIC (which this requirement does not affect).

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

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

Our operations are in many instances conducted in currencies other than our functional currency or the functional currencies of our subsidiaries. Fluctuations in the value of currencies could cause us to incur currency exchange losses. We do not currently employ a hedging strategy against exchange rate risk. We cannot assert with any assurance that we will not suffer losses as a result of unfavorable fluctuations in the exchange rates between the U.S. dollar, the euro, the Canadian dollar and other currencies.

# 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, breaches, 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 the NASDAQ Capital Market ("NASDAQ") or the Toronto Stock Exchange ("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 both NASDAQ and TSX under the symbol "AEZS". 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 common Shares 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 U.S., have had no meaningful relationship to current or historical financial results, asset values, book value or many other criteria based on conventional measures of the value of shares.

As adjusted for and giving effect to the Share Consolidation, between January 1, 2016 and December 31, 2016, the closing price of our Common Shares ranged from \$2.67 to \$4.94 per share on NASDAQ and from C\$3.85 to C\$6.62 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 U.S., Canada and other countries;
- developments or disputes concerning patent or proprietary rights;
- actual or anticipated fluctuations in our revenues or expenses;
- · general market conditions and fluctuations for the emerging growth and biopharmaceutical market sectors; and
- economic conditions in the U.S., Canada or abroad.

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

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

To date, we have not declared or paid any dividends on our Common Shares. We currently intend to retain our future earnings, if any, to finance further research and the overall commercial expansion of our business. As a result, the return on an investment in our 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. For example, in connection with our At Market Issuance ("ATM") Sales Agreement with H.C. Wainwright & Co., LLC (the "April 2016 ATM Program"), we may, at our discretion, from time to time during the term of the April 2016 ATM Program, sell up to a maximum of 3,000,000 Common Shares through ATM issuances on the NASDAQ Stock Market, up to an aggregate amount of approximately \$10 million at market prices prevailing at the time of the sale of the Common Shares. Under both our April 2016 ATM Program and our shelf registration statement on Form F-3 or any replacement thereof upon its expiration, we may issue and sell additional Common Shares by way of one or more ATM distribution programs.

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 15, 2017, there were:

13,473,063	Common Shares issued and outstanding		
Preferred Shares issued and outstanding			
3,779,245 Common Shares issuable upon exercise of outstanding warrants			
968,264	Stock Options outstanding		
567,665	Additional Common Shares available for future grants under our stock option plan		

In addition, the price of our 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.

In the event we were to lose our foreign private issuer status as of June 30 of a given financial year, we would be required to comply with the Exchange Act's domestic reporting regime, which could 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 U.S. or (2) (a) a majority of our executive officers and of our directors must not be U.S. citizens or residents, (b) more than 50 percent of our assets cannot be located in the U.S. and (c) our business must be administered principally outside the U.S.

In 2016, our management conducted its annual assessment of the various facts and circumstances underlying the determination of our status as a foreign private issuer and, based on the foregoing, our management has determined that, as of the date of such determination and as of June 30, 2016, we continued to be a foreign private issuer.

There can be no assurance, however, that we will remain a foreign private issuer either in 2017 or in future financial years.

If we were to lose our foreign private issuer status as of June 30 of any given financial year, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. 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 U.S. domestic issuer under U.S. securities laws may be higher than the cost we have historically incurred as a foreign private issuer. In addition, if we were to lose our foreign private issuer status, we would no longer qualify under the Canada-U.S. multijurisdictional disclosure system to benefit from being able to file registration statements on Form F-10 (even if we satisfy the other conditions to eligibility), which could make it longer and more difficult to register our securities and raise funds by way of public, registered offerings in the U.S., 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 would expect that a potential loss of foreign private issuer status at some future point in time could increase our legal, financial reporting and accounting compliance costs, and it is difficult at this time to estimate by how much our legal, financial reporting and accounting compliance costs may increase in such eventuality.

# 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 29486; 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.

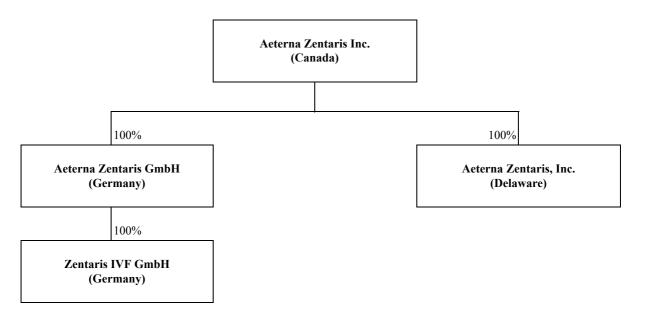
On December 30, 2002, we acquired Zentaris AG, a biopharmaceutical company based in Frankfurt, Germany. Zentaris was a spin-off of Asta Medica GmbH, a former pharmaceutical company affiliated with Degussa AG.

In May 2004, we changed our name to Aeterna Zentaris Inc. and on May 11, 2007, Zentaris GmbH was renamed Aeterna Zentaris GmbH ("AEZS GmbH"). AEZS GmbH conducts our drug development efforts. In September 2007, we incorporated Aeterna Zentaris, Inc. under the laws of Delaware. This whollyowned 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 and since the year ended December 31, 2013, 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 the 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.



Our Common Shares are listed for trading on both NASDAQ and TSX 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 29486.

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 financial 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 have two Phase 3 product candidates in development. 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 finalize the development and pursue registration of our principal product candidates -- Zoptrex<sup>TM</sup> (zoptarelin doxorubicin) and Macrilen<sup>TM</sup> (macimorelin) in oncology and endocrinology, respectively -- and to commercialize oncology, endocrinology and women's health products that we may acquire, in-license or promote. The registration of Zoptrex<sup>TM</sup> is subject to receiving positive top-line results, and the registration of Macrilen<sup>TM</sup> is subject to the outcome of our meeting with the FDA scheduled for the end of March 2017. Our vision is to become a growth-oriented specialty biopharmaceutical company.

# Overview of our Drug Development Efforts

Status of Our Drug Pipeline

# Pipeline Supporting Long-Term Growth

	Indications	Preclinical	Phase 1	Phase 2	Phase 3	In Registration
Macrilen™	Evaluation of Adult Growth Hormone Deficiency					
Zoptrex <sup>TM</sup>	Endometrial cancer					
<b>Zoptrex</b> <sup>™</sup>	Ovarian cancer					
Zoptrex <sup>™</sup>	Prostate cancer					
AEZS-138	Oncology					

# Outsourcing and Out-Licensing Non-Strategic Activities/Assets

	Indications	Discovery research	Preclinical	Phase 1
Compound Library	Discovery research conducted at MUSC (Medical University of South Carolina)			
Projects for out-li AEZS-120	censing  Prostate cancer vaccine			

Our drug development efforts are focused currently on two compounds, Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup>, which are in Phase 3 clinical development, and on an 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**<sup>TM</sup>

Overview

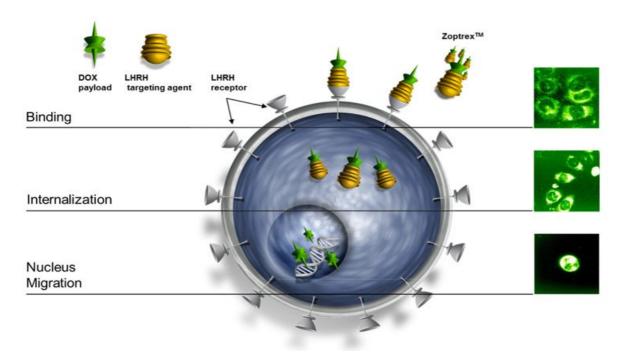
Zoptrex<sup>TM</sup> represents a new targeting concept in oncology using a hybrid molecule composed of a synthetic peptide carrier, zoptarelin, and a well-known chemotherapy agent, doxorubicin, resulting in a cytotoxic conjugate. Zoptarelin is a luteinizing hormone-releasing hormone ("LHRH") agonist, a modified natural hormone with affinity for the LHRH receptor. 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 patients with advanced or metastatic tumors. Zoptrex<sup>TM</sup> is our proposed tradename for zoptarelin doxorubicin. The proposed tradename is subject to approval by the FDA.

Zoptrex<sup>TM</sup> 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<sup>TM</sup> 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 (**zopt**arelin doxorubicin in endometrial cancer). ZoptEC is a fully-recruited (over 500 patients), open-label, randomized-controlled study, comparing the efficacy and safety of Zoptrex<sup>TM</sup> to doxorubicin alone. Patients were centrally randomized in a 1:1 ratio and received either Zoptrex<sup>TM</sup> (267 mg/m<sub>2</sub>) or doxorubicin (60 mg/m<sub>2</sub>) intravenously, every three weeks and for up to nine cycles. Response was 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

The ZoptEC study was designed to permit the final analysis of the data from the study to occur following the deaths of 384 patients. On January 30, 2017, we announced the occurrence of the 384th death, representing the clinical endpoint of the study. We expect clinical database lock and reporting of top-line results to occur in April 2017. If the results of the ZoptEC study warrant doing so, we expect to file a new drug application ("NDA") in the United States for Zoptrex<sup>TM</sup> in the third quarter of 2017. We are now moving forward with our planning to commercialize Zoptrex<sup>TM</sup>, looking toward commercial launch of the product in 2018, assuming positive Phase 3 results and that the NDA is granted.



The illustration above depicts the believed mode of action of our hybrid cytotoxic compound Zoptrex<sup>TM</sup>. 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 the cancer cell.

ZoptEC was 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 agreed to assume 30% (up to \$10 million) of the clinical and regulatory costs for ZoptEC. 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<sup>TM</sup> in this indication, up to a specified maximum amount.

We are attempting to commercialize Zoptrex<sup>TM</sup> 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 61,000 new cases and 10,000 deaths annually. This disease primarily affects post-menopausal women at an average age of 60 years at diagnosis. To the best of our knowledge, there is no systemic therapy approved in either the United States or Europe (except in Germany, where doxorubicin is approved for this indication) for treating advanced or recurrent endometrial cancer.

We have licensed the development, commercialization and certain other rights to Zoptrex<sup>TM</sup> to Sinopharm A-Think for China, Hong Kong and Macau; to an affiliate of Orient EuroPharma Co., Ltd. for Taiwan and southeast Asia; to Rafa Laboratories, Ltd for Israel and the Palestinian territories and to Specialised Therapeutics Asia Pte Ltd for Australia and New Zealand.

# Development History

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

- In 2007, a Phase 2 open-label, non-comparative, multi-center 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, multi-center and multinational Phase 2 study "AGO-GYN 5" was conducted by the German AGO Study Group (Arbeitsgemeinschaft Gynäkologische Onkologie / Gynaecologic Oncology Working Group), in cooperation with clinical sites in Europe. An intravenous infusion of Zoptrex™ (267 mg/m²) 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/m²; (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) OS 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 Zoptrex<sup>™</sup> 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<sup>™</sup> at a dose of 267 mg/m² 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<sup>™</sup> was efficacious and well tolerated in patients with advanced endometrial

cancer; (ii) the safety profile confirmed the dose of 267 mg/m²; (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% compared 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<sup>TM</sup> was similar to that reported for modern triple combination chemotherapy, but was achieved with lower toxicity.

- On April 27, 2015, we announced that the independent Data Safety Monitoring Board ("DSMB") for the ZoptEC study had completed a pre-specified first interim futility analysis following the deaths of approximately 124 patients in the study and recommended that the Phase 3 study continue as planned.
- On October 13, 2015, we announced that the DSMB had completed a pre-specified second interim analysis of the efficacy and safety of Zoptrex™ in the ZoptEC study following the deaths of approximately 192 patients in the study and recommended that the ZoptEC study continue as planned.
- On January 30, 2017, we announced the occurrence of the 384th death in the ZoptEC study. We stated in the announcement that we expect to lock the clinical database and to report top-line results in April 2017.

#### 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	Comments/ Clinical History/ Commercial History
Lenvatinib (E7080)	Paclitaxel	Tyrosine kinase VEGFR2 inhibitor, multi-targeted	Recurrent Enometrial cancer		Eisai, OSUCCC	MTD of lenvatinib when given w/ paclitaxel	Previous Phase 2 discontinued by Eisai for combo therapy trials
MK-2206	Monotherapy	Serine/ threonine kinase Akt inhibitor		Phase 2, two-arm, only patients with PIK3CA mutation	US NCI (Astra Zeneca-Merck partnered drug)		90-patient trial, still ongoing, but not recruiting patients
Buparlisib (BKM120)	Monotherapy	Phosphatidyl inositol-3- kinase (PI3K)-Akt- mTOR pathway inhibitor	Second-line endometrial cancer	Phase 2 (ENDOPIK)	Novartis	ORR/PFS out to six months	56-patient trial, PFS/tumor response data in H2/16, study completed Q1/15
GSK 2141795	Mekinist (trametinib, MEK inhibitor)	Akt inhibitor	Recurrent, persistent endometrial cancer	Phase 2, 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-patients, interim PFS data by H1/17
Virexxa (Cridanimod sodium)	Progesterone		Recurrent, persistent endometrial cancer (PrR-negative)	Phase 2	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		US NCI (Exelixis not identified as partner)	ORR/PFS out to three months	72-patient, still recruiting
LY3023414	Monotherapy	PI3K-mTOR dual inhibitor	Recurrent endometrial cancer	Phase 2 (multiple cancer forms)	MSKC, Eli Lilly	Three-month CBR, one- year O/S	25-patient, single-arm, estimated completion Q3/17

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

Drug	Co-administered drugs & comparator arm	Target	Indication	Clinical Trial/ Approval Status	Innovator	Primary Endpoint	Comments/ Clinical History/ Commercial History
IMMU-132	Monotherapy	TROP-2-targeted mAb linked to SN38 (metabolite of irinotecan)	Endometrial cancer	Phase 1/2 (multiple epithelial cancers being tested simultane-ously)	Immuno medics		250-patient, estimated completion Q2/18
KPT-330 (Selinexor)	Monotherapy	XPO1 (nuclear export protein) antagonist	Advanced gynecologic cancers	Phase 2	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 1/2		rate	80-patient, adverse event rate & response rate data in H2/17
Bevacizumab (Genentech's Avastin)	Monotherapy	VEGF-A inhibitor	Recurrent, Persistent Endometrial Cancer	Phase 2 Interventional			56 -patient, study completed in H2/11, no Phase 3 listed

#### Additional Indications

We believe that Zoptrex<sup>TM</sup> 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<sup>TM</sup>. 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/m², three at 210 mg/m², and seven at 267 mg/m². 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/m² 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/m²) 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 Zoptrex™ 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<sup>TM</sup> in prostate cancer. This was a single-arm Simon Optimum design Phase 2 study of Zoptrex<sup>TM</sup> in 25 patients with CRPC. Patients received Zoptrex<sup>TM</sup> (210 mg/m²) 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<sup>TM</sup> 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/m², (ii) 210 mg/m², and (iii) 267 mg/m²). Overall, Zoptrex<sup>TM</sup> 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/m² 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 CB as the primary endpoint and 13 patients achieved SD. Maximal PSA response was stable in 20 patients. Pain assessment improved for 11 patients. Zoptrex<sup>TM</sup> 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<sup>TM</sup> was well tolerated and met the primary efficacy endpoint in castration- and taxane-resistant prostate cancer patients.
- On February 14, 2017, we announced that Dr. Pinski presented the abstract of his Phase 1/2 trial of Zoptrex<sup>™</sup> in castration and taxane-resistant prostate cancer at the ASCO/ASTRO/SVO 2017 Genitourinary Cancer Symposium.

We believe that immuno-modulatory and targeted therapies have been key areas of innovation in oncology over the last few years. Zoptrex<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> for indications other than endometrial cancer by seeking development partners to assist with the effort.

#### Macrilen<sup>TM</sup>

Macrilen<sup>TM</sup> 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<sup>TM</sup> has been granted orphan-drug designation by the FDA for use in evaluating growth hormone deficiency ("GHD"). If approved by the FDA, Macrilen<sup>TM</sup> would be the first orally administered drug indicated for the evaluation of adult growth hormone deficiency ("AGHD"). Macrilen<sup>TM</sup> is our proposed proprietary trade name for macimorelin, being subject to approval by the FDA. On December 16, 2016 we were advised by the EMA that Macrilen<sup>TM</sup> was rejected as proposed invented name for macimorelin because of its similarity to the names of other medicines. We intend to appeal this decision.

Competitors for Macrilen<sup>TM</sup> 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 has historically been considered the gold standard for the evaluation of AGHD because of its high sensitivity and specificity. However, the ITT is inconvenient to both patients and physicians, administered intravenously (IV), 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 includes additional costs associated with the patient being closely 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 Stimulation Test ("GST") 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 with the most common being nausea during and after the test. This test is administered intramuscularly (IM).
- The GHRH + ARG test (growth hormone releasing hormone-arginine stimulation) 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 the ITT and the GST. 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 (IV).

Oral administration of Macrilen<sup>TM</sup> offers convenience and simplicity over the current GHD tests used, all of which require either intravenous or intramuscular administration. Additionally, Macrilen<sup>TM</sup> 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<sup>TM</sup> has not thus far. These factors may be limiting the use of GHD testing and may potentially enable Macrilen<sup>TM</sup> to become the product of choice in evaluating AGHD. We believe that Macrilen<sup>TM</sup>, 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 and more convenient than the ITT because it does not require the patient to become hypoglycemic;
- Macrilen<sup>TM</sup> is administered orally, while the ITT requires an intravenous injection of insulin;
- Macrilen<sup>TM</sup> is a more robust test than the ITT leading to evaluable test results;
- Macrilen<sup>TM</sup> results are highly reproducible;
- the evaluation of AGHD using Macrilen<sup>TM</sup> is less time-consuming and labor-intensive than the ITT; and
- the evaluation can be conducted in the physician's office rather than in a hospital-like setting.

We believe that approximately 40,000 AGHD tests will be conducted annually, in the U.S, after the introduction of Macrilen<sup>TM</sup>. In addition, based on published information from the U.S. Centers for Disease Control and Prevention, different scientific publications and Navigant Research, we estimate that the total potential US market for AGHD evaluation is approximately 150,000 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 sequelae and reduction in quality of life. GHD may develop in approximately 19% of both severe and moderate hospitalized TBI victims.

#### Development History

The following is a summary of the history of our development of Macrilen<sup>TM</sup>:

- We out-licensed the development compound maximorelin acetate to Ardana Bioscience in 2004. Ardana Bioscience subsequently initiated the clinical development program of maximorelin 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<sup>TM</sup> 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<sup>TM</sup> for use in evaluating AGHD. The pivotal Phase 3 trial was designed to investigate the safety and efficacy of the oral administration of Macrilen<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> in the evaluation of AGHD. Mean peak growth hormone ("GH") levels in AGHD patients and controls following Macrilen<sup>TM</sup> 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<sup>TM</sup>. In contrast, 61% of AGHD subjects and 30% of controls experienced AEs with L ARG+GHRH. The most common AEs after Macrilen<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup>. Overall, this study demonstrated that Macrilen<sup>TM</sup> 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<sup>TM</sup> 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 Phase 3 study of Macrilen<sup>TM</sup> 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<sup>TM</sup> for the evaluation of AGHD, as well as a dedicated thorough QT study to evaluate the effect of Macrilen<sup>TM</sup> on myocardial repolarization. The confirmatory Phase 3 clinical study of Macrilen<sup>TM</sup>, 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)", was designed as a two-way crossover study with the ITT as the benchmark comparator and involved 31 sites in the United States and Europe. The study population was planned to include at least 110 subjects (at least 55 ITT-positive and 55 ITT-negative) with a medical history documenting risk factors for AGHD, and was planned to include a spectrum of subjects from those with a low risk of having AGHD to those with a high risk of having the condition.
- 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<sup>TM</sup> 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 Macrillen<sup>TM</sup>.
- On October 26, 2016, we announced completion of patient recruitment for the confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup> as a growth hormone stimulation test for the evaluation of AGHD.

- The dedicated thorough QT study to evaluate the effect of maximorelin on the QT interval, as requested by the FDA in the CRL, was conducted and completed in 2016.
- On January 4, 2017, we announced that, based on an analysis of top-line data, the confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup> failed to achieve one of its co-primary endpoints. Under the study protocol, the evaluation of AGHD with Macrilen<sup>TM</sup> would be considered successful, if the lower bound of the two-sided 95% confidence interval for the primary efficacy variables was 75% or higher for "percent negative agreement" with the ITT, and 70% or higher for the "percent positive agreement" with the ITT. While the estimated percent negative agreement met the success criteria, the estimated percent positive agreement did not reach the criteria for a successful outcome. Therefore, the results did not meet the pre-defined equivalence criteria which required success for both the percent negative agreement and the percent positive agreement.
- On February 13, 2017, we announced that, after reviewing the raw data on which the top-line data were based, we had concluded that Macrilen™ had demonstrated performance supportive of achieving FDA registration and that we intended to pursue registration. The announcement set forth the facts on which our conclusion was based. The Company will meet with the FDA at the end of March 2017 to discuss this position.
- On March 7, 2017, we announced that the Pediatric Committee ("PDCO") EMA agreed to the Company's Pediatric Investigation Plan ("PIP") for Macrilen<sup>TM</sup> and agreed that the Company may defer conducting the PIP until after it files a Marketing Authorization Application ("MAA") seeking marketing authorization for the use of Macrilen<sup>TM</sup> for the evaluation of AGHD. The decision will permit the Company to file an MAA substantially earlier than if it were required to complete the PIP before filing.

# 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<sup>TM</sup>. 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 the ZoptEC study 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 \$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 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 13 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 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-resources 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 had a two-year term that started in November 2014. The term was recently extended for one year. 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 45 days' prior written notice.

Effective September 1, 2016, we terminated our agreement with ASCEND Therapeutics US LLC to co-promote a non-patch transdermal hormone replacement therapy product because of we were dissatisfied with the financial results of our efforts.

Our sales force is currently promoting two products:

- 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 promotional services agreement (the "EMD Serono Agreement") with EMD Serono Inc. ("EMD Serono"), which we entered into in May 2015 and amended as of December 31, 2016. The EMD Serono Agreement, as amended, provides that we will promote Saizen® in specific agreed-upon US territories to adult and pediatric endocrinologists in exchange for a sales commission that is based upon new patient starts ("NPS") of the product. The EMD Serono Agreement has a five-year term that began in May 2015, which is not subject to a specified extension period, and is subject to customary termination provisions. Both parties to the EMD Serono Agreement have the right to terminate the EMD Serono Agreement for convenience at any time after October 31, 2017, by giving three months' advance written notice to the other party.
- 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"), which was amended effective as of June 1, 2016, pursuant to which we have the exclusive right to promote APIFINY® throughout the entire United States. We receive a commission for each test performed resulting from our targeted promotion without regard to a baseline. The Armune Agreement, as amended, has a three-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 22 (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 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 Investigational New Drug ("IND") application, or comparable foreign regulatory submission. 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's Center for Drug Evaluation and Research (CDER) under the Federal Food, Drug and Cosmetic Act of 1938, as amended (the "FDCA"), the Public Health Service Act and other federal statutes and regulations, subjects pharmaceutical products to rigorous review. In order to market and sell a new drug product in the United States, we must first test it and send CDER evidence from these tests to prove that the drug is safe and effective for its intended use. In most cases, these tests include extensive preclinical, clinical, and laboratory tests. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the company's data and proposed labeling. If this independent and unbiased review establishes that a drug's health benefits outweigh its known risks, the drug is approved for sale. CDER does not test the drug itself but it does conduct limited research in the areas of drug quality, safety, and effectiveness standards. Before approving a new drug or marketing application, the FDA may conduct pre-approval inspections of the developer of the drug (the "sponsor"), 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/or extra surveillance to monitor the effects of approved products, or place conditions on any approvals that could restrict the commercial applications of a product. 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 whereby a sponsor must test new drugs on animals for toxicity. Multiple species are used to gather basic information on the safety and efficacy of the compound being investigated and/or researched. The FDA regulates preclinical studies under a series of regulations called the current GLP regulations as well as regulatory requirements found in Part 21 subchapter D of the Code of Federal Regulations. If the sponsor violates these regulations, the FDA may require that the sponsor replicate those studies or can subject the sponsor to enforcement actions or penalties as described further below. The sponsor then submits to the FDA an IND application based on the results from initial testing that include the drug's composition and manufacturing, along with a plan for testing the drug on humans. The FDA reviews the IND to ensure that the proposed studies (clinical trials) do not place human subjects at unreasonable risk of harm. FDA also verifies that there are adequate informed consent and human subject protections in place.

After a sponsor submits an IND application, it must wait 30 days before starting a clinical trial to allow FDA time to review the prospective study. If FDA finds a problem, it can order a clinical hold to delay an investigation, or interrupt a clinical trial if problems occur during the study. After the IND application is in effect, 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 (typically 20-80 healthy volunteers), primarily for safety at one or more doses. The goal in this phase is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted. Phase 2 studies begin if Phase 1 studies do not reveal unacceptable toxicity. 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. The number of subjects in Phase 2 studies typically ranges from a few dozen to about 300. This phase aims to obtain preliminary data on whether a drug works in people who have a certain disease or condition. At the end of Phase 2, the FDA and sponsor try to come to an agreement on how large-scale studies in Phase 3 should be done.

Phase 3 studies begin if evidence of effectiveness if shown in Phase 2. 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 as they combine two phases. Even if patients participate in initial human testing and a Phase 1/2 study is carried out, the sponsor is still responsible for obtaining all the data usually obtained in both Phase 1 and Phase 2 studies.

The sponsor must submit to the FDA the results of the preclinical and clinical testing, together with, among other things, detailed information on the manufacture and composition of the product, in the form of a New Drug Application ("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 are intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 people but are not expected to recover the costs of developing and marketing a treatment drug. The designation provides the sponsor 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<sup>TM</sup> for the treatment of advanced ovarian cancer and for Macrilen<sup>TM</sup> 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 sponsor 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 sponsor 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 sponsor 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, a sponsor 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 U.S., 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 3D. 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. There can be no assurance 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 regulatory approval in a given country or territory for such drugs so as to be eligible for any market exclusivity protection.

Our drug development efforts are currently focused on two compounds, Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup>, which recently completed 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.

### ZoptrexTM:

We have licensed the 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) \$400,000 upon the first grant of regulatory approval for a Licensed Product in the U.S., Canada, the EU 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) 2.5% 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 1.75% nor more than 2.5% of the sublicensee's net sales of the Licensed Product.

The following patents are covered by the Tulane Agreement:

- U.S. 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 expired 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 expired 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 expired 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 expired in November 2016.

In early 2015, we filed a European patent application directed to a novel method of manufacturing Zoptrex<sup>TM</sup>. 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 U.S., 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<sup>TM</sup>, 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<sup>TM</sup>:

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<sup>TM</sup>:

- 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<sup>TM</sup> 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<sup>TM</sup>. 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<sup>TM</sup>. This patent expires in February 2027.

## <u>Disorazol Z - LHRH conjugates (AEZS-138)</u>:

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 expires 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 expires 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 expires 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, 2016 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 registered address is located in Montreal, Canada. 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, 2016.

Location	Use of space	Square Footage	Type of interest
315 Sigma Drive, Suite 302D, Summerville SC 29486	Partially occupied for management, administration, commercial operations and business development	4,623	Leasehold
Weismüllerstr. 50 D-60314	Occupied for management, R&D, business development and administration	36,168	Leasehold
Frankfurt-am-Main, Germany			

#### Item 4A Unresolved Staff Comments

None.

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

#### **Key Developments**

### **Zoptrex**<sup>TM</sup>

Zoptrex<sup>TM</sup> 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. Zoptrex<sup>TM</sup> is our proposed trade name for zoptarelin doxorubicin. The proposed trade name is subject to approval by the FDA.

We believe that Zoptrex<sup>TM</sup> 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<sup>TM</sup> in this indication. In addition, contingent on the success of the ZoptEC (**Zopt**arelin 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 Zoptrex<sup>TM</sup>, including ovarian, prostate, breast and potentially, bladder cancer.

The following paragraphs describe recent key developments with respect to Zoptrex<sup>TM</sup>:

- On October 13, 2015, we announced that an independent data and safety monitoring board ("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.
- On June 14, 2016, we announced that our licensee, Sinopharm A-Think Pharmaceuticals Co., Ltd. ("Sinopharm"), which is affiliated with the largest state-owned pharmaceutical company in the People's Republic of China, submitted an Investigational New Drug application ("IND") for Zoptrex™ to the Chinese State Food and Drug Administration ("CFDA"), remaining on track to commence its clinical program in 2017.
- On July 1, 2016, we announced that we had entered into an exclusive License Agreement with Cyntec Co., Ltd. ("Cyntec"), an affiliate of Orient EuroPharma Co., Ltd. ("OEP") for Zoptrex<sup>TM</sup> for the initial indication of endometrial cancer. Under the terms of the License Agreement, we were paid a non-refundable upfront cash payment in consideration for the license to Cyntec of our intellectual property related to Zoptrex<sup>TM</sup> and the grant to Cyntec of the right to commercialize Zoptrex<sup>TM</sup> in a territory consisting of Taiwan and nine countries in southeast Asia (the "OEP Territory"). Cyntec has also agreed to make additional payments to us upon achieving certain pre-established regulatory and commercial milestones. Furthermore, we will receive royalties based on future net sales of Zoptrex<sup>TM</sup> in the OEP Territory. Cyntec will be responsible for the development, registration, reimbursement and commercialization of the product in the OEP Territory. We entered into related Technology Transfer and Supply Agreements with another affiliate of OEP, pursuant to which we will transfer to such affiliate the technology necessary to permit the affiliate to manufacture finished Zoptrex<sup>TM</sup> using quantities of the active pharmaceutical ingredient purchased from us pursuant to the Supply Agreement.

- On July 31, 2016, we announced that we had entered into an exclusive License Agreement with Rafa Laboratories Ltd ("Rafa") for Zoptrex<sup>TM</sup> for the initial indication of endometrial cancer. Under the terms of the License Agreement, we were paid a non-refundable upfront cash payment in consideration for the license to Rafa of our intellectual property related to Zoptrex<sup>TM</sup> and the grant to Rafa of the right to commercialize Zoptrex<sup>TM</sup> in a territory consisting of Israel and the Palestinian territories (the "Rafa Territory"). Rafa has also agreed to make additional payments to us upon achieving certain pre-established regulatory and commercial milestones. Furthermore, we will receive royalties based on future net sales of Zoptrex<sup>TM</sup> in the Rafa Territory. Rafa will be responsible for the development, registration, reimbursement and commercialization of the product in the Rafa Territory. We entered into a related Supply Agreement with Rafa pursuant to which we will sell finished Zoptrex<sup>TM</sup> to Rafa.
- On October 12, 2016, we announced that we had entered into an exclusive License Agreement with Specialised Therapeutics Asia Pte Ltd ("STA") for Zoptrex™ for the initial indication of endometrial cancer. Under the terms of the License Agreement, we were paid a non-refundable upfront cash payment in consideration for the license to STA of our intellectual property related to Zoptrex™ and the grant to STA of the right to commercialize Zoptrex™ in a territory consisting of Australia and New Zealand (the "STA Territory"). STA has also agreed to make additional payments to us upon achieving certain pre-established regulatory and commercial milestones. Furthermore, we will receive royalties based on future net sales of Zoptrex™ in the STA Territory. STA will be responsible for the development, registration, reimbursement and commercialization of the product in the STA Territory. We entered into a related Supply Agreement with STA pursuant to which we will sell finished Zoptrex™ to STA.
- On January 30, 2017, we announced the completion of the clinical phase of the pivotal Phase 3 ZoptEC study with the occurrence of the 384<sup>th</sup> death. We currently expect to lock the clinical database and to report top-line results in April 2017. With the completion of the clinical portion of this trial, we will now focus on analyzing the data and, if warranted by the results, submitting a new drug application later this year.

#### Macrilen<sup>TM</sup>

Macrilen<sup>TM</sup>, a ghrelin receptor agonist, is a novel orally-active small molecule that stimulates the secretion of growth hormone. Macrilen<sup>TM</sup> has been granted orphan drug designation by the FDA for the evaluation of growth hormone deficiency. We own the worldwide rights to this novel patented compound. Macrilen<sup>TM</sup> is our proposed trade name for macimorelin. The proposed trade name is subject to approval by the FDA. On December 16, 2016 we were advised by the EMA that Macrilen<sup>TM</sup> was rejected as the proposed invented name for macimorelin because of its similarity to the names of other medicines. We intend to appeal this decision.

We recently concluded a confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup> for the evaluation of growth hormone deficiency in adults ("AGHD"). The confirmatory trial was an open-label, randomized, two-way crossover study that compared the results of the evaluation of AGHD using Macrilen<sup>TM</sup> to the results of the evaluation of AGHD using a procedure known as the "Insulin Tolerance Test" (the "ITT") on the same patient. The trial involved patients, each of whom was evaluated for AGHD using both Macrilen<sup>TM</sup> and the ITT. Thirty of the patients were evaluated using Macrilen<sup>TM</sup> a second time to measure the repeatability of the result obtained using Macrilen<sup>TM</sup> as the evaluation method. The study population consisted of more than 110 patients who were suspected of having AGHD as a result of the presence of one or more symptoms. This segment of the population included a range of patients from those considered at low risk of having AGHD to those considered at high risk. The study population also included 25 healthy subjects, who had no risk of having AGHD.

On January 4, 2017, we announced that the confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup> failed to achieve its objective of validating a single oral dose of macimorelin for the evaluation of AGHD, using the ITT as a comparator. Based on an analysis of top-line data, macimorelin did not achieve equivalence to the ITT as a means of diagnosing AGHD. Under the study protocol, the evaluation of AGHD with Macrilen<sup>TM</sup> would have been considered successful if the lower bound of the two-sided 95% confidence interval for the primary efficacy variables was 75% or higher for "percent negative agreement" with the ITT, and 70% or higher for the "percent positive agreement" with the ITT. While the estimated percent negative agreement met the success criteria, the estimated percent positive agreement did not reach the criteria for a successful outcome. Therefore, the results did not meet the pre-defined equivalence criteria which required success for both the percent negative agreement and the percent positive agreement.

On February 13, 2017, we announced that, following a comprehensive review of the data obtained from the confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup> for the evaluation of AGHD using the ITT as a comparator, we concluded that Macrilen<sup>TM</sup> demonstrated performance supportive of FDA registration consideration. The press release in which we made such announcement set forth the facts on which our conclusion was based. We will meet with the FDA at the end of March 2017 to discuss this position.

### Pre-clinical developments

On January 13, 2016, we announced that, in addition to our focus on Zoptrex<sup>™</sup>, we are also focusing on AEZS-138/Disorazol Z, because we believe that it is an ideal compound for the formation of cytotoxic conjugates with peptides, proteins and antibodies to selectively target cancer cells. AEZS-138 is a cytotoxic conjugate in preclinical development. It is a conjugate based on Disorazol Z and the LHRH receptor agonist that is utilized in Zoptrex<sup>™</sup>. We believe that the peptide directs the compound specifically to the 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 13 full-time sales representatives and a three person sales-management staff in the US. The sales representatives are employed by a contract sales organization and provide services to us pursuant to our contract with the contract sales organization while we employ the sales-management staff. Maintaining a sales force is an essential part of our strategy to transform the Company into a commercially operating specialty biopharmaceutical company. We do not believe that it is practical for a company of our size to sustain itself solely on a portfolio of internally derived products: development takes too long, costs too much money and entails too much risk. Therefore, we are seeking to acquire or to in-license products that fit our areas of therapeutic interest and capabilities and that are available on what we consider to be reasonable commercial terms.

Our sales force currently co-promotes two products that are owned by others: Saizen® and APIFINY®. Until September 1, 2016, we co-promoted a third product, EstroGel®.

### Saizen®

On May 8, 2015, we announced that we had entered into a promotional services agreement with EMD Serono, allowing us to promote Saizen<sup>®</sup> [somatropin (rDNA origin) for injection] to designated medical professionals in specified US territories. Saizen<sup>®</sup> is a recombinant human growth hormone registered in the US for the treatment of pediatric growth hormone deficiency and AGHD. Under this agreement, we were promoting Saizen<sup>®</sup> to designated pediatric endocrinologists and we were receiving commissions based on new, eligible patient starts on Saizen<sup>®</sup> above an agreed-upon base line. This agreement was amended in December 2016. The EMD Serono agreement, as amended, provides that we will promote Saizen<sup>®</sup> in specific agreed-upon US territories to both adult and pediatric endocrinologists in consideration for a sales commission that is based upon new, eligible patient starts, without any baseline.

### APIFINY®

During the fourth quarter of 2015, we signed a co-marketing agreement with Armune BioScience, Inc. ("Armune") giving us the right to promote this product to specified targets in the United States. APIFINY® is the only cancer-specific, non-PSA based blood test for the evaluation of the risk of prostate cancer. As such, it is an important adjunct to the traditional PSA test.

On April 27, 2016, we announced that we had entered into a new co-marketing agreement with Armune that gives us the exclusive right to promote APIFINY® throughout the entire United States. Under the terms of the new co-marketing agreement, we receive a commission for every APIFINY® test ordered. The amount of the commission varies depending upon the payer. For commercial insurance tests, we receive an upfront payment when the test is performed and, within 30 to 90 days, an additional percentage of the reimbursement, minus the amount of the upfront payment. For all other tests, we receive a flat fee at the time the test is performed.

# Corporate Activities

### Public offerings and related events

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 on January 13, 2016, 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.

On April 1, 2016, we entered into an "At-the-Market" ("ATM") sales agreement under which we are able, at our discretion and from time to time, to sell up to 3 million of our common shares through ATM issuances on the NASDAQ for aggregate gross proceeds of up to approximately \$10 million (the "ATM Program"). The ATM Program provides that common shares are to be sold at market prices prevailing at the time of sale and, as a result, prices may vary. Between April 1, 2016 and March 15, 2017, we issued approximately 1.4 million common shares at an average issuance sales price of \$3.62 per share pursuant to our ATM Program. The shelf registration statement pursuant to which this ATM Program was established expires on March 28, 2017.

On September 12, 2016, all 8,064 remaining Series B Warrants that had been issued in connection with a financing in March 2015 expired without having been exercised.

On November 1, 2016, we completed a registered direct offering of 2,100,000 units (the "Units"), with each Unit consisting of one common share or one prefunded warrant to purchase one common share and 0.45 of a warrant to purchase one common share (the "November 2016 Offering"). Total gross cash proceeds raised through the November 2016 Offering amounted to approximately \$7.6 million, less cash transaction costs of approximately \$1.0 million, including the placement agent's fee and expenses. The warrants are exercisable six months after their date of issuance and for a period of three years thereafter at an exercise price of \$4.70 per share. The warrants contain a call provision which provides that, in the event our common shares trade at or above \$10.00 on the principal trading market for our common shares during a specified measurement period and subject to a minimum volume of trading during such measurement period, then, subject to certain conditions, we have the right to call for cancellation all or any portion of the warrants which are not exercised by holders within 10 trading days following receipt of a call notice from us. Upon complete exercise for cash, these warrants would result in the issuance of an aggregate of 945,000 common shares that would generate additional proceeds of approximately \$4.4 million, although these warrants may be exercised on a "net" or "cashless" basis.

#### 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 believed that the second amended complaint also failed to state a claim. 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 filed a motion for reconsideration of the Court's March 2, 2016 order on March 16, 2016 and filed an answer to the second amended complaint on April 6, 2016. On June 30, 2016, the Court issued an order denying our motion for reconsideration. As a result, the lawsuit will proceed to the class certification phase and the discovery process has commenced. During the second quarter of 2016, we exceeded the deductible amount applicable to this claim. Therefore, we believe that most of the costs for our defense in future periods will be borne by the insurers who provide directors' and officers' liability insurance to us, subject to our policy limits.

While we believe that we have meritorious defenses and intend to defend this lawsuit vigorously, management cannot currently predict the outcome of this suit or reasonably estimate any potential loss that may result from this suit. Accordingly, we have not recorded any liability related to the lawsuit. No assurance can be given with respect to the ultimate outcome of such proceedings, and we could incur substantial unreimbursed legal fees, damages, settlements, judgments, and other expenses in connection with these proceedings that may not qualify for coverage under, or may exceed the limits of, our applicable D&O Insurance and could have a material adverse impact on our financial condition, results of operations, liquidity and cash flows.

# A. Operating Results

# **Consolidated Statements of Comprehensive Loss Information**

	Three months ended	December 31,	Years en	ded December 31,	
(in thousands, except share and per share data)	2016	2015	2016	2015	2014
	\$	\$	\$	\$	\$
Revenues					
Sales commission and other	94	41	414	297	_
License fees	210	61	497	248	11
	304	102	911	545	11
Operating expenses					
Research and development costs	4,619	4,243	16,495	17,234	23,716
General and administrative expenses	1,757	3,953	7,147	11,308	9,840
Selling expenses	1,526	1,764	6,745	6,887	3,850
	7,902	9,960	30,387	35,429	37,406
Loss from operations	(7,598)	(9,858)	(29,476)	(34,884)	(37,395)
(Loss) gain due to changes in foreign currency exchange rates	(396)	(315)	(70)	(1,767)	1,879
Change in fair value of warrant liability	(245)	3,030	4,437	(10,956)	18,272
Warrant exercise inducement fee	<u> </u>	(2,926)	<u> </u>	(2,926)	_
Other finance income	19	26	150	305	168
Net finance (costs) income	(622)	(185)	4,517	(15,344)	20,319
Loss before income taxes	(8,220)	(10,043)	(24,959)	(50,228)	(17,076)
Income tax expense	_	_	_	_	(111)
Net loss from continuing operations	(8,220)	(10,043)	(24,959)	(50,228)	(17,187)
Net income from discontinued operations	_	25	_	85	623
Net loss	(8,220)	(10,018)	(24,959)	(50,143)	(16,564)
Other comprehensive loss:					
Items that may be reclassified subsequently to profit or loss:					
Foreign currency translation adjustments	870	249	569	1,509	(1,158)
Items that will not be reclassified to profit or loss:					
Actuarial gain (loss) on defined benefit plans	1,143	(116)	(1,479)	844	(1,833)
Comprehensive loss	(6,207)	(9,885)	(25,869)	(47,790)	(19,555)
Net loss per share (basic and diluted) from continuing operations <sup>1</sup>	(0.71)	(1.46)	(2.41)	(18.17)	(29.12)
Net income per share (basic and diluted) from discontinued	(0.71)	(1.40)		(10.17)	(27.12)
operations <sup>1</sup>				0.03	1.06
Net loss per share (basic and diluted) <sup>1</sup>	(0.71)	(1.46)	(2.41)	(18.14)	(28.06)
Weighted average number of shares outstanding:1					
Basic	11,565,210	6,874,460	10,348,879	2,763,603	590,247
Diluted	11,614,234	7,302,816	10,665,149	3,424,336	590,247

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

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.

#### 2016 compared to 2015

#### Revenues

**Sales commission and other** were \$0.1 million and \$0.4 million for the three and twelve months ended December 31, 2016 and \$41,000 and \$0.3 million for the same periods in 2015, respectively, and thus increased in 2016 as compared to 2015. In 2016, those revenues mainly resulted from our sales team exceeding pre-established unit sales baseline thresholds under our co-promotion agreement to sell Saizen<sup>®</sup>. We also generated sales commission in connection with our promotion of APIFINY<sup>®</sup>. In the corresponding periods in 2015, sales commission and other revenues were mainly related to EstroGel<sup>®</sup>.

After a good first quarter, the results of our co-promotion of Saizen® during the second, third and fourth quarters of 2016 were disappointing. The demand for Saizen® appears to be more seasonal than we previously realized. Additionally, the non-commercial and self-pay business slowed in part due to competitive price pressures. Further, a recent decision by a large commercial health insurance provider to exclude Saizen® from its formulary was recently announced, taking effect in 2017. Therefore, in December 2016, we negotiated an amended agreement with EMD Serono in order to receive commission on each new patient start, without any baseline, as well as being able to promote to adult endocrinologists. As described in the "Key Developments" section above, the original agreement included a baseline that we needed to exceed before receiving commissions.

License fees were \$0.2 million and \$0.5 million for the three and twelve months ended December 31, 2016, respectively, as compared to \$0.1 million and \$0.2 million for the same periods in 2015. The increase is explained by the out-licensing agreements that we entered into in 2016 for Zoptrex<sup>TM</sup>, as described in the "Key Developments" section above.

#### **Operating Expenses**

Research and Development ("R&D") costs were \$4.6 million and \$16.5 million for the three and twelve months ended December 31, 2016, respectively, compared to \$4.2 million and \$17.2 million for the same periods in 2015.

The increase in our R&D costs for the three months ended December 31, 2016, as compared to the same period in 2015, is mainly attributable to higher comparative third-party costs, as described below.

The decrease in our R&D costs for the twelve months ended December 31, 2016, as compared to the same period in 2015, is attributable to lower employee compensation and benefits costs, lower facilities rent and maintenance costs as well as lower other costs. A substantial portion of this decrease is due to the realization of cost savings in connection with our ongoing efforts 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"). The R&D costs for the year ended December 31, 2016 were lower than anticipated mainly because we were able to negotiate reductions to a change order received from our principal R&D third-party service provider.

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

	Three mont Decemb		Years	ended December 3	1,
(in thousands)	2016	2015	2016	2015	2014
	<b>\$</b>	\$	\$	\$	\$
Third-party costs	3,233	2,899	11,829	11,891	11,356
Employee compensation and benefits	845	905	3,216	3,699	8,430 *
Facilities rent and maintenance	232	224	873	940	2,160
Other costs**	309	231	579	727	1,901
Gain on disposal of equipment	_	(16)	(2)	(23)	(131)
	4,619	4,243	16,495	17,234	23,716

<sup>\*</sup> Includes a provision for restructuring in the amount of \$2.2 million.

<sup>\*\*</sup>Includes mainly depreciation, amortization, impairment and operating foreign exchange losses.

The following table summarizes third-party R&D costs, by product candidate, incurred by the Company during the three-month periods ended December 31, 2016 and 2015.

(in thousands, except percentages)

	Three months ended December 31,			
Product Candidate	2016		201	5
	\$	%	\$	%
Zoptrex <sup>TM</sup>	1,453	44.9	1,488	51.3
Macrilen <sup>TM</sup>	1,568	48.5	977	33.7
LHRH - Disorazol Z	86	2.7	73	2.5
Erk inhibitors	16	0.5	71	2.5
Other	110	3.4	290	10.0
	3,233	100.0	2,899	100.0

The following table summarizes third-party R&D costs, by product candidate, incurred by the Company during the years ended December 31, 2016, 2015 and 2014.

(in thousands, except percentages)

(· · · · · · · · · · · · · · · · · · ·	Years ended December 31,					
Product Candidate	2016		201	5	201	4
	\$	%	\$	%	\$	%
Zoptrex <sup>TM</sup>	6,742	57.0	8,635	72.6	9,668	85.1
Macrilen™	4,326	36.6	1,555	13.1	404	3.6
LHRH - Disorazol Z	294	2.5	212	1.8	257	2.3
Erk Inhibitors	130	1.1	1,081	9.1	488	4.3
Other	337	2.8	408	3.4	539	4.7
	11,829	100.0	11,891	100.0	11,356	100.0

As shown above, a substantial portion of the quarter-to-date and year-to-date R&D costs relate to development initiatives associated with Zoptrex<sup>TM</sup>, and in particular with our pivotal Phase 3 ZoptEC clinical trial initiated in 2013 with Ergomed. Third-party costs attributable to Zoptrex<sup>TM</sup> decreased considerably during the twelve months ended December 31, 2016, as compared to the same period in 2015, mainly due to the fact that dosing of patients in the ZoptEC trial was completed in February 2016. This is consistent with our expectations, as we completed the study during the first quarter of 2017 and we expect to report top-line results in April 2017.

In addition, during 2015, we initiated the new confirmatory Phase 3 clinical trial of Macrilen™, which explains the increase in costs for this product candidate. The first patient was enrolled in the fourth quarter of 2015, we announced completion of patient recruitment in the fourth quarter of 2016 and we announced top-line results of the trial on January 4, 2017. Finally, in 2015, we also decided to suspend our efforts on internally developing Erk inhibitor, a molecule for potential cancer therapies, to conserve our resources for other projects.

Excluding the impact of foreign exchange rate fluctuations, we expect that we will incur overall R&D costs of between \$19.0 million and \$20.0 million for the year ended December 31, 2017. Although we expect a decrease in costs related to the contract research organization following the end of the clinical trials, this will be offset by the costs associated with the NDA preparation for both products, the FDA submission fee for Zoptrex<sup>TM</sup>, if the results of the clinical trial warrant submitting a new drug application, as well as by the investments needed in inventory prior to the potential commercial launch of both Macrilen<sup>TM</sup> and Zoptrex<sup>TM</sup> and by the costs related to the validation of a second supplier for both products to be able to fulfill the expected demand.

General and administrative ("G&A") expenses were \$1.8 million and \$7.1 million for the three and twelve months ended December 31, 2016, respectively, as compared to \$4.0 million and \$11.3 million for the same periods in 2015. The decrease in our G&A costs for the three months and twelve months ended December 31, 2016, as compared to the same periods in 2015, is due to the recording of a provision, in the fourth quarter of 2015, related to a corporate restructuring that we announced on October 12, 2015 (the "Corporate Restructuring"). The Corporate Restructuring included the restructuring of our finance and accounting staff and the closure of our office in Quebec City. As a result of the Corporate Restructuring, recurring G&A expenses also decreased

in 2016, as compared to 2015. Finally, the comparative decrease for the three-month and twelve-month periods is also explained by certain transaction costs allocated to warrants in connection with the completion of share issuances in March and December 2015.

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 slightly increase in 2017, as compared to 2016, because we expect to hire additional employees in connection with the potential commercialization of our products. We expect that G&A expenses will range between \$7.5 million and \$8.5 million in 2017.

Selling expenses were \$1.5 million and \$6.7 million for the three and twelve months ended December 31, 2016, respectively, as compared to \$1.8 million and \$6.9 million for the same periods in 2015. The selling expenses for the three and twelve months ended December 31, 2016 and 2015 represent mainly the costs of our contracted sales force related to the co-promotion activities as well as our internal sales management team. The selling expenses remained relatively stable during 2016 and are slightly below what we anticipated because we postponed some expenses related to the potential commercial launch of Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup> mainly because the related clinical trials took more time than expected.

Based on currently available information, we expect selling expenses to range between \$7.0 million and \$8.0 million in 2017. The expected increase in 2017 as compared to 2016 is mainly due to the fact that we are starting to prepare for the expected commercial launch of Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup>.

Net finance (costs) income were (\$0.6) million and \$4.5 million for the three and twelve months ended December 31, 2016, as compared to (\$0.2) million and (\$15.3) million, for the same periods in 2015. These increases in finance income or decreases in finance costs are mainly attributable to the change in fair value recorded in connection with our warrant liability. Such change in fair value results from the periodic "mark-to-market" revaluation, via the application of option pricing models, of outstanding share purchase warrants. During 2016, the "mark-to-market" warrant valuation was impacted by the expiration of the remaining Series B Warrants. During 2015, the change in assumptions that were applied to determine the fair value of the alternate cashless exercise feature included in the Series B Warrants significantly impacted the "mark-to-market" valuation. Furthermore, the closing price of our common shares, which, on the NASDAQ, fluctuated from \$3.25 to \$4.94 during the three-month period and \$2.67 to \$4.94 during the twelve-month period ended December 31, 2016, respectively, compared to \$4.00 to \$11.43 and \$4.00 to \$84.20 during the same periods in 2015, also had a direct impact on the change in fair value of warrant liability.

In addition, with specific reference to 2015, finance costs were also impacted by the warrant exercise inducement fee paid to certain holders of the Series B Warrants.

Net loss for the three and twelve months ended December 31, 2016 was (\$8.2) million and \$(25.0) million, or (\$0.71) and (\$2.41) per basic and diluted share, as compared to a net loss of \$(10.0) million and \$(50.1) million, or (\$1.46) and (\$18.14) per basic and diluted share, for the same periods in 2015. The decrease in net loss for the three months ended December 31, 2016, as compared to the same period in 2015, is due largely to lower G&A expenses, as presented above. The decrease in net loss for the twelve months ended December 31, 2016, as compared to the same period in 2015, is due largely to lower operating expenses and higher comparative net finance income, as presented above.

## 2015 compared to 2014

## Revenues

Revenues were \$0.5 million for the year ended December 31, 2015 compared to \$0.01 million for the same period 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 related to Zoptrex<sup>TM</sup>. We deferred this non-refundable payment and we amortize it on a straightline basis over a four-year period. In addition, we generated sales commission in connection with our co-promotion efforts related to EstroGel®, which we no longer promote.

### **Operating Expenses**

**R&D costs** were \$17.2 million for the year ended December 31, 2015 compared to \$23.7 million for the same period in 2014.

The decrease for the year ended December 31, 2015, as compared to the same period in 2014, is mainly 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 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.

A substantial portion of third-party R&D costs in 2015 related to development initiatives associated with Zoptrex<sup>TM</sup>, 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<sup>TM</sup> 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. In addition, during the year 2015, we started the new confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup>, which explains the increase in costs for this product candidate.

**General and administrative ("G&A") expenses** were \$11.3 million for the year ended December 31, 2015, as compared to \$9.8 million for the same period 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 share issuances in March and December 2015.

**Selling expenses** were \$6.9 million for the year ended December 31, 2015, as compared to \$3.9 million for the same period in 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.

**Net finance (costs) income** were \$(15.3) million for the year ended December 31, 2015, as compared to \$20.3 million for the same period in 2014 and 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 option pricing models, of share purchase warrants that were outstanding during the relevant period. The "mark-to-market" warrant valuation was most notably impacted by the issuance of 3.1 million additional share purchase warrants in 2015 and by the closing price of our common shares, which, on the NASDAQ, fluctuated from \$4.00 to \$84.20 during the year ended December 31, 2015 and from \$52.00 to \$150.00 during the year ended December 31, 2014.

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 2014, that the FDA had issued a complete response letter ("CRL") in connection with our new drug application ("NDA") for Macrilen<sup>TM</sup>. The lower closing price of our shares following our announcement of the CRL resulted in a lower Black-Scholes valuation of our share purchase warrants that were outstanding 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.

In addition, with specific reference to 2015, finance costs were also impacted by the warrant exercise inducement fee paid to certain holders of the Series B Warrants.

**Net loss** for the year ended December 31, 2015 was \$(50.1) million, or \$(18.14) per basic and diluted share compared to \$(16.6) million, or \$(28.06) per basic and diluted share for the same period in 2014. The increase in our net loss from continuing operations 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.

### **Quarterly Consolidated Results of Operations Information**

(in thousands, except for per share data)	Three months ended			
	<b>December 31, 2016</b>	September 30, 2016	June 30, 2016	March 31, 2016
	<u> </u>	\$	\$	\$
Revenues	304	269	96	242
Loss from operations	(7,598)	(7,703)	(7,184)	(6,991)
Net loss	(8,220)	(6,055)	(7,008)	(3,676)
Net loss per share (basic and diluted)*	(0.71)	(0.61)	(0.71)	(0.37)
	Three months ended			
(in thousands, except for per share data)		i nree months	enaea	
(in thousands, except for per share data)	December 31, 2015	September 30, 2015	June 30, 2015	March 31, 2015
(in thousands, except for per share data)	December 31, 2015			March 31, 2015
(in thousands, except for per share data)  Revenues		September 30, 2015	June 30, 2015	
	\$	September 30, 2015 \$	June 30, 2015	\$
Revenues	<b>\$</b>	September 30, 2015 \$ 173	June 30, 2015 \$	<b>\$</b> 73

<sup>\*</sup> Net 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 loss per share amounts may not equal full-year net loss per share.

Historical quarterly results of operations and net loss 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 unpredictable quarterly variations attributable to our net finance income (costs), which in turn are comprised mainly 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 have historically 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.

#### **Condensed Consolidated Statement of Financial Position Information**

	As at Dec	ember 31,
(in thousands)	2016	2015
	\$	\$
Cash and cash equivalents <sup>1</sup>	21,999	41,450
Trade and other receivables and other current assets	744	944
Restricted cash equivalents	496	255
Property, plant and equipment	204	256
Other non-current assets	8,216	8,593
Total assets	31,659	51,498
Payables and other current liabilities <sup>2</sup>	3,778	4,770
Current portion of deferred revenues	426	244
Warrant liability	6,854	10,891
Non-financial non-current liabilities <sup>3</sup>	14,389	13,978
Total liabilities	25,447	29,883
Shareholders' equity	6,212	21,615
Total liabilities and shareholders' equity	31,659	51,498

<sup>1.</sup> Approximately \$1.5 million was denominated in EUR as at December 31, 2016 and December 31, 2015, and approximately \$3.7 and \$4.4 million were denominated in Canadian dollars as at December 31, 2016 and December 31, 2015, respectively.

<sup>2.</sup> Approximately \$0.6 million was related to our provision for restructuring as at December 31, 2016.

<sup>3.</sup> Comprised mainly of employee future benefits, provisions for onerous contracts and non-current portion of deferred revenues.

The decrease in cash and cash equivalents as at December 31, 2016, as compared to December 31, 2015, is due to the net cash used in operating activities and variations in components of our working capital and by the increase in restricted cash equivalents. The decrease was partially offset by the net proceeds generated by the sale and issuance of common shares under our ATM Program and as part of the November 2016 Offering as well as the upfront cash payments received in consideration for the licenses to Cyntec, Rafa and STA.

The increase in restricted cash equivalents is mainly explained by the fact that we launched a corporate credit card program, which requires us to set aside a reserve of a certain sum of funds.

The increase in the current portion of deferred revenues is explained by the out-licensing agreement signed with Cyntec during the third quarter of 2016.

The decrease in our warrant liability from December 31, 2015 to December 31, 2016 is due to a net fair value revaluation gain of \$4.4 million, which was recorded pursuant to our periodic "mark-to-market" revaluation of the underlying outstanding warrants. The revaluation gain is mainly explained by the decrease of the price of our common shares during the period as well as the impact of the expiration of the Series B Warrants. This was partially offset by the fair value attributable to the warrants issued in the November 2016 Offering.

The increase in non-financial non-current liabilities from December 31, 2015 to December 31, 2016 is mainly due to a decrease in the discount rate used to estimate our employee future benefits obligation.

The decrease in shareholders' equity as at December 31, 2016, as compared to December 31, 2015, is attributable primarily to the recording of a net loss for the twelve-month period and an actuarial loss on our pension-related employee benefit obligation for the same period. This was partly offset by the increase in our share capital following the issuance of common shares and warrants in the November 2016 Offering.

### **Outstanding Share Data**

As at March 15, 2017, we had 13.5 million common shares issued and outstanding, as well as 968,264 stock options outstanding. Share purchase warrants outstanding as at March 15, 2017 represented a total of 3,779,245 equivalent common shares.

#### **Recent Accounting Pronouncements**

The IASB continues to issue new and revised IFRS. A listing of the recent accounting pronouncements promulgated by the IASB and not yet adopted by the Company is included in note 4 to the Company's December 31, 2016 consolidated financial statements which are included in Item 18 of this Annual Report on Form 20-F.

### B. Liquidity, Cash Flows 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 drawdowns under various ATM programs.

While the Company had \$22.0 million of cash and cash equivalents as at December 31, 2016, we believe that our cash and cash resources will not be sufficient to fund operations for the next twelve months unless our expenditures are reduced or further financing is obtained. See the section below titled "Summary of key expectations for revenues, operating expenses and cash flows". Our ability to continue as a going concern is dependent upon raising additional financing through equity, debt and/or other non-dilutive funding and partnerships. There can be no assurance that we will have sufficient capital to fund our ongoing operations or the development or commercialization of our products without future financings. There can be no assurance that additional financing will be available on acceptable terms or at all. We are currently pursuing financing alternatives that may include equity, debt, and non-dilutive financing alternatives, including co-development through potential collaborations, strategic partnerships or other transactions with third parties. If we are unable to obtain additional financing when required, we may have to substantially reduce or eliminate planned expenditures or we may be unable to continue our operations. These uncertainties cast substantial doubt as to the ability of the Company to meet its obligations as they come due and, accordingly, the appropriateness of the use of accounting principles applicable to a going concern. The Company's ultimate success, its ability to raise additional financing, whether through equity, debt or other sources of funding and, consequently, to continue as a going concern, is also dependent upon at least one of the two internally developed compounds obtaining positive results in their currently ongoing Phase 3 studies.

On April 1, 2016, we entered into an ATM sales agreement under which we are able, at our discretion and from time to time, to sell up to 3 million of our common shares through ATM issuances on the NASDAQ for aggregate gross proceeds of up to approximately \$10 million. The ATM program provides that common shares are to be sold at market prices prevailing at the time of sale and, as a result, prices may vary. Subsequent to December 31, 2016, the Company issued an additional 555,068 common shares under the April 2016 ATM Program at an average price of approximately \$3.20 per share for gross proceeds of approximately \$1.8 million. The shelf registration statement pursuant to which this program was established expires on March 28, 2017.

On November 1, 2016, we completed a registered direct offering of 2,100,000 units (the "Units"), with each Unit consisting of one common share or one prefunded warrant to purchase one common share and 0.45 of a warrant to purchase one common share (the "November 2016 Offering"). Total gross cash proceeds raised through the November 2016 Offering amounted to approximately \$7.6 million, less cash transaction costs of approximately \$1.0 million, including the placement agent's fee and expenses. The warrants are exercisable six months after their date of issuance and for a period of three years thereafter at an exercise price of \$4.70 per share. The warrants contain a call provision which provides that, in the event our common shares trade at or above \$10.00 on the principal trading market of our common shares during a specified measurement period and subject to a minimum volume of trading during such measurement period, then, subject to certain conditions, we have the right to call for cancellation all or any portion of the warrants which are not exercised by holders within 10 trading days following receipt of a call notice from us. Upon complete exercise for cash, these warrants would result in the issuance of an aggregate of 945,000 common shares that would generate additional proceeds of approximately \$4.4 million, although these warrants may be exercised on a "net" or "cashless" basis.

The variations in our liquidity by activity are explained below.

(in thousands)	Three months en		Year	s ended December	r 31,
	2016	2015	2016	2015	2014
		\$	<b>\$</b>	\$	\$
Cash and cash equivalents - Beginning of period	21,052	38,345	41,450	34,931	43,202
Cash flows from operating activities:					
Cash used in operating activities from continuing operations	(8,131)	(8,419)	(29,010)	(33,929)	(30,787)
Cash provided by (used in) operating activities from discontinued operations		25	_	85	(295)
	(8,131)	(8,394)	(29,010)	(33,844)	(31,082)
Cash flows from financing activities:	_	_			
Net proceeds from issuance of common shares and warrants	9,361	14,987	9,924	49,427	24,358
Payment pursuant to warrant amendment agreements and Series B Warrants exercise inducement fee	_	(2,926)	_	(8,629)	_
	9,361	12,061	9,924	40,798	24,358
Cash flows from investing activities:					
Net cash (used in) provided by investing activities from continuing operations	(9)	(6)	(314)	913	(61)
	(9)	(6)	(314)	913	(61)
Effect of exchange rate changes on cash and cash equivalents	(274)	(556)	(51)	(1,348)	(1,486)
Cash and cash equivalents - End of period	21,999	41,450	21,999	41,450	34,931

#### **Operating Activities**

#### 2016 compared to 2015

Cash used in operating activities totaled \$8.1 million and \$29.0 million for the three and twelve months ended December 31, 2016, as compared to \$8.4 million and \$33.8 million for the same periods in 2015. The decrease in cash used in operating activities for the twelve months and three months ended December 31, 2016, as compared to the same periods in 2015, is mainly due to lower operating expenses. Cash used in operations was lower than initially anticipated mainly because we incurred less R&D costs as explained in the operating expenses variance analysis section above.

We expect net cash used in operating activities to range from \$30 million to \$32 million for the year ending December 31, 2017 as we finalize our Zoptrex<sup>TM</sup> Phase 3 program as well as preparing for Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup> NDA submission and commercial launch and as we expect to generate higher revenues in connection with the promotion of Saizen<sup>®</sup> and APIFINY<sup>®</sup>. This guidance may vary significantly in future periods as it assumes that the Zoptrex<sup>TM</sup> Phase 3 study will be positive and that we will be able to register Macrilen<sup>TM</sup>. It can also be significantly impacted by ongoing business development initiatives.

#### 2015 compared to 2014

Cash used in operating activities totaled \$33.8 million and \$31.1 million for the years ended December 31, 2015 and 2014, respectively. The increase in cash used in operating activities for the year ended December 31, 2015, as compared to the same period in 2014, was mainly due to higher trade accounts payable settlements and higher payments in connection with the restructuring programs.

#### **Financing Activities**

### 2016 compared to 2015

Cash flows from financing activities totaled \$9.4 million and \$9.9 million for the three and twelve months ended December 31, 2016, as compared to \$12.1 million and \$40.8 million for the same periods in 2015. The decrease is mainly due to lower net proceeds received from the issuance of common shares and warrants in 2016 as compared to 2015.

### 2015 compared to 2014

Cash flows from financing activities totaled \$40.8 million and \$24.4 million for the years ended December 31, 2015 and 2014, respectively. The increase was mainly due to higher net proceeds received from the issuance of common shares and warrants in 2015 as compared to 2014.

## **Investing Activities**

### 2016 compared to 2015

Cash (used in) provided by investing activities totaled \$(0.01) million and \$(0.3) million for the three and twelve months ended December 31, 2016, as compared to \$(0.01) million and \$0.9 million for the same periods in 2015. The twelve-month period ended December 31, 2016 includes the increase of restricted cash equivalents that were required for the corporate credit card program. The twelve-month period ended December 31, 2015 included proceeds received in relation to the disposal of equipment in connection with our Resource Optimization Program in the first quarter of 2015.

We expect net cash used in investing activities to range from \$1.0 million to \$1.5 million for the year ending December 31, 2017 as we will have to invest in IT as well as in manufacturing capacity while we are preparing for the potential commercial launch of Macrillen<sup>TM</sup> and Zoptrex<sup>TM</sup>.

# Critical Accounting Policies, Estimates and Judgments

Our consolidated financial statements as at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014 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 when 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, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014. Those are included in Item 18 of this Annual Report on Form 20-F.

#### **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 "Key Developments" at the beginning of this Item 5. You can also find relevant information in our consolidated financial statements in Item 18 as well as the details of amounts spent during the last three years in the "Operating Results" section of this Item 5.

### D. Trend Information

Outlook for 2017

### **Product Development**

## **Zoptrex**<sup>TM</sup>

As our pivotal Phase 3 ZoptEC study of Zoptrex<sup>TM</sup> in women with advanced, recurrent, or metastatic endometrial cancer nears announcement of top-line results, we are expanding our commercialization planning for Zoptrex<sup>TM</sup>. Our commercialization efforts are focused on the development of a scientific platform, the identification of key opinion leaders and the expansion of market research initiatives. On January 30, 2017, we announced the completion of the clinical phase of the pivotal Phase 3 ZoptEC study with the occurrence of the 384<sup>th</sup> death. We currently expect to lock the clinical database and to report top-line results in April 2017 and, if the results of the trial warrant doing so, we would then expect to file the NDA for Zoptrex<sup>TM</sup> during the second half of 2017, looking toward commercial launch of the product in late 2018, assuming positive Phase 3 results and that our NDA is approved by the FDA.

### Macrilen<sup>TM</sup>

On January 4, 2017, we announced that the confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup> failed to achieve its objective of validating a single oral dose of macimorelin for the evaluation of AGHD using the ITT as a comparator. However, on February 13, 2017, we announced that, following a comprehensive review of the data obtained from the confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup>, we concluded that Macrilen<sup>TM</sup> demonstrated performance supportive of FDA registration consideration. The press release in which we made such announcement set forth the facts on which our conclusion was based. The Company will meet with the FDA at the end of March 2017 to discuss this position. If the FDA agrees with our position, we would then expect to file an NDA for Macrilen<sup>TM</sup> during the third quarter of 2017. We would then expect to obtain FDA approval, following a six-month review period, and to begin the commercialization of the drug at the beginning of 2018.

We believe that, in the US alone, there are approximately 2,500 endocrinologists that we could target as potential prescribers of Macrilen<sup>TM</sup> and that approximately 40,000 confirmatory tests for AGHD will be conducted each year after the introduction of Macrilen<sup>TM</sup>, if it is approved by the FDA, which represents the target market for Macrilen<sup>TM</sup> at the time of its anticipated commercialization. Furthermore, we believe that Macrilen<sup>TM</sup>, if it is approved, is likely to be rapidly adopted by physicians as the preferred means of evaluating AGHD. Furthermore, we believe that there is a significant opportunity for Macrilen<sup>TM</sup> in the evaluation of AGHD in traumatic brain injury patients. As reported by the US Centers for Disease Control and Prevention, approximately 215,000 adults are hospitalized for traumatic brain injury in the US each year. Because approximately 20% of such patients are at risk of developing growth hormone deficiency, traumatic brain injury patients represent a potentially significant market expansion opportunity for Macrilen<sup>TM</sup>.

#### **Commercial Operations**

### Saizen®

After a good first quarter, the results of our promotional efforts with respect to Saizen® in the second, third and fourth quarters of 2016 were disappointing. We believe that the decline in results from our promotional efforts for Saizen® is mainly due to seasonality because our target physicians treat pediatric patients. We believe that pediatric patients are more likely to be evaluated for and to have growth hormone therapy for small stature syndrome initiated at the beginning of a school year and that, therefore, consultations of pediatric endocrinologists generally increase with the beginning of the school year. Increased physician visits typically result in increased numbers of statements-of-medical-necessity ("SMN").

Physicians desiring to prescribe Saizen® (or any similar product) for new patients (other than patients who will bear the cost of the treatment without seeking insurance coverage) must first submit a SMN to a patient's insurance provider. The insurance provider will make its coverage decision on the basis of the SMN. If the insurance provider accepts the statement of medical necessity and related documentation, the patient receives coverage for the cost of the medication. Often, the patient's insurance provider's coverage decision determines whether or not the patient receives treatment because of the expense of the drug. This process takes several months following the beginning of school year. Additionally, the non-commercial and self-pay business slowed in part due to competitive price pressures. Further, a recent decision by a large commercial health insurance provider to exclude Saizen® from its formulary was recently announced, taking effect in 2017. We expect this decision to cause a reduction in new patient starts.

Therefore, in December 2016, we amended our agreement with EMD Serono in order to receive commissions on each new patient start (without any baseline), as well as being able to promote to adult endocrinologists. The addition of adult-endocrinologist targets to our promotional efforts is expected to expand our market opportunities. This will also mitigate the seasonality because SMN for adult patients do not appear to be impacted by the apparent seasonality observed related to pediatric patients.

## <u>APIFIN</u>Y®

During the fourth quarter of 2015, we signed a co-marketing agreement with Armune. On April 27, 2016, we announced that we had entered into a new co-marketing agreement with Armune pursuant to which we acquired the exclusive right to promote APIFINY® throughout the United States, effective as of June 1, 2016. We expect continued growth in this business over the coming quarters. In August 2016, we announced that we had expanded the promotion of APIFINY® to Florida, following Armune's receipt of a clinical laboratory license from that state. Armune is also currently pursuing agreements with regional and national laboratories.

### Summary of key expectations for revenues, operating expenditures and cash flows

We will continue to record commission revenues in relation to our promotional services agreement for Saizen® and 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 and Cyntec, as described in the "Key Developments" section of this MD&A. In addition, if top-line results of Zoptrex<sup>TM</sup> (which we expect to be available in April 2017) are positive, we will receive additional milestone payments.

Our main focus for R&D efforts will be to prepare our NDA submission for Macrilen<sup>TM</sup>, if the FDA agrees with our assessment of the data from the confirmatory Phase 3 trial, and for Zoptrex<sup>TM</sup>, if the results of ZoptEC warrant doing so. Excluding the impact of future foreign exchange rate fluctuations, we expect that we will incur R&D costs of between \$19.0 million and \$20.0 million for the year ending December 31, 2017. This mainly includes NDA preparation costs for Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup>, the NDA submission fee for Zoptrex<sup>TM</sup> and investment in inventory prior to the potential FDA approval and commercial launch. We will also have to incur costs in connection with the validation of a second supplier for both products to be able to fulfill the expected demand.

We expect that selling expenses will increase for the year ending December 31, 2017, as compared to the year ended December 31, 2016, mainly due to the fact that we are starting to prepare for the potential commercial launch of Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup>. Based on currently available information, we expect selling expenses to range between \$7.0 million and \$8.0 million during the year ending December 31, 2017.

Excluding the impact of foreign exchange rate fluctuations, we expect that our G&A expenses will slightly increase for the year ending December 31, 2017, as compared to the year ended December 31, 2016, mainly due to the fact that we are starting to prepare for the potential commercial launch of Zoptrex<sup>TM</sup> and Macrilen<sup>TM</sup>. Based on currently available information, we expect G&A expenses to range between \$7.5 million and \$8.5 million during the year ending December 31, 2017.

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 2017 will range from \$30.0 million to \$32.0 million, as we continue to fund ongoing operating activities and working capital requirements.

We expect net cash used in investing activities to range from \$1.0 million to \$1.5 million for the year ending December 31, 2017 as we will have to invest in IT as well as in manufacturing capacity while we are preparing for the potential commercial launch of Macrillen<sup>TM</sup> and Zoptrex<sup>TM</sup>.

The preceding summary with regard to our revenue, operating expenditures and cash flow expectations excludes any consideration of any potential strategic commercial initiatives 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 revenues. 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**

The nature and extent of our exposure to risks arising from financial instruments, including credit risk, liquidity risk and market risk (share price risk) and how we manage those risks are described in note 21 to the Company's annual audited consolidated financial statements as at December 31, 2016 and 2015 and for the years ended December 31, 2016, 2015 and 2014.

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

### E. Off-Balance Sheet Arrangements

As at December 31, 2016, 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

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, 2016 are as follows:

(in thousands)	Minimum lease payments	Minimum sublease receipts	Service and manufacturing
	\$	\$	\$
Less than 1 year	1,341	(351)	2,891
1 - 3 years	2,012	(151)	83
4 - 5 years	1,101	_	_
Total	4,454	(502)	2,974

In accordance with the assumptions used in our employee future benefit obligation calculation as at December 31, 2016, undiscounted benefits expected to be paid are as follows:

(in thousands)	\$
Less than 1 year	420
1-3 years	891
4-5 years	937
More than 5 years	15,165
Total	17,413

### 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 15, 2017:

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	President and Chief Executive Officer
Egbert, Carolyn Texas, United States	Chair of the Board of Directors
Ernst, Juergen North Rhine-Westphalia, Germany	Director
Guenther, Eckhard Hessen, Germany	Vice President, Alliance Management
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 — Mr. Cardiff was appointed to our Board of Directors (the "Board") on January 29, 2016 and elected as a director by our shareholders at our 2016 annual meeting. 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-profit 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. 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 — Ms. Egbert has served as a director on our Board since August 2012 and as Chair of our Board since May 2016. 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 board. 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** — Mr. 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 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 and as Vice President, Alliance Management in June 2016. 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.

Geneviève Lemaire was appointed our interim Corporate Controller in August 2015 and subsequently our Vice President, Finance and Chief Accounting 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 has served 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, C.M., FCPA, FCA — Mr. 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 — Mr. Newport was appointed to our Board on January 29, 2016 and elected as a director by our shareholders at our 2016 annual meeting. 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 Board of Directors 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 in Canada.

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 currency. Unless otherwise indicated, all 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, the amounts have been converted from such person's home country currency to US dollars based on the following annual average exchange rates: for the financial year ended December 31, 2016: €1.000 = US\$1.110 and CAN\$1.000 = US\$0.754; for the financial year ended December 31, 2015: €1.000 = US\$1.110 and CAN\$1.000 = US\$0.783; and for the financial year ended December 31, 2014: €1.000 = US\$1.329 and CAN\$1.000 = US\$0.905.

#### **Compensation of Outside Directors**

The compensation paid to members of our Board 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 "NGCC"). The NGCC is composed of four Outside Directors, each of whom is independent, namely Ms. Carolyn Egbert (Chair), Mr. Juergen Ernst, Mr. Michael Cardiff and Mr. Ken Newport.

The manner in which our Outside Directors are compensated was revised in 2016. Prior to July 1, 2016, our Outside Directors were paid an annual retainer, the amount of which depended on the position held on the Board, and attendance fees. Annual retainers and attendance fees were paid quarterly to our Outside Directors as follows:

Type of Compensation	Annual Compensation Prior to July 1, 2016 (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
NGCC Chair Retainer	12,000
NGCC Member Retainer	2,000
NGCC Meeting Attendance Fees	1,000 per meeting

All amounts in the above table were paid to Board and committee members in their home country currency.

Effective as of July 1, 2016, our Outside Directors are paid an annual retainer for their service to the Corporation. Chairs and members of Committees are paid additional annual retainers for such service. Our Outside Directors will not be paid fees for their attendance of meetings, unless some circumstance dictates that an unusual and burdensome number of meetings must be held. If such a circumstance occurs, the Board of Directors may institute meeting payments. The annual retainers are paid in quarterly installments on or about the last day of each calendar quarter. All payments will be calculated in US dollars. The amount of each payment will be converted to the Outside Director's home currency based on the exchange rate prevailing on the date of payment, as determined by our finance department. Each Outside Director will be paid the equivalent value of the payment in his or her home currency, net of any withholdings or deductions required by applicable law. The annual retainers were prorated from July 1, 2016, except that the Chair of the Board received a prorated annual retainer, retroactive to May 10, 2016, the date on which she assumed the duties of Chair of the Board.

The amounts of the annual retainers are set forth in the following table:

Type of Compensation	Annual Retainer for the year 2016 (in US\$)
Chair of the Board Retainer	80,000
Board Member Retainer	40,000
Audit Committee Chair Retainer	20,000
Audit Committee Member Retainer	5,000
NGCC Chair Retainer	15,000
NGCC Member Retainer	3,000

The 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. All 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**

During the financial year ended December 31, 2016, we requested that our Directors, officers and employees agree to voluntarily surrender and cancel, without any consideration therefor, certain outstanding options to acquire our Common Shares because the exercise price of such options was substantially in excess of the current price of our Common Shares. The number of options to acquire our Common Shares that we may issue is limited to 11.4% of the number of our issued and outstanding Common Shares; therefore, the voluntary surrender by our Directors of options to acquire Common Shares increased the number of options that may be issued under our Stock Option Plan. In response to such request, our Directors surrendered 480 options to acquire our Common Shares, which options had a weighted average exercise price of CAN\$717.18 and 4,941 options to acquire our Common Shares, which options had a weighted average exercise price of \$133.45. The following table shows all awards outstanding to each Outside Director as at December 31, 2016:

			Option-based Aw	Share-based Awards						
Name	Issuance Date	Number of Securities Underlying Unexercised Options <sup>(1)</sup>	Option Exercise Price	Option Expiration Date	Value of Unexercised In- the-money Options <sup>(2)</sup>	Issuance Date	Number of Shares or Units of Shares that have Not Vested	Market or Payout Value of Share-based Awards that have Not Vested		
	(mm-dd- yyyy)	(#)	(\$)	(mm-dd-yyyy)	(\$)	(mm-dd- yyyy)	(#)	(\$)		
Cardiff, Michael	05-10-2016	20,000	3.48	05-09-2023	2,400	_	_	_		
	12-06-2016	7,850	3.45	12-06-2023	1,178	_	_	_		
Egbert, Carolyn	05-10-2016	10,000	3.48	05-09-2023	1,200	_	_	_		
	12-06-2016	7,850	3.45	12-06-2023	1,178	_	_	_		
Ernst, Juergen	05-10-2016	10,000	3.48	05-09-2023	1,200	_	_	_		
	12-06-2016	7,850	3.45	12-06-2023	1,178	_	_	_		
Limoges, Gérard	05-10-2016	10,000	3.48	05-09-2023	1,200	_	_	_		
	12-06-2016	7,850	3.45	12-06-2023	1,178	_	_	_		
Newport, Ken	05-10-2016	20,000	3.48	05-09-2023	2,400	_	_	_		
	12-06-2016	7,850	3.45	12-06-2023	1,178	_	_	_		

<sup>(1)</sup> The number of securities underlying unexercised options represents all awards outstanding as at December 31, 2016.

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

<sup>(2) &</sup>quot;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 on the last trading day of the fiscal year (December 30, 2016) of \$3.60 and the exercise price of the options, multiplied by the number of unexercised options.

#### **Total Compensation of Outside Directors**

The table below summarizes the total compensation paid to our Outside Directors during the financial year ended December 31, 2016 (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 <sup>(1)</sup>	Non-Equity Incentive Plan Compensation	Pension Value	All Other Compensation	Total
	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)
Cardiff, Michael	32,337	_	78,000	_	_	_	110,337
Egbert, Carolyn	79,547	_	50,000	_	_	_	129,547
Ernst, Juergen	56,077	_	50,000	_	_	_	106,077
Lapalme, Pierre (2)	6,456	_	_	_	_	_	6,456
Limoges, Gérard	46,866	_	50,000	_	_	_	96,866
Newport, Kenneth	32,337		78,000	_	_	_	110,337

<sup>(1)</sup> 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 (\$3.48 and \$3.45) multiplied by the Black-Scholes factor as at such date (81%) and the number of stock options granted on such date.

During the financial year ended December 31, 2016, we paid an aggregate amount of \$253,620 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 option- based awards granted in 2016.

### **Compensation of Executive Officers**

The following is disclosure of information related to the compensation that we paid to our "Named Executive Officers" during 2016. For the 2016 year, our "Named Executive Officers" were as follows:

- Mr. David A. Dodd, who served as our Chief Executive Officer during all of 2016;
- Mr. Keith Santorelli, who served as our Vice President, Finance and Chief Accounting Officer and as our interim principal financial officer from January 1, 2016 up to and including February 18, 2016;
- Ms. Genevieve Lemaire, who served as our Vice President, Finance and Chief Accounting Officer and as our interim principal financial officer pursuant to a services contract and not as our employee, from February 18, 2016; and
- Messrs. Philip A. Theodore, our Senior Vice President, Chief Administrative Officer, General Counsel and Corporate Secretary, and Jude Dinges, our Senior Vice President and Chief Commercial Officer; and Dr. Richard Sachse, our Senior Vice President and Chief Scientific and Chief Medical Officer, who were our three most highly compensated executive officers (other than our Chief Executive Officer, our current and former Chief Accounting Officer and interim principal financial officer) during 2016.

### **Compensation Discussion & Analysis**

### Compensation Philosophy and Objectives

Our Board, through the NGCC, establishes our executive compensation program that is market-based and at a competitive percentile grouping for both total cash and total direct compensation. The NGCC 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 companies;
- providing the opportunity for executives to participate in equity-based incentive compensation plans;
- · aligning executive compensation with our corporate objectives; and
- attracting and retaining highly qualified individuals in key positions.

<sup>(2)</sup> Mr. Lapalme did not stand for election at our annual meeting of shareholders held on May 10, 2016.

#### **Compensation Elements**

Our executive compensation is targeted at the 50th percentile for small cap biopharmaceutical companies within both the local and national markets 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 NGCC (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 our executive officers regardless of share price. In determining individual base salaries, the NGCC 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 NGCC 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 NGCC 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 NGCC'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 was 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. The Board adopted a policy regarding stock option grants in December 2014 (the "2014 Stock Option Policy"), which provides that each Named Executive Officer is eligible to receive options to acquire our Common Shares having a value, based on the Black-Scholes option pricing model, equal to a specified multiple of his or her salary. The specified multiple for the President and Chief Executive Officer is 1.5. The specified multiple for each other Named Executive Officer is 0.75. 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 NGCC is authorized to engage its own independent consultant to advise it with respect to executive compensation matters. While the NGCC 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 NGCC 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 NGCC 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 NGCC 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 NGCC 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 President and Chief Executive Officer and our Senior Vice Presidents and their target bonuses have not been increased since 2013. Therefore, the NGCC did not repeat or update the benchmarking process in 2014, 2015 or 2016 because it concluded that doing so would not provide additional meaningful data, considering the expense of the process. However, the NGCC, as a matter of good governance, will review and assess the current compensation program and make appropriate adjustments, if any, during 2017.

#### Risk Assessment of Executive Compensation Program

The Board, through the NGCC, 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 NGCC 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 NGCC 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 NGCC 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 NGCC 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 NGCC 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 NGCC 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 NGCC believes that our executive compensation program does not encourage or reward any unnecessary or excessive risk-taking behaviour.

Our directors, executive officers and employees are prohibited from purchasing, selling or otherwise trading in derivative securities relating to our Common Shares. Derivative securities are securities whose value varies in relation to the price of our securities. Examples of derivative securities include warrants to purchase our Common Shares, and put or call options written on our Common Shares, as well as individually arranged derivative transactions, such as 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. Options to acquire Common Shares issued pursuant to our Stock Option Plan are not derivative securities for this purpose.

### 2016 Compensation

Base Salary. The base salaries of our President and Chief Executive Officer and our Senior Vice Presidents were not increased in 2016 because the NGCC determined that our financial position did not justify an increase in base salaries.

Short-Term, Non-Equity Incentive Compensation. The Board, based on the NGCC's recommendation, adopted the following performance objectives for 2016:

Objectives for 2016		Result					
Strengthen Financial Leadership	Hire new CFO	Offer extended to candidate who accepted. Fit later determined not to be correct and offer withdrawn with mutual agreement. Subsequently, conducted retained search. Hiring decision postponed until top-line results are reported for both Macrilen <sup>TM</sup> and Zoptrex <sup>TM</sup> .					
Financing	Secure minimum of \$15 Million Ensure minimum of two years of cash	\$15.5 million raised in December 2015 financing; additional approximately \$10 million raised in September and October 2016. Total capital raised: \$25.5 million.  Determined that raising two years of cash would result in excessive dilution on the eve of potential value-creation events.					
Commercial Revenues (EstroGel®, Saizen® & Apifiny®)	Achieve minimum of \$7.5 Million in annual revenues:  o EstroGel®: \$2.0 M  o Saizen®: \$2.5 M  o Apifiny®: \$2.0 M  o Product t/b/d: \$1.0 M	Revenues far below target.  EstroGel®: Owner of product lost Express Scripts access, the largest reimbursement coverage for the product in the US; despite AEZS performance increasing units versus declining market, immaterial commission was earned; we terminated the promotion on August 31, 2016.  Saizen®: Owner of product lost major managed care contracts, as well as regional contracts; changed strategy to focus only on self-pay & Medicaid; co-promotion agreement renegotiated in December 2016 to remove baseline and include adult endocrinologists.  Apifiny®: Anticipated major lab agreement (Quest and/or LabCorp) and CMS reimbursement, targeted for Spring 2016, did not occur. NY-state license remains outstanding.					
Zoptrex <sup>TM</sup>	Report top-line results within eight weeks of trial completion Complete sub-studies	Trial not concluded by year-end 2016. Sub-studies completed on schedule.					
Macrilen™	Complete confirmatory trial Report top-line results within eight weeks of completion	Trial was completed by year-end. Top-line results reported within target schedule in early 2017.					
Foreign Private Issuer Status Review and Recommendation	Complete review of FPI status and recommendations	Analytical method developed and reviewed with counsel; analysis conducted and FPI status maintained.					
Business Development	Complete in-license, acquisition or promotion agreement(s) with minimum annual revenue/commission opportunity of \$15 million during first 12-months	Obtained exclusive US rights to promote Apifiny®. Focus shifted to out-licensing products; AEZS capital structure not supportive of most targeted deals.					

The Chief Executive Officer recommended to the NGCC that we award cash bonuses to two of our Named Executive Officers with respect to 2016. The NGCC concurred with the Chief Executive Officer's recommendation as did the full Board. Mr. Philip A. Theodore, our Senior Vice President, Chief Administrative Officer, General Counsel and Corporate Secretary, was awarded a cash bonus with respect to 2016 in the amount of \$64,000, which represented approximately 50% 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 2016 in the amount of €50,000 (equivalent to \$55,500), which represented 50% of his target bonus. The bonuses were recommended by the Chief Executive Officer based on performance he deemed significant.

#### Long-Term Equity Compensation

The NGCC approved option awards to our Named Executive Officers on December 6, 2016 in accordance with the 2014 Stock Option Policy. Mr. Dodd was awarded 257,035 stock options (a multiple of 1.5 times his salary), Dr. Sachse was awarded 57,630 stock options (a multiple of 0.75 times his salary) and Messrs. Dinges and Theodore were each awarded 86,580 stock options (a multiple of 0.75 times their salaries). The stock options have an exercise price of \$3.45 and vest in three annual installments, commencing on December 6, 2017. Following the December 6, 2016 grants, the NGCC determined that granting stock options to Dr. Sachse based solely on a multiple of his salary was inequitable given his significant contributions to the Corporation and its subsidiaries during 2016. Therefore, the Board, based on the NGCC's recommendation, awarded 28,950 additional options to Dr. Sachse on December 16, 2016. Such options have an exercise price of \$3.80 and vest in three annual installments, commencing on December 16, 2017.

#### 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 NGCC.

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 15, 2017, represented approximately 1.5 million Common Shares. There were 968,264 options outstanding under the Stock Option Plan representing approximately 7.2% of all issued and outstanding Common Shares on March 15, 2017.

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 NGCC; 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 NGCC, 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 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 NGCC, as the case may be. 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.

Unless the Board or the NGCC 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. +-

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 more 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 tendary 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 only 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 that 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 that 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, or
- any cancellation of an option and the re-grant of that option under different terms, or
- 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, 2016. Ms. Lemaire serves as our Vice President, Finance and Chief Accounting Officer pursuant to a service contract and is not entitled to receive option-based or share-based awards.

				Share-based Awards															
Name	Issuance Date	Number of Securities Underlying Unexercised Options <sup>(1)</sup>		Securities Underlying Unexercised		Securities Underlying Unexercised		Securities Underlying Unexercised		Securities Underlying Unexercised		Securities Exerci Underlying Unexercised		Option Exercise Price	Option Expiration Date	Value of Unexercised In- the-money Options <sup>(2)</sup>	Issuance Date	Number of Shares or Units of shares that have Not Vested	Market or Payout Value of Share-based Awards that have Not Vested
	(mm-dd-yyyy)	(#)		(\$)	(mm-dd-yyyy)	(\$)		(#)	(\$)										
	04/15/2013	3,000	3)	198.00	04/14/2023	_	ı	_	_										
Dodd, David A.	12/04/2014	4,750		76.00	12/04/2021	_	_	_	_										
Dodd, David A.	12/21/2015	85,000		4.58	12/20/2022	_	_	_	_										
	12/06/2016	257,035		3.45	12/06/2023	38,555	_	_	_										
	12/21/2015	40,000		4.58	12/20/2022	_	_	_	_										
Sachse, Richard <sup>(4)</sup>	11/08/2016	2,800		3.50	11/08/2023	280	_	_	_										
Sacrise, Richard	12/06/2016	57,360		3.45	12/06/2023	8,644	_	_	_										
	12/16/2016	28,950		3.80	12/16/2023	_	_	_	_										
	11/27/2013	1,500	5)	112.00	11/26/2023	_	_	_	_										
Dinges, Jude	12/04/2014	1,660		76.00	12/04/2021	_	_	_	_										
Dinges, sude	12/21/2015	40,000		4.58	12/20/2022	_	_	_	_										
	12/06/2016	86,580		3.45	12/06/2023	12,987	_	_	_										
	10/06/2014	1,500	6)	134.00	10/05/2021	_	_	_	_										
Theodore, Philip	12/04/2014	500		76.00	12/04/2021	_	_	_	_										
i neodore, i miip	12/21/2015	40,000		4.58	12/20/2022	_	_	_	_										
	12/06/2016	86,850		3.45	12/06/2023	12,987	_	_	_										

- (1) The number of securities underlying unexercised options represents all awards outstanding at December 31, 2016.
- (2) "Value of unexercised in-the-money options" at financial year-end is calculated based on the difference between the closing price of the Common Shares on the NASDAQ on the last trading day of the year (December 30, 2016) of \$3.60 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) Dr. Sachse voluntarily surrendered 2,800 unvested options, having a weighted average exercise price of \$104.39, during financial year 2016.
- (5) 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.
- (6) 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 were no share-based awards outstanding at December 31, 2016.

See "Summary of the Stock Option Plan" for more details on the Stock Option Plan.

### 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, 2016. Ms. Lemaire serves as our Vice President, Finance and Chief Accounting Officer pursuant to a services contract and is not entitled to receive incentive plan awards.

Name	Option-based awards — Value vested during the year <sup>(1)</sup>	Share-based awards — Value vested during the year	Non-equity incentive plan compensation — Value earned during the year
	(\$)	(\$)	(\$)
Dodd, David A.	_	_	_
Santorelli, Keith	_	_	_
Sachse, Richard	_	_	55,500
Dinges, Jude	_	_	_
Theodore, Philip A.	_	_	64,000

<sup>(1)</sup> 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, 2016, 2015 and 2014. 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 Ms. Lemaire's cash payments were made in Canadian dollars and Dr. Sachse's cash payments were made in euros.

							ncentive plan					
Name and principal position	Years	Salary		Share based awards	Option based awards (1)	Annual incentive plan	Long-term incentive plans	Pension Value		All other compensation (2)		Total compensation
		(\$)		(\$)	(\$)	(\$)	(\$)	(\$)		(\$)		(\$)
Dodd, David A.	2016	475,000		_	712,500	_	_	_		_		1,187,500
President and Chief Executive Officer	2015	475,000		_	358,690	_	_	_		_		833,690
Executive Officer	2014	475,000		_	291,914	100,000	_	_		_		866,914
Santorelli, Keith	2016	32,954	(3)	_	_	_	_	_		340,600	(4)	373,554
Interim Principal Financial	2015	244,800		_	_	_	_	_		-		244,800
Officer	2014	240,000		_	82,554	_	_	_		-		322,554
Lemaire, Genevieve	2016	_		_	_	_	_	_		210,156	(5)	210,156
Vice President, Finance and Chief Accounting	2015	_		_	_	_	_	_		_		_
Officer	2014	_		_	_	_	_	_		_		_
Sachse, Richard	2016	222,000		_	257,000	55,500	_	37,067	(6)	_		571,567
Senior Vice President, Chief Scientific Officer	2015	221,900		_	168,795	111,000	_	47,349	(6)	_		549,044
and Chief Medical Officer	2014	265,752		_	235,017	62,463	_	27,239	(6)	-		590,471
Dinges, Jude	2016	320,000		_	240,000	_	_	_		-		560,000
Senior Vice President and	2015	320,000		_	168,795	_	_	_		_		488,795
Chief Commercial Officer	2014	320,000		_	102,016	25,000	_	_		_		447,016
Theodore, Philip A. Senior Vice President,	2016	320,000		_	240,000	64,000				_		624,000
Chief Administrative Officer and General	2015	320,000		_	168,795	35,000				_		523,795
Counsel	2014	67,692	(7)		189,433	_	_			-		257,125

(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 multiplied by the Black-Scholes factor as at such date and the number of stock options granted on such date. The following table sets forth the value of the option-based awards and the corresponding Black-Scholes factor:

Date of Grant	Value of Grant	Black-Scholes Factor
January 16, 2014	\$129.00	80.17%
May 9, 2014	\$107.00	79.90%
October 6, 2014	\$134.00	78.96%
December 4, 2014	\$76.00	80.86%
December 21, 2015	\$4.58	92.14%
November 9, 2016	\$3.50	80.35%
December 6, 2016	\$3.45	80.57%
December 16, 2016	\$3.80	80.68%

- (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, 2016. 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) 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. His employment with us terminated on February 18, 2016 after he fulfilled his obligations to us pursuant to the transition agreement. The indicated salary amount represents salary earned and paid to Mr. Santorelli up until the date of his departure.
- (4) Represents severance payment, perquisites and other personal benefits paid to Mr. Santorelli in 2016, of which \$336,600 was paid in February 2016 as a termination payment.
- (5) Ms. Lemaire became our Vice President, Finance and Chief Accounting Officer on February 18, 2016 upon the departure of Mr. Santorelli. She provides services to us as a contractor and not as an employee. She is compensated for her services at the rate of CDN\$170 per hour. She is not entitled to participate in or to receive benefits pursuant to any of our programs customarily made available to our employees. The amount shown represents all payments to her pursuant to her agreement with us.
- (6) 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, 2016, as well as changes in the foreign exchange rate, his contributions being made in euros.

Accumulated value at start of year	Compensatory	Accumulated value at year end		
\$73,529	\$37,067	\$106,391		

(7) 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 President and Chief Executive Officer is governed by our executive compensation policy described in the section titled "Compensation of Executive Officers", and the President and Chief Executive Officer participates, together with the other Named Executive Officers, in all of our incentive plans.

Mr. Dodd's total earned salary during the financial year ended December 31, 2016 was \$475,000. Mr. Dodd was not awarded an annual incentive bonus with respect to 2016.

For the financial year ended December 31, 2016, the NGCC recommended that 257,035 stock options be granted to Mr. Dodd under our Stock Option Plan. The grant to Mr. Dodd is included in the Summary Compensation Table above under the column captioned "Option-Based Awards". See Section 6.3.6 of this Circular, "Long-Term Equity Compensation – Summary of the Stock Option Plan", for a complete description of the Stock Option Plan.

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

#### Pension, retirement or similar benefits

As at December 31, 2016, the Company and its subsidiaries had accrued pension, retirement or similar benefits obligations amounting to \$13.4 million. See note 17 - Employee future benefits, to the audited consolidated financial statements included in Item 18 of this Annual Report on Form 20-F.

#### 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 NGCC.

### **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 to this Annual Report on Form 20-F), 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 Gérard Limoges (Chair), Michael Cardiff and Ken Newport.

#### **NGCC**

The NGCC 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 board member nominees and directors' compensation, as well as serving in a leadership role for our corporate governance practices. It is also responsible for taking all reasonable actions to ensure that appropriate human resources policies, procedures and systems, e.g., recruitment and retention policies, competency and performance metrics and measurements, training and development programs, and market-based, competitive compensation and benefits structures, are in place so that we can attract, motivate and retain the quality of personnel required to achieve our business objectives. The NGCC also assists the Board in discharging its responsibilities relating to the recruitment, retention, development, assessment, compensation and succession planning for our executive and senior management members.

Thus, the NGCC 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 NGCC, reviews the Chief Executive Officer's corporate strategy, goals and performance objectives and evaluates and measures his or her performance and compensation against the achievement of such goals and objectives.

The NGCC 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 NGCC is of the view that our executive compensation program should not encourage senior executives to take inappropriate or unreasonable risk. In this regard, the NGCC recommends the implementation of compensation methods that appropriately connect a portion of senior executive compensation with 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 NGCC is also responsible for establishing 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), Juergen Ernst, Michael Cardiff and Ken Newport.

## D. Employees

As at December 31, 2016, we had a total of 47 active employees, of which 37 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) 10 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, noncompetition and assignment of all intellectual property rights developed during the employment period.

## E. Share ownership

The table below sets forth information as of March 15, 2017 provided to us by our directors and executive officers concerning their ownership of Common Shares and stock options of the Company:

Name	No. of Common Shares owned or held	Percent <sup>(1)</sup>	No. of stock options held <sup>(2)</sup>	No. of currently exercisable options
Cardiff, Michael	_	_	27,850	_
Dinges, Jude	6,533	*	129,740	15,941
Dodd, David A.	34,003	*	349,785	34,501
Egbert, Carolyn	1,920	*	17,850	_
Ernst, Juergen	1,348	*	17,850	_
Guenther, Eckhard	_	_	15,398	1,667
Lemaire, Geneviève	2,350	*	_	_
Limoges, Gérard	1,200	*	17,850	_
Newport, Kenneth	_	_	27,850	_
Sachse, Richard	_	_	129,380	13,334
Teifel, Michael	_	_	30,350	3,334
Theodore, Philip A.	10,894	*	128,580	14,668
Total	58,248	*	892,483	83,445

Less than 1%

See "Summary of the Stock Option Plan" for more details on the Stock Option Plan.

#### 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 15, 2017, no individual or entity beneficially owned, directly or indirectly, or exercised control or direction over our Common Shares carrying more than 5% of the voting rights attached to all our Common Shares.

## **United States Shareholders**

As at February 28, 2017, there were 11 holders of record of our Common Shares, of which two were registered with an address in the United States holding in the aggregate approximately 99.77% 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".

<sup>(1)</sup> Based on 12,917,995 Common Shares outstanding as at December 31, 2016.

<sup>(2)</sup> 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".

## B. Related party transactions

As at December 31, 2016, all related party transactions were eliminated upon consolidation.

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

	NASDA	NASDAQ (US\$)		CAN\$)
	High	Low	High	Low
2016	4.94	2.67	6.62	3.85
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
2017				
First quarter <sup>1</sup>	3.65	2.45	4.81	3.24
2016				
Fourth quarter	4.94	3.25	6.62	4.40
Third quarter	3.73	3.30	4.83	4.26
Second quarter	4.38	3.01	5.69	3.90
First quarter	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
Most recent 6 months				
February 2017	3.35	2.80	4.43	3.62
January 2017	3.65	2.45	4.81	3.24
December 2016	4.10	3.40	5.52	4.45
November 2016	4.00	3.25	5.30	4.40
October 2016	4.94	3.34	6.62	4.46
September 2016	3.73	3.35	4.82	4.39

<sup>(1)</sup> Up to and including March 14, 2017.

#### B. Plan of distribution

Not applicable.

C. Markets

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

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, as amended and restated on March 21, 2013 (the "bylaws"). Our Articles are on file with Corporations 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 our 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, we are required by the CBCA 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 the NGCC, such committee, comprised of at least 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 as a director, officer, employee or agent of an affiliate of us;
- 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 NGCC.

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.

We have also agreed to indemnify and save harmless our directors and senior corporate officers as well as the managing directors of our German subsidiary pursuant to various Director and Officer Indemnification Agreements against certain charges, damages, awards, settlements, liabilities, interest, judgments, fines, penalties, statutory obligations, professional fees and retainers and other expenses of whatever nature or kind, provided that any such costs, charges, professional fees and other expenses are reasonable (collectively, "Expenses") and from and against all Expenses sustained or incurred by the indemnified party as a result of serving as a director, officer or employee of the Company (or its subsidiary) in respect of any act, matter, deed or thing whatsoever made, done, committed, permitted, omitted or acquiesced in by the indemnified party as a director, officer or employee of the Company (or its subsidiary). The form of Director and Officer Indemnification Agreement has been furnished to the SEC as Exhibit 99.1 to our Report on Form 6-K dated October 21, 2016.

#### **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 15, 2017, there were approximately 13.5 million 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 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"). Our shareholders approved, ratified and confirmed the Rights Plan at our Annual Meeting of Shareholders on May 10, 2016.

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 incorporated by reference as Exhibit 2.1 to this Annual Report on Form 20-F.

For the purposes of this summary and as set out in the Rights Plan, the term "NI 62-104" refers to National Instrument 62-104-*Take-Over Bids and Issuer Bids* adopted by 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.

#### Operation of the Rights Plan

Pursuant to the terms of the Rights Plan, one right was issued in respect of each common share outstanding at 5:01 p.m. on March 29, 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 NI 62-104)) must remain open for deposits of securities thereunder, in the applicable circumstances at such time, pursuant to NI 62-104;
  - 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 NI 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 ceased to be 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.

Our bylaws include an advance notice provision (the "Advance Notice Requirement"). 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 10<sup>th</sup> 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 15<sup>th</sup> 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 Articles 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 US 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<sup>TM</sup> 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<sup>TM</sup> in the Territory. Sinopharm will be responsible for the development, production, registration and commercialization of Zoptrex<sup>TM</sup> in the Territory.

Sinopharm is required to use commercially reasonable efforts to develop, manufacture and commercialize Zoptrex<sup>TM</sup> in the Territory, in order to maximize the net sales derived from Zoptrex<sup>TM</sup> during the royalty term of the License Agreement. In particular, Sinopharm is required to use commercially reasonable efforts to: (i) develop Zoptrex<sup>TM</sup> 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<sup>TM</sup> in the Territory within a specified period of time following the approval of Zoptrex<sup>TM</sup> 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<sup>TM</sup> in the Territory; and (v) seek to maximize sales of Zoptrex<sup>TM</sup> in the Territory. Sinopharm's failure to use commercially reasonable efforts to develop, manufacture and commercialize Zoptrex<sup>TM</sup> would be a material breach of the License Agreement.

The License Agreement imposes on Sinopharm the responsibility for marketing, promoting and selling Zoptrex<sup>TM</sup> 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<sup>TM</sup>, importing, exporting or transporting Zoptrex<sup>TM</sup> for commercial sale, conducting medical education activities, conducting clinical studies that are not required to obtain or maintain regulatory approval of Zoptrex<sup>TM</sup> 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 4.13, 4.14 and 4.15 to this Annual Report on Form 20-F.

#### **Employment and Service Agreements**

We have, or one of our subsidiaries has, entered into an employment agreement and, in some cases, a change of control agreement (collectively, the "Employment Agreements") with each of our Named Executive Officers except for Ms. Genevieve Lemaire, who provides services to us as a contractor and not as an employee and 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 financial results and position justify payment of a bonus and subject to the determination and approval of the NGCC 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 and Dinges 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 certain severance payments. Mr. Dodd is entitled to receive 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")). Mr. Dinges 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, prorated 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 and Dinges, 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.

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, each of 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 that 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 agreements apply 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 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 new employment, and (ii) the date on which the non-competition provision expires.

The table below shows estimated incremental payments triggered pursuant to termination of employment of our Named Executive Officers who remained employed on December 31, 2016 in accordance with the termination provisions described above. The amounts shown for Messrs. Dodd and Dinges would be paid to them in US dollars. The amount shown for Dr. Sachse would be paid to him in euros.

Name	Termination Provisions Value (\$) <sup>(1)</sup> (2) 1.662.009		
Dodd, David	1,662,009		
Sachse, Richard	111,000		
Dinges, Jude	505,230		

- (1) The termination values assume that the triggering event took place on the last business day of our financial year-end (December 31, 2016).
- 2) Value of earned/unused vacation and amounts owing for expense reimbursement are not included as they are not considered as "incremental" payments made in connection with termination of employment.

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. If a Change of Control had occurred on December 31, 2016, Mr. Dodd would have been entitled to receive incremental payments in the amount of approximately \$2,078,839. Such amount does not include the value of earned and unused vacation and amounts owing for expense reimbursement because such amounts are not considered as "incremental" payments made in connection with termination of employment.

For the purposes of the Employment Agreements (including the annexes and schedules thereto) of Messrs. Dodd and Dinges:

- 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 wilful negligence in the performance of his duties; and
- termination of employment by the executive officer for "Good Reason" means,
  - o 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
  - o 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.

We entered into an Amended and Restated Consulting Agreement with Ms. Genevieve Lemaire effective as of February 18, 2016. The Consulting Agreement indicates that Ms. Genevieve Lemaire will fulfill all responsibilities of the position of Vice President Finance and Chief Accounting Officer. The Company agrees to pay the Consultant for her services performed under this Agreement at an hourly rate of CDN\$170. This Agreement shall terminate 120 days after the date of hire of a Chief Financial Officer (unless both parties agree on a different period before this Agreement expires). At the conclusion of the Agreement, the consultant will be paid a bonus in the amount of CDN\$20,000.

#### 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 applicable to a holder of Common Shares 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 (a "holder"). 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, (v) that has entered or will enter into a "derivative forward agreement", as defined in the Tax Act, in respect of Common Shares, or (vi) that receives dividends on Common Shares under or as part of a dividend rental arrangement as defined in the Tax Act. 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 exchange rates determined in accordance with the Tax Act. 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 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. In certain circumstances, subsection 55(2) of the Tax Act may treat a taxable dividend received by a Canadian holder that is a corporation as proceeds of disposition or a capital gain. 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. 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 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 but not for the 2016 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 2017 or 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 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 not a PFIC for the 2016 taxable year. However, no assurance can be provided that the Company will not be classified as a PFIC for 2017 and, therefore, no assurance can be provided that a US Holder will be able to claim a reduced rate for dividends paid in 2017 or 2018 (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 9, 2017 to be furnished to the SEC on Form 6-K, which provides information including directors' and officers' remuneration and indebtedness and principal holders of securities. Additional financial information is provided in our audited annual financial statements for the year ended December 31, 2016 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".

#### 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 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 the loans and receivables in the table above. 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 rating of at least "P-2" 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, 2016, trade accounts receivable for an amount of approximately \$155,000 were with three counterparties, and no trade accounts receivable were past due and none were 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 of 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 in the Company's consolidated 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 occurring outside 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 the absence of sufficient corresponding revenues. The Company's ability to continue future operations until and beyond December 31, 2017 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, which could include using any then available "at-the-market" equity issuance program 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. See note 1 - Summary of business, going concern, reporting entity and basis of preparation of the Company's consolidated financial statements included in Item 18 of this Annual Report on Form 20-F for further details.

#### (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 option pricing models, of currently outstanding share purchase warrants. 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 in the consolidated statements of comprehensive loss, has been and may continue in future periods to be materially affected most notably by changes in the Company's common share closing price, which on the NASDAQ, has ranged from \$2.67 to \$4.94 during the year ended December 31, 2016.

If variations in the market price of our common shares of -30% and +30% were to occur, the impact on the Company's net loss related to the warrant liability held at December 31, 2016 would be as follows:

(in thousands)	Carrying amount	-30%	+30%
	\$	\$	\$
Warrant liability	6,854	2,656	(2,448)
Total impact on net loss – decrease / (increase)		2,656	(2,448)

#### 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.

Not applicab	le.
	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
evaluated the	pervision and with the participation of our management, including the Chief Executive Officer and the acting principal financial officer, we have effectiveness of our disclosure controls and procedures as at December 31, 2016. Based on that evaluation, the Chief Executive Officer and pal financial officer have concluded that these disclosure controls and procedures were effective as at December 31, 2016.
Managemen	t's Annual Report on Internal Control over Financial Reporting
reporting is a	ment is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for boses in accordance with IFRS as issued by the IASB.

Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of Aeterna Zentaris; (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 Company are being made only in accordance with authorizations of Company management; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized

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

Management conducted an evaluation of the effectiveness of our 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

acquisition, use or disposition of Company assets that could have a material effect on the financial statements.

has concluded that our internal control over financial reporting was effective as at December 31, 2016.

Item 12.

Not applicable.

Not applicable.

Not applicable.

*C*.

D.

**Debt securities** 

Warrants and rights

Other securities

American depositary shares

with the policies or procedures may deteriorate.

**Description of Securities Other than Equity Securities** 

#### **Changes in Internal Controls over Financial Reporting**

There have been no changes in our internal control over financial reporting during the year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

#### Item 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 16A, 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 Messrs. Michael Cardiff and Ken Newport, 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 was 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 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 incorporated by reference 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-Corporate 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 incorporated by reference 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 29486.

# Item 16C. Principal Accountant Fees and Services

(All amounts are in US dollars)

## (a) Audit Fees

During the financial years ended December 31, 2016 and 2015, the Company's principal accountant, PricewaterhouseCoopers LLP, billed \$363,962 and \$473,515, respectively, for the audit of the Company's annual consolidated financial statements and for services rendered in connection with statutory and regulatory filings.

## (b) Audit-related Fees

During the financial years ended December 31, 2016 and 2015, the Company's principal accountant, PricewaterhouseCoopers LLP, billed \$164,477 and \$57,524, 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, 2016 and 2015, the Company's principal accountant, PricewaterhouseCoopers LLP, billed \$17,153 and \$24,269, respectively, for services related to tax compliance, tax planning and tax advice.

#### (d) All Other Fees

During the financial years ended December 31, 2016 and 2015, the Company'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, we are required to disclose whether our Audit Committee has adopted specific policies and procedures for the engagement of non-audit services and to prepare a summary of these policies and procedures. The Audit Committee Charter (incorporated by reference as Exhibit 11.3 to this Annual Report on Form 20-F) provides that it is such committee's responsibility to approve all audit engagement fees and terms as well as reviewing policies for the provision of non-audit services by the external auditors and, when required, the framework for pre-approval of such services. The Audit Committee delegates to its Chairman the pre-approval of such non-audit fees. The pre-approval by the Chairman is then presented to the Audit Committee at its first scheduled meeting following such pre-approval.

For each of the years ended December 31, 2016 and 2015, there were no non-audit services provided by our 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 December 31, 2016, no person other than the full-time, permanent employees of our principal accountant, PricewaterhouseCoopers LLP, performed more than 50% of the audit work on our financial statements.

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

None.

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

None.

Item 16F. 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 96 to 141.

Consolidated Financial Statements As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014 (presented in thousands of US dollars)

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

# To the Shareholders of Aeterna Zentaris Inc.

We have audited the accompanying consolidated financial statements of Aeterna Zentaris Inc. and its subsidiaries, which comprise the consolidated statements of financial position as at December 31, 2016 and December 31, 2015 and the consolidated statements of changes in shareholders' equity, comprehensive loss and cash flows for each of the three years in the period ended December 31, 2016, and the related notes, which comprise a summary of significant accounting policies and other explanatory information.

#### Management's responsibility for the consolidated financial statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with Canadian generally accepted auditing standards and the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement. Canadian generally accepted auditing standards also require that we comply with ethical requirements.

An audit involves performing procedures to obtain audit evidence, on a test basis, about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. We were not engaged to perform an audit of the company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting principles and policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained in our audits is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Aeterna Zentaris Inc. and its subsidiaries as at December 31, 2016 and December 31, 2015 and their financial performance and their cash flows for each of the three years in the period ended December 31, 2016 in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

## **Emphasis of matter**

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in note 1 to the consolidated financial statements, Aeterna Zentaris Inc. and its subsidiaries have suffered recurring losses from operations and has cash outflows from operating activities that raise substantial doubt about their ability to continue as a going concern. Management's plans in regard to these matters are also described in note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Pricewaterhouse Coopers LLP

Quebec, Quebec, Canada March 15, 2017

<sup>1</sup> CPA auditor, CA, public accountancy permit No. A121191

# Consolidated Statements of Financial Position

(in thousands of US dollars)

	<b>December 31, 2016</b>	<b>December 31, 2015</b>	
	<u> </u>	\$	
ASSETS			
Current Assets			
Cash and cash equivalents (note 6)	21,999	41,450	
Trade and other receivables (note 7)	365	598	
Prepaid expenses and other current assets	379	346	
	22,743	42,394	
Restricted cash equivalents	496	255	
Property, plant and equipment (note 8)	204	256	
Identifiable intangible assets (note 9)	70	237	
Other non-current assets	593	520	
Goodwill (note 10)	7,553	7,836	
	31,659	51,498	
LIABILITIES			
Current liabilities			
Payables and accrued liabilities (note 11)	3,745	4,172	
Provision for restructuring costs (note 12)	33	598	
Current portion of deferred revenues (note 5)	426	244	
Current portion of warrant liability (note 13)	<del>-</del>	1,411	
	4,204	6,425	
Deferred revenues (note 5)	474	487	
Warrant liability (note 13)	6,854	9,480	
Employee future benefits (note 17)	13,414	12,656	
Provisions and non-current liabilities (note 14)	501	835	
	25,447	29,883	
SHAREHOLDERS' EQUITY			
Share capital (note 15)	213,980	204,596	
Other capital	88,590	87,508	
Deficit	(298,059)	(271,621)	
Accumulated other comprehensive income	1,701	1,132	
	6,212	21,615	
	31,659	51,498	

Going concern (note 1)

Commitments and contingencies (note 24) Subsequent events (note 25)

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

# Approved by the Board of Directors

/s/ Carolyn Egbert	/s/ Gérard Limoges
Carolyn Egbert	Gérard Limoges
Chair of the Board	Director

Consolidated Statements of Changes in Shareholders' Equity For the years ended December 31, 2016, 2015 and 2014

(in thousands of US dollars, except share data)

	Common shares (number of) 1, 2	Share capital	Pre-funded warrants	Other capital	Accumulated other Deficit comprehensive loss		Total	
		\$	\$	\$	\$	\$	\$	
Balance - January 1, 2016	9,928,697	204,596	_	87,508	(271,621)	1,132	21,615	
Net loss					(24,959)	_	(24,959)	
Other comprehensive income (loss):								
Foreign currency translation adjustments	_	_	_	_	_	569	569	
Actuarial loss on defined benefit plan (note 17)	_	_	_	_	(1,479)	_	(1,479)	
Comprehensive loss					(26,438)	569	(25,869)	
Share issuances in connection with a public offering (note 15)	1,150,000	3,377					3,377	
Pre-funded warrant issuances in connection with a public offering (note 15)	_	_	2,789	_	_	_	2,789	
Share issuances pursuant to the exercise of pre-funded warrants (note 15)	950,000	2,789	(2,789)	_	_	_	_	
Share issuances in connection with "At-the- Market" drawdowns (note 15)	889,298	3,218	_	_	_	_	3,218	
Share-based compensation costs	_	_	_	1,082	_	_	1,082	
Balance - December 31, 2016	12,917,995	213,980	_	88,590	(298,059)	1,701	6,212	

<sup>&</sup>lt;sup>1</sup> Issued and paid in full.

Adjusted to reflect the November 17, 2015 100-to-1 Share Consolidation (see note 1 - Summary of business, liquidity risk, reporting entity, share consolidation and basis of preparation; and note 15 - Share capital).

Consolidated Statements of Changes in Shareholders' Equity For the years ended December 31, 2016, 2015 and 2014

(in thousands of US dollars, except share data)

	Common shares (number of) 1, 2	Share capital	Pre-funded warrants	Other capital	Deficit	Accumulated other comprehensive income (loss)	Total
		\$	\$	\$	\$	\$	\$
Balance - January 1, 2015	655,091	150,544	_	86,639	(222,322)	(377)	14,484
Net loss	_		_		(50,143)	_	(50,143)
Other comprehensive income:							
Foreign currency translation adjustments	_	_	_	_	_	1,509	1,509
Actuarial gain on defined benefit plan (note 17)	_	_	_	_	844	_	844
Comprehensive loss	_	_		_	(49,299)	1,509	(47,790)
Share issuances in connection with public offerings (note 15)	3,250,481	14,322		_	_	_	14,322
Pre-funded warrant issuances in connection with a public offering (note 15)	_	_	8,653	_	_	_	8,653
Share issuances pursuant to the exercise of pre-funded warrants (note 15)	346,294	8,653	(8,653)	_	_	_	_
Share issuances pursuant to the exercise of warrants (other than pre-funded warrants) (notes 13 and 15)	5,676,831	31,077	_	_	_	_	31,077
Share-based compensation costs		_	_	869	_	_	869
Balance - December 31, 2015	9,928,697	204,596		87,508	(271,621)	1,132	21,615
=		mon shares nber of) <sup>1, 2</sup>	Share capital	Other capital	Deficit	Accumulated other comprehensive income (loss)	Total
			\$	\$	\$	\$	\$
Balance - January 1, 2014		453,120	134,101	86,107	(203,925)	781	17,064
Net loss		_	_	_	(16,564)	_	(16,564)
Other comprehensive loss:							
Foreign currency translation adjustments		_	_	_	_	(1,158)	(1,158)
Actuarial loss on defined benefit plans (note	17)	_	_	_	(1,833)	_	(1,833)
Comprehensive loss		_		_	(18,397)	(1,158)	(19,555)
Share issuances in connection with a public offer 15)	ring (note	110,000	4,340	_		_	4,340
Share issuances in connection with "At-the-Mar drawdowns (note 15)	ket"	91,971	12,103	_	_	_	12,103
Share-based compensation costs		_	_	532	_	_	532
Balance - December 31, 2014		655,091	150,544	86,639	(222,322)	(377)	14,484

Issued and paid in full.

Adjusted to reflect the November 17, 2015 100-to-1 Share Consolidation (see note 1 - Summary of business, going concern, reporting entity and basis of preparation and note 15 - Share capital).

Consolidated Statements of Comprehensive Loss

For the years ended December 31, 2016, 2015 and 2014

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

		ar ended December 31		
_	2016	2015	2014	
	\$	\$	\$	
Revenues	44.4	207		
Sales commission and other	414	297	_	
License fees (note 5)	497	248	11	
Operating expenses (note 16)	911	545	11	
	17.405	17.224	22.716	
Research and development costs	16,495	17,234	23,716	
General and administrative expenses	7,147	11,308	9,840	
Selling expenses	6,745	6,887	3,850	
<u> </u>	30,387	35,429	37,406	
Loss from operations	(29,476)	(34,884)	(37,395)	
(Loss) gain due to changes in foreign currency exchange rates	(70)	(1,767)	1,879	
Change in fair value of warrant liability (note 13)	4,437	(10,956)	18,272	
Warrant exercise inducement fee (note 13)	_	(2,926)	_	
Other finance income	150	305	168	
Net finance (costs) income	4,517	(15,344)	20,319	
Loss before income taxes	(24,959)	(50,228)	(17,076)	
Income tax expense (note 19)	<u> </u>		(111)	
Net loss from continuing operations	(24,959)	(50,228)	(17,187)	
Net income from discontinued operations	_	85	623	
Net loss	(24,959)	(50,143)	(16,564)	
Other comprehensive loss:				
Items that may be reclassified subsequently to profit or loss:				
Foreign currency translation adjustments	569	1,509	(1,158)	
Items that will not be reclassified to profit or loss:				
Actuarial (loss) gain on defined benefit plans (note 17)	(1,479)	844	(1,833)	
Comprehensive loss	(25,869)	(47,790)	(19,555)	
Net loss per share (basic and diluted) from continuing operations (note 23) <sup>1</sup>	(2.41)	(18.17)	(29.12)	
Net income per share (basic and diluted) from discontinued operations (note 23) <sup>1</sup>	_	0.03	1.06	
Net loss per share (basic and diluted) (note 23) <sup>1</sup>	(2.41)	(18.14)	(28.06)	
Weighted average number of shares outstanding (notes 15 and 23):1				
Basic	10,348,879	2,763,603	590,247	
Diluted	10,665,149	3,424,336	590,247	

Adjusted to reflect the November 17, 2015 100-to-1 Share Consolidation (see note 1 - Summary of business, liquidity risk, reporting entity, share consolidation and basis of preparation; and note 15 - Share capital).

Consolidated Statements of Cash Flows

For the years ended December 31, 2016, 2015 and 2014

(in thousands of US dollars)

	Year ended December 31			
	2016	2015	2014	
_	\$	\$	\$	
Cash flows from operating activities				
Net loss from continuing operations	(24,959)	(50,228)	(17,187)	
Items not affecting cash and cash equivalents:				
Change in fair value of warrant liability (note 13)	(4,437)	10,956	(18,272)	
Provision for restructuring costs (note 12)	(8)	932	2,489	
Depreciation, amortization and impairment (notes 8 and 9)	280	341	878	
Share-based compensation costs (note 15)	1,082	919	497	
Employee future benefits (note 17)	382	351	605	
Amortization of deferred revenues (note 5)	(345)	(248)	_	
Foreign exchange loss (gain) on items denominated in foreign currencies	87	1,581	(1,164)	
Gain on disposal of property, plant and equipment	(1)	(264)	(66)	
Amortization of prepaid expenses and other non-cash items	(83)	154	2,640	
Gain associated with the extinguishment of warrant liability (note 15)	_	(162)	_	
Transaction cost allocated to warrants issued (note 15)	56	2,208	666	
Series B Warrant exercise inducement fee (note 13)	_	2,926	_	
Changes in operating assets and liabilities (note 18)	(1,064)	(3,395)	(1,873)	
Net cash provided by (used in) operating activities of discontinued operations		85	(295)	
Net cash used in operating activities	(29,010)	(33,844)	(31,082)	
Cash flows from financing activities				
Proceeds from issuances of common shares, warrants, (including pre-funded warrants), net of cash transaction costs of \$1,107 in 2016, \$4,223 in 2015 and \$1,348 in 2014 (note 15)	9,924	49,427	24.358	
Series B Warrant exercise inducement fee (note 13)	_	(2,926)		
Payment pursuant to warrant amendment agreements (note 15)	_	(5,703)	_	
Net cash provided by financing activities	9,924	40,798	24,358	
Cash flows from investing activities	,	<u> </u>	,	
Purchase of property, plant and equipment (note 8)	(66)	(26)	(127)	
Disposals of property, plant and equipment (note 8)	2	505	66	
(Increase) decrease in restricted cash equivalents	(250)	434	_	
Net cash (used in) provided by investing activities	(314)	913	(61)	
Effect of exchange rate changes on cash and cash equivalents	(51)	(1,348)	(1,486)	
Net change in cash and cash equivalents	(19,451)	6,519	(8,271)	
Cash and cash equivalents – Beginning of the year	41,450	34,931	43,202	
Cash and cash equivalents – End of the year	21,999	41,450	34,931	
Cash and cash equivalents - End of the year		11,100	3 1,531	

Notes to Consolidated Financial Statements

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

#### 1 Summary of business, going concern, reporting entity and basis of preparation

#### Summary of Business

Aeterna Zentaris Inc. ("Aeterna Zentaris" or the "Company") is a specialty biopharmaceutical company engaged in developing and commercializing novel treatments in oncology, endocrinology and women's health.

## Going Concern

These consolidated financial statements have been prepared on a going concern basis, which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business. Since the Company's inception, the Company's operations have been financed through the sale of shares and warrants, revenue from license agreements and commissions, interest income on funds available for investment, government grants and tax credits and other non-dilutive financing sources. For the twelve months ended December 31, 2016, the Company did not generate any meaningful revenues from operations, and the Company has incurred significant operating losses and negative cash flows from operations since inception and has an accumulated deficit of \$298,059,000 as at December 31, 2016.

The ability of the Company to continue operating as a going concern is dependent upon raising additional financing through equity and non-dilutive sources of funding, including partnerships and licensing arrangements. There can be no assurance that the Company will have sufficient capital to fund its ongoing operations, or to develop or commercialize any products without future financings. The foregoing factors indicate the existence of a material uncertainty that may cast substantial doubt as to the Company's continued ability to meet its obligations as they come due and, accordingly, the appropriateness of the use of accounting principles applicable to a going concern. The Company is currently pursuing financing alternatives that may include equity, debt, and non-dilutive financing alternatives, including co-development through potential collaborations, strategic partnerships or other transactions with third parties. There can be no assurance that additional financing will be available on acceptable terms or at all. If the Company is unable to obtain additional financing when required, the Company may have to substantially reduce or eliminate planned expenditures or the Company may be unable to continue operations. The Company's ultimate success, its ability to raise additional financing, whether through equity, debt or other sources of funding and, consequently, to continue as a going concern, is also dependent upon at least one of the two internally developed compounds obtaining positive results in their Phase 3 studies.

These consolidated financial statements do not reflect the adjustments to the carrying values of assets and liabilities and the reported expenses and statement of financial position classifications that would be necessary if the Company were unable to realize its assets and discharge its liabilities as a going concern in the normal course of operations. Such adjustments could be material.

#### Reporting entity

The accompanying consolidated financial statements include the accounts of Aeterna Zentaris Inc., an entity incorporated under the *Canada Business Corporations Act*, and its wholly owned subsidiaries (collectively referred to as the "Group"). Aeterna Zentaris Inc. is the ultimate parent company of the Group.

The Company currently has three wholly owned direct and indirect subsidiaries, Aeterna Zentaris GmbH ("AEZS Germany"), based in Frankfurt, Germany, Zentaris IVF GmbH, a wholly owned subsidiary of AEZS Germany, based in Frankfurt, Germany, and Aeterna Zentaris, Inc., an entity incorporated in the state of Delaware and with offices in Summerville, South Carolina, in the United States.

The registered office of the Company is located at 1 Place Ville Marie, Suite 2500, Montreal, Quebec H3B 1R1, Canada.

The Company's common shares are listed on both the Toronto Stock Exchange (the "TSX") and on the NASDAQ Capital Market (the "NASDAQ").

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#### Basis of presentation

#### (a) Statement of compliance

These consolidated financial statements as at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014 have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The accounting policies adopted in these consolidated financial statements are consistent with those of the previous financial year and previous quarter.

These consolidated financial statements were approved by the Company's Board of Directors on March 15, 2017.

The accompanying consolidated financial statements were prepared on a going concern basis, under the historical cost convention, except for the warrant liability, which is measured at fair value.

The preparation of financial statements in accordance with IFRS requires the use of certain critical accounting estimates and the exercise of management's judgment in applying the Company's accounting policies. Areas involving a high degree of judgment or complexity and areas where assumptions and estimates are significant to the Company's consolidated financial statements are discussed in note 3 - Critical accounting estimates and judgments.

#### (b) Principles of consolidation

These consolidated financial statements include any entity in which the Company directly or indirectly holds more than 50% of the voting rights or over which the Company exercises control. The Company controls an entity when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. An entity is included in the consolidation from the date that control is transferred to the Company, while any entities that are sold are excluded from the consolidation from the date that control ceases. All inter-company balances and transactions are eliminated on consolidation.

## (c) Foreign currency

Items included in the financial statements of the Group's entities are measured using the currency of the primary economic environment in which the entities operate (the "functional currency"). On January 1, 2015, the Company and its US subsidiary, Aeterna Zentaris, Inc., changed their functional currency from the Euro ("EUR") to the US dollar, given that changes to underlying transactions, events and conditions indicated that the US dollar more appropriately reflects the primary economic environment in which these entities operate. This change in functional currency was accounted for prospectively. The functional currency of the German subsidiaries remains the EUR.

Assets and liabilities of the German subsidiaries are translated from EUR balances at the period-end exchange rates, and the results of operations are translated from EUR amounts at average rates of exchange for the period. The resulting translation adjustments are included in accumulated other comprehensive income within shareholders' equity.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the underlying transaction. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities not denominated in the functional currency are recognized in the consolidated statement of comprehensive loss.

Foreign exchange gains and losses that relate to cash and cash equivalents are presented within finance income or finance costs in the consolidated statement of comprehensive loss. All other foreign exchange gains and losses are presented in the consolidated statement of comprehensive loss within operating expenses.

#### (d) Share consolidation (reverse stock split)

On November 17, 2015, the Company effected a consolidation of its issued and outstanding common shares on a 100-to-1 basis (the "Share Consolidation"). The Share Consolidation affected all shareholders, option holders and warrant holders uniformly and thus did not materially affect any security holder's percentage of ownership interest. All references in these consolidated financial statements to common shares, options and share purchase warrants have been retroactively adjusted to reflect the Share Consolidation.

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#### 2 Summary of significant accounting policies

The accounting policies set out below have been applied consistently to all years presented in these consolidated financial statements and have been applied consistently by all Group entities.

#### Cash and cash equivalents

Cash and cash equivalents consist of unrestricted cash on hand and balances with banks, as well as short-term interest-bearing deposits, such as money market accounts, that are readily convertible to known amounts of cash and are subject to an insignificant risk of changes in value, with a maturity of three months or less from the date of acquisition.

#### Restricted cash equivalents

Restricted cash equivalents are comprised of bank deposits, related to a guarantee for long-term operating leases obligation and for a corporate credit card program that cannot be used for current purposes.

### Property, plant and equipment and depreciation

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

	Methods	Annual rates and period
Equipment	Declining balance and straight-line	20%
Furniture and fixtures	Declining balance and straight-line	10% and 20%
Computer equipment	Straight-line	25% and 331/3%
Leasehold improvements	Straight-line	Remaining lease term

Depreciation expense, which is recorded in the consolidated statement of comprehensive loss, is allocated to the appropriate functional expense categories to which the underlying items of property, plant and equipment relate.

## Identifiable intangible assets and amortization

Identifiable intangible assets with finite useful lives consist of in-process R&D acquired in business combinations, patents and trademarks. In-process R&D acquired in business combinations is recognized at fair value at the acquisition date. Patents and trademarks are comprised of costs, including professional fees incurred in connection with the filing of patents and the registration of trademarks for product marketing and manufacturing purposes, net of related government grants, impairment losses, where applicable, and accumulated amortization. Identifiable intangible assets with finite useful lives are amortized, from the time at which the assets are available for use, on a straight-line basis over their estimated useful lives of eight to fifteen years for in-process R&D and patents and ten years for trademarks. Amortization expense, which is recorded in the consolidated statement of comprehensive loss, is allocated to the appropriate functional expense categories to which the underlying identifiable intangible assets relate.

## Goodwill

Goodwill represents the excess of the purchase price over the fair values of the net assets of entities acquired at their respective dates of acquisition. Goodwill is carried at cost less accumulated impairment losses. Goodwill is allocated to each cash-generating unit ("CGU") or group of CGUs that are expected to benefit from the related business combination.

## Impairment of assets

Items of property, plant and equipment and identifiable intangible assets with finite lives subject to depreciation or amortization, respectively, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. Management is required to assess at each reporting date whether there is any indication that an asset may be impaired. Where such an indication exists, the asset's recoverable amount is compared to its carrying value, and an impairment loss is recognized for the amount by which the asset's carrying amount

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exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows, or CGU. In determining value in use of a given asset or CGU, estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. Impairment losses are allocated to the appropriate functional expense categories to which the underlying identifiable intangible assets relate, and are recorded in the consolidated statement of comprehensive loss.

Items of property, plant and equipment and amortizable identifiable intangible assets with finite lives that suffered impairment are reviewed for possible reversal of the impairment if there has been a change, since the date of the most recent impairment test, in the estimates used to determine the impaired asset's recoverable amount. However, an asset's carrying amount, increased due to the reversal of a prior impairment loss, must not exceed the carrying amount that would have been determined, net of depreciation or amortization, had the original impairment not occurred.

Goodwill is not subject to amortization and instead is tested for impairment annually or more often if there is an indication that the CGU to which the goodwill has been allocated may be impaired. Impairment is determined for goodwill by assessing whether the carrying value of a CGU, including the allocated goodwill, exceeds its recoverable amount, which is the higher of fair value less costs to sell and value in use. In the event that the carrying amount of goodwill exceeds its recoverable amount, an impairment loss is recognized in an amount equal to the excess. Impairment losses related to goodwill are not subsequently reversed.

### Share purchase warrants

Share purchase warrants are classified as liabilities when the Company does not have the unconditional right to avoid delivering cash to the holders in the future. Each of the Company's share purchase warrants contains a written put option, arising upon the occurrence of a Fundamental Transaction, as that term is defined in the share purchase warrants, including a change of control. As a result of the existence of these put options, and despite the fact that the repurchase feature is conditional on a defined contingency, the share purchase warrants are required to be classified as a financial liability, since such contingency could ultimately result in the transfer of assets by the Company.

The warrant liability is initially measured at fair value, and any subsequent changes in fair value are recognized as gains or losses through profit or loss. Any transaction costs related to the share purchase warrants are expensed as incurred.

The warrant liability is classified as non-current, unless the underlying share purchase warrants are about to expire or be settled within 12 months from the end of a given reporting period.

### **Employee benefits**

Salaries and other short-term benefits

Salaries and other short-term benefit obligations are measured on an undiscounted basis and are recognized in the consolidated statement of comprehensive loss over the related service period or when the Company has a present legal or constructive obligation to make payments as a result of past events and when the amount payable can be estimated reliably.

Post-employment benefits

The Company's subsidiary in Germany maintains defined contribution and unfunded defined benefit plans, as well as other benefit plans for its employees. For defined benefit pension plans and other post-employment benefits, net periodic pension expense is actuarially determined on a quarterly basis using the projected unit credit method. The cost of pension and other benefits earned by employees is determined by applying certain assumptions, including discount rates, the projected age of employees upon retirement, the expected rate of future compensation and employee turnover.

The employee future benefits liability is recognized at its present value, which is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid and that have terms to maturity approximating the terms of the related future benefit liability. Actuarial gains and losses that arise in calculating the present value of the defined benefit obligation are recognized in other, net of tax, and simultaneously reclassified in the deficit in the consolidated statement of financial position in the year in which the actuarial gains and losses arise and without recycling to the consolidated statement of comprehensive loss in subsequent periods.

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For defined contribution plans, expenses are recorded in the consolidated statement of comprehensive loss as incurred—namely, over the period that the related employee service is rendered.

Termination benefits

Termination benefits are recognized in the consolidated statement of comprehensive loss when the Company is demonstrably committed, without the realistic possibility of withdrawal, to a formal detailed plan to terminate employment earlier than originally expected. Termination benefit liabilities expected to be settled after 12 months from the end of a given reporting period are discounted to their present value, where material.

#### **Financial instruments**

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

Financial assets and liabilities are offset, and the net amount is reported in the consolidated statement of financial position, when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle on a net basis or realize the asset and settle the liability simultaneously.

#### (a) Classification

Financial assets at fair value through profit or loss

Financial assets at FVTPL are financial assets held for trading. Fair value is defined as the amount at which the financial assets could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. A financial asset is classified as at FVTPL if the instrument is acquired or received as consideration principally for the purpose of selling in the short-term. Financial assets at FVTPL are classified as current assets if expected to be settled within 12 months from the end of a given reporting period; otherwise, the assets are classified as non-current

As at December 31, 2016 and 2015, the Company held no assets classified as financial assets at FVTPL.

Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Loans and receivables are included in current assets, except for instruments with maturities greater than 12 months after the end of a given reporting period or where restrictions apply that limit the Company from using the instrument for current purposes, which are classified as non-current assets.

The Company's loans and receivables are comprised of cash and cash equivalents, trade and other receivables and restricted cash equivalents.

Financial liabilities at fair value through profit or loss

Financial liabilities at FVTPL are financial liabilities held for trading. A financial liability is classified as at FVTPL if the instrument is acquired or incurred principally for the purpose of selling or repurchasing in the short-term or where the Company does not have the unconditional right to avoid delivering cash or another financial asset to the holders in certain circumstances. Financial liabilities at FVTPL are classified as current liabilities if required to be settled within 12 months from the end of a given reporting period; otherwise, the liabilities are classified as non-current.

Financial liabilities at FVTPL are currently comprised of the Company's warrant liability.

Other financial liabilities

Other financial liabilities include trade accounts payable and accrued liabilities, provision for restructuring and other non-current liabilities.

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#### (b) Recognition and measurement

Financial assets at fair value through profit or loss

Financial assets at FVTPL are recognized on the settlement date, which is the date on which the asset is delivered to the Company. Financial assets at FVTPL are initially recognized at fair value, and transaction costs are expensed immediately in the consolidated statement of comprehensive loss. Financial assets at FVTPL are derecognized when the right to receive cash flows from the underlying investment have expired or have been transferred and when the Group has transferred substantially all risks and rewards of ownership. Gains and losses arising from changes in the fair value of financial assets at FVTPL are presented in the consolidated statement of comprehensive loss within finance income or finance costs in the period in which they arise.

Loans and receivables

Loans and receivables are recognized on the settlement date and are measured initially at fair value and subsequently at amortized cost using the effective interest rate method.

Financial liabilities at fair value through profit or loss

Financial liabilities at FVTPL are recognized on the settlement date. Financial liabilities at FVTPL are initially recognized at fair value, and transaction costs are expensed immediately in the consolidated statement of comprehensive loss. Gains and losses arising from changes in the fair value of financial liabilities at FVTPL are presented in the consolidated statement of comprehensive loss in the period in which they arise.

Other financial liabilities

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

### (c) Impairment

Financial assets measured at amortized cost are reviewed for impairment at each reporting date. Where there is objective evidence that impairment exists for a financial asset measured at amortized cost, an impairment charge equivalent to the difference between the asset's carrying amount and the present value of estimated future cash flows is recorded in the consolidated statement of comprehensive loss. The expected cash flows exclude future credit losses that have not been incurred and are discounted at the financial asset's original effective interest rate.

Impairment charges related to financial assets carried at amortized cost are reversed if, in a subsequent period, the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognized. However, the reversal cannot result in a carrying amount of the financial asset that exceeds what the amortized cost would have been had the impairment not been recognized at the date the impairment is reversed.

# Share capital

Common shares are classified as equity. Incremental costs that are directly attributable to the issuance of common shares and stock options are recognized as a deduction from equity, net of any tax effects.

Where offerings result in the issuance of units (where each unit is comprised of a common share of the Company and a share purchase warrant, exercisable in order to purchase a common share or fraction thereof), proceeds received in connection with those offerings are allocated between Share capital and Share purchase warrants based on the residual method. Proceeds are allocated to warrant liability based on the fair value of the share purchase warrants, and the residual amount of proceeds is allocated to Share capital. Transaction costs in connection with such offerings are allocated to the liability and equity unit components in proportion to the allocation of proceeds.

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#### **Provisions**

Provisions represent liabilities to the Company for which the amount or timing is uncertain. Provisions are recognized when the Company has a present legal or constructive obligation as a result of past events, such as organizational restructuring, when it is probable that an outflow of resources will be required to settle the obligation and where the amount can be reliably estimated. Provisions are not recognized for future operating losses.

Provisions are made for any contracts which are deemed onerous. A contract is onerous if the unavoidable costs of meeting the obligations under the contract exceed the economic benefits expected to be received under it. Provisions for onerous contracts are measured at the present value of the lower of the expected cost of terminating the contract and the expected net cost of continuing with the contract. Present value is determined based on expected future cash flows that are discounted at a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The unwinding of the discount is recognized in finance costs.

## Revenue recognition

Licensing revenues and multiple element arrangements

The Company is currently in a phase in which certain potential products are being further developed or marketed jointly with partners and licensees. Existing licensing agreements usually involve one-time payments (upfront payments), payments for R&D services in the form of cost reimbursements, milestone payments and royalty receipts for licensing and marketing product candidates. Revenues associated with those multiple-element arrangements are allocated to the various elements based on their relative fair value.

Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered obligation(s). The consideration received is allocated among the separate units based on each unit's fair value, and the applicable revenue recognition criteria are applied to each of the separate units.

License fees representing non-refundable payments received at the time of executing the license agreements are recognized as revenue upon signature of the license agreements when the Company has no significant future performance obligations under a multiple element arrangement and collectibility of the fees is probable. When there are future performance obligations under a multiple element arrangement, upfront payments received at the beginning of licensing agreements are deferred and recognized as revenue on a systematic basis over the period during which the related services are rendered and all obligations are performed.

# Milestone payments

Milestone payments, which are generally based on developmental or regulatory events, are recognized as revenue when the milestones are achieved, collectibility is assured, and when the Company has no significant future performance obligations in connection with the milestones.

## Sales Commission

Revenues from sales commission are recognized when all the following conditions are satisfied:

- i. the amount of revenue can be measured reliably; and
- ii. it is probable that the economic benefits associated with the transaction will flow to the Company.

The Company is responsible for promoting some products. Therefore, there is no continuing involvement following the patient starting the treatment and buying the products.

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#### **Share-based compensation costs**

The Company operates an equity-settled share-based compensation plan under which the Company receives services from directors, senior executives, employees and other collaborators as consideration for equity instruments of the Company.

The Company accounts for all forms of share-based compensation using the fair value-based method. Fair value of stock options is determined at the date of grant using the Black-Scholes option pricing model, which includes estimates of the number of awards that are expected to vest over the vesting period. Where granted share options vest in installments over the vesting period (defined as graded vesting), the Company treats each installment as a separate share option grant. Share-based compensation expense is recognized over the vesting period, or as specified vesting conditions are satisfied, and credited to Other Capital.

Any consideration received by the Company in connection with the exercise of stock options is credited to Share Capital. Any Other Capital component of the share-based compensation is transferred to Share Capital upon the issuance of shares.

#### Current and deferred income tax

Income tax on profit or loss comprises current and deferred tax. Tax is recognized in profit or loss, except that a change attributable to an item of income or expense recognized as other comprehensive (loss) income or directly in equity is also recognized directly in other comprehensive (loss) income or directly in equity. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation and establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

The current income tax charge is calculated in accordance with tax rates and laws that have been enacted or substantively enacted by the reporting date in the countries where the Company's subsidiaries operate and generate taxable income.

Deferred income tax is recognized on temporary differences (other than, where applicable, temporary differences associated with unremitted earnings from foreign subsidiaries and associates to the extent that the investment is essentially permanent in duration, and temporary differences associated with the initial recognition of goodwill) arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements and on unused tax losses or R&D non-refundable tax credits in the Group. Deferred income tax is determined using tax rates and laws that have been enacted or substantively enacted by the reporting date.

Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income taxes assets and liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities where there is an intention to settle the balances on a net basis.

## Research and development costs

Research costs are expensed as incurred. Development costs are expensed as incurred, except for those that meet generally accepted criteria for deferral, in which case the costs are capitalized and amortized to operations over the estimated period of benefit. No development costs have been capitalized during any of the periods presented.

# **Discontinued operations**

A discontinued operation is a component of the Company that has been disposed of, or is classified as held for sale, and represents a separate major line of business or geographical area of operations and/or is part of a single co-ordinated plan to dispose of a separate major line of business or geographical area of operations. Classification as a discontinued operation occurs upon the earlier of the disposal of the operation (or disposal group) or the date at which the operation meets the criteria for classification as held for sale. When an operation is classified as discontinued, comparative statements of comprehensive loss and cash flows are presented as if the operations had been discontinued at the beginning of the earliest comparative period presented.

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#### Net (loss) income per share

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

Diluted net (loss) income per share is calculated based on the weighted average number of common shares outstanding during the year, plus the effects of dilutive common share equivalents, such as stock options and share purchase warrants. This method requires that diluted net (loss) income per share be calculated using the treasury stock method, as if all common share equivalents had been exercised at the beginning of the reporting period, or period of issuance, as the case may be, and that the funds obtained thereby were used to purchase common shares of the Company at the average trading price of the common shares during the period.

## 3 Critical accounting estimates and judgments

The preparation of consolidated financial statements in accordance with IFRS requires management to make judgments, estimates and assumptions that affect the reported amounts of the Company's 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 the Company's consolidated financial statements are prepared.

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

### (a) Critical accounting estimates and assumptions

Critical accounting estimates and assumptions are those that have a significant risk of causing material adjustment and are often applied to matters or outcomes that are inherently uncertain and subject to change. As such, management cautions that future events often vary from forecasts and expectations and that estimates routinely require adjustment.

The following discusses the most significant accounting estimates and assumptions that the Company has made in the preparation of the consolidated financial statements.

Fair value of the warrant liability and stock options

Determining the fair value of the warrant liability and stock options requires judgment related to the choice of a pricing model, the estimation of stock price volatility and the expected term of the underlying instruments. Any changes in the estimates or inputs utilized to determine fair value could result in a significant impact on the Company's future operating results, liabilities or other components of shareholders' equity. Fair value assumptions used are described in note 13 - Warrant liability and 15 - Share capital.

# Goodwill impairment

The annual impairment assessment related to goodwill requires to estimate the recoverable amount, which has been determined using fair value less costs of disposal. This evaluation is based on estimates that are derived from current market capitalization and on other factors, including assumptions related to relevant industry-specific market analyses and potential costs to dispose. The Company also concluded that there was only one CGU as management monitors goodwill on an overall entity basis. Future events, including a significant reduction in the Company's share price, could cause the assumptions utilized in the impairment tests to change, resulting in a potentially adverse effect on the Company's future results due to increased impairment charges.

### Employee future benefits

The determination of expenses and obligations associated with employee future benefits requires the use of assumptions, such as the discount rate to measure obligations, the projected age of employees upon retirement, the expected rate of future compensation and estimated employee turnover. Because the determination of the cost and obligations associated with employee future benefits requires the use of various assumptions, there is measurement uncertainty inherent in the actuarial valuation process. Actual results will differ from results that are estimated based on the aforementioned assumptions. Additional information is included in note 17 - Employee future benefits.

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

Income taxes

The estimation of income taxes includes evaluating the recoverability of deferred tax assets based on an assessment of Group entities' ability to utilize the underlying future tax deductions against future taxable income prior to expiry of those deductions. Management assesses whether it is probable that some or all of the deferred income tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income, which in turn is dependent upon the successful commercialization of the Company's products. To the extent that management's assessment of any Group entity's ability to utilize future tax deductions changes, the Company would be required to recognize more or fewer deferred tax assets, and future income tax provisions or recoveries could be affected. Additional information is included in note 19 - Income taxes.

(b) Critical judgments in applying the Company's accounting policies

Revenue recognition

Management's assessments related to the recognition of revenues related to arrangements containing multiple elements are based on judgment. Judgment is necessary to identify separate units of accounting and to allocate related consideration to each separate unit of accounting. Where deferral of upfront payments or license fees is deemed appropriate, subsequent revenue recognition is often determined based upon the assessment of the Company's continuing involvement in the arrangement, the benefits expected to be derived by the customer and, where applicable, expected patent lives. Additional information is included in note 5 - Deferred revenues related to licensing arrangements and co-development agreement.

#### 4 Recent accounting pronouncements

Not yet adopted

In January 2016, the IASB issued amendments to IAS 12, *Income taxes* to clarify the requirements for recognizing deferred tax assets on unrealized losses. The amendments clarify the accounting for deferred tax where an asset is measured at fair value and that fair value is below the asset's tax base. They also clarify certain other aspects of accounting for deferred tax assets. The amendments are effective from January 1, 2017. The Company is currently assessing the impact, if any, which these amendments may have on the Company's consolidated financial statements.

In January 2016, the IASB issued an amendment to IAS 7, *Statement of cash flows*, introducing an additional disclosure that will enable users of financial statements to evaluate changes in liabilities arising from financing activities. The amendment is part of the IASB's Disclosure Initiative, which continues to explore how financial statement disclosure can be improved. The amendment is effective from January 1, 2017. The Company believes that the information already provided in note 13 will be sufficient to meet this new requirement.

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. 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. The Company is currently assessing the impact, if any, that these new standards may have on the Company's consolidated financial statements.

Notes to Consolidated Financial Statements

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

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. The Company is currently assessing the impact, if any, that this new standard may have on the Company's consolidated financial statements.

In November 2016, the IFRS Interpretations Committee issued an Interpretation on how to determine the date of the transaction when applying IAS 21, *The Effects of Changes in Foreign Exchange Rates*. The Interpretation applies where an entity either pays or receives consideration in advance for foreign currency-denominated contracts. The Interpretation provides guidance for when a single payment/receipt is made, as well as for situations where multiple payments/receipts are made. The Interpretation is effective for annual periods beginning on or after January 1, 2018. The Company is currently assessing the impact, if any, which these amendments may have on the Company's 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. The Company is currently assessing the impact, if any, that this new standard may have on the Company's consolidated financial statements.

### 5 Deferred revenues related to licensing arrangements and co-development agreement

Zoptrex<sup>TM</sup> License Agreements

On July 1, 2016, the Company entered into a License Agreement with Cyntec Co., Ltd. ("Cyntec"), an affiliate of Orient EuroPharma Co., Ltd. ("OEP") for Zoptrex<sup>TM</sup> (zoptarelin doxorubicin) for the initial indication of endometrial cancer. Under the terms of the License Agreement, the Company was paid a non-refundable upfront cash payment (the "License Fee") in consideration for the license to Cyntec of the Company's intellectual property related to Zoptrex<sup>TM</sup> and the grant to Cyntec of the right to commercialize Zoptrex<sup>TM</sup> in a territory consisting of Taiwan and nine countries in southeast Asia (the "OEP Territory"). Cyntec has also agreed to make additional payments to the Company upon achieving certain pre-established regulatory and commercial milestones. Furthermore, the Company will receive royalties based on future net sales of Zoptrex<sup>TM</sup> in the OEP Territory. Cyntec will be responsible for the development, registration, reimbursement and commercialization of the product in the OEP Territory. The Company also entered into related Technology Transfer and Supply Agreements with another affiliate of OEP, pursuant to which the Company will transfer to such affiliate the technology necessary to permit the affiliate to manufacture finished Zoptrex<sup>TM</sup> using quantities of the active pharmaceutical agreement purchased from the Company pursuant to the Supply Agreement.

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

The Company has substantial continuing involvement in the aforementioned arrangements, including the transfer of documentation, know-how and materials, as well as the provision of technical assistance, such as quality systems implementation, analytical and stability testing, territory-specific development initiatives, and other services.

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As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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The Company has applied the provisions of IAS 18, *Revenue* ("IAS 18"), and has determined that all deliverables and performance obligations contemplated by the agreements with Cyntec/OEP and Sinopharm should be accounted for as a single unit of accounting, limited to amounts that are not contingent upon the delivery of additional items or the meeting of other specified performance conditions which are not known, probable or estimable at the time at which the agreements with OEP and Sinopharm were entered into.

The Company has deferred the non-refundable License and Transfer Fees and is amortizing the related payment as revenue on a straight-line basis over the period during which the aforementioned services are rendered and obligations are performed.

In determining the period over which the License and Transfer Fee revenues are to be recognized, the Company concluded that its significant continuing involvement in the aforementioned agreements will span approximately until the end of December 2018. However, the Company may adjust the amortization period based on appropriate facts and circumstances not yet known, that would significantly change the duration of the Company's continuing involvement and performance obligations or benefits expected to be derived by OEP and Sinopharm.

Future milestone payments will be recognized as revenue individually and in full upon the actual achievement of the related milestone, given the substantive nature of each milestone. Lastly, upon initial commercialization and sale of the developed product, the Company will recognize royalty revenues as earned, based on the contractual percentage applied to the actual net sales achieved by OEP or Sinopharm, as per the LA.

Pursuant to the Sinopharm agreements, the Company was required to remit to the Chinese tax authorities \$111,000 of the gross proceeds received from Sinopharm. This amount, which was withheld at source, was recognized as income tax expense in the consolidated statement of comprehensive loss, in 2014, in accordance with the provision of IAS 12, *Income Taxes*.

## Ergomed agreement

On April 10, 2013, the Company entered into a co-development and revenue-sharing agreement ("CDRSA") with Ergomed Clinical Research Limited ("Ergomed"), pursuant to which Ergomed agreed to assist the Company in the clinical development program for Zoptrex<sup>TM</sup> for the purpose of maximizing the commercialization potential of Zoptrex<sup>TM</sup> with the ultimate aim of selling or licensing Zoptrex<sup>TM</sup>. Concurrently with the execution of the CDRSA, the Company entered into a master services agreement ("MSA") with Ergomed for a Phase 3 clinical trial of Zoptrex<sup>TM</sup> in endometrial cancer, pursuant to which Ergomed provided clinical development services with respect to the co-development initiative referred to above.

Under the CDRSA, Ergomed will not charge the Company for 30% of the total costs of the Phase 3 clinical trial of Zoptrex<sup>TM</sup> up to a maximum of \$10,000,000. As of December 31, 2016, the amount not charged by Ergomed totaled approximately \$9,400,000. While Ergomed will not directly contribute any cash proceeds towards the completion of the activities contemplated by the CDRSA, Ergomed, as primary supplier of a substantial portion of Zoptrex<sup>TM</sup> related clinical and regulatory activities, will contribute to the overall funding of the initiative via the application of a 30% discount from the costs set forth in the MSA until the cumulative total of such reductions reaches a maximum of \$10,000,000. Ergomed will be entitled to receive an agreed upon single-digit percentage of any future net income (as defined in the CDRSA) or other proceeds related to the licensing of Zoptrex<sup>TM</sup> in endometrial cancer indication, up to a specified maximum amount.

The Company recognizes R&D costs associated with the CDRSA and MSA net of the 30% discount, as services are rendered by Ergomed in the consolidated statement of comprehensive loss. During the years ended December 31, 2016, 2015 and 2014, the Company expensed a total of \$4,435,929, \$7,140,000, \$7,195,000, respectively, pursuant to the CDRSA and MSA.

Notes to Consolidated Financial Statements

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

# 6 Cash and cash equivalents

	Decembe	December 31,		
	2016	2015		
	\$	\$		
Cash on hand and balances with banks	21,999	11,233		
Interest-bearing deposits with maturities of three months or less	_	30,217		
	21,999	41,450		

# 7 Trade and other receivables

	December 31,		
	2016	2015	
	\$	\$	
Trade accounts receivable	155	180	
Value added tax	130	291	
Other	80	127	
	365	598	

# 8 Property, plant and equipment

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

	Cost					
	Equipment	Furniture and fixtures	Computer equipment	Leasehold improvements	Total	
	\$	\$	\$	\$	\$	
At January 1, 2015	6,812	1,106	1,534	1,055	10,507	
Additions	2	8	16	_	26	
Disposals / Retirements	(2,108)	(1,021)	(719)	(962)	(4,810)	
Impact of foreign exchange rate changes	(667)	(74)	(85)	(74)	(900)	
At December 31, 2015	4,039	19	746	19	4,823	
Additions	27	_	19	20	66	
Disposals / Retirements	_	_	(3)	_	(3)	
Impact of foreign exchange rate changes	(147)	_	(25)	(2)	(174)	
At December 31, 2016	3,919	19	737	37	4,712	

Notes to Consolidated Financial Statements

Recurring depreciation expense

Impact of foreign exchange rate changes

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

Accumulated depreciation Furniture and Leasehold Computer **Equipment** Total fixtures equipment improvements \$ \$ \$ At January 1, 2015 6,313 1,087 1,448 862 9,710 Disposals / Retirements (1,957)(1,015)(719)(882)(4,573)Impairment loss\* 70 70 138 1 36 15 190 Recurring depreciation expense Impact of foreign exchange rate changes (73)(82)(54)(830)(621)11 At December 31, 2015 3,873 683 4,567 Disposals / Retirements (2) (2)

2

36

(25)

4

112

(169)

4,508

At December 31, 2016 2 692 15

70

(144)

<sup>\*</sup>Related to R&D equipment impaired as a result of a restructuring (note 12 - Restructuring).

	Carrying amount					
	Equipment \$	Furniture and fixtures \$	Computer equipment \$	Leasehold improvements	Total \$	
At December 31, 2015	166	19	63	8	256	
At December 31, 2016	120	17	45	22	204	

Depreciation of \$112,000 (\$260,000 in 2015 and \$577,000 in 2014) is presented in the consolidated statement of comprehensive loss as follows: \$80,000 (\$231,000 in 2015 and \$530,000 in 2014) in R&D costs, \$11,000 (\$13,000 in 2015 and \$47,000 in 2014) in general and administrative ("G&A") expenses and \$21,000 (16,000 in 2015 and nil in 2014) in selling expenses.

Notes to Consolidated Financial Statements

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

## 9 Identifiable intangible assets

Identifiable intangible assets with finite useful lives consist entirely of in-process R&D costs, patents and trademarks. Changes in the carrying value of the Company's identifiable intangible assets with finite useful lives are summarized below.

	Year ended December 31, 2016			Year ended December 31, 2015		
	Cost	Accumulated amortization	Carrying value	Cost	Accumulated amortization	Carrying value
	\$	\$	\$	\$	\$	\$
Balances - Beginning of the year	31,151	(30,914)	237	35,032	(34,680)	352
Additions	5	_	5	_	_	_
Disposal/Retirements	_	_	_	(538)	538	_
Impairment loss*	_	(85)	(85)	_	_	_
Recurring amortization expense*	_	(83)	(83)	_	(81)	(81)
Impact of foreign exchange rate changes	(1,124)	1,120	(4)	(3,343)	3,309	(34)
Balances – End of the year	30,032	(29,962)	70	31,151	(30,914)	237

<sup>\*</sup> Recorded as R&D costs in the consolidated statements of comprehensive (loss) income.

## 10 Goodwill

The change in carrying value is as follows:

	Cost	Accumulated impairment loss	Carrying amount	
	\$	\$	\$	
At January 1, 2015	8,687	_	8,687	
Impact of foreign exchange rate changes	(851)	_	(851)	
At December 31, 2015	7,836		7,836	
Impact of foreign exchange rate changes	(283)	_	(283)	
At December 31, 2016	7,553		7,553	

# 11 Payables and accrued liabilities

	Decemb	per 31,
	2016	2015
	<u> </u>	\$
Trade accounts payable	2,044	2,488
Accrued research and development costs	340	312
Salaries, employment taxes and benefits	156	256
Current portion of onerous contract provisions (note 14)	295	334
Other accrued liabilities	910	782
	3,745	4,172
Other accrued liabilities		

Notes to Consolidated Financial Statements

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

## 12 Restructuring

On August 7, 2014, the Company's Nominating, Governance and Compensation Committee and Board of Directors approved a global resources optimization program (the "Resource Optimization Program"), which was rolled out as part of a strategy to transition Aeterna Zentaris into a commercially operating specialty biopharmaceutical organization. As at December 31, 2016, the Resource Optimization Program was substantially complete.

On October 9, 2015, the Company's Board of Directors approved a plan to restructure the Company's finance and accounting operations and to close the Company's Quebec City office (the "Corporate Restructuring"). The Company transferred all functions performed by the five employees in its Quebec City office to other personnel. As of December 31, 2016, the Corporate Restructuring was complete.

The change in the Company's provision for restructuring costs can be summarized as follows:

	Resource Optimization Program	Corporate Restructuring	Total
	\$	\$	<b>\$</b>
At January 1, 2015	1,651	_	1,651
Provision recognized	_	1,244	1,244
Utilization of provision	(1,154)	(636)	(1,790)
Change in the provision	(265)	(47)	(312)
Impact of foreign exchange rate changes	(157)	(4)	(161)
At December 31, 2015	75	557	632
Less: non-current portion	(34)	_	(34)
	41	557	598
At December 31, 2015	75	557	632
Utilization of provision	(43)	(523)	(566)
Change in the provision	_	(8)	(8)
Impact of foreign exchange rate changes	1	(26)	(25)
At December 31, 2016	33	_	33

## 13 Warrant liability

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

	Year ended December 31,			
	2016	2015	2014	
	\$	\$	\$	
Balance – Beginning of the year	10,891	8,225	18,010	
Share purchase warrants issued during the year (note 15)	400	28,678	8,487	
Derecognition due to early expiry (note 15)	_	(5,865)	_	
Share purchase warrants exercised during the year	_	(31,103)	_	
Change in fair value of share purchase warrants	(4,437)	10,956	(18,272)	
Balance - End of year	6,854	10,891	8,225	
Less: current portion	_	(1,411)	_	
Balance – End of the year	6,854	9,480	8,225	

Expired (note 15)

Balance - End of the year

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A summary of the activity related to the Company's share purchase warrants is provided below.

(8,064)

3,779,245

Year ended December 31, 2016 2015 2014 Weighted Weighted Weighted average average average exercise price exercise price exercise price Number (US\$) Number Number (US\$) (US\$) 2,842,309 104.46 154.49 Balance - Beginning of the year 11.67 287,852 201,074 Issued (note 15) 945,000 3,076,956 \*\* 88,000 4.70 6.28 Exercised (298,088)4.24

(224,111)

2,842,309

66.90

11.67

750.00

104.46

(1,222)

287,852

4.23

9.94

The following table summarizes the share purchase warrants outstanding and exercisable as at December 31, 2016:

Exercise price (\$)	Number	Weighted average remaining contractual life (years)
3.41	447,574	3.19
4.70	945,000	3.34
7.10	2,331,000	3.95
185.00	25,996	1.58
345.00	29,675	0.80
	3,779,245	3.67

<sup>\*</sup> As adjusted (note 15 - Share capital)

<sup>\*\* 298,382</sup> of which represent the Series B Warrants (see note 15 - Share capital), which were exercisable on an alternate cashless basis, as discussed below.

Notes to Consolidated Financial Statements

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The table presented below shows the inputs and assumptions applied to the Black-Scholes option pricing model in order to determine the fair value of all outstanding warrants outstanding as at December 31, 2016. The Black-Scholes option pricing model uses "Level 2" inputs, as defined by IFRS 13, *Fair value measurement* ("IFRS 13") and as discussed in note 21 - Financial instruments and financial risk management.

	Number of equivalent shares	Market- value per share price (\$)	Weighted average exercise price (\$)	Risk-free annual interest rate (a)	Expected volatility (b)	Expected life (years)	Expected dividend yield (d)
October 2012 Investor Warrants	29,675	3.60	345.00	0.85%	55.98%	0.80	0.00%
July 2013 Warrants	25,996	3.60	185.00	1.05%	133.23%	1.58	0.00%
March 2015 Series A Warrants (e)	447,574	3.60	3.41	1.51%	117.06%	3.19	0.00%
December 2015 Warrants	2,331,000	3.60	7.10	1.68%	108.03%	3.95	0.00%
November 2016 Warrants (f)	945,000	3.60	4.70	1.15%	108.18%	1.90	0.00%

- (a) Based on United States Treasury Government Bond interest rates with a term that is consistent with the expected life of the warrants.
- (b) Based on the historical volatility of the Company's stock price over the most recent period consistent with the expected life of the warrants, as well as on future expectations.
- (c) Based upon time to expiry from the reporting period date, except for the November 2016 Warrants (see note (f) below).
- (d) The Company has not paid dividends and it does not intend to pay dividends in the foreseeable future.
- (e) For the March 2015 Series A Warrants, the inputs and assumptions applied to the Black-Scholes option pricing model have been further adjusted to take into consideration the value attributed to certain anti-dilution provisions. Specifically, the weighted average exercise price is subject to adjustment (see note 15 Share capital).
- (f) For the November 2016 Warrants, the Company estimated the fair value attributable to the warrants by applying probability to multiple Black-Scholes pricing models, to which the weighed average assumptions included in the table above were applied. In addition, the Company reduced fair value of these warrants to take into consideration the fair value of the \$10.00 call option, which was also calculated using the Black-Scholes pricing model with similar assumptions as described above. (see description in note 15 Share capital).

## **Series B Warrants**

In addition to the availability of standard cashless exercise provisions, the Series B Warrants (defined and discussed in note 15 - Share capital) were entitled to be exercised on an alternate cashless basis in accordance with their terms. Such an exercise permitted the holder to obtain a number of common shares equal to: 200% of (i) the total number of common shares with respect to which the Series B Warrant was then being exercised multiplied by (ii) 81.00 divided by (iii) 85% of the quotient of (A) the sum of the per share volume weighted average price ("VWAP") of the common share for each of the five lowest trading days during the fifteen trading day period ending on and including the trading day immediately prior to the applicable Exercise Date, divided by (B) five, less (iv) the total number of common shares with respect to which the Series B Warrant is then being exercised.

Exercises of Series B Warrants on an alternate cashless basis resulted in the issuance of a substantially larger number of the Company's common shares than would have been otherwise issued following a standard cash or cashless exercise of the Series B Warrants.

Management has determined that, in light of the alternate cashless exercise feature and of actual Series B Warrant exercises since original issuance, application of the Black-Scholes option pricing model did not appropriately reflect the fair value of the Series B Warrants outstanding at a given statement of financial position date. Instead, management has determined that the application of an intrinsic valuation method is more representative of the market value of the Series B Warrants.

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On November 2, 2015, the Company 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 Series B Warrants held by them, at a maximum exercise ratio of approximately 33.23 common shares per warrant in accordance with the alternate cashless exercise feature in such Series B Warrants. We paid the Participating Holders a total of \$2,925,653 pursuant to the aforementioned agreements.

The 8,064 Series B Warrants remaining on December 31, 2015 expired on September 12, 2016 without having been exercised.

#### 14 Provisions and non-current liabilities

		Decer	nber 31,
		2016	2015
		\$	\$
Onerous contract provisions (detailed below)		404	703
Non-current portion of provision for restructuring costs (note 12)		_	34
Other		97	98
		501	835
Onerous contract provisions			-
	Cetrotide® onerous contracts*	Onerous lease**	Total
	\$	\$	\$
At January 1, 2015	998	338	1,336
Additional provision recognized	170	_	170
Utilization of provision	(278)	(108)	(386)
Unwinding of discount and effect of changes in the discount and			
foreign exchange rates	(87)	4	(83)
At December 31, 2015	803	234	1,037
Less: current portion (note 11)	(225)	(109)	(334)
	578	125	703
At December 31, 2015	803	234	1,037
Change in the provision	(24)		(24)
Utilization of provision	(196)	(113)	(309)
Unwinding of discount and effect of changes in the discount and	(170)	(113)	(307)
foreign exchange rates	(9)	4	(5)
At December 31, 2016	574	125	699
Less: current portion (note 11)	(181)	(114)	(295)
	393	11	404

Recorded following the transfer of the Cetrotide® Business (discontinued operations).

Represents the present value of the future lease payments that the Company is obligated to make pursuant to a non-cancellable operating lease in the United States, net of estimated future sublease income. The estimate may vary as a result of changes in the utilization of the leased premises and of the sublease arrangement. The remaining term of the lease is approximately one year as at December 31, 2016.

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#### 15 Share capital

The Company has an unlimited number of authorized common shares (being voting and participating shares) with no par value, as well as an unlimited number of preferred, first and second ranking shares, issuable in series, with rights and privileges specific to each class, with no par value.

#### **Share consolidation**

The 655,984,512 common shares issued and outstanding immediately prior to the Share Consolidation, which became legally effective on November 17, 2015, were consolidated into 6,559,846 common shares (the "Post-Consolidation Shares"). The Post-Consolidation Shares began trading on each of the TSX and NASDAQ at the opening of markets on November 20, 2015. The number of outstanding stock options and share purchase warrants were adjusted on the same basis with proportionate adjustments being made to each stock option and share purchase warrant exercise price.

All share, option and share purchase warrant and per share, option and share purchase warrant data have been retroactively adjusted in these consolidated financial statements to reflect and give effect to the Share Consolidation as if it occurred at the beginning of the earliest period presented.

## Common shares issued in connection with "At-the-Market" ("ATM") drawdowns

May 2014 ATM Program

On May 9, 2014, the Company entered into an ATM sales agreement (the "May 2014 ATM Program"), under which the Company was able, at its discretion and from time to time, to sell up to 140,187 of its common shares through ATM issuances on the NASDAQ for aggregate gross proceeds not to exceed \$15,000,000. The May 2014 ATM Program provided that common shares were to be sold at market prices prevailing at the time of sale and, as a result, prices varied.

Between July 1, 2014 and December 31, 2014, the Company issued a total of 89,951common shares under the May 2014 ATM Program at an average price of approximately \$136.00 per share for aggregate gross proceeds of approximately \$12,200,000 less cash transaction costs of \$305,430 and previously deferred transaction costs of \$71,575.

April 2016 ATM Program

On April 1, 2016, the Company entered into an ATM sales agreement (the "April 2016 ATM Program"), under which the Company is able, at its discretion and from time to time, to sell up to 3 million common shares through ATM issuances on the NASDAQ for aggregate gross proceeds of up to approximately \$10 million. The ATM program provides that common shares are to be sold at market prices prevailing at the time of sale and, as a result, prices may vary. The shelf registration statement pursuant to which the April 2016 ATM Program was established expires on March 28, 2017.

Between April 1, 2016 and December 31, 2016, the Company issued a total of 889,298 common shares under the April 2016 ATM Program at an average price of approximately \$3.89 per share for aggregate gross proceeds of approximately \$3.5 million less cash transaction costs of approximately \$107,000 and previously deferred transaction costs of approximately \$130,000. Because of these issuances, the exercise price of the March 2015 Series A warrants was adjusted to \$3.41 pursuant to the anti-dilution provisions contained in such warrants.

# **Public offerings**

January 2014 Offering

On January 14, 2014, the Company completed a public offering (the "January 2014 Offering") of 110,000 units, at a purchase price of \$120.00 per unit, with each unit consisting of one common share and 0.8 of a warrant to purchase a common share. The related warrants (the "January 2014 Warrants") represent the right to acquire an aggregate of 88,000 common shares, as discussed below.

Total gross cash proceeds raised through the January 2014 Offering amounted to \$13,200,000, less cash transaction costs of approximately \$1,034,000 and previously deferred transaction costs of \$5,000.

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The Company issued the January 2014 Warrants to the investors who participated in the January 2014 Offering. The exercise price of such warrants is \$125.00 per share, subject to adjustment pursuant to certain anti-dilution provisions. These warrants were exercisable at any time during their five-year term and, upon complete exercise, would have resulted in the issuance of an aggregate of 88,000 common shares that would generate additional proceeds for an amount that would be determined based on the then adjusted exercise price.

The Company estimated the fair value attributable to the January 2014 Warrants as of the date of grant by applying the Black-Scholes pricing model, to which the following assumptions were applied: a risk-free annual interest rate of 1.64%, an expected volatility of 102.31%, an expected life of 5 years and a dividend yield of 0.0%. As a result, the fair value of the share purchase warrants was estimated at \$8,487,000.

Total gross proceeds of the January 2014 Offering were allocated as follows: \$8,487,000 was allocated to Warrant liability, and the balance of \$4,713,000 was allocated to Share capital. Transaction costs were allocated to the liability and equity components in proportion to the allocation of proceeds. As such, an amount of \$666,000 was allocated to the share purchase warrants and immediately recognized in general and administrative expenses in the consolidated statement of comprehensive (loss) income, and an amount of \$373,000 was allocated to Share capital.

In connection with the January 2014 Offering, the holders of warrants issued as part of a financing in November 2013 (the "November 2013 Warrants"), who participated in the January 2014 Offering agreed to waive certain anti-dilution provisions of such warrants solely in connection with the January 2014 Offering, and agreed to an adjustment of the exercise price of such warrants following the closing of the January 2014 Offering from their original exercise price of \$160.00 per share to an exercise price equal to \$125.00 per share. The exercise price of the November 2013 Warrants held by the sole holder who did not participate in the January 2014 Offering, was further reduced by \$5.00 per share.

March 2015 Offering

On March 11, 2015, the Company completed a public offering of 596,775 units (the "Units"), 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").

Total gross cash proceeds raised through the March 2015 Offering amounted to \$37,000,000, less cash transaction costs of approximately \$2,560,000 and previously deferred transaction costs of \$7,000.

The Series A Warrants were exercisable during a five-year term at an initial exercise price of \$81.00 per share, and the Series B Warrants were exercisable during an 18-month term at an initial exercise price of \$81.00 per share. The Series A Warrants are and the Series B Warrants were subject to certain anti-dilution provision and may at any time be exercised on a standard cashless basis and, in addition, the Series B Warrants were exercisable on an alternate net cashless basis. The exercise of Series B Warrants performed on an alternate net cashless basis resulted 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. See also note 13 - Warrant liability. The remaining 8,064 Series B Warrants expired in September 2016.

Between May 26, 2015 and December 31, 2015, 290,318 of the Series B Warrants were exercised on an alternate cashless basis, resulting in the issuance of 5,670,118 common shares.

The Company estimated the fair value attributable to the Series A and Series B warrants as of the date of grant by applying the Black-Scholes pricing model, to which the following assumptions were applied: Series A warrants: a risk-free annual interest rate of 1.59%, an expected volatility of 95.11%, an expected life of 5 years and a dividend yield of 0.0%; Series B warrants: a risk-free annual interest rate of 0.47%, an expected volatility of 97.34%, an expected life of 18 months and a dividend yield of 0.0%. As a result, on March 11, 2015, the total fair value of the share purchase warrants was estimated at \$20,980,000.

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The Series C Warrants were offered in the March 2015 Offering to investors whose purchase of Units would have resulted in their beneficially owning more than an "initial beneficial ownership limitation" of either 4.9% or 9.9% of our common shares following the offering. The Series C Warrants, which were exercisable immediately upon issuance and for a period of five years at an exercise price of \$62.00 per share, were fully exercised between March 23, 2015 and June 15, 2015. Total gross proceeds payable to the Company in connection with the exercise of the Series C Warrants were prefunded by investors and therefore were included in the proceeds of the offering. No additional consideration was required to be paid to the Company upon exercise of the Series C Warrants.

Total gross proceeds of the March 2015 Offering were allocated as follows: \$20,980,000 was allocated to the warrant liability, \$9,296,000 was allocated to pre-funded warrants, and the balance of \$6,724,000 was allocated to Share capital. Transaction costs were allocated to the liability and equity components in proportion to the allocation of proceeds. As such, an amount of \$1,451,000 was allocated to the warrant liability and immediately recognized in general and administrative expenses in the consolidated statement of comprehensive loss, an amount of \$473,000 was allocated to Share capital and an amount of \$643,000 was allocated to pre-funded warrants. Upon exercise of the Series C Warrants, the net proceeds initially allocated to the pre-funded warrants were re-allocated to Share capital.

In connection with the March 2015 Offering, the holders of 211,230 of the 219,000 then outstanding warrants issued by the Company in connection with public offerings completed in November 2013 and January 2014 entered into an amendment agreement that caused such previously issued warrants to expire and terminate. The Company made a cash payment in the aggregate amount of \$5,703,000 out of the proceeds of the March 2015 Offering as consideration to the relevant warrantholders in exchange for the latter agreeing to the aforementioned amendment. Upon expiry of the warrants in question, the Company recognized a gain of \$5,865,000 and derecognized the expired warrants. The gain on derecognition was recorded, net of the aforementioned amendment fee, within finance income in the accompanying condensed interim consolidated statement of comprehensive loss. For holders of the remaining 7,770 outstanding warrants issued by the Company in connection with the November 2013 and the January 2014 offerings who did not enter into a warrant amendment agreement, the exercise price of the corresponding warrants was reduced to \$14.00 per share in accordance with the terms thereof.

## December 2015 Offering

On December 14, 2015, the Company completed a public offering of 3,000,000 common shares at a purchase price of \$5.54 per share and 2,100,000 warrants to purchase one common share at a purchase price of \$0.01 per warrant (the "December 2015 Offering").

In connection with the December 2015 Offering, the Company granted the underwriter a 45-day over-allotment option to separately acquire up to an additional 330,000 common shares at the same purchase price of \$5.54 per share and/or up to an additional 231,000 warrants at the same purchase price of \$0.01 per warrants. The underwriter exercised its option in full with respect to the 231,000 warrants for market stabilization purposes but did not exercise any of its option in respect of common shares.

Total gross cash proceeds raised through the December 2015 Offering amounted to approximately \$16,650,000, less cash transaction costs of approximately \$1,638,000.

The warrants are exercisable for a period of five years at an exercise price of \$7.10 per share. Upon complete exercise for cash, these warrants would result in the issuance of an aggregate of 2,331,000 common shares that would generate additional proceeds for an amount of \$16,550,100. However, those warrants may at any time be exercised on a "net" or "cashless" basis.

The Company estimated the fair value attributable to the warrants as of the date of grant by applying the Black-Scholes pricing model, to which the following assumptions were applied: a risk-free annual interest rate of 1.68%, an expected volatility of 107.57%, an expected life of 5 years and a dividend yield of 0.0%. As a result, on December 14, 2015, the total fair value of the share purchase warrants was estimated at \$7,698,000.

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Total gross proceeds of the December 2015 Offering were allocated as follows: \$7,698,000 was allocated to the warrant liability and \$8,952,000 was allocated to Share capital. Transaction costs were allocated to the liability and equity components in proportion to the allocation of proceeds. As such, an amount of \$757,000 was allocated to the warrant liability and immediately recognized in general and administrative expenses in the consolidated statement of comprehensive loss, an amount of \$881,000 was allocated to Share capital.

In connection with the December 2015 Offering and in accordance with the anti-dilution provisions, the exercise prices of the January 2014 and March 2015 Series A and Series B warrants were adjusted to \$0.00 and \$4.95, respectively. The remaining January 2014 Warrants were exercised on December 30, 2015 and no longer remain outstanding.

November 2016 Offering

On November 1, 2016, the Company completed a registered direct offering of 2,100,000 units (the "Units"), with each Unit consisting of one common share or one pre-funded warrant to purchase one common share and 0.45 of a warrant to purchase one common share (the "November 2016 Offering").

Total gross cash proceeds raised through the November 2016 Offering amounted to approximately \$7.6 million, less cash transaction costs of approximately \$1.0 million, and previously deferred transactions costs of approximately \$27,000. The warrants are exercisable six months after their date of issuance and for a period of three years thereafter at an exercise price of \$4.70 per share.

The warrants contain a call provision which provides that, in the event the Company's common shares trade at or above \$10.00 on the market during a specified measurement period and subject to a minimum volume of trading during such measurement period, then, subject to certain conditions, the Company has the right to call for cancellation all or any portion of the warrants which are not exercised by holders within 10 trading days following receipt of a call notice from the Company. Upon complete exercise for cash, these warrants would result in the issuance of an aggregate of 945,000 common shares that would generate additional proceeds of approximately \$4.4 million, although these warrants may be exercised on a "net" or "cashless" basis. See also note 13-Warrant liability.

The Company estimated the fair value attributable to the warrants as of the date of grant by applying probability to multiple Black-Scholes pricing models, to which the following weighed average assumptions were applied: a risk-free annual interest rate of 0.63%, an expected volatility of 112.48%, an expected life of 1.63 years and a dividend yield of 0.0%. In addition, the Company reduced the fair value of these warrants to take into consideration the fair value of the \$10.00 call option, which was also calculated using the Black-Scholes pricing model with similar assumptions as described above. As a result, on November 1, 2016, being the date of issuance, the total fair value of the share purchase warrants was estimated at \$400,000.

The pre-funded warrants were offered in the November 2016 Offering to the investor because purchase of Units would have resulted in their beneficially owning more than an "initial beneficial ownership limitation" of 4.9% of our common shares following the offering. The pre-funded warrants, which were exercisable immediately upon issuance and for a period of five years at an exercise price of \$3.60 per share, were fully exercised between November 10, 2016 and December 19, 2016. Total gross proceeds payable to the Company in connection with the exercise of the pre-funded warrants were pre-funded by the investor and therefore were included in the proceeds of the offering. No additional consideration was required to be paid to the Company upon exercise of the pre-funded warrants.

Total gross proceeds of the November 2016 Offering were allocated as follows: \$400,000 was allocated to the warrant liability, \$3,239,000 was allocated to the pre-funded warrants, and the balance of \$3,921,000 was allocated to Share capital. Transaction costs were allocated to the liability and equity components in proportion to the allocation of proceeds. As such, an amount of \$56,000 was allocated to the warrant liability and immediately recognized in general and administrative expenses in the consolidated statement of comprehensive loss, an amount of \$544,000 was allocated to Share capital and an amount of \$450,000 was allocated to pre-funded warrants. Upon exercise of the pre-funded warrants, the net proceeds initially allocated to the pre-funded warrants were re-allocated to Share capital.

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### Shareholder rights plan

The Company has a shareholder rights plan (the "Rights Plan") that provides the Board of Directors and the Company's shareholders with additional time to assess any unsolicited take-over bid for the Company and, where appropriate, to pursue other alternatives for maximizing shareholder value. Under the Rights Plan, one right has been issued for each currently issued common share, and one right will be issued with each additional common share to be issued. The Rights Plan was approved, ratified and confirmed by the Company's shareholders at its annual meeting of shareholders held on May 10, 2016.

#### Stock options

The Company has in place a stock option plan (the "Stock Option Plan") for its directors, senior executives, employees and other collaborators who provide services to the Company. The total number of common shares that may be issued under the Stock Option Plan cannot exceed 11.4% of the total number of issued and outstanding common shares at any given time. The Company's Board of Directors amended the Stock Option Plan on March 20, 2014 and the Company's Shareholders approved, ratified and confirmed the Stock Option Plan on May 10, 2016.

Options granted under the Stock Option Plan prior to the 2014 amendment expire after a maximum period of ten years following the date of grant. Options granted after the 2014 amendment expire after a maximum period of seven years following the date of grant.

The following tables summarize the activity under the Stock Option Plan.

Years	ended	December 31,

	2016 20		2014		14	
US dollar-denominated options	Number	Weighted average exercise price (US\$)	Number	Weighted average exercise price (US\$)	Number	Weighted average exercise price (US\$)
Balance – Beginning of the year	272,874	25.88	33,956	187.36	17,575	339.61
Granted	713,573	3.47	243,000	5.17	19,515	93.03
Forfeited	(10,034)	99.22	(4,082)	136.17	(3,134)	453.77
Cancelled	(9,874)	157.00	_	_	_	_
Balance – End of the year	966,539	7.23	272,874	25.88	33,956	187.36

# Years ended December 31,

	20	2016 2015		2014		
Canadian dollar-denominated options	Number	Weighted average exercise price (CAN\$)	Number	Weighted average exercise price (CAN\$)	Number	Weighted average exercise price (CAN\$)
Balance – Beginning of the year	3,787	845.46	4,909	1,010.40	6,484	1,290.50
Forfeited	(1,028)	967.63	(271)	923.20	(810)	748.53
Cancelled	(901)	758.00	_	_	_	_
Expired	_	_	(851)	1,772.17	(765)	3,661.77
Balance – End of the year	1,858	820.27	3,787	845.46	4,909	1,010.40

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## US\$ options outstanding as at December 31, 2016

Exercise price (US\$)	Number	Weighted average remaining contractual life (years)	Weighted average exercise price (US\$)
3.45 to 3.47	611,075	6.93	3.45
3.48 to 4.19	102,498	6.54	3.57
4.20 to 40.29	234,000	5.97	4.58
40.30 to 114.00	10,325	5.04	86.15
114.01 to 2,178.00	8,641	5.09	295.77
	966,539	6.62	7.23

## US\$ options exercisable as at December 31, 2016

Exercise price (US\$)	Number	Weighted average remaining contractual life (years)	Weighted average exercise price (US\$)
4.20 to 40.29	78,004	5.97	4.58
40.30 to 114.00	7,818	5.12	88.62
114.01 to 2,178.00	7,925	5.13	310.88
	93,747	5.83	37.48

## CAN\$ options both outstanding and exercisable December 31, 2016

Exercise price (CAN\$)	Number	Weighted average remaining contractual life (years)	Weighted average exercise price (CAN\$)
330.00 to 480.00	530	1.89	367.70
480.01 to 741.00	502	2.93	570.00
741.01 to 1,002.00	471	3.87	912.00
1,002.01 to 1,941.00	222	0.94	1,092.00
1,941.01 to 2,790.00	133	0.01	2,790.00
	1,858	2.43	820.27

As at December 31, 2016, the total compensation cost related to unvested US Dollar stock options not yet recognized amounted to \$2,057,188 (\$1,221,998 in 2015). This amount is expected to be recognized over a weighted average period of 1.71 years (1.70 years in 2015).

The Company settles stock options exercised through the issuance of new common shares as opposed to purchasing common shares on the market to settle stock option exercises.

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## Fair value input assumptions for US dollar-denominated options granted

The table below shows the assumptions, or weighted average parameters, applied to the Black-Scholes option pricing model in order to determine share-based compensation costs over the life of the awards.

		Years ended December 31,		
		2016	2015	
Expected dividend yield	(a)	0.0 %	0.0 %	
Expected volatility	<b>(b)</b>	115.1 %	110.5 %	
Risk-free annual interest rate	(c)	1.80 %	1.79 %	
Expected life (years)	(d)	4.92	5.77	
Weighted average share price		\$3.47	\$5.65	
Weighted average exercise price		\$3.47	\$5.17	
Weighted average grant date fair value		\$2.80	\$4.69	

<sup>(</sup>a) The Company has not paid dividends and it does not intend to pay dividends in the foreseeable future.

The Black-Scholes pricing models referred above use "Level 2" inputs in calculating fair value, as defined by IFRS 13, and as discussed in note 21 - Financial instruments and financial risk management.

<sup>(</sup>b) Based on the historical volatility of the Company's stock price over the most recent period consistent with the expected life of the stock options, as well as on future expectations.

<sup>(</sup>c) Based on United States Treasury Government Bond interest rates with a term that is consistent with the expected life of the stock options.

<sup>(</sup>d) Based upon historical data related to the exercise of stock options, on post-vesting employment terminations and on future expectations related to exercise behavior.

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## 16 Operating expenses

Components of the Company's operating expenses from continuing operations include the following:

	Years ended December 31,		
	2016	2015	2014
	\$	\$	\$
Key management personnel compensation <sup>(1)</sup>			
Salaries and short-term employee benefits	2,430	2,957	2,405
Termination benefits (note 12)	_	843	439
Post-employment benefits	78	119	77
Share-based compensation costs	1,051	828	392
_	3,559	4,747	3,313
Other employees compensation:			
Salaries and short-term employee benefits	3,574	4,431	7,663
Termination benefits (note 12)	_	245	1,984
Post-employment benefits	500	511	832
Share-based compensation costs	31	91	105
_	4,105	5,278	10,584
Goods and services <sup>(2)</sup>	21,217	21,429	19,016
Leasing costs, net of sublease receipts of \$345 in 2016, \$380 in 2015 and \$344 in 2014 <sup>(3)</sup>	1,131	1,452	1,802
Refundable tax credits and grants	_	(23)	(131)
Onerous contract expenses resulting from the Resource Optimization Program and from the Corporate Restructuring (note 12)	_	(202)	563
Transaction costs related to share purchase warrants	56	2,208	666
Depreciation and amortization	195	271	488
Impairment losses	85	70	390
Operating foreign exchange losses	39	199	715
	22,723	25,404	23,509
	30,387	35,429	37,406

<sup>(1)</sup> Key management includes the Company's directors and members of the executive management team.

Most of the employment agreements entered into between the Company and its executive officers include termination provisions, whereby the executive officers would be entitled to receive benefits that would be payable if the Company were to terminate the executive officers' employment without cause or if their employment is terminated following a change of control. Separation benefits generally are calculated based on an agreed-upon multiple of applicable base salary and incentive compensation and, in certain cases, other benefit amounts.

<sup>(2)</sup> Goods and services include third-party R&D costs, laboratory supplies, professional fees, contracted sales force costs, marketing services, insurance and travel expenses.

<sup>(3)</sup> Leasing costs also include changes in the onerous lease provision (note 14 - Provisions and non-current liabilities), other than attributable to the unwinding of the discount.

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### 17 Employee future benefits

The Company's subsidiary in Germany provides unfunded defined benefit pension plans and unfunded post-employment benefit plans for certain groups of employees. Provisions for pension obligations are established for benefits payable in the form of retirement, disability and surviving dependent pensions.

The unfunded defined benefit pension plans are final salary pension plans, which provide benefits to members (or to their surviving dependents) in the form of a guaranteed level of pension payable for life. The level of benefits provided depends on the member's length of service and on his or her base salary in the final years leading up to retirement. Current pensions vary in accordance with applicable statutory requirements, which foresee an adjustment every three years on an individual basis that is based on inflationary increases or in relation to salaries of comparable groups of active employees in the Company. An adjustment may be denied by the Company if the Company's financial situation does not allow for an increase in pensions. These plans are unfunded, and the Company meets benefit payment obligations as they fall due.

The change in the Company's accrued benefit obligations is summarized as follows:

	Pension benefit plans Years ended December 31,		Other benefit plans Years ended December 31,			
	2016	2015	2014	2016	2015	2014
•	\$	\$	\$	\$	\$	\$
Balance – Beginning of year	12,375	14,619	14,646	281	433	762
Current service cost	87	103	176	13	14	24
Interest cost	282	260	476	_	8	25
Actuarial loss (gain) arising from changes in financial assumptions	1,479	(844)	1,833	_	(34)	(96)
Benefits paid	(399)	(410)	(411)	(60)	(97)	(210)
Impact of foreign exchange rate changes	(627)	(1,353)	(2,101)	(17)	(43)	(72)
Balance – End of year	13,197	12,375	14,619	217	281	433
Amounts recognized:						
In comprehensive loss	(369)	(363)	(652)	(13)	12	47
In other comprehensive loss	(852)	2,197	268	17	43	72

The cumulative amount of actuarial net losses recognized in other comprehensive loss as at December 31, 2016 is approximately \$4,971,000 (approximately \$3,492,000 as at December 31, 2015 and approximately \$4,336,000 as at December 31, 2014).

The significant actuarial assumptions applied to determine the Company's accrued benefit obligations are as follows:

	Pension benefit plans		Other benefit plans				
	Year	Years ended December 31,			Years ended December 31,		
Actuarial assumptions	2016	2016 2015		2016	2015	2014	
	%	%	%	%	%	%	
Discount rate	1.60	2.40	2.00	1.60	2.40	2.00	
Pension benefits increase	1.80	1.80	1.80	1.80	2.40	1.80	
Rate of compensation increase	2.00	2.00	2.00	2.00	2.00	2.00	

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The calculation of the pension benefit obligation is sensitive to the discount rate assumption. Since January 1, 2016, management determined that the discount rate assumption should be adjusted from 2.4% to 1.6% as a result of changes in the European economic environment.

Assumptions regarding future mortality are set based on actuarial advice in accordance with published statistics and experience in Germany. These assumptions translate into an average remaining life expectancy in years for a pensioner retiring at age 65:

	2016	2015	2014
Retiring at the end of the reporting period:			
Male	20	20	19
Female	24	24	23
Retiring 20 years after the end of the reporting period:			
Male	22	22	22
Female	26	26	26

The most recent actuarial reports give effect to the pension and post-employment benefit obligations as at December 31, 2016. The next actuarial reports are planned for December 31, 2017.

In accordance with the assumptions used as at December 31, 2016, undiscounted defined pension benefits expected to be paid are as follows:

	\$
2017	420
2018	436
2019	455
2020	466
2021	471
Thereafter	15,165
	17,413

The weighted average duration of the defined benefit obligation is 16.8 years.

Total expenses for the Company's defined contribution plan in its German subsidiary amounted to approximately \$129,000 for the year ended December 31, 2016 (\$159,000 for 2015 and \$223,954 for 2014).

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## 18 Supplemental disclosure of cash flow information

	Years ended December 31,		
	2016	2015	2014
	\$	\$	\$
Changes in operating assets and liabilities:			
Trade and other receivables	228	270	(578)
Prepaid expenses and other current assets	(45)	(111)	(2,453)
Other non-current assets	(233)	58	(204)
Payables and accrued liabilities	(313)	(1,013)	1,732
Deferred revenues	555	_	1,101
Provision for restructuring costs (note 12)	(566)	(1,840)	(687)
Employee future benefits (note 17)	(459)	(507)	(621)
Provisions and other non-current liabilities	(231)	(252)	(163)
	(1,064)	(3,395)	(1,873)

During the year ended December 31, 2014, the Company paid approximately \$111,000 in income taxes in the form of foreign jurisdiction withholding tax on payments received pursuant to the agreements entered into with Sinopharm, as discussed in note 5 - Deferred revenues related to licensing arrangements and co-development agreement.

# 19 Income taxes

Significant components of current and deferred income tax expense are as follows:

	Years ended December 31,				
	2016	2015	2014		
	<u> </u>	\$	\$		
Current tax expense	_	_	111		
Deferred tax:					
Origination and reversal of temporary differences	9,199	8,581	10,785		
Adjustments in respect of prior years	36	_	5		
Change in unrecognized tax assets	(9,235)	(8,581)	(10,790)		
Income tax expense			111		

The reconciliation of the combined Canadian federal and provincial income tax rate to the income tax expense is provided below:

	Years ended December 31,			
	2016	2014		
Combined Canadian federal and provincial statutory income				
tax rate	26.9%	26.9%	26.9%	

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	Years ended December 31,		
	2016	2015	2014
	\$	\$	\$
Income tax recovery based on combined statutory income tax			
rate	6,714	13,511	4,426
Change in unrecognized tax assets	(9,235)	(8,581)	(10,790)
Change in unrecognized tax assets related to OCI	436	(269)	585
Share issuance costs	224	<del>_</del>	_
Permanent difference attributable to the use of local currency for			
tax reporting	(30)	(1,297)	145
Change in enacted rates used	(16)	_	_
Permanent difference attributable to net change in fair value of			
warrant liability	1,194	(3,754)	4,408
Share-based compensation costs	(291)	(248)	(133)
Difference in statutory income tax rate of foreign subsidiaries	972	1,135	1,398
Permanent difference attributable to expiring loss carry forward	_	(563)	_
Foreign withholding tax	_	_	(111)
Adjustments in respect of prior years	36	_	5
Other	(4)	66	(44)
			(111)

Income tax expense in each of the years ended December 31, 2016 and December 31, 2015 was nil as compared to an income tax expense of \$111,000 for the year ended December 31, 2014, which represents current taxation in the form of foreign jurisdiction tax withholdings on payments pursuant to the License Agreement entered into with Sinopharm (note 5 - Deferred revenues related to licensing arrangements and co-development agreement).

Deferred income tax assets are recognized to the extent that the realization of the related tax benefit through reversal of temporary differences and future taxable profits is probable.

Loss before income taxes

Loss before income taxes is attributable to the Company's tax jurisdictions as follows:

	Ye	Years ended December 31,			
	2016	2015	2014		
	<u> </u>	\$	\$		
Germany	(19,179)	(20,500)	(29,672)		
Canada	(5,659)	(29,496)	12,867		
United States	(121)	(232)	(271)		
	(24,959)	(50,228)	(17,076)		

Notes to Consolidated Financial Statements

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

Significant components of deferred tax assets and liabilities are as follows:

	As at Decem	ber 31,
	2016	2015
	<u> </u>	\$
Deferred tax assets		
Non-current:		
Operating losses carried forward	1,009	1,355
Intangible assets	5,199	6,242
	6,208	7,597
Deferred tax liabilities		
Current:		
Payables and accrued liabilities	109	327
	109	327
Non-current:		
Property, plant and equipment	7	9
Deferred revenues	5,658	6,868
Warrant liability	386	390
Other	48	3
	6,099	7,270
	6,208	7,597
Deferred tax assets (liabilities), net		_

Significant components of unrecognized deferred tax assets are as follows:

	December 31,		
	2016	2015	
	\$	\$	
Deferred tax assets			
Current:			
Deferred revenues and other provisions	217	167	
	217	167	
Non-current:			
Deferred Revenues	_	155	
Operating losses carried forward	71,654	64,471	
Research and development costs	9,195	9,207	
Unused tax credits	8,019	7,977	
Employee future benefits	2,275	1,919	
Property, plant and equipment	175	219	
Share issuance expenses	941	1,226	
Onerous contract provisions	26	96	
Intangible assets	189	190	
Other	144	197	
	92,618	85,657	
Unrecognized deferred tax assets	92,835	85,824	

Notes to Consolidated Financial Statements

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

As at December 31, 2016, amounts and expiry dates of tax attributes to be deferred for which no deferred tax asset was recognized were as follows:

	Canada	
	Federal	Provincial
-	\$	\$
2028	6,429	5,043
2029	4,791	4,773
2030	4,104	4,089
2031	1,753	1,737
2032	4,250	4,250
2033	3,721	3,721
2034	4,153	4,153
2035	9,752	9,786
2036	11,259	11,259
	50,212	48,811

The Company has estimated non-refundable R&D investment tax credits of approximately \$8,019,000 which can be carried forward to reduce Canadian federal income taxes payable and which expire at dates ranging from 2018 to 2035. Furthermore, the Company has unrecognized tax assets in respect of operating losses to be carried forward in Germany and in the United States. The federal tax losses amount to approximately \$184,386,000 in Germany, for which there is no expiry date, and to \$1,340,000 in the United States, which expire as follows:

	United States
	<u> </u>
2028	369
2029	178
2034	151
2035	447
2036	195
	1,340

The operating loss carryforwards and the tax credits claimed are subject to review, and potential adjustment, by tax authorities. Other deductible temporary differences for which tax assets have not been booked are not subject to a time limit, except for share issuance expenses which are amortizable over five years.

## 20 Capital disclosures

The Company's 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 and working capital requirements.

Over the past several years, the Company has raised capital via public equity offerings and drawdowns under various ATM sales programs as its primary source of liquidity, as discussed in note 15 - Share capital.

The capital management objective of the Company 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 the Company's product development portfolio and to pursue appropriate commercial opportunities as they may arise.

The Company is not subject to any capital requirements imposed by any regulators or by any other external source.

Notes to Consolidated Financial Statements

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

### 21 Financial instruments and financial risk management

Financial assets (liabilities) as at December 31, 2016 and December 31, 2015 are presented below.

December 31, 2016	Loans and receivables	Financial liabilities at FVTPL	Other financial liabilities	Total
	\$	\$	\$	\$
Cash and cash equivalents (note 6)	21,999	_	_	21,999
Trade and other receivables (note 7)	235	_	_	235
Restricted cash equivalents	496	_	_	496
Payables and accrued liabilities (note 11)	_	_	(3,352)	(3,352)
Provision for restructuring costs (note 12)	_	_	(33)	_
Warrant liability (note 13)	_	(6,854)	_	(6,854)
Other non-current liabilities (note 14)	_	_	(98)	(98)
	22,730	(6,854)	(3,483)	12,393

December 31, 2015	Loans and receivables	Financial liabilities at FVTPL	Other financial liabilities	Total
	\$	\$	\$	\$
Cash and cash equivalents (note 6)	41,450	_	_	41,450
Trade and other receivables (note 7)	297	_	_	297
Restricted cash equivalents	255	_	_	255
Payables and accrued liabilities (note 11)	_	_	(3,837)	(3,837)
Provision for restructuring costs (note 12)	_	_	(625)	(625)
Warrant liability (note 13)	_	(10,891)	_	(10,891)
Other non-current liabilities (note 14)	_	_	(98)	(98)
	42,002	(10,891)	(4,560)	26,551

#### Fair value

The Black-Scholes valuation methodology uses "Level 2" inputs in calculating fair value, as defined in IFRS 13, which establishes a hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The input levels discussed in IFRS 13 are:

Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than quoted prices included within Level 1 that are observable for an asset or liability, either directly (i.e. prices) or indirectly (i.e. derived from prices).

Level 3 – Inputs for an asset or liability that are not based on observable market data (unobservable inputs).

The carrying values of the Company's cash and cash equivalents, trade and other receivables, restricted cash equivalents, payables and accrued liabilities, provision for restructuring costs and other non-current liabilities approximate their fair values due to their short-term maturities or to the prevailing interest rates of the related instruments, which are comparable to those of the market.

Notes to Consolidated Financial Statements

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

#### 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 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 the loans and receivables in the table above. 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 rating of at least "P-2" 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, 2016, trade accounts receivable for an amount of approximately \$155,000 were with three counterparties, and no trade accounts receivable were past due and none were 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 of 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 in the Company's consolidated 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 note 20 - Capital disclosures, 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 occurring outside 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 the absence of sufficient corresponding revenues. The Company's ability to continue future operations until and beyond December 31, 2017 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, which could include using any then available "at-the-market" equity issuance program 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. See note 1 - Summary of business, going concern, reporting entity and basis of preparation for further details.

# (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 option pricing models, of currently outstanding share purchase warrants. These valuation models are impacted, among other inputs, by the market price of the Company's common

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

shares. As a result, the change in fair value of the warrant liability, which is reported in the consolidated statements of comprehensive loss, has been and may continue in future periods to be materially affected most notably by changes in the Company's common share closing price, which on the NASDAQ, has ranged from \$2.67 to \$4.94 during the year ended December 31, 2016.

If variations in the market price of our common shares of -30% and +30% were to occur, the impact on the Company's net loss related to the warrant liability held at December 31, 2016 would be as follows:

	Carrying		
	amount	-30%	+30%
	\$	\$	\$
Warrant liability	6,854	2,656	(2,448)
Total impact on net loss – decrease / (increase)		2,656	(2,448)

## 22 Segment information

The Company operates in a single operating segment, being the biopharmaceutical segment.

#### Geographical information

Revenues by geographical area are detailed as follows:

	Y	Years ended December 31,		
	2016	2015	2014	
	<u> </u>	\$	\$	
United States	410	217	6	
China	249	302	_	
Singapore	101	_	_	
British Virgin Islands	100	_	_	
Switzerland	_	312	956	
Other	51	45	86	
	911	876	1,048	
Amounts presented:				
Within discontinued operations	<u> </u>	331	1,037	
Within continuing operations	911	545	11	
	911	876	1,048	

Revenues have been allocated to geographic regions based on the country of residence of the Company's external customers or licensees.

Non-current assets\* by geographical area are detailed as follows:

	December 31,		
	2016	2015	
	\$	\$	
Germany	7,793	8,280	
United States	2	_	
Canada	32	49	
	7,827	8,329	

<sup>\*</sup> Non-current assets include property, plant and equipment, identifiable intangible assets and goodwill.

# Aeterna Zentaris Inc.

Notes to Consolidated Financial Statements

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

Major customers representing 10% or more of the Company's revenues in each of the last three years are as follows:

	Years ended December 31,			
	2016	2015	2014	
·	<b>\$</b>	\$	\$	
Company 1*	_	312	956	
Company 2	20	217	_	
Company 3	249	302	_	
Company 4	222	_	_	
Company 5	167	_	_	
Company 6	101	_	_	
Company 7	100	_	_	

Related to Cetrotide® (discontinued operations).

## 23 Net loss per share

The following table sets forth pertinent data relating to the computation of basic and diluted net (loss) income per share attributable to common shareholders.

	Years ended December 31,			
	2016	2015	2014	
	\$	\$	\$	
Net loss from continuing operations	(24,959)	(50,228)	(17,187)	
Net income from discontinued operations	_	85	623	
Net loss	(24,959)	(50,143)	(16,564)	
Basic weighted average number of shares outstanding	10,348,879	2,763,603	590,247	
Dilutive effect of stock options *	_	5,094	_	
Dilutive effect of share purchase warrants *	316,270	655,639	_	
Diluted weighted average number of shares outstanding *	10,665,149	3,424,336	590,247	
Items excluded from the calculation of diluted net loss per share because the exercise price was greater than the average market price of the common shares				
Stock options	968,397	36,661	23,242	
Warrants (number of equivalent shares)	3,331,671	55,671	287,852	

<sup>\*</sup> Net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding during the relevant period. Diluted weighted average number of shares reflects the dilutive effect of equity instruments, such as any "in the money" stock options and share purchase warrants. In periods with reported net losses, all stock options and share purchase warrants are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal, and thus existing stock options and share purchase warrants have not been included in the computation of net loss per share because to do so would be anti-dilutive.

## Aeterna Zentaris Inc.

Notes to Consolidated Financial Statements

As at December 31, 2016 and December 31, 2015 and for the years ended December 31, 2016, 2015 and 2014

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

#### 24 Commitments and contingencies

The Company is committed to various operating leases for its premises. 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, 2016 are as follows:

	Minimum lease payments	Minimum sublease receipts	Service and manufacturing	
	\$	\$	\$	
Less than 1 year	1,341	(351)	2,891	
1 - 3 years	2,012	(151)	83	
4 - 5 years	1,101	_	_	
Total	4,454	(502)	2,974	

### Contingencies

In the normal course of operations, the Company may become involved in various claims and legal proceedings related to, for example, contract terminations and employee-related and other matters. No contingent liabilities have been accrued as at December 31, 2016 or 2015.

### 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<sup>TM</sup> 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. The Company subsequently filed a motion to dismiss the second amended complaint. On March 2, 2016, the Court issued an order granting the Company's motion to dismiss the complaint in part and denying it in part. The Court dismissed certain of the Company's current and former officers from the lawsuit. The Court allowed the claim that the Company omitted material facts from its public statements during the Class Period to proceed against the Company and its 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.

The Company filed a motion for reconsideration of the Court's March 2, 2016 order on March 16, 2016 and filed an answer to the second amended complaint on April 6, 2016. On June 30, 2016, the Court issued an order denying the Company's motion for reconsideration. As a result, the lawsuit will proceed to the class certification phase and the discovery process has commenced.

The Company's directors' and officers' insurance policies ("D&O Insurance") provide for reimbursement of certain costs and expenses incurred in connection with the defense of this lawsuit, including legal and professional fees, as well as other loss (damages, settlements, and judgments), if any, subject to certain policy exclusions, restrictions, limits, deductibles and other terms. The Company believes that the D&O Insurance applies to the purported lawsuit; however, the insurers have issued standard reservations of rights letters reserving all rights under the D&O Insurance. Legal and professional fees are expensed as incurred, and no reserve is established for them. During the second quarter of 2016, the Company exceeded the deductible amount applicable to this claim. Therefore, the Company believes that the insurers will bear most of the costs for the Company's defense in future periods, subject to the Company's policy limits.

## Aeterna Zentaris Inc.

Notes to Consolidated Financial Statements

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

While the Company believes that it has meritorious defenses and intends to defend this lawsuit vigorously, management cannot currently predict the outcome of this suit or reasonably estimate any potential loss that may result from this suit. Accordingly, the Company has not recorded any liability related to the lawsuit. No assurance can be given with respect to the ultimate outcome of such proceedings, and the Company could incur substantial unreimbursed legal fees, damages, settlements, judgments, and other expenses in connection with these proceedings that may not qualify for coverage under, or may exceed the limits of, its applicable D&O Insurance and could have a material adverse impact on the Company's financial condition, results of operations, liquidity and cash flows.

### 25 Subsequent events

On January 4, 2017, the Company announced that the confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup> (macimorelin) failed to achieve its objective of validating a single oral dose of macimorelin for the evaluation of growth hormone deficiency in adults ("AGHD"), using the "Insulin Tolerance Test" (the "ITT") as a comparator. Based on an analysis of top-line data, macimorelin did not achieve equivalence to the ITT as a means of diagnosing AGHD. Under the study protocol, the evaluation of AGHD with Macrilen<sup>TM</sup> would be considered successful, if the lower bound of the two-sided 95% confidence interval for the primary efficacy variables was 75% or higher for "percent negative agreement" with the ITT, and 70% or higher for the "percent positive agreement" with the ITT. While the estimated percent negative agreement met the success criteria, the estimated percent positive agreement did not reach the criteria for a successful outcome. Therefore, the results did not meet the pre-defined equivalence criteria which required success for both the percent negative agreement and the percent positive agreement. However, on February 13, 2017, the Company announced that, following a comprehensive review of data obtained from the confirmatory Phase 3 clinical trial, it concluded that Macrilen<sup>TM</sup> has demonstrated performance supportive of achieving FDA registration and that the Company intends to pursue registration. The announcement set forth the facts on which the Company's conclusion was based. The Company will meet with the FDA at the end of March 2017 to discuss this position.

On January 30, 2017, the Company announced the occurrence of the 384th death in the pivotal Phase 3 study for Zoptrex<sup>TM</sup> in women with advanced, recurrent or metastatic endometrial cancer, representing the clinical endpoint of the study. The Company currently expects to lock the clinical database and to report top-line results in April 2017.

Subsequent to December 31, 2016, the Company issued an additional 555,068 common shares under the April 2016 ATM Program at an average price of approximately \$3.20 per share for gross proceeds of approximately \$1.8 million.

### Item 19. Exhibits

#### **Exhibit Index**

- 1.1 Restated Certificate of Incorporation and Restated Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 99.2 to the Registrant's report on Form 6-K furnished to the Commission on May 25, 2011)
- 1.2 Certificate of Amendment and Articles of Amendment of the Registrant (incorporated by reference to Exhibit 99.2 to the Registrant's report on Form 6-K furnished to the Commission on October 3, 2012)
- 1.3 Certificate of Amendment and Articles of Amendment of the Registrant (incorporated by reference to Exhibit 99.1 to the Registrant's report on Form 6-K furnished to the Commission on November 17, 2015)
- 1.4 Amended and Restated By-Law One of the Registrant (incorporated by reference to Exhibit 1.3 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2012 filed with the Commission on March 22, 2013)
- 2.1 Shareholder Rights Plan Agreement between the Registrant and Computershare Trust Company of Canada, as Rights Agent, dated as at March 29, 2016 (incorporated by reference to Exhibit 99.1 to the Registrant's report on Form 6-K furnished to the Commission on March 30, 2016)
- 4.1 Second Amended and Restated Stock Option Plan of the Registrant (incorporated by reference to Exhibit 4.1 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2013 filed with the Commission on March 21, 2014)
- 4.2 Employment Agreement dated November 1, 2013 between Jude Dinges and a subsidiary of the Registrant (incorporated by reference to Exhibit 4.4 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2013 filed with the Commission on March 21, 2014)
- 4.3 Employment Agreement dated April 15, 2013 between David A. Dodd and a subsidiary of the Registrant (incorporated by reference to Exhibit 4.5 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2013 filed with the Commission on March 21, 2014)
- 4.4 Service Contract dated January 1, 2014 between Richard Sachse, MD and Aeterna Zentaris GmbH, a subsidiary of the Registrant (incorporated by reference to Exhibit 4.8 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2013 filed with the Commission on March 21, 2014)
- 4.5 Employment Agreement dated November 11, 2013 between Keith Santorelli and a subsidiary of the Registrant (incorporated by reference to Exhibit 4.5 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)
- 4.6 Amendment #1 to Employment Agreement dated May 29, 2014 between a subsidiary of the Registrant and Keith Santorelli (incorporated by reference to Exhibit 4.6 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)
- 4.7 Amendment #2 to Employment Agreement, dated October 9, 2015, between a subsidiary of the Registrant and Keith Santorelli (incorporated by reference to Exhibit 4.7 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2015 filed with the Commission on March 29, 2016)
- 4.8 Transition letter agreement, dated October 9, 2015, between a subsidiary of the Registrant and Keith Santorelli (incorporated by reference to Exhibit 4.8 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2015 filed with the Commission on March 29, 2016)
- 4.9 Amended and Restated Consulting Agreement dated February 17, 2016 between Genevieve Lemaire and the Registrant
- 4.10 Master Collaboration Agreement by and between Aeterna Zentaris GmbH, a subsidiary of the Registrant, and Sinopharm A-think Pharmaceuticals Co., Ltd, dated as of December 1, 2014 (incorporated by reference to Exhibit 99.2 of the Registrant's report on Form 6-K furnished to the Commission on December 11, 2014).
- 4.11 License Agreement by and between Aeterna Zentaris GmbH, a subsidiary of the Registrant, and Sinopharm A-think Pharmaceuticals Co., Ltd, dated as of December 1, 2014 (incorporated by reference to Exhibit 99.3 of the Registrant's report on Form 6-K furnished to the Commission on December 11, 2014).
- 4.12 Technology Transfer and Technical Assistance, Agreement by and between Aeterna Zentaris GmbH, a subsidiary of the Registrant, and Sinopharm A-think Pharmaceuticals Co., Ltd, dated as of December 1, 2014 (incorporated by reference to Exhibit 99.4 of the Registrant's report on Form 6-K furnished to the Commission on December 11, 2014).
- 8.1 Subsidiaries of the Registrant
- 11.1 Code of Ethical Conduct of the Registrant (incorporated by reference to Exhibit 11.1 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2008 filed with the Commission on March 30, 2009)
- 11.2 Code of Business Conduct and Ethics for Members of the Board of Directors (incorporated by reference to Exhibit 11.2 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)
- 11.3 Audit Committee Charter of the Registrant (incorporated by reference to Exhibit 11.3 of the Registrant's Annual Report on Form 20F for the financial year ended December 31, 2014 filed with the Commission on March 17, 2015)
- 12.1 Certification of the Principal Executive Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002
- 12.2 Certification of the Principal Financial Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002
- 13.1 Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 13.2 Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 15.1 Consent of the Independent Auditors

# **SIGNATURES**

The registrant hereby of	certifies that it mee	ts all of the requirem	ents for filing on I	Form 20-F and	I that it has duly	caused and authorized	the undersigned t	o sign
this annual report on it	s behalf.							

AETERNA ZENTARIS INC.

/s/ David A. Dodd

David A. Dodd President and Chief Executive Officer

Date: March 15, 2017

### AMENDED AND RESTATED CONSULTING AGREEMENT

THIS AMENDED AND RESTATED CONSULTING AGREEMENT (this "*Agreement*"), dated as of February 17, 2016, is between Aeterna Zentaris Inc., a corporation with an address at 2500-1 PLACE Ville Marie Montréal Québec H3B 1R1, Canada (the "*Company*"), and Geneviève Lemaire, *CPA, CA, CPA (Illinois)*, with an address at 44 Montée du Bois Franc, Lac-Beauport, Québec, Canada G3B 1Y5 (the "*Consultant*").

The parties agree as follows:

- 1. Consulting Service. The Consultant agrees that during the term of this Agreement:
  - (A) The Consultant's role will be to fill all responsibilities of the position of Vice President, Finance and Chief Accounting Officer of the Company for an interim period, performing the specific duties listed on <a href="Exhibit 1">Exhibit 1</a> to this Agreement. The Board of Directors of the Company has appointed you to such office effective as of the termination of the employment of Keith Santorelli at the close of business on February 18, 2016. As an officer of the Company elected by the Board, you will be covered by the Company's D&O policy, which will be confirmed by an acknowledgment obtained from our primary D&O carrier.
  - (B) The Consultant will devote best efforts to such position as consultant and an independent contractor to the Company. In addition, the Consultant will be available to train the new Corporate Controller when this person will be hired and will provide advice and assistance to the Company from time to time as requested by the Company's Audit Committee and Management. The Consultant shall be available during the term of this Agreement to assist the Company as requested by Management and at the Company's sole discretion to offer consulting, advice, and assistance or to perform other activities related to the finance function of the Company. The Consultant shall be acting in the capacity of an independent contractor, and not as an employee of the Company. The Consultant shall not be subject to the direct control or supervision of the Management of the Company with respect to the time spent, research undertaken, or procedures followed in the performance of consulting services rendered hereunder.
  - (C) The Consultant shall exercise a reasonable degree of skill, prudence and care in performing these services.
  - (D) Nothing contained in this Agreement shall limit or restrict the Consultant from serving as an employee, officer or director of other companies or entities, and the Consultant may provide consulting services for other companies or organizations, provided that such activities do not conflict with the services and activity that the Consultant is rendering to the Company or any of its subsidiaries or the services or activities of the Company and its subsidiaries.
  - (E) The Consultant shall be available to render such consulting services to the Company under this Agreement during the term of this Agreement. The Consultant shall not be obligated to render any services under this Agreement during such period when she is unable to do so due to illness, disability or injury;
  - (F) The Consultant shall not enter into agreements or make commitments on behalf of the Company, except when approved by management and permitted in the delegation of authority approved by the Board of Directors.
  - (G) It is possible that the Consultant will have to travel to fulfill her responsibilities. The Company will reimburse all out of pocket expenses incurred.

## 2. Compensation.

- (A) The Company agrees to pay the Consultant for her services performed under this Agreement at an hourly rate of CDN\$170 (one hundred and seventy dollars). Such fees will be paid directly to the Consultant upon presentation of detailed invoice. The parties agree that the Consultant shall not be entitled to participate in or to receive benefits pursuant to any Company program customarily made available to Company employees. The Consultant acknowledges that she is not being covered by any worker compensation policy or program provided or managed by the Company.
- (B) At the conclusion of Consultant's arrangement with the Company on the terms set out herein, Consultant will be paid a bonus in the amount of CDN\$20,000.
- 3. <u>Term and Termination</u>. The term of this Agreement shall continue indefinitely ("*Term*"), unless otherwise terminated in accordance with the provisions set forth below.
  - (A) Termination for Cause. The Company may terminate this Agreement at any time for "Just Cause". Termination for Just Cause shall be defined as:

    (i) If the Consultant shall have engaged in conduct involving fraud, deceit, personal dishonesty, or breach of fiduciary duty; (ii) If the Consultant shall have violated any banking law or regulation, memorandum of understanding, cease and desist order, or other agreement with any banking agency having jurisdiction over the Company which, in the judgment of the Company, has adversely affected, or may adversely affect, the business or reputation of the Company as determined by the Company; (iii) If the Consultant shall have become subject to continuing intemperance in the use of alcohol or drugs which has adversely affected, or may adversely affect, the business or reputation of the Company as determined by the Company; (iv) If the Consultant shall have filed, or had filed against her, any petition under the federal bankruptcy laws or any provincial insolvency laws; or (v) If any regulatory authority having jurisdiction over the Company, or its subsidiaries, initiates any proceedings against the Consultant.

### AMENDED AND RESTATED CONSULTING AGREEMENT

- (B) <u>Termination following Recruitment of CFO</u>. The Company intends to commence a search for a Senior Vice President, Chief Financial Officer in the near future. The Company cannot predict the duration of the search; however, the Company believes that the search may require five to six months. The Company will keep you informed of the status of the search and may request that you participate in the review of résumés or that you interview candidates. In any event, you will be notified when a candidate is hired and this Agreement shall terminate 120 days after the date of hire of the CFO (unless we agree on a different period before this Agreement expires).
- (C) <u>Disability or Death</u>. In the event of the disability or death of the Consultant, this Agreement shall terminate without further action by the Company; provided that the Company shall be obligated to pay the Consultant (or her estate) for any periods of work performed prior to disability or death of the Consultant.
- 5. <u>Confidential Business</u>. The Consultant, during the Term of this Agreement, will not, without the express written consent of Company, directly or indirectly communicate or divulge to, or use for her own benefit or for the benefit of any other person, firm, association, or corporation, any trade secrets, proprietary data or other confidential information communicated to or otherwise learned or acquired by the Consultant from the Company while serving as a consultant, except that the Consultant may disclose such matters to the extent that disclosure is (a) requested by the Company or (b) required by a court or other governmental agency of competent jurisdiction.

### 6. General.

- (A) <u>Entire Agreement and Amendments.</u> This Agreement is the entire agreement between the parties and supersedes all earlier and simultaneous agreements regarding the subject matter. This Agreement may be amended only in a written document, signed by both parties.
- (B) <u>Independent Contractors, Third Party Beneficiaries, and Subcontractors</u>. The parties acknowledge that they are independent contractors under this Agreement, and except if expressly stated otherwise, neither the Consultant, nor any of her employees or agents, has the power or authority to bind or obligate the Company. Except if expressly stated, no third party is a beneficiary of this Agreement.
- (C) <u>Assignment</u>. This Agreement binds and inures to the benefit of the parties' successors and assigns. This Agreement may not be assigned, delegated, sublicensed or otherwise transferred by the Consultant in whole or in part without the prior written consent of Company. Any transfer, assignment, delegation or sublicense by the Consultant without such consent is invalid.
- (D) No Waivers, Cumulative Remedies. A party's failure to insist upon strict performance of any provision of this Agreement is not a waiver of any of its rights under this Agreement. Except if expressly stated otherwise, all remedies under this Agreement, at law or in equity, are cumulative and nonexclusive.
- (E) <u>Severability</u>. If any portion of this Agreement is held to be unenforceable, the unenforceable portion must be construed as nearly as possible to reflect the original intent of the parties, the remaining portions remain in full force and effect, and the unenforceable portion remains enforceable in all other contexts and jurisdictions.
- (F) <u>Notices</u>. All notices, including notices of address changes, under this Agreement must be sent by registered or certified mail or by overnight commercial delivery to the address set forth in this Agreement by each party.
- (G) <u>Captions and Plural Terms</u>. All captions are for purposes of convenience only and are not to be used in interpretation or enforcement of this Agreement. Terms defined in the singular have the same meaning in the plural and vice versa.
- (H) Governing Law. This Agreement shall be governed by the laws of the Province of Québec (without giving effect to internal choice of law rules).
- (I) <u>Language of Agreement</u>. The parties have expressly requested that the present document be drafted in English. *Les parties ont expressément demandé* à ce que le présent document soit rédigé en anglais.

**IN WITNESS WHEREOF**, the parties execute this Agreement. Each person who signs this Agreement below represents that such person is fully authorized to sign this Agreement on behalf of the applicable party.

COMPANY CONSULTANT

By: /s/ David A. Dodd By: /s/ Geneviève Lemaire

Name: David A. Dodd Name: Geneviève Lemaire

Title: Chairman, President and CEO Title: CPA, CA, CPA (Illinois)

### AMENDED AND RESTATED CONSULTING AGREEMENT

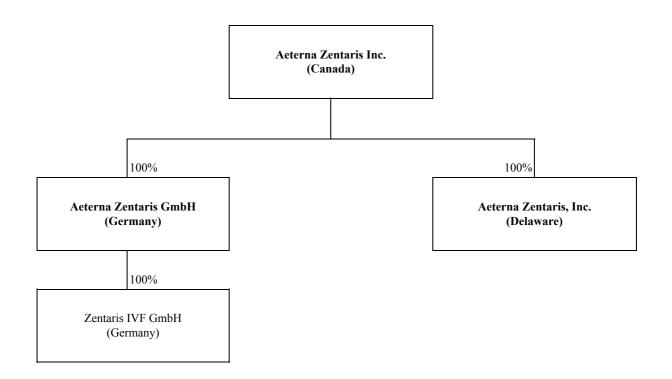
### EXHIBIT 1

As our Chief Accounting Officer, your principal responsibilities will be as follows:

- Supervising all other accounting personnel in the US and Germany
- Managing the Company's relationship with PWC
- Supervising the monthly and quarterly closes of the Company's books
- Supervising the preparation of quarterly financial statements
- Signing the certifications of our filings as required by US and Canadian securities authorities
- Developing a plan for transitioning our reporting basis from IFRS to US GAAP and starting the conversion process
- · Leading the transition into the Company of the new CFO
  - o This process should begin with your proposal of a transition plan for review by me and David Dodd, our CEO
  - O During the transition period, there will be times in which you will need to be present in the Summerville office
- Participating in Operating Committee meetings to provide information to other senior managers regarding the Company's financial condition and the status of your activities
- Participating in Board Meetings and Board conference calls, as required of the position of Vice President, Finance and Chief Accounting Officer

# SUBSIDIARIES OF THE REGISTRANT

# AETERNA ZENTARIS INC.



### Certification of the Principal Executive Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002

### Certification

### I, David A. Dodd, certify that:

- 1. I have reviewed this annual report on Form 20-F of Aeterna Zentaris Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as at, and for, the periods presented in this report:
- 4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as at the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
- 5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 15, 2017

/s/ David A. Dodd

David A. Dodd President and Chief Executive Officer (principal executive officer)

### Certification of the Principal Financial Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002

#### Certification

- I, Genevieve Lemaire, certify that:
- 1. I have reviewed this annual report on Form 20-F of Aeterna Zentaris Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as at, and for, the periods presented in this report:
- 4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as at the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
- 5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 15, 2017

/s/ Genevieve Lemaire

Genevieve Lemaire
Vice President and Chief Accounting Officer
(acting principal financial officer)

Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

### **CERTIFICATION PURSUANT TO**

### 18 U.S.C. SECTION 1350,

### AS ADOPTED PURSUANT TO

### SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Aeterna Zentaris Inc. (the "Company") on Form 20-F for the year ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David A. Dodd, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 15, 2017

/s/ David A. Dodd

David A. Dodd

President and Chief Executive Officer

Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

### **CERTIFICATION PURSUANT TO**

### 18 U.S.C. SECTION 1350,

### AS ADOPTED PURSUANT TO

### SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Aeterna Zentaris Inc. (the "Company") on Form 20-F for the year ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Genevieve Lemaire, Vice President and Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**Dated: March 15, 2017** 

/s/ Genevieve Lemaire

Genevieve Lemaire

Vice President and Chief Accounting Officer

## CONSENT OF INDEPENDENT AUDITOR

We hereby consent to the incorporation by reference in the registration statements on Form F-3 (No. 333-194547), Form F-10/A (No. 333-208789) and Form S-8 (No. 333-210561) of Aeterna Zentaris Inc. of our report dated March 15, 2017 relating to the consolidated financial statements, which appears in this Form 20-F.

Pricewaterhouse Coopers LLP'

Quebec, Quebec, Canada March 15, 2017

 $^{\rm 1}$  CPA auditor, CA, public accountancy permit No. A121191