

Aeterna Zentaris Inc.  
Form 20-F  
April 01, 2019

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

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FORM 20-F

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

OR

Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the fiscal year ended  
December 31, 2018

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

Summerville, South Carolina, USA

29486

(Address of Principal Executive Offices)

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315 Sigma Drive

Summerville, South Carolina

29486

(Name, Telephone, E-mail and Address of Company Contact Person)

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

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

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

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

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as at the close of the period covered by the annual report: 16,440,760 Common Shares as at December 31, 2018.

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

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

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards<sup>†</sup> provided pursuant to Section 13(a) of the Exchange Act.

<sup>†</sup> The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012

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

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

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

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

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## 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", "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 "U.S.\$" are to United States ("U.S.") 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, 2018.

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 warrant holders 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 U.S. 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 "will," "expects," "believes," "intends," "would," "could," "may," "anticipates," and similar terms that relate to future events, performance, or our results. Forward-looking statements involve known risks and uncertainties, including those 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 U.S. Securities and Exchange Commission ("SEC"). 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, our now heavy dependence on the success of Macrilen™ (macimorelin) and related out-licensing arrangements and the continued availability of funds and resources to successfully launch the product, the ability of Aeterna Zentaris to enter into out-licensing, development, manufacturing and marketing and distribution agreements with other pharmaceutical companies and keep such agreements in effect, reliance on third parties for the manufacturing and commercialization of our product candidates, potential disputes with third parties, leading to delays in or termination of the manufacturing, development, out-licensing or commercialization of our product candidates, or resulting in significant litigation or arbitration, and, more generally, uncertainties related to the regulatory process, the ability of the Company to efficiently commercialize or out-license Macrilen™ (macimorelin), the degree of market acceptance of Macrilen™ (macimorelin), our ability to obtain necessary approvals from the relevant regulatory authorities to enable us to use the desired brand names for our products, the impact of securities class action litigation, on our cash flow, results of operations and financial position; any evaluation of potential strategic alternatives to maximize potential future growth and stakeholder value may not result in any such alternative being pursued, and even if pursued, may not result in the anticipated benefits, 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 U.S. 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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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 income (loss) information set forth in this Item 3.A. with respect to the years ended December 31, 2018, 2017 and 2016 and the consolidated statement of financial position information as at December 31, 2018 and 2017 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 income (loss) information with respect to the years ended December 31, 2015 and 2014 and the consolidated statement of financial position information as at December 31, 2016, 2015 and 2014 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.

The Company has not declared or paid any dividends per share during the periods covered by the selected financial data.

## Consolidated Statements of Comprehensive Income (Loss) Information

(in thousands of U.S. dollars, except share and per share data)

Derived from consolidated audited financial statements prepared in accordance with IFRS, as issued by the IASB

	December 31,				
	2018	2017	2016	2015	2014
	\$	\$	\$	\$	\$
Revenues					
License fees	24,325	458	497	248	11
Product sales	2,167	—	—	—	—
Royalty income	184	—	—	—	—
Sales commission and other	205	465	414	297	—
	26,881	923	911	545	11
Cost of sales	2,104	—	—	—	—
Research and development costs	2,932	10,704	16,495	17,234	23,716
General and administrative expenses	8,894	8,198	7,147	11,308	9,840
Selling expenses	3,109	5,095	6,745	6,887	3,850
	17,039	23,997	30,387	35,429	37,406
Income (loss) from operations	9,842	(23,074)	(29,476)	(34,884)	(37,395)
Settlements	(1,400)	—	—	—	—
Gain (loss) due to changes in foreign currency exchange rates	656	502	(70)	(1,767)	1,879
Change in fair value of warrant liability	263	2,222	4,437	(10,956)	18,272
Warrant exercise inducement fee	—	—	—	(2,926)	—
Other finance income	278	75	150	305	168
Net finance income (costs)	1,197	2,799	4,517	(15,344)	20,319
Income (loss) before income taxes	9,639	(20,275)	(24,959)	(50,228)	(17,076)
Income tax recovery (expense)	(5,452)	3,479	—	—	(111)
Net income (loss) from operations	4,187	(16,796)	(24,959)	(50,228)	(17,187)
Net income from discontinued operations	—	—	—	85	623
Net (loss) income	4,187	(16,796)	(24,959)	(50,143)	(16,564)
Other comprehensive income (loss):					
Items that may be reclassified subsequently to profit or loss:					
Foreign currency translation adjustments	(260)	(1,430)	569	1,509	(1,158)
Items that will not be reclassified to profit or loss:					
Actuarial gain (loss) on defined benefit plans	193	694	(1,479)	844	(1,833)
Comprehensive (loss) income	4,120	(17,532)	(25,869)	(47,790)	(19,555)
Basic Net income (loss) per share from continuing operations <sup>(1)</sup>	0.25	(1.12)	(2.41)	(18.17)	(29.12)
Diluted Net income (loss) per share from continuing operations <sup>(1)</sup>	0.24	(1.12)	(2.41)	(18.17)	(29.12)
Net income per share (basic and diluted) from discontinued operations <sup>1</sup>	—	—	—	0.03	1.06
Net (loss) income per share (basic) <sup>1</sup>	0.25	(1.12)	(2.41)	(18.14)	(28.06)
Net (loss) income per share (diluted) <sup>1</sup>	0.24	(1.12)	(2.41)	(18.14)	(28.06)
Weighted average number of shares outstanding:					
Basic	16,440,760	14,958,704	10,348,879	2,763,603	590,247
Diluted	17,034,812	14,958,704	10,348,879	2,763,603	590,247



<sup>1</sup> Adjusted to reflect the November 17, 2015 100-to-1 Share Consolidation

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## Consolidated Statement of Financial Position Information

(in thousands of U.S. dollars)

Derived from consolidated financial statements prepared in accordance with IFRS, as issued by the IASB

	As at December 31,				
	2018	2017	2016	2015	2014
	\$	\$	\$	\$	\$
Cash and cash equivalents	14,512	7,780	21,999	41,450	34,931
Restricted cash equivalents	418	381	496	255	760
Total assets	25,011	22,195	31,659	51,498	47,435
Warrant liability (current and non-current portion)	3,634	3,897	6,854	10,891	8,225
Share capital	222,335	222,335	213,980	204,596	150,544
Shareholders' (deficiency) equity	1,907	(2,783 )	6,212	21,615	14,484

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 in nature.

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. If we are unsuccessful in generating new revenue, increasing our revenues 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 commercialize products. Consequently, we have incurred operating losses historically and in each of the last several years. As at December 31, 2018, we had an accumulated deficit of approximately \$310 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 focus on the commercialization of Macrilen™ (macimorelin). In developing, acquiring, or out-licensing Macrilen™ (macimorelin), we could incur additional operating losses for at least the next several years. If we do not ultimately generate sufficient revenue from a commercialized product and 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. In 2018, our primary source of liquidity was the \$24.0 million licensing payment received from Strongbridge Biopharma plc in January 2018.

We stated in our management's discussion and analysis of financial condition and results of operations for the year ended 2018 that we expect existing cash balances and operating cash flows will provide us with adequate funds to support our current operating plan for at least twelve months. There can be no assurance, however, that unplanned capital requirements or other future events, will not require us to seek debt or equity financing and, if so required, that it will be available on terms acceptable to us, if at all.

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 with us. Accordingly, as a result of the foregoing, we continue to review traditional sources of financing, such as private and public debt or various equity financing alternatives, as well as other alternatives to enhance shareholder value, including, but not limited to, non-traditional sources of financing, such as strategic alliances with third parties, the sale of assets or licensing of our technology or intellectual property, a combination of operating and related initiatives or a substantial reorganization of our business. 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. If we do not ultimately achieve operating profitability, an investment in our Common Shares or other securities could result in a significant or total loss. 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.

If we are unable to successfully commercialize or out-license Macrilen™ (macimorelin), or if we experience significant delays in doing so, our business would be materially harmed, and the future and viability of our Company could be imperiled.

Our principal focus is on the licensing and development of Macrilen™ (macimorelin) and we currently do not have any other product. The Company is a party to a license and assignment agreement with a subsidiary of Novo Nordisk A/S ("Novo") to carry out development, manufacturing, registration and commercialization of Macrilen™ (macimorelin) in the U.S. and Canada (the "License and Assignment Agreement"). The Company continues to explore licensing opportunities worldwide.

The commercial success of Macrilen™ (macimorelin) depends on several factors, including the following:

- receipt of approvals from foreign regulatory authorities;
- successfully contracting with qualified third-party suppliers to manufacture Macrilen™ (macimorelin);
- developing appropriate distribution and marketing infrastructure and arrangements for our product;
- launching and growing commercial sales of the product;
- out-licensing Macrilen™ (macimorelin) to third parties; and
- acceptance of the product in the medical community, among patients and with third party payers.

If we are unable to successfully achieve any of these factors, our business, financial condition and results of operations may be materially adversely affected.

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 timing and willingness of any current or future collaborators to invest the resources necessary to commercialize Macrilen™ (macimorelin);



not obtaining necessary regulatory approvals from the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and other agencies that may delay or prevent us from obtaining approval of a pediatric indication for Macrilen™ (macimorelin), which may affect the price of our securities;

- the timing of regulatory submissions and approvals;
- 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 licensing partners; and
- failure to enter into new or the expiration or termination of current agreements with suppliers who manufacture Macrilen™ (macimorelin).

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 the value of our other securities could fluctuate significantly or decline.

If we are unable to successfully complete the pediatric clinical trial program for Macrilen™ (macimorelin), or if such clinical trial takes longer to complete than we project, our ability to execute any related business strategy will be adversely affected.

If we experience delays in identifying and contracting with sites and/or in-patient enrollment in our pediatric clinical trial program for Macrilen™ (macimorelin), 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 pediatric clinical trial within an acceptable time-frame, if at all. If we or our contract resource organization (a "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, among other requirements:

- meet the requirements of these authorities from multiple countries and jurisdictions and their related statutes, regulations, and guidances;
- meet the requirements for informed consent;
- meet the requirements for institutional review boards; and
- meet the requirements for good clinical practices

We are currently dependent on certain strategic relationships with third parties for the development, manufacturing and licensing of Macrilen™ (macimorelin) and we may enter into future collaborations for the development, manufacturing and licensing of Macrilen™ (macimorelin).

We are currently dependent on certain strategic relationships with third parties for the development, manufacturing and licensing of Macrilen™ (macimorelin), and may enter into future collaborations for the development, manufacturing and licensing of Macrilen™ (macimorelin). Our arrangements with these third parties may not provide us with the benefits we expect and may expose us to a number of risks.

Currently, we are dependent on Novo to commercialize Macrilen™ (macimorelin) in the U.S and Canada. Most of our potential revenue consists of contingent payments, including regulatory milestones and royalties on the sale of Macrilen™ (macimorelin). The milestone and royalty revenue that we may receive under this collaboration will depend upon Novo's ability to successfully introduce, market and sell Macrilen™ (macimorelin) in the United States. If Novo does not devote sufficient time and resources to its collaboration arrangement with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be materially adversely affected.





Our reliance on relationships with Novo and other potential third parties 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 to third parties. These agreements create certain additional risks. The occurrence of any of the following or other events may delay or impair commercialization of Macrilen™ (macimorelin):

- in certain circumstances, third parties may assign their rights and obligations under these agreements to other third parties without our consent or approval;

- 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 Macrilen™ (macimorelin);

- 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 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 Macrilen™ (macimorelin); and

- disputes may arise between us and the third parties that could result in the delay or termination of the manufacturing or commercialization of Macrilen™ (macimorelin), 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.

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 manufacturing and commercializing Macrilen™ (macimorelin), which would likely cause a drop in the price of our Common Shares.

We may be unsuccessful in consummating further out-licensing arrangements for Macrilen™ (macimorelin) on favorable terms and conditions, or we may be significantly delayed in doing so.

As part of our product development and commercialization strategy, we are evaluating out-licensing opportunities for Macrilen™ (macimorelin) in addition to the License and Assignment Agreement. If we elect to collaborate with third parties in respect of Macrilen™ (macimorelin), we may not be able to negotiate a collaborative arrangement for Macrilen™ (macimorelin) on favorable terms and conditions, if at all. Should any partner fail to successfully commercialize Macrilen™ (macimorelin), our business, financial condition and results of operations may be adversely affected.

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

We may require significant additional capital to fund our commercial operations and may require additional capital to pursue planned clinical trials and regulatory approvals. Although we have capital from the License and Assignment Agreement, we do not anticipate generating significant revenues from operations in the near future other than from the License and Assignment Agreement, 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, 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.

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

- the duration of changes to and results of our clinical trials for any future products going forward;
  - unexpected delays or developments in seeking regulatory approvals;
  - the time and cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
  - unexpected developments encountered in implementing our business development and commercialization strategies;
  - the potential addition of commercialized products to our portfolio;
  - the outcome of current and future 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 Macrilen™ (macimorelin) are and will be subject to strict and ongoing regulation, even with marketing approval by the FDA and EMA for Macrilen™ (macimorelin). Compliance with such regulation will be expensive and consume substantial financial and management resources. For example, the EMA approval for macimorelin was conditioned on our agreement to conduct 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 current or future products and other regulations. 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 a product 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, complete withdrawal of a marketing application, exclusion from government healthcare programs, import or export bans or restrictions, and/or criminal prosecution and penalties. Any of these penalties could delay or prevent the promotion, marketing or sale of a product. Even with marketing approval for Macrilen™ (macimorelin), such product approval could be subject to restrictions or withdrawals. Regulatory requirements are subject to change.

On December 20, 2017, the FDA granted marketing approval in the United States for Macrilen™ (macimorelin) to be used in the diagnosis of patients with adult growth hormone deficiency ("AGHD") and on January 16, 2019, the EMA granted marketing approval in Europe for macimorelin for the diagnosis of AGHD. Regulatory authorities generally approve products for specified 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 or untitled letters, fines, injunctions, civil penalties,

recalls or seizures of products and related publicity requirements, total or partial suspension of production, import or export bans or restrictions, refusal of the government to renew marketing applications, complete withdrawal of a marketing

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application, criminal prosecution and penalties, suspension or withdrawals of previously granted regulatory approvals, 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 licensees' or collaborators', business and marketing activities for various reasons.

From time to time, new legislation is passed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA, EMA and other health authorities. Additionally, regulations and guidance are often revised or reinterpreted by health agencies in ways that may significantly affect our business Macrilen™ (macimorelin). 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 a product 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 Macrilen™ (macimorelin), 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 Macrilen™ (macimorelin) 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 Donald Trump. Additionally, in the U.S., states have also passed legislation and proposed bills that are aimed at drug pricing transparency, which will likely impact drug pricing. There can be no assurance as to how this scrutiny on pricing of pharmaceutical products will impact future pricing of Macrilen™ (macimorelin).

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. Since January 2017, the U.S. Congress has proposed various bills to revise the ACA. Additionally, President Donald Trump has suggested similar action and enacted Executive Orders to curtail the ACA and its impacts on healthcare in the U.S. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation, or potential legislation, regulation, and orders or their impact 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 or our licensees market products or interact with health care practitioners in a manner that violates healthcare fraud and abuse laws, we or our licensees 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 current product, certain federal and state healthcare laws and regulations pertaining to fraud and abuse are and will be applicable to our business. We and our licensees 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 and our licensee's 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, through the Physician Payment Sunshine Act, 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 or our licensees for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, cause reputational harm and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state laws may prove costly.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The ACA also made several important changes to the federal anti-kickback statute, false claims laws, and healthcare fraud statute by weakening the intent requirement under the anti-kickback and healthcare fraud statutes that may make it easier for the government or



whistleblowers to charge such fraud and abuse violations. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. In addition, the ACA increases penalties for fraud and abuse violations. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and negatively impact our financial results.

If Macrilen™ (macimorelin) does not gain market acceptance, we may be unable to generate significant revenues.

Market acceptance of Macrilen™ (macimorelin) depends 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 Macrilen™ (macimorelin) 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 Macrilen™ (macimorelin).

If Macrilen™ (macimorelin) does not gain market acceptance among physicians, patients, healthcare payers and others in the medical community, who may not accept or utilize Macrilen™ (macimorelin), our ability to generate significant revenues from Macrilen™ (macimorelin) 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 Macrilen™ (macimorelin), 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. Macrilen™ (macimorelin), if successfully commercialized, may compete with a number of drugs, therapies, products and tests currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Macrilen™ (macimorelin) may also compete with new products currently under development by others or with products which may be less expensive than Macrilen™ (macimorelin). There can be no assurance that our efforts to increase market penetration in our core markets and existing geographic markets will be successful. Our failure to do so could have an adverse effect on our operating results and would likely cause a drop in the price of our Common Shares.

We may expend our limited resources to pursue a particular product or indication and fail to capitalize on other products 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 Macrilen™ (macimorelin), and we are doing so for specific indications. As a result, we may forego or delay pursuit of opportunities for other potential indications for Macrilen™ (macimorelin) which there may be a greater likelihood of success or may prove to have greater commercial potential. Research programs to identify new product candidates or pursue alternative indications for Macrilen™ (macimorelin) 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 may 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 any clinical trials, the uncertainties inherent in the regulatory approval process and delays in achieving manufacturing or marketing arrangements sufficient to commercialize Macrilen™ (macimorelin). There can be no assurance that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our schedule for launching of Macrilen™ (macimorelin) outside of the U.S. If we fail to achieve one or more of these milestones as planned, the price of our Common Shares would likely decline.

If we fail to obtain acceptable prices or adequate reimbursement for Macrilen™ (macimorelin), our ability to generate revenues will be diminished.

Our ability or that of our licensee(s) to successfully commercialize Macrilen™ (macimorelin) will depend significantly on our or their 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. Macrilen™ (macimorelin) may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us or our licensee(s) to sell our products on a competitive basis. It may not be possible to negotiate favorable reimbursement rates for Macrilen™ (macimorelin). Adverse pricing and reimbursement conditions would also likely diminish our ability to induce third parties to in-license Macrilen™ (macimorelin).

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 that proposals to implement similar government controls will 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 Donald 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. Additionally, there is drug pricing reform taking place at the state level in the U.S., in the form of laws and bills, that will impact how pharmaceutical companies can market and sell drug products and at what price. Further, third-party payers 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 a product 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 a product and could adversely affect our profitability. In addition, in the U.S., Canada and many other countries, pricing and/or profitability of some or all prescription pharmaceuticals and biopharmaceuticals are subject to government control.

If we or our licensee(s) fail to obtain acceptable prices or an adequate level of reimbursement for Macrilen™ (macimorelin), the sales of Macrilen™ (macimorelin) would be adversely affected or there may be no commercially viable market for Macrilen™ (macimorelin).

Competition in our targeted markets is intense, and development by other companies could render Macrilen™ (macimorelin) non-competitive.

The biopharmaceutical field is highly competitive. New products developed by other companies in the industry could render Macrilen™ (macimorelin) uncompetitive. Competitors are developing and testing products and technologies that would compete with Macrilen™ (macimorelin). Some of these products may be more effective or have an entirely different approach or means of accomplishing the desired effect than Macrilen™ (macimorelin). 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.

We may not obtain adequate protection for Macrilen™ (macimorelin) through our intellectual property.

We rely heavily on our proprietary information in developing and manufacturing Macrilen™ (macimorelin). Our success depends, in large part, on our ability to protect our competitive position through patents, trade secrets, trademarks and other intellectual property rights. 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 Macrilen™ (macimorelin).

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. 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 and prevent infringement.

Our patents 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 Macrilen™ (macimorelin). 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 for Macrilen™ (macimorelin). The patents issued

or to be issued to us for Macrilen™ (macimorelin) 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. 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 Macrilen™ (macimorelin) in the marketplace.

We may infringe the intellectual property rights of others.

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

If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business. 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, re-examination 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 current or future products.

We have filed applications for trademark registrations, including Macrilen™ (macimorelin), in various jurisdictions, including the U.S. We may file applications for other possible trademarks for Macrilen™ (macimorelin). No assurance can be given that any of our trademarks will be registered elsewhere, or that the use of any registered or unregistered trademarks will confer a competitive advantage in the marketplace.

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 contract resource organizations, medical institutions and clinical investigators to enroll qualified patients and to 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 to the FDA, 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 products 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 that are favorable or 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 rely on third parties to manufacture and supply Macrilen™ (macimorelin). 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 Macrilen™ (macimorelin). To be successful, Macrilen™ (macimorelin) has 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 Macrilen™ (macimorelin) or the materials used in its manufacture. If we are unable to do so ourselves or to arrange for third-party manufacturing or supply of Macrilen™ (macimorelin) or materials, or to do so on commercially reasonable terms, we may not be able to commercialize Macrilen™ (macimorelin) through our licensees. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

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

We are highly dependent on our management and our clinical, regulatory and scientific staff, the loss of whose services might adversely impact our ability to achieve our objectives. Recruiting and retaining qualified management and clinical, scientific and regulatory personnel is critical to our success. Reductions in our staffing levels have eliminated redundancies in key capabilities and skill sets among our full-time staff and required us to rely more heavily on outside consultants and third parties. We have been unable to increase the compensation of our associates to the extent required to remain fully competitive for their services, which



increased our employee retention risk. The competition for qualified personnel in the biopharmaceutical field is intense, and if we are not able to continue to 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 a securities class-action litigation matter and we may be subject to similar or other litigation in the future.

The Company and certain of our current and former officers are defendants in a class-action lawsuit pending in the U.S. District Court for the District of New Jersey, brought on behalf of shareholders of the Company. The lawsuit alleges 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™ (macimorelin), and the prospects for the approval of the Company's New Drug Application for the product by the FDA. The plaintiffs represent a class comprised of purchasers of the Company's common shares during the Class Period and seek damages, costs and expenses and such other relief as determined by the Court. The Company considers the claims that have been asserted in the lawsuit to be without merit and is vigorously defending against them. The Company cannot, however, predict at this time the outcome or potential losses, if any, with respect to this lawsuit.

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 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 are required to satisfy before any insurance applies to a claim, unreimbursed legal fees 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; however, the insurer has reserved its rights to contest the applicability of the insurance to such claims 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 sale and use of Macrilen™ (macimorelin) 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 as well as products liability insurance. 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 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, our principal operating subsidiary, AEZS Germany, may become subject to insolvency proceedings if it is illiquid or "over-indebted" in accordance with German law.

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. 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.

German law, which governs our principal operating subsidiary, AEZS Germany imposes an obligation on the managing director of AEZS Germany to institute insolvency proceedings of that subsidiary if the managing director concludes that AEZS Germany is insolvent because it is either illiquid or "over-indebted" in accordance with the provisions of German law.

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 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 or officers 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 (i) 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 (ii) 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.

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 of the Canadian securities administrators. 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 - 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 a PFIC for the 2015 taxable year, but were not a PFIC for the 2016, 2017 and 2018 taxable years. 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 2018 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 pre-existing 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 - 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.

Our net operating losses may be limited for U.S. federal income tax purposes under Section 382 of the Internal Revenue Code.

If a corporation with net operating losses ("NOLs") undergoes an "ownership change" within the meaning of Section 382 of the United States Internal Revenue Code of 1986, as amended, then such corporation's use of such "pre-change" NOLs to offset income incurred following such ownership change may be limited. Such limitation also may apply to certain losses or deductions that are "built-in" (i.e., attributable to periods prior to the ownership change but not yet taken into account for tax purposes) as of the date of the ownership change that are subsequently recognized. An ownership change generally occurs when there is either (i) a shift in ownership involving one or more "5% shareholders"; or (ii) an "equity structure shift" and, as a result, the percentage of stock of the corporation owned by one or more 5% shareholders (based on value) has increased by more than 50 percentage points over the lowest percentage of stock of the corporation owned by such shareholders during the "testing period" (generally the 3 years preceding the testing date). In general, if such change occurs, the corporation's ability to utilize its net operating loss carry-forwards and certain other tax attributes would be subject to an annual limitation, as described below. The unused portion of any such net operating loss carry-forwards or tax attributes each year is carried forward, subject to the same limitation in future years. The impact of an ownership change on state NOL carryforwards may vary from state to state. Recent legislation added several limitations to the ability to claim deductions for NOLs, including a deduction limit equal to 80% of taxable income and a restriction on NOL carryback deductions.

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.

Data 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.

Our business processes personal information, both in connection with clinical activities and our employees. The use of this information is critical to our operations and innovation, including the development of our products, as well as management of our employees. New and evolving regulations, such as the European Union General Data Protection Regulation, could bring increased scrutiny of our data management in the future. Any cyber-attacks or other failure to protect critical and sensitive systems and information could damage our reputation, prompt litigation or lead to regulatory sanctions, all of which could materially affect our financial condition and results of operation.

#### Risks Relating to our Common Shares

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

Our Common Shares are currently listed on 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.

Between January 1, 2018 and December 31, 2018, the closing price of our Common Shares ranged from \$1.19 to \$3.87 per share on NASDAQ and from C\$1.53 to C\$5.10 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:

• developments regarding current or future third-party suppliers and licensee(s);

• clinical and regulatory developments regarding Macrilen™ (macimorelin);  
• delays in our anticipated clinical development or commercialization timelines;  
• announcements by us regarding technological, regulatory or other matters;  
• arrivals or departures of key personnel;

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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. 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. As a result, the return on an investment in our Common Shares, or any of our other securities, 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 or other Convertible Securities, could dilute the interests of our existing shareholders, and could substantially decrease the trading price of our Common Shares.

We may issue equity securities in the future for a number of reasons, including to finance our operations and business strategy, to satisfy our obligations upon the exercise of options or warrants or for other reasons. Our stock option plan generally permits us to have outstanding, at any given time, stock options that are exercisable for a maximum number of Common Shares equal to 11.4% of all then issued and outstanding Common Shares. As at December 31, 2018, there were:

16,440,760 Common Shares issued and outstanding;

no issued and outstanding Preferred Shares;

115,844 Common Shares issuable upon exercise of warrants that we previously issued in March 2015, which had a weighted average exercise price as of December 31, 2018 of \$1.07 per Common Share, 2,331,000 Common Shares

issuable upon exercise of warrants that we previously issued in December 2015, which had a weighted average exercise price as of December 31, 2018 of \$7.10 per Common Share, and 945,000 Common Shares issuable upon exercise of warrants that we previously issued in November 2016, which had a weighted average exercise price as of December 31, 2018 of \$4.70 per Common Share;

888,816 Common Shares that underlie outstanding stock options and deferred share units granted under our Plans, having a weighted average exercise price of \$3.66 per Common Share;

869 Common Shares that underlie outstanding stock options and deferred share units granted under our Plans, having a weighted average exercise price of C\$743.56 per Common Share; and

246,619 additional Common Shares available for future grants under our Stock Option Plan, and 737,942 additional Common Shares available for future grants under our Long Term Incentive Plan. The maximum number of Common Shares issuable under the Plans may equal 11.4% of the issued and outstanding Common Shares at any given time.

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 2018, 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, 2018, we continued to be a foreign private issuer. There can be no assurance, however, that we will remain a foreign private issuer either in 2019 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 pharmaceutical therapies, currently focused on the development and commercialization of Macrilen™ (macimorelin), including through out-licensing arrangements and pursuing in-licensing opportunities.

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 1155 René-Lévesque Blvd, West 41<sup>st</sup> Floor, Montréal, Quebec, Canada H3B 3V2 c/o Stikeman Elliott, LLP. Our principal executive offices are located at 315 Sigma Drive, Summerville, South Carolina 29486; our telephone number is (843) 900-3223 and our website is [www.zentaris.com](http://www.zentaris.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. The SEC also maintains a website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy statements and other information regarding registrants that file electronically with the SEC.

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 Germany"). AEZS Germany conducts our drug development efforts. In September 2007, we incorporated Aeterna Zentaris, Inc. under the laws of Delaware. This wholly-owned subsidiary, which is based in the Charleston, South Carolina area, conducts certain of our administrative and commercial operations. 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 Germany, based in Frankfurt, Germany; Zentaris IVF GmbH, a direct wholly-owned subsidiary of AEZS Germany based in Frankfurt, Germany; and Aeterna Zentaris, Inc., an entity incorporated in the State of Delaware 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, 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

Our primary business strategy is to finalize the development, manufacturing, registration and commercialization of Macrilen™ (macimorelin) through the License and Assignment Agreement in the United States and Canada. We continue to explore various alternatives to monetize our rights to Macrilen™ (macimorelin) in other countries around the globe, including whether to find other license partners in these jurisdictions or to use our internal resources to commercialize Macrilen™ (macimorelin) in one or more of these countries. Our vision is to become a growth-oriented specialty biopharmaceutical company.

### Macrilen™ (macimorelin)

Macrilen™ (macimorelin) 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™ (macimorelin) was granted orphan-drug designation by the FDA for use in evaluating growth hormone deficiency ("GHD").

Competitors for Macrilen™ (macimorelin) 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 an accurate 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™ (macimorelin) offers convenience and simplicity over the current GHD tests used, all of which require either intravenous or intramuscular administration. Additionally, Macrilen™ (macimorelin) 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™ (macimorelin) has not thus far. These factors may be limiting the use of GHD testing and may potentially enable Macrilen™ (macimorelin) to become the product of choice in evaluating AGHD. We believe that Macrilen™ (macimorelin) 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™ (macimorelin) is administered orally, while the ITT requires an intravenous injection of insulin;
- Macrilen™ (macimorelin) is a more robust test than the ITT leading to evaluable test results;
- Macrilen™ (macimorelin) results are highly reproducible;
- the evaluation of AGHD using Macrilen™ (macimorelin) 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 60,000 AGHD tests will be conducted annually, in the U.S, after the introduction of Macrilen™ (macimorelin). 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 U.S. 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™ (macimorelin):

##### 2004 - 2014

We out-licensed the development compound macimorelin acetate to Ardana Bioscience in 2004. Ardana Bioscience subsequently initiated the clinical development program of macimorelin acetate as an orally active compound intended to be used in the diagnosis of AGHD, however in 2008 Ardana Bioscience filed for bankruptcy so we terminated the license and regained rights to the compound. On October 19<sup>th</sup>, 2009, we announced that we would continue the macimorelin clinical development program for use in evaluating the AGHD and assumed the sponsorship of the Investigational New Drug Application (IND). On December 20, 2010, we announced we had reached agreement with the FDA on a Special Protocol Assessment ("SPA") for Macrilen™ (macimorelin), enabling us to complete the ongoing registration study required to gain approval for use in evaluating AGHD. On July 26, 2011, we announced the completion of the Phase 3 study of Macrilen™ (macimorelin) 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™ (macimorelin) in the United States. On June 26, 2012, we announced that the final results from a Phase 3 trial for Macrilen™ (macimorelin) showed that the drug is safe and effective in evaluating AGHD. In November 2013, we filed an NDA for Macrilen™ (macimorelin) 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™ (macimorelin) 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 for FDA clearance and approval.

##### 2015 - present

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 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™ (macimorelin) 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™ (macimorelin) 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™ (macimorelin) for the evaluation of AGHD, as well as a dedicated thorough QT study to evaluate the effect of Macrilen™ (macimorelin) on myocardial repolarization. The confirmatory Phase 3 clinical study of



Macrilen™ (macimorelin), entitled "Confirmatory validation of oral macimorelin as a growth hormone (GH) stimulation test (ST) for the diagnosis of 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.

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On May 26, 2015, we announced that we had received written scientific advice from the EMA regarding the further development plan, including the study design, for the new confirmatory Phase 3 clinical study of Macrilen™ (macimorelin) 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 U.S. and European approval, if the study is successful.

On November 19, 2015, we announced the enrollment of the first patient in the confirmatory Phase 3 clinical study of Macrilen™ (macimorelin).

On October 26, 2016, we announced completion of patient recruitment for the confirmatory Phase 3 clinical trial of Macrilen™ (macimorelin) as a growth hormone stimulation test for the evaluation of AGHD. In addition, we completed the dedicated QT study as requested by the FDA in the CRL to evaluate the effect of Macrilen™ (macimorelin) on the QT interval.

On January 4, 2017, we announced that, based on an analysis of top-line data, the confirmatory Phase 3 clinical trial of Macrilen™ (macimorelin) failed to achieve one of its co-primary endpoints. Under the study protocol, the evaluation of AGHD with Macrilen™ (macimorelin) 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™ (macimorelin) 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 met 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™ (macimorelin) 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™ (macimorelin) for the evaluation of AGHD.

On July 18, 2017, we were provided a PDUFA date of December 30, 2017 by the FDA.

On November 27, 2017, the EMA accepted our MMA submission for Macrilen™ (macimorelin).

On December 20, 2017, the FDA approved the market authorization for Macrilen™ (macimorelin), to be used in the diagnosis of patients with adult growth hormone deficiency (AGHD).

On January 16, 2018, the Company, through AEZS Germany, entered into the License and Assignment Agreement to carry out development, manufacturing, registration, regulatory and supply chain services for the commercialization of Macrilen™ (macimorelin) in the U.S. and Canada as further described below.

In the August 2018, Volume 103, Issue 8 edition of The Journal of Clinical Endocrinology and Metabolism, the pivotal Phase 3 data from the macimorelin confirmatory trial was published by Jose M. Garcia, MD, PhD, et al., titled 'Macimorelin as a Diagnostic Test for Adult GH Deficiency'.

On November 19, 2018, we announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending a marketing authorization for macimorelin.

On January 16, 2019, the Company announced that the EMA has granted marketing authorization for macimorelin. Macrilen™ (macimorelin) License and Assignment Agreement

On January 16, 2018, the Company, through AEZS Germany, entered into the License and Assignment Agreement with Strongbridge Ireland Limited ("Strongbridge") to carry out development, manufacturing, registration, regulatory and supply chain services for the commercialization of Macrilen™ (macimorelin) in the U.S. and Canada. This agreement provides (i) for the "right to use" license relating to the Adult Indication; (ii) for the right to acquire a license for the Pediatric Indication if and when the FDA approves a pediatric indication; (iii) that the licensee is to fund 70% of the costs of a pediatric clinical trial submitted for approval to the EMA and FDA (the "PIP") to be run by the Company with customary oversight from a joint steering committee (the "JSC"); and (iv) the Interim Supply

Arrangement.

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Effective December 19, 2018, Strongbridge sold the United States and Canadian rights to Macrilen™ (macimorelin) under the License and Assignment Agreement to Novo for a payment plus tiered royalties on net sales and Novo will fund Strongbridge's Macrilen™(macimorelin) field organization as a contract field force to promote the product in the United States for up to three years.

(i) Adult Indication

Under the terms of the License and Assignment Agreement, and for as long as Macrilen™ (macimorelin) is patent-protected, the Company will be entitled to a 15% royalty on annual net sales up to \$75.0 million and an 18% royalty on annual net sales above \$75.0 million. Following the end of patent protection in United States or Canada for Macrilen™ (macimorelin), the Company is entitled to a 5% royalty on net sales in that country. In addition, the Company will receive one-time payments ranging from \$4.0 million to \$100.0 million upon the achievement of commercial milestones going from \$25.0 million annual net sales up to \$500.0 million annual net sales.

In January 2018, the Company received a cash payment of \$24.0 million from Strongbridge and on July 23, 2018, Strongbridge launched product sales of Macrilen™ (macimorelin) in the United States.

(ii) Pediatric Indication

Upon approval by the FDA of a pediatric indication for Macrilen™ (macimorelin), the Company will receive a one-time milestone payment from Strongbridge of \$5.0 million.

(iii) PIP study

We have initiated an open label, single dose trial to investigate the pharmacokinetics, pharmacodynamics, safety and tolerability of macimorelin in pediatric patients from two to less than 18 years of age with suspected growth hormone deficiency ("GHD"). Under the terms of the License and Assignment Agreement, the licensee will pay 70% and the Company will pay the remaining 30% of the research and development costs associate with the PIP. During 2018, the Company invoiced Strongbridge \$358,000 as its share of the costs incurred by the Company under the PIP; such amounts have been collected in full.

(iv) Interim supply arrangement

The Company has agreed to supply ingredients for the manufacture of Macrilen™ (macimorelin) during an interim period at a price that is set 'at cost', without any profit margin. During 2018, the Company invoiced \$2,108,000 and has received payment in full of these invoices under an interim supply agreement.

Rest of world commercialization of macimorelin

On January 16, 2019, we announced that the EMA had granted marketing authorization for macimorelin for the diagnosis of AGHD. AGHD may occur in an adult patient who has a history of childhood onset GHD or may occur during adulthood as an acquired condition. Considering a population of 510 million for the European Union, research based on incidence prevalence suggests that at least 35,000 adults could be afflicted with GHD. This milestone marks a key development in our European commercialization strategy and we are in discussions with a variety of companies regarding licensing and/or distribution opportunities in the rest of the world.

Monetization of non-strategic assets

Other pipeline prospects for the Company include preclinical work done on AEZS-120, a prostate cancer vaccine, discovery research for ERK-inhibitors for Oncology indications; and discovery research conducted at the Medical University of South Carolina on Compound Library as well as other research and clinical development projects that have been undertaken by our German subsidiary.

2017 and earlier - Zoptrex™

Zoptrex™ is a complex molecule that combines a synthetic peptide carrier with doxorubicin, a well-known chemotherapy agent. The synthetic peptide carrier is a luteinizing hormone-releasing hormone ("LHRH") agonist, a modified natural hormone with affinity for the LHRH receptor. The design of the compound allows for the specific binding and selective uptake of the cytotoxic conjugate by LHRH receptor-positive tumors.

On January 30, 2017, we announced the completion of the clinical phase of the pivotal Phase 3 ZoptEC (Zoptarelin Doxorubicin in Endometrial Cancer) study with the occurrence of the 384th death.

On May 1, 2017, we announced that the ZoptEC pivotal Phase 3 clinical study of Zoptrex™ (zoptarelin doxorubicin) in women with locally advanced, recurrent or metastatic endometrial cancer did not achieve its primary endpoint of demonstrating a statistically significant increase in the median period of overall survival of patients treated with Zoptrex™ (zoptarelin doxorubicin) as compared to patients treated with doxorubicin and we discontinued its development. Similarly, we discontinued the development of AEZS-138/Disorazol Z, as it was based on the same concept as Zoptrex™ (zoptarelin doxorubicin).

We have licensed the development, commercialization and certain other rights to Zoptrex™ 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.

We do not anticipate significant revenues from the Sinopharm License Agreement in the future other than the amortization of the remaining deferred revenue.

#### Other

Our commercial operations were significantly reduced in the fourth quarter of 2017. We eliminated our contract sales team in its entirety, as well as remaining sales management in November 2017, in accordance with the terms of our agreement with inVentiv Commercial Services, LLC, an affiliate of inVentiv Health, Inc. ("inVentiv"), a contract-sales organization. Our agreement with inVentiv commenced in November 2014.

Pursuant to termination of the inVentiv agreement, we ended our co-promotion with EMD Serono, Inc. ("EMD Serono") and Armune BioScience, Inc. ("Armune").

Until September 1, 2016, we co-promoted a product, EstroGel®, and until termination of our sales team in November 2017, the inVentiv sales force promoted 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 promoted Saizen® pursuant to our promotional services agreement (the "EMD Serono Agreement") with EMD Serono Inc. which we entered into in May 2015 and amended as of December 31, 2016. The EMD Serono Agreement, as amended, provided that we were to promote Saizen® in specific agreed-upon U.S. territories to adult and pediatric endocrinologists in exchange for a sales commission that was based upon new patient starts of the product. The agreement was terminated in accordance with its terms in December 2017.

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, 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, which allowed us to exclusively promote APIFINY® throughout the entire United States. We received a commission for each test performed resulting from our targeted promotion without regard to any established baseline. The Armune Agreement, as amended, had a three-year term that renewed automatically for successive one-year periods. The parties agreed in January 2018 that the Armune Agreement was terminated.

#### Geographic Areas

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 25 (Segment information) to our consolidated financial statements included in this Annual Report on Form 20-F at Item 18.

#### Seasonality

As a specialty biopharmaceutical company, the Company does not consider any of its products or services to be seasonal.

#### 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 or our licensees 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 is 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 Macrilen™ (macimorelin) 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 U. S., 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 4 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 3.D. 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.

Macrilen™ (macimorelin):

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 Germany, as licensee. Macrilen™ is the approved marketing name for macimorelin as licensed under the License and Assignment Agreement for commercialization in the U.S. and Canada, only.

The following patents and patent applications relate to macimorelin:

U.S. patent 6,861,409 covers macimorelin 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 macimorelin 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 macimorelin 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 macimorelin 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 macimorelin 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 macimorelin. 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 macimorelin. This patent expires in February 2027.

U.S. provisional patent applications Serial No. 62/607,866 was filed on December 19, 2017 and Serial No. 62/609,059 was filed on December 21, 2017. Both are identical and are directed to a method of assessing growth hormone deficiency comprising oral administration of a macimorelin containing composition and collecting one or two post-administration samples.

A non-provisional U.S. application was filed on May 30, 2018 drawing the priority of both provisional applications. The US-PTO issued a Notice of Allowance on January 09, 2019. If granted, a patent would presumably expire December 19, 2037.

A PCT application was filed December 18, 2018 drawing the priority of both provisional U.S. applications. In addition to the method of assessing growth hormone deficiency comprising oral administration of a macimorelin containing composition and collecting one or two post-administration samples, the PCT application also covers a similar method of assessing growth hormone deficiency using 3 post-administration samples.

Zoptrex™

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 Germany, 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 licensed patents. 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 licensed patents, 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.

All patents covered by the Tulane Agreement expired by November 2016. In early 2015, we filed a European patent application directed to a novel method of manufacturing Zoptrex™. Within the 12 months priority period, we also filed an international patent application for the manufacturing process, as well as national patent applications in selected countries, including the U.S., China, and Taiwan, Japan and India. As a consequence of the negative Phase 3 ZoptEC study received in April 2017, we ceased further Zoptrex™ development and intellectual property filings.

Disorazol Z - LHRH conjugates (AEZS-138):

We own a number of patents that relate to our Disorazol Z - LHRH conjugates. As a consequence of the negative Phase III ZoptEC study received in April 2017, we ceased further Disorazol Z - LHRH conjugate development and intellectual property filings.

### 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, 2018 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 and our largest office is located in Frankfurt, Germany. We do not own any real property. The following table sets forth information with respect to our main facilities as at December 31, 2018.

Location	Use of space	Square Footage	Type of interest
315 Sigma Drive, Summerville SC 29486	Occupied for management, administration, commercial operations and business development	300	Leasehold
Weismüllerstr. 50 D-60314 Frankfurt-am-Main, Germany	Occupied for management, R&D, business development and administration	36,168	Leasehold

We believe that our current facilities are adequate to meet our ongoing needs and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Item 4A Unresolved Staff Comments

Not required.

Item 5. Operating and Financial Review and Prospects

Key Developments

Macrilen™ (macimorelin) license agreement

Macrilen™ (macimorelin), a ghrelin receptor agonist, is a novel orally-active small molecule that stimulates the secretion of growth hormone. The FDA has granted marketing approval for Macrilen™ (macimorelin) to be used in the diagnosis of AGHD.

On January 16, 2018, the Company, through AEZS Germany, entered into the License and Assignment Agreement to carry out development, manufacturing, registration, regulatory and supply chain services for the commercialization of Macrilen™ (macimorelin) in the United States and Canada. This agreement provides (i) for the "right to use" license relating to the Adult Indication; (ii) for the right to acquire a license for the Pediatric Indication if and when the FDA approves a pediatric indication; (iii) that the licensee is to fund 70% of the costs of a pediatric clinical trial submitted for approval to the EMA and FDA (the "PIP") to be run by the Company with customary oversight from a joint steering committee (the "JSC"); and (iv) for the Interim Supply Arrangement.

(i) Adult Indication

Under the terms of the License and Assignment Agreement, and for as long as Macrilen™ (macimorelin) is patent-protected, the Company will be entitled to a 15% royalty on annual net sales up to \$75.0 million and an 18% royalty on annual net sales above \$75.0 million. Following the end of patent protection in United States or Canada for Macrilen™ (macimorelin), the Company is entitled to a 5% royalty on net sales in that country. In addition, the Company will receive one-time payments ranging from \$4.0 million to \$100.0 million upon the achievement of commercial milestones going from \$25.0 million annual net sales up to \$500.0 million annual net sales.

In January 2018, the Company received a cash payment of \$24.0 million from Strongbridge and on July 23, 2018, Strongbridge launched product sales of Macrilen™ (macimorelin) in the United States.

(ii) Pediatric Indication

Upon approval by the FDA of a pediatric indication for Macrilen™ (macimorelin), the Company will receive a one-time milestone payment from Strongbridge of \$5.0 million.

(iii) PIP study

We have initiated an open label, single dose trial to investigate the pharmacokinetics, pharmacodynamics, safety and tolerability of macimorelin in pediatric patients from two to less than 18 years of age with suspected GHD. Under the terms of the License and Assignment Agreement, the licensee will pay 70% and the Company will pay the remaining 30% of the research and



development costs associate with the PIP. During 2018, the Company invoiced Strongbridge \$358,000 as its share of the costs incurred by the Company under the PIP; such amounts have been collected in full.

(iv) Interim supply arrangement

The Company has agreed to supply ingredients for the manufacture of Macrilen™ (macimorelin) during an interim period at a price that is set 'at cost', without any profit margin. During 2018, the Company invoiced \$2,108,000 and has received payment in full of these invoices under an interim supply agreement.

Novo Nordisk purchase of Strongbridge License Agreement

Effective December 19, 2018, Strongbridge sold the United States and Canadian rights to Macrilen™ under the License and Assignment Agreement to Novo and Novo will fund Strongbridge's Macrilen™ (macimorelin) field organization as a contract field force to promote the product in the United States for up to three years.

Rest of world commercialization of macimorelin

On January 16, 2019, we announced that the European Medicines Agency ("EMA") had granted marketing authorization for macimorelin for the diagnosis of AGHD. AGHD may occur in an adult patient who has a history of childhood onset GHD or may occur during adulthood as an acquired condition. Considering a population of 510 million for the European Community, research based on incidence prevalence suggests that at least 35,000 adults could be afflicted with GHD. This milestone marks a key development in our European commercialization strategy and we are in discussions with a variety of companies regarding licensing and/or distribution opportunities in the rest of world ("ROW").

Monetization of non-strategic assets

On May 1, 2017, we announced that the ZoptEC pivotal Phase 3 clinical study of Zoptrex™ (zoptarelin doxorubicin) in women with locally advanced, recurrent or metastatic endometrial cancer did not achieve its primary endpoint of demonstrating a statistically significant increase in the median period of overall survival of patients treated with Zoptrex™ (zoptarelin doxorubicin) as compared to patients treated with doxorubicin, and we discontinued its development. Similarly, we discontinued the development of AEZS-138/Disorazol Z, as it was based on the same concept as Zoptrex™ (zoptarelin doxorubicin).

Other pipeline prospects for the Company include preclinical work done on AEZS-120, a prostate cancer vaccine, discovery research for ERK-inhibitors for Oncology indications; and discovery research conducted at the Medical University of South Carolina on Compound Library as well as other research and clinical development projects which have been undertaken by our German subsidiary.

Commercial Operations

Our commercial operations were significantly reduced in the fourth quarter of 2017. We eliminated our contract sales team in its entirety, as well as remaining sales management in November 2017, in accordance with the terms of our agreement with inVentiv Commercial Services, LLC, an affiliate of inVentiv Health, Inc. ("inVentiv"), a contract-sales organization.

Pursuant to termination of the inVentiv agreement, we ended our co-promotion with EMD Serono, Inc. and Armune BioScience, Inc.

Until termination of our sales team in November 2017, the inVentiv sales force promoted two products during 2017: Saizen® [somatropin (rDNA origin) for injection] is a prescription medicine indicated for the treatment of growth hormone deficiency in children and adults. We promoted Saizen® pursuant to our promotional services agreement (the "EMD Serono Agreement") with EMD Serono, which we entered into in May 2015 and amended as of December 31, 2016. The EMD Serono Agreement, as amended, provided that we were to promote Saizen® in specific agreed-upon U.S. territories to adult and pediatric endocrinologists in exchange for a sales commission that was based upon new patient starts of the product. The agreement was terminated in accordance with its terms on December, 13 2017.

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, which allowed us to exclusively promote APIFINY® throughout the entire United States. We received a commission for each test performed resulting from our

targeted promotion without regard to any established baseline. The Armune Agreement, as amended, had a three-year term that renewed automatically for successive one-year periods. The parties agreed in January 2018 that the Armune Agreement was terminated.

### Leadership

On May 8, 2018, the following individuals were elected to the Board of Directors: Carolyn Egbert, Michael Cardiff, Juergen Ernst, Gerard Limoges, Dr. Brent Norton, Jonathan Pollack, and Robin Smith Hoke. On September 25, 2018, we announced the appointment of Leslie Auld as Senior Vice President, Chief Financial Officer. On March 26, 2019, the Company announced that Mr. Cardiff has resigned from the board of directors for personal reasons.

### Special Committee

On March 12, 2019, the Company announced that its board of directors has formed a special committee of independent directors (the "Special Committee") to review strategic options available to the Company. The Special Committee has approved the engagement by the Company of a financial advisor that is working with management to assist the Special Committee and the board of directors in considering a wide range of transactions (including opportunities for the license of Macrilen outside of the United States and Canada, or other monetization transactions relating to Macrilen. Management has evaluated whether material uncertainties exist relating to events or conditions as described in Note 4 of our Financial Statements included in this Form 20-F, and has considered the following in making that critical judgment.

The Company's current operating budget and cash flows from operating activities in 2019 are expected to decline compared with 2018, however, the Company believes it will continue to generate growth in its royalty income, which, when combined with its forecasted cash and cash equivalents, the Company believes will provide liquidity that is in excess of its costs for at least, but not limited to, twelve months from the date of approval of these financial statements.

### Contingencies

#### Securities class action litigation

The Company and certain of its current and former officers are defendants in a class-action lawsuit pending in the U.S. District Court for the District of New Jersey, brought on behalf of shareholders of the Company. The lawsuit alleges 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™ (macimorelin) and the prospects for the approval of the Company's New Drug Application for the product by the FDA. The plaintiffs represent a class comprised of purchasers of the Company's common shares during the Class Period and seek damages, costs and expenses and such other relief as determined by the Court. The Company considers the claims that have been asserted in the lawsuit to be without merit and is vigorously defending against them. The Company cannot, however, predict at this time the outcome or potential losses, if any, with respect to this lawsuit.

#### Other litigation

In late July 2017, the Company terminated for cause the employment agreement of Mr. David A. Dodd, the former President and Chief Executive Officer and it also terminated the employment of Mr. Philip A. Theodore, the former Senior Vice President, Chief Administrative Officer, General Counsel and Corporate Secretary. On August 3, 2017, the Company filed a lawsuit against both Messrs. Dodd and Theodore for damages suffered by the Company for breach of confidence and/or breach of fiduciary duty in an amount to be determined prior to trial. On December 21, 2017, Messrs. Dodd and Theodore brought a counterclaim against the Company and its Chair, Carolyn Egbert, in the amount of CAN\$6.0 million alleging, among other things, that defamatory statements were made against Messrs. Dodd and Theodore. On December 21, 2018, the matter was amicably resolved with the Company making a payment to Mr. Dodd in the amount of \$775,000. The parties consider their contractual relationship as having been terminated. Cogas Consulting, LLC ("Cogas") filed a lawsuit against the Company in state court in Fulton County, Georgia on February 2, 2018. The lawsuit was removed to federal court in Georgia. In the lawsuit, Cogas alleged that its employee (and sole shareholder) John Sharkey was entitled to a "success fee" commission on the Strongbridge License Agreement. Cogas was claiming damages in the form of a lost commission on the transaction. Cogas claims its commission is 5% on payments the Company receives within the first three years after January 14, 2018 including 5% of the \$24.0 million Strongbridge already paid the Company, plus 5% of any royalty Strongbridge pays the Company through January 17, 2021. On November 5, 2018, the matter was amicably resolved with the Company making a payment to Cogas in the amount of \$625,000. The parties now consider their contractual relationship as

having been terminated.

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## A. Operating Results

## Consolidated Statements of Comprehensive Loss Information

(in thousands, except share and per share data)	Three months ended		Years ended December 31,		
	December 31,		2018	2017	2016
	2018	2017	2018	2017	2016
	\$	\$	\$	\$	\$
Revenues					
License fees	(332 )	119	24,325	458	497
Product sales	1,446	—	2,167	—	—
Royalty income	184	—	184	—	—
Sales commission and other	94	59	205	465	414
	1,392	178	26,881	923	911
Cost of sales	1,413	—	2,104	—	—
Gross income	(21 )	178	24,777	923	911
Operating expenses					
Research and development costs	767	526	2,932	10,704	16,495
General and administrative expenses	1,665	2,778	8,894	8,198	7,147
Selling expenses	588	452	3,109	5,095	6,745
	3,020	3,756	14,935	23,997	30,387
Income (loss) from operations	(3,041)	(3,578)	9,842	(23,074)	(29,476)
Settlements	(1,400)	—	(1,400)	—	—
Gain (loss) due to changes in foreign currency exchange rates	64	72	656	502	(70 )
Change in fair value of warrant liability	(1,489)	(478 )	263	2,222	4,437
Other finance income	104	21	278	75	150
Net finance income (costs)	(1,321)	(385 )	1,197	2,799	4,517
Income (loss) before income taxes	(5,762)	(3,963)	9,639	(20,275)	(24,959)
Income tax recovery (expense)	636	3,479	(5,452 )	3,479	—
Net income (loss)	(5,126)	(484 )	4,187	(16,796)	(24,959)
Other comprehensive income (loss):					
Items that may be reclassified subsequently to profit or loss:					
Foreign currency translation adjustments	(13 )	(238 )	(260 )	(1,430 )	569
Items that will not be reclassified to profit or loss:					
Actuarial gain (loss) on defined benefit plans	(418 )	59	193	694	(1,479 )
Comprehensive income (loss)	(5,557)	(663 )	4,120	(17,532)	(25,869)
Basic Net income (loss) per share	(0.31 )	(0.03 )	0.25	(1.12 )	(2.41 )
Diluted Net income (loss) per share	(0.31 )	(0.03 )	0.24	(1.12 )	(2.41 )

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.

2018 compared with 2017

Fourth Quarter

Revenues

Our total revenue for the three-month period ended December 31, 2018 was \$1.4 million as compared with \$0.2 million for the same period in 2017, representing an increase of \$1.2 million. The 2018 revenue comprised the net impact of \$1.4 million in product sales less the \$0.2 million reclassification of the \$24.0 million license revenue associated with the Pediatric Indication, to the consolidated statements of financial position. For the same period in 2017, total revenue was comprised of \$0.1 million in license fees and \$0.1 million in sales commission and other. The increase in product sales in the fourth quarter of 2018 arises from the sale of Macrilen™ (macimorelin) inventory to our licensee for sale in the United States.

Cost of sales

Our total cost of goods sold for the three-month period ended December 31, 2018 was \$1.4 million as compared with nil for the same period in 2017. The 2018 balance reflects the cost of Macrilen™ (macimorelin) inventory sold under an interim supply agreement to our licensee for future sales in the United States.

Operating expenses

Our total operating expenses for the three-month period ended December 31, 2018 was \$3.0 million as compared with \$3.8 million for the same period in 2017, representing a decrease of \$0.8 million. This net decline arises primarily from a \$1.1 million decrease in general and administration expenses, offset by a \$0.2 million increase in research and development costs and a \$0.1 million increase in selling expenses. These increases are in-line with the expected impact of the roll-out of our PIP study beginning in the third quarter of 2018.

Settlements

In the three-month period ended December 31, 2018, \$1.4 million was classified as settlements as compared with nil in the same period in 2017. These were costs to settle a lawsuit against the Company from two of its former executives and former sales agent.

Net finance costs

Our net finance loss for the three-month period ended December 31, 2018 was \$1.3 million, as compared to \$0.4 million for the same period in 2017, representing an increase of \$0.9 million. The increase in net finance costs is primarily due to the change in fair value of warrant liability. Such change in fair value results from the periodic "mark-to-market" revaluation, via the application of pricing models, of outstanding share purchase warrants. The closing price of our common shares, which, on the NASDAQ, fluctuated from \$1.19 to \$3.87 during the twelve-month period ended December 31, 2018, compared to \$2.67 to \$2.70 during the same period in 2017, also had a direct impact on the change in fair value of warrant liability.

Net loss

For the three-month period ended December 31, 2018, we reported a consolidated net loss of \$5.1 million, or \$0.31 loss per common share, as compared with a consolidated net loss of \$0.5 million, or \$0.03 loss per common share, for the three-month period ended December 31, 2017. The \$4.6 million increase in net loss, as compared with 2017, results primarily from a \$2.8 million in tax expense, \$1.4 million increase in cost of goods, \$0.9 million increase in finance costs and \$1.4 million increase in settlements, offset by \$1.2 million increase in total revenues. In the fourth quarter of 2018, unlike in 2017, we earned \$0.2 million in royalty income from our licensee, expensed \$1.4 million in settlement costs and had actively begun the EMA and FDA pediatric study for Macrilen™ (macimorelin).

Fiscal Year-End

Revenues

Our total revenue for the year ended December 31, 2018 was \$26.9 million as compared with \$0.9 million for the same period in 2017, representing an increase of \$26.0 million. The 2018 revenue comprised \$24.3 million in license revenue, \$2.2 million in product sales and \$0.2 million in royalty income and \$0.2 million in sales commissions as compared with \$0.4 million in license fee and \$0.5 million in sales commission in 2017. The increase in total revenue in 2018 relates to license fees and product sales associated with executing the License and Assignment Agreement signed for Macrilen™ (macimorelin) in January 2018.



#### Cost of sales

Our total cost of goods sold for the year ended December 31, 2018 was \$2.1 million as compared with nil for the same period in 2017, reflecting the sale of Macrilen™ (macimorelin) inventory pursuant to an interim supply agreement under the License and Assignment Agreement.

#### Operating expenses

Our total operating expenses for the year ended December 31, 2018 was \$14.9 million as compared with \$24.0 million for the same period in 2017, representing a decline of \$9.1 million. This was primarily due to a \$7.8 million decrease in research and development costs and a \$2.0 million decrease in selling expenses, offset by \$0.7 million increase in general and administration expenses.

#### Research and development

In 2018, our focus was on our pediatric clinical trial submitted for approval to the EMA and FDA (the "PIP study") for Macrilen™ (macimorelin), for which we received \$0.4 million from our licensee for their share of such costs. This study was initiated in the third quarter of 2018 with active screening of patients beginning in early 2019.

In 2017, we spent \$2.5 million on third-party costs associated with the ZoptEC pivotal Phase 3 clinical study of Zoptrex™ (zoptarelin doxorubicin) and \$1.2 million on Macrilen™ (macimorelin) third-party costs. In addition, we recorded \$2.6 million in severance accruals and other directly related costs and an onerous lease provision related to the 2017 German Restructuring. This restructuring resulted from the May 2017 announcement that the ZoptEC pivotal Phase 3 clinical study of Zoptrex™ (zoptarelin doxorubicin) did not achieve its primary endpoint of demonstrating a statistically significant increase in the median period of overall survival of patients treated with Zoptrex™ (zoptarelin doxorubicin) as compared to patients treated with doxorubicin.

#### General and administrative expenses

These costs were higher in 2018 than expected as we incurred significant legal costs in the course of reaching settlement agreements for \$1.4 million, as previously discussed in Contingencies Other litigation.

#### Selling expenses

These costs are in-line with expectations and lower in 2018 than in 2017 due to the Q1 2018 termination of our North American sales team and their co-promotion activities as we shifted our focus to the commercialization of Macrilen™ (macimorelin) in markets in the rest of the world.

#### Settlements

In 2018, \$1.4 million was expensed for settlements as compared with nil in the same period in 2017. These were costs to settle a two lawsuits against the Company from two of its former executives and from its former sales agent.

#### Net finance income

Our net finance income for the year ended December 31, 2018 was \$1.2 million, as compared to \$2.8 million for the same period in 2017, representing a decrease of \$1.6 million. The decline in net finance income is primarily due to the change in fair value of our warrant liability. Such change in fair value results from the periodic "mark-to-market" revaluation via the application of pricing models to our outstanding share purchase warrants. The closing price of our common shares, which, on the NASDAQ, fluctuated from \$1.19 to \$3.87 during the twelve-month period ended December 31, 2018, compared to \$2.67 to \$2.70 during the same period in 2017, also had a direct impact on the change in fair value of warrant liability.

#### Net Income

For the year ended December 31, 2018, we reported a consolidated net income of \$4.2 million, or \$0.25 per common share, as compared with a consolidated net loss of \$16.8 million, or \$1.12 loss per common share, for the year ended December 31, 2017. The \$21.0 million improvement in results, as compared with 2017, arose primarily from a \$23.9 million increase in gross profit and \$9.1 million reduction in operating expenses, offset by \$8.9 million movement in



income taxes from recovery to (expense) and \$1.6 million decrease in net finance income.

2017 compared to 2016

Revenues

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Sales commission and other were \$0.1 million and \$0.5 million for the three and twelve months ended December 31, 2017 and \$0.1 million and \$0.4 million for the same periods in 2016, and thus increased in 2017 as compared to 2016. In 2017, those revenues mainly resulted from our sales team exceeding pre-established unit sales baseline thresholds under our co-promotion agreement to sell Saizen®. We also generated sales commission in connection with our promotion of APIFINY®. In the corresponding periods in 2016, sales commission and other revenues were mainly related to EstroGel®.

License fees were \$0.1 million and \$0.5 million for the three and twelve months ended December 31, 2017, as compared to \$0.2 million and \$0.5 million for the same periods in 2016. The Company has deferred revenues at December 31, 2017 of \$541,000 relating to non-refundable upfront payments it previously received for licensing and technology transfer arrangements that it entered into with respect to the development of Zoptrex™ in various territories. Due to events that occurred in 2018, the Company does not anticipate development of Zoptrex™ under the licensing agreements, therefore the Company's remaining carrying amount of deferred revenues was recognized in the first quarter of 2018 as income.

#### Operating Expenses

R&D costs were \$0.5 million and \$10.7 million for the three and twelve months ended December 31, 2017, compared to \$4.6 million and \$16.5 million for the same periods in 2016. R&D costs decreased for the three-month and twelve-month periods ended December 31, 2017 as compared to the same period in 2016. The decrease in R&D costs is mainly attributable to lower comparative third-party costs, as described below, partially offset by the recording, in the third quarter of 2017, of a provision in connection with the 2017 German Restructuring.

Additionally, the decrease in our R&D costs for the twelve months ended December 31, 2017, as compared to the same period in 2016, 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, 2017 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.

A substantial portion of the R&D costs relates to development initiatives associated with Zoptrex™, and with our pivotal Phase 3 ZoptEC clinical trial initiated in 2013 with Ergomed. Third-party costs attributable to Zoptrex™ decreased considerably during the twelve months ended December 31, 2017, as compared to the same period in 2016, mainly since we completed the clinical portion of the ZoptEC trial during the first quarter of 2017 which was partially offset by the additional liability recognized following the negative Zoptrex™ top-line results.

Third-party costs attributable to Zoptrex™ decreased during the three and twelve months ended December 31, 2017, as compared to the same period in 2016, mainly since we closed out the study and related activities in the second quarter following the negative Zoptrex™ top-line results on May 1, 2017. The negative costs for the three-month period ended December 31, 2017 are mainly explained by lower close out costs as compared to the accrual made in the second quarter.

Third-party costs attributable to Macrilen™ (macimorelin) decreased during the three and twelve months ended December 31, 2017, as compared to the same period in 2016. This is mainly since we completed the Phase 3 clinical trial at the end of 2016. The costs incurred in 2017 related to the detailed analysis of the top-line results as well as the preparation of the NDA filing which

was submitted on June 30, 2017. The costs reversal in the fourth quarter of 2017 are explained mainly by the reductions to close out costs.

G&A expenses were \$2.8 million and \$8.2 million for both the three and twelve-month periods ended December 31, 2017, as compared to \$1.8 million and \$7.1 million for the same periods in 2016. The increase in our G&A costs for the three and twelve months ended December 31, 2017, as compared to the same period in 2016, is mainly due to outside legal costs.

Selling expenses were \$0.5 million and \$5.1 million for the three and twelve months ended December 31, 2017, as compared to \$1.5 million and \$6.7 million for the same periods in 2016. Selling expenses for the three and twelve months ended December 31, 2017 and 2016 represent mainly the costs of our sales force related to the co-promotion activities as well as our sales management team. The decrease in selling expenses is explained by the elimination of sales representatives. In the fourth quarter, we eliminated all sales representatives as part of the restructuring efforts.

Net finance income (costs) was \$(0.4) million and \$2.8 million for the three and twelve months ended December 31, 2017, as compared to \$(0.6) million and \$4.5 million, for the same periods in 2016. The decrease in finance income is mainly attributable

to the change in fair value of warrant liability. Such change in fair value results from the periodic "mark-to-market" revaluation, via the application of pricing models, of outstanding share purchase warrants. The closing price of our common shares, which, on the NASDAQ, fluctuated from \$0.84 to \$3.65 during the twelve-month period ended December 31, 2017, compared to \$2.67 to \$4.94 during the same period in 2016, also had a direct impact on the change in fair value of warrant liability.

Net loss for the three and twelve months ended December 31, 2017 was \$0.5 million and \$16.8 million (or \$0.03 and \$1.12 per share), as compared to a net loss of \$8.2 million and \$25.0 million (or \$0.71 and \$2.41 per share) for the same periods in 2016. The decrease in net loss for the three-month period ended December 31, 2017 is a result of the reduction in third party R&D costs. The reduction is attributed to closing out the Zoptrex study and successful completion in the U.S. of the Macrilen™ (macimorelin) filing.

#### Selected quarterly financial data

(in thousands, except for per share data)	Three months ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
	\$	\$	\$	\$
Revenues	1,392	663	168	24,658
Net income (loss)	(5,126)	(2,509)	(2,602)	14,424
Net income (loss) per share [basic]	(0.31)	(0.15)	(0.16)	0.88
Net income (loss) per share [diluted]	(0.31)	(0.15)	(0.16)	0.87
(in thousands, except for per share data)	Three months ended			
	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
	\$	\$	\$	\$
Revenues	178	241	243	261
Net loss	(484)	(9,631)	(2,550)	(4,131)
Net loss per share [basic and diluted]	(0.03)	(0.61)	(0.18)	(0.31)

\* 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, 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 many factors that often do not occur on a linear or predictable basis. Our selling expenses have been consistent but can also vary on a quarter-over-quarter basis due to the ramping up of pre-commercialization activities associated with Macrilen™ (macimorelin).

## Condensed Consolidated Statement of Financial Position Information

(in thousands)	December 31,	
	2018	2017
	\$	\$
Cash and cash equivalents	14,512	7,780
Trade and other receivables and other current assets	1,504	1,047
Restricted cash equivalents	418	381
Inventory	240	554
Property, plant and equipment	65	101
Deferred tax assets	—	3,479
Other non-current assets	8,272	8,853
Total assets	25,011	22,195
Payables and accrued liabilities and income taxes payable	4,635	2,814
Current portion of provision for restructuring and other costs	887	2,469
Current portion of deferred revenues	74	486
Warrant liability	3,634	3,897
Non-financial non-current liabilities <sup>(1)</sup>	13,874	15,312
Total liabilities	23,104	24,978
Shareholders' equity (deficiency)	1,907	(2,783)
Total liabilities and shareholders' equity	25,011	22,195

<sup>1</sup> Comprised mainly of employee future benefits, provisions for restructuring and other costs and non-current portion of deferred revenues.

The increase in cash and cash equivalents as at December 31, 2018, as compared to December 31, 2017, is due to the receipt of \$24.0 million as the payment from the execution of the License and Assignment Agreement.

The increase in payables and other current liabilities is mainly attributable to taxes payable owing for the payments received from our Macrilien™(macemorelin) licensee in 2018.

The decrease in non-financial non-current liabilities from December 31, 2017 to December 31, 2018 is primarily due to the decline in future obligations with employee future benefits and our restructuring and other costs.

The improvement in shareholders' equity (deficiency) as at December 31, 2018, as compared to December 31, 2017, is attributable to the net income of \$4.2 million earned in 2018 as compared with the net loss of \$(16.8) million in 2017.

#### Outstanding Share Data

As at March 29, 2019 we had 16,440,760, Common Shares issued and outstanding, as well as 888,816 US dollar-denominated awards (including deferred share units and stock options) and 869 Canadian dollar-denominated stock options, outstanding. Share purchase warrants outstanding as at March 29, 2019 represented a total of 3,391,844 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 5 to the Company's December 31, 2018 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 generally been financed through certain transactions impacting our cash flows from operating activities, public equity offerings and issuances under various ATM programs. In 2018, we are investing the \$24.0 million up front payment received from Strongbridge to fund operations and capital expenditures.

Since inception, we have incurred significant expenses in its efforts to develop and commercialize products.

Consequently, we have incurred operating losses and negative cash flow from operations historically and in each of the last several years except for the year ended December 31, 2018 when the Company earned revenue from the sale of a license for the adult indication of Macrilen™ (macimorelin) in the United States and Canada. As at December 31, 2018, we had an accumulated deficit of \$310 million.

We have \$14,512 of cash and cash equivalents as at December 31, 2018, and management believes it has sufficient liquidity to meet its current obligations and continue its planned level of expenses for at least, but not limited to the next twelve months after the date of the issuance of this Annual Report on Form 20-F. We are focused on managing our operating expenses, and have the discretion to limit research and development costs, administrative expenses and capital expenditures in order to maintain our liquidity, until such time that additional sources of funding can be obtained. Our principal focus is on the licensing and development of Macrilen™ (macimorelin) and we currently do not have any other approved product.

As described above under “Special Committee,” our current operating budget and cash flows from operating activities in 2019 are expected to decline compared with 2018, however, we believe we will experience an increase in our royalty income, which, when combined with our forecasted cash flows, will provide sufficient liquidity to finance operations and meet our commitments for at least, but not limited to, twelve months from the date of issuance of this Annual Report on Form 20-F.

#### License and Assignment Agreement

On January 16, 2018, the Company entered into the License and Assignment Arrangement.

##### (i) Adult Indication

Under the terms of the license agreement, and for as long as Macrilen™ (macimorelin) is patent-protected, the Company will be entitled to a 15% royalty on annual net sales up to \$75.0 million and an 18% royalty on annual net sales above \$75.0 million. Following the end of patent protection in United States or Canada for Macrilen™ (macimorelin), the Company will be entitled to a 5% royalty on net sales in that country. In addition, the Company will also receive one-time payments ranging from \$4.0 million to \$100.0 million upon the achievement of commercial milestones going from \$25.0 million annual net sales up to \$500.0 million annual net sales.

##### (ii) Pediatric Indication

Upon approval by the FDA of a pediatric indication for Macrilen™ (macimorelin), the Company will receive a one-time milestone payment of \$5.0 million. This amount will be recognized once it is probable that it will be received.

##### (iii) PIP study

We have initiated an open label, single dose trial to investigate the pharmacokinetics, pharmacodynamics, safety and tolerability of macimorelin in pediatric patients from two to less than 18 years of age with suspected growth hormone deficiency ("GHD"). Under the terms of the License and Assignment Agreement, the licensee will pay 70% and the Company will pay the remaining 30% of the research and development costs associate with the PIP. During 2018, the Company invoiced Strongbridge \$358,000 as its share of the costs incurred by the Company under the PIP; such amounts have been collected in full.

##### (iv) Interim Supply Arrangement

The Company has agreed under the contract to supply ingredients for the manufacture of Macrilen™ (macimorelin) during an interim period at a price that is set ‘at cost’, without any profit margin. The Company believes the stand-alone selling price of the manufacturing ingredients to be their cost, as that approximates the amount at which Strongbridge would be able to procure those same goods with other suppliers. During 2018, the Company invoiced \$2,108,000 and has received payment in full of these invoices under the Interim Supply Arrangement.

#### Novo purchase of Strongbridge License Agreement

Effective December 19, 2018, Strongbridge sold the United States and Canadian rights to Macrilen™ (macimorelin) to Novo and Novo will fund Strongbridge's Macrilen™ (macimorelin) contract field force to promote the product in the

United States for up to three years.

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## Public Offerings

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 "April 2016 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. During the year ended December 31, 2017, 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 \$1.8 million. The shelf registration statement pursuant to which this program was established expired on March 28, 2017.

On March 28, 2017, we commenced a new ATM offering pursuant to its existing ATM Sales Agreement, dated April 1, 2016, under which we were able, at our discretion, from time to time, to sell up to a maximum of 3 million common shares through ATM issuances on the NASDAQ, up to an aggregate amount of \$9.0 million (the "March 2017 ATM Program"). The common shares were to be sold at market prices prevailing at the time of the sale of the common shares and, as a result, sale prices varied.

Between March 28, 2017 and April 18, 2017, we issued a total of 597,994 common shares under the March 2017 ATM Program at an average issuance price of \$2.97 per share for aggregate gross proceeds of \$1.8 million less cash transaction costs of \$55,000 and previously deferred financing costs of \$65,000.

On April 27, 2017, we entered into a new ATM Sales Agreement (the "New ATM Sales Agreement"), and filed with the SEC a prospectus supplement (the "Prospectus Supplement") related to sales and distributions of up to a maximum of 2,240,000 common shares through ATM issuances on the NASDAQ, up to an aggregate amount of \$6.9 million under the New ATM Sales Agreement. The common shares will be sold at market prices prevailing at the time of the sale of the common shares and, as a result, prices may vary. The New ATM Sales Agreement and the Prospectus Supplement superseded and replaced the March 2017 ATM Program, which itself had superseded and replaced the April 2016 ATM Program. The Prospectus Supplement supplements the base prospectus included in our Shelf Registration Statement on Form F-3, as amended (the "2017 Shelf Registration Statement"), which was declared effective by the SEC on April 27, 2017. The 2017 Shelf Registration Statement allows us to offer up to \$50 million of common shares and is effective for a three-year period. Between May 30, 2017 and December 31, 2017, we issued 1.8 million common shares at an average issuance price of \$1.71 per share under the New ATM Sales Agreement.

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 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 \$7.6 million, less cash transaction costs of \$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				
	ended December 31, 2018		Years ended December 31, 2017		
	2018	2017	2018	2017	2016
	\$	\$	\$	\$	\$
Cash and cash equivalents - Beginning of period	16,800	12,173	7,780	21,999	41,450
Cash flows from operating activities:					
Net cash used in operating activities	(2,679 )	(4,527 )	6,825	(22,913)	(29,010)
	(2,679 )	(4,527 )	6,825	(22,913)	(29,010)
Cash flows from financing activities:					
Net proceeds from issuance of common shares	—	—	—	7,788	9,924
Proceeds from warrants exercised (note 19)	—	—	—	242	—
	—	—	—	8,030	9,924
Cash flows from investing activities:					
Net cash provided by (used in) investing activities	4	140	(35 )	307	(314 )
	4	140	(35 )	307	(314 )
Effect of exchange rate changes on cash and cash equivalents	387	(6 )	(58 )	357	(51 )
Cash and cash equivalents - End of period	14,512	7,780	14,512	7,780	21,999

#### Operating Activities

##### 2018 compared to 2017

Cash provided by operating activities totaled \$6.8 million for year ended December 31, 2018, as compared to \$22.9 million used by operating activities in the same period in 2017, which is a net provision of cash from operating activities of \$29.7 million. This increase is primarily due to the \$24.0 million license payment received from Strongbridge in January 2018.

##### 2017 compared to 2016

Cash used in operating activities totaled \$4.5 million and \$22.9 million for the three and twelve months ended December 31, 2017 as compared to \$8.1 million and \$29.0 million for the same periods in 2016. The decrease in cash used in operating activities for the twelve months ended December 31, 2017, as compared to the same periods in 2016, is mainly due to lower operating expenses.

#### Financing Activities

##### 2018 compared to 2017

Cash flows from financing activities were nil for the year ended December 31, 2018, as compared to \$8.0 million for the same period in 2017. During 2018, we have focused on commercializing Macrilen™ (macimorelin) though the application of the \$24.0 milestone payment from Strongbridge to our operating costs and working capital needs. This is a change from the same period in 2017 when we raised capital from certain At-The-Market programs.

##### 2017 compared to 2016

Cash flows from financing activities totaled \$0.0 million and \$8.0 million for the three and twelve months ended December 31, 2017, as compared to \$9.4 million and 49.9 million for the same periods in 2016. The decrease is mainly due to higher net proceeds received from the November 2016 Offering.

#### Investing Activities

##### 2018 compared to 2017

Cash flows from investing activities totaled \$0.0 million for the year ended December 31, 2018, as compared with \$0.3 million for the same period in 2017. We have reduced our investment in non-current assets over the last number of years.

2017 compared to 2016

Cash (used in) provided by investing activities totaled \$0.1 million and \$0.3 million for the three and twelve months ended December 31, 2017, as compared to \$0.0 million and (\$0.3) million for the same periods in 2016.

Critical Accounting Policies, Estimates and Judgments

Our consolidated financial statements as at December 31, 2018 and December 31, 2017 and for the years ended December 31, 2018, 2017 and 2016 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.

Critical accounting estimates and assumptions, as well as critical judgments used in applying accounting policies in the preparation of our interim condensed consolidated financial statements were the same as those that applied to our annual consolidated financial statements as of December 31, 2018 and December 31, 2017 and for the years ended December 31, 2018, 2017 and 2016.

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, G&A expenses, working capital and capital expenditures.

Over the past several years, we have increasingly raised capital via public equity offerings and drawdowns and issuances under various ATM sales programs as our primary source of liquidity. In 2018, we invested the \$24.0 million up front payment received from Strongbridge to fund operations and capital expenditures.

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 4.B. Business Overview" and "Key Developments" at the beginning of this Item 5. Over the past three years, our research and development activities have encompassed a 2016 confirmatory Phase 3 clinical trial of Macrilen<sup>TM</sup>(macimorelin), a 2017 unsuccessful Phase 3 clinical study of Zoptrex<sup>TM</sup> (zoptarelin doxorubicin) and the 2018 initiation of pediatric indication study for Macrilen<sup>TM</sup>(macimorelin) for which our licensee is paying 70% of the costs. You can also find relevant information in our consolidated financial statements in Item 18.

D. Trend Information

Outlook for 2019

By the end of December 2018, the License and Assignment Agreement for the U.S. and Canadian rights to Macrilen<sup>TM</sup> (macimorelin) had been purchased by Novo Nordisk from Strongbridge. In January 2019, the JSC met to discuss Novo's commercialization plan for the United States, their supply chain needs and the status of the PIP study.

Quarterly meetings will continue as forecasts for sales, inventory build and purchases as well as clinical trial needs continue to occur.

The January 2019 announcement of marketing authorization for macimorelin for the diagnosis of AGHD by the EMA has further validated the clinical profile and commercial value of macimorelin.



On March 12, 2019, we announced that our board of directors formed the Special Committee to review our strategic options. The Special Committee has approved the engagement of Torreya, a global investment bank specializing in life sciences, as its financial advisor. Torreya is working with management to assist the Special Committee and the board of directors in considering a wide range of transactions (including opportunities for the license of macimorelin outside of the United States and Canada, other monetization transactions relating to macimorelin or the potential sale of the Company).

Our priority is the commercialization of macimorelin; however, we continue to pursue out-licensing opportunities of our non-strategic assets, as they arise.

#### Summary of key expectations for revenues and operating expenditures

The following represents forward-looking information and users are cautioned that actual results may vary.

The January 2018 licensing of Macrilen™ (macimorelin) for its commercialization in the United States and Canada was a significant turning point for the Company and the further development and commercialization of Macrilen™ (macimorelin) in 2019 is the Company's primary focus.

To that end, we expect that research and development costs will be up to \$2.0 million for the year ending December 31, 2019 and will comprise commercial service, consultant, employee and patent costs related to the PIP study and to follow-up studies agreed with the EMA. In the third quarter of 2018, we began invoicing our licensee for its 70% share of the PIP study costs. In 2019, we will continue this collaboration and will work with Novo to optimize this trial.

In addition, we expect our general and administrative expenses to range between \$6.5 million and \$7.5 million for the year ending December 31, 2019 and will consist primarily of employee, insurance, rent, as well as legal and public company costs.

We are working with Torreya on European and the rest of the world business development activities to support the commercialization of macimorelin outside of Canada and the United States.

#### 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, 2018 and 2017 and for the years ended December 31, 2018, 2017 and 2016.

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, 2018, 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, 2018 are as follows:

(in thousands)	Minimum lease payments	Minimum sublease receipts	Service and manufacturing
	\$	\$	\$
Less than 1 year	408	(117 )	2,180
1 - 3 years	533	(24 )	—
4 - 5 years	60	—	—
More than 5 years	5	—	—
Total	1,006	(141 )	2,180



In accordance with the assumptions used in our employee future benefit obligation calculation as at December 31, 2018, undiscounted benefits expected to be paid in Euros are as follows:

(in thousands)	Euros
Less than 1 year	453
1 – 3 years	921
4 – 5 years	944
More than 5 years	13,658
Total	15,976

Item 6. Directors, Senior Management and Employees

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A. Directors and senior management

The following table sets forth information about our directors and our senior corporate officers as at March 29, 2019:

Name and Place of Residence	Position with Aeterna Zentaris
Ammer, Nicola Frankfurt, Germany	Chief Medical Officer, Vice President Clinical Development
Auld, Leslie Ontario, Canada	Senior Vice President, Chief Financial Officer
Egbert, Carolyn Texas, United States	Chair of the Board of Directors
Ernst, Juergen North Rhine-Westphalia, Germany	Director
Garrison, Brian Pennsylvania, United States	Senior Vice President, Global Commercial Operations
Grau, Günther Frankfurt, Germany	Vice President, Finance
Guenther, Eckhard Hessen, Germany	Vice President, Alliance Management
Limoges, Gérard Quebec, Canada	Director
Norton, Brent Ontario, Canada	Director
Pollack, Jonathan Ontario, Canada	Director
Smith Hoke, Robin Ohio, United States	Director
Teifel, Michael Hessen, Germany	Vice President, Non-Clinical Sciences
Ward, Michael Illinois, United States	President and Chief Executive Officer

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

Nicola Ammer was appointed as our Vice President, Clinical Development and as Chief Medical Officer in January 2018. She serves as one of our executive officers. Dr. Ammer, who is based in the Frankfurt, Germany, office of our German subsidiary, began her career in the pharmaceutical medicine environment in the CRO business in 2002 and gained profound knowledge of all aspects of clinical research & development in various positions with increasing responsibility, including a Director of Clinical Operations. She joined Aeterna Zentaris GmbH in March 2015 as

Clinical Program Director and took over the role of the Head of Clinical Development in January 2016. She possesses numerous skills in the area of pharmaceutical medicine and contributed significantly to the successful completion of the macimorelin clinical development program in the adult indication. Dr. Ammer obtained the license to practice medicine in 1995 after completion of her academic studies at the University of Essen. She was awarded a doctorate diploma in medicine by the University of Münster in 2004 and a Master of Science in Pharmaceutical Medicine by the University Duisburg-Essen in 2009.

Leslie Auld was appointed as our Senior Vice President, Chief Financial Officer in September 2018. She has over twenty-five years of accounting, finance and pharmaceutical industry experience, with increasingly senior roles at PricewaterhouseCoopers,



Helix BioPharma Corp., Luminex Diagnostics (formerly TM BioScience Corp.), Attwell Capital Inc. (formerly Fralex Therapeutics) and GeneNews Limited. A Chartered Professional Accountant, Ms. Auld graduated with an Honors Bachelor of Science degree in Pharmacology & Toxicology from the University of Western Ontario and has a Master of Business Administration degree from the University of Toronto.

Carolyn 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. (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 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.

Brian Garrison became our Senior Vice President, Global Commercial Operations in December 2017. For the last three years he has held the roles of National Sales Director, managing the co-promotion efforts for two endocrinology products and a urology diagnostic and as the Marketing Director for Macrilen™(macimorelin). Mr. Garrison worked at Amgen, Inc. where he held the role of Oncology Reimbursement Marketing Director. In this position, he was in charge of the Field Reimbursement Team and the Oncology Call Center for all of Amgen's oncology brands. Mr. Garrison also worked on the access strategy for several of the key oncology brands, such as Neulasta®, Neupogen®, Vectibix® and Imlytic®. Also, while at Amgen, Mr. Garrison served as a Marketing Manager in the Inflammatory Business Unit working on key access programs for Enbrel®. Prior to his work on Enbrel®, Mr. Garrison was a Sales Manager for the Bone Health Business Unit, launching the first-in-class biologic therapy for osteoporosis, Prolia®. Mr. Garrison began his career at Merck & Co. where he held various positions of increasing responsibility in sales and marketing, winning top national sales honors, both as a representative and sales manager. Mr. Garrison is a combat veteran, leading an infantry platoon with the 10<sup>th</sup> Mountain Division through combat operations in the Horn of Africa. Mr. Garrison is a graduate of the U.S. Military Academy, West Point, where he was commissioned as an Infantry officer, serving ten years active duty in the U.S. Army.

Günther Grau was appointed as our Vice President, Finance in February 2018. Mr. Grau, has been part of the Company since 2000. He began his career in the pharmaceutical industry at ASTA Medica AG, a predecessor of our Company, in 1995, assuming roles of increasing responsibility in areas of internal and external accounting during his career. Mr. Grau obtained a diploma in Business Administration from the Philipps-University, Marburg, in 1991.

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.

G rard Limoges, C.M., FCPA, FCA 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 Universit  de Montr al (HEC Montr al) 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 Agr es du Qu bec). 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.

Dr. Brent Norton has served as a director on our Board since 2018. Dr. Norton is a business leader in the life science industry with operational and director experience across several successful enterprises which have achieved significant product sales and returns for investors. He uses his cross functional knowledge to develop strategy, raise capital and build important relationships in the academic and business community. Dr. Norton founded PreMD, completing IPO's and listings on both the Toronto Stock Exchange and the American Stock Exchange. Operationally, he has research and development and commercial operations, led transactions with AstraZeneca, Eli Lilly, L'Oreal, Parke Davis/Pfizer, etc., and taken products through the FDA to global out-licensing with Johnson & Johnson. He is a founding Director of Novadaq Technologies (TSX:NDQ, NASDAQ:NVDQ) and was recently sold to Stryker Corporation. Dr. Norton has been an active member of several boards in Canada and the United States. He is a Venture Partner at Lumira Capital, Executive Chairman & CEO of Ortho RTI, a member of the Research Committee for CAMH, an Advisory BOD member for the Ivey International Centre for Health Innovation, a Director of Alpine Ontario and Past-President and Director of the Osler Bluff Ski Club.

Jonathan Pollack has served as a director on our Board since 2018. Mr. Pollack is the President of The JMP Group, a private investment and consulting firm. He is also a director of several public and private companies including CECO Environmental Corp. (NASDAQ:CECE) and is an officer of AcuityAds Holdings, Inc. (TSX-V:AT). Mr. Pollack also served as a director of API Technologies Corp. (NASDAQ: ATNY), Pinetree Capital Ltd. (TSX:PNP), Hanfeng Evergreen Inc. (TSX:HF) and Lifebank Corp. (TSX-V:LBK). Previously, he served as Executive Vice President of API Technologies Corp. (NASDAQ:ATNY), a leading provider of RF/microwave, microelectronics and security technologies for critical and high-reliability applications from 2009 and as a director from 2007 until January 2011 when it was sold. From March 2005 through its sale in 2009, he served as the Chief Financial Officer and Corporate Secretary of Kaboose Inc. Prior thereto, he worked in investment banking in New York. Mr. Pollack received a Master of Science in Finance from the London School of Economics and a Bachelor of Commerce from McGill University. He sits on the boards of several philanthropic organizations including the Mt. Sinai Hospital Foundation, the Crescent School Foundation, and the Sterling Hall School Foundation.

Robin Smith Hoke has served as a director on our Board since 2018. Ms. Hoke is a business and legal executive with over 25 years of healthcare and pharmaceutical experience in various legal and business roles where she focused on operations, strategy, business development, acquisitions, strategic relationships, and commercialization. Ms. Hoke currently serves as President & CEO of Leiters, a 503B FDA registered outsourcing service provider with manufacturing facilities in Denver, Colorado and San Jose, California. She also serves as a member of the Board of Directors of Camargo Pharmaceutical Services, LLC., a privately held 505(b)(2) global drug development and regulatory services company in Cincinnati, Ohio. She previously served as a member of the board of Oncobiologics, Inc., a publicly held clinical stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex biosimilar therapeutics. She previously served as chair of the Board of Directors and interim chief executive officer at Ricerca Biosciences, LLC, a pre-clinical CRO. Prior to Ricerca, Ms. Hoke served as the president of GeneraMedix, Inc., a specialty generic injectable company and held senior legal and business roles at Cardinal Health, Inc. She also spent time with Abbott Laboratories, Inc., and served as a partner in the business law firm of Kegler, Brown, Hill & Ritter, Co., L.P.A.

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.

Michael Ward became our President and Chief Executive Officer in July 2017. He has over thirty years of executive and legal experience in the healthcare, pharmaceutical and technology industries. Most recently, Mr. Ward served as Chief Compliance & Legal Officer and Corporate Secretary for Sagent Pharmaceuticals, a global specialty generic pharmaceutical company, and led its sale to Nichi-Iko Pharmaceutical Co., Ltd. for \$736 million. Mr. Ward has served as Strategic Advisor to Benevolent Capital Partners for the last five years and is an inactive Partner with Outside GC LLC. Prior to Sagent Pharmaceuticals, Mr. Ward was Vice President, Assistant General Counsel of Global Compliance, Ethics & Litigation and Chief Privacy Officer at CDK Global. Mr. Ward has served in several executive roles and was responsible for business development, compliance, legal and operational

matters in the healthcare, pharmaceutical and technology industries during his career. Mr. Ward graduated from Albion College and Case Western Reserve University Law School.

There are no family relationships between any of the persons named above and no arrangement with any customers, major shareholders, suppliers or others pursuant to which any person above was selected as a director or executive officer.

#### 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 U.S. dollars and, to the extent a director or officer has been paid in a currency other than U.S. dollars, the amounts have been converted from such person's home country currency to U.S. dollars based on the following annual average exchange rates: for the financial year ended December 31, 2018: €1.000 = U.S.\$1.181 and CAN\$1.000 = U.S.\$0.772; for the financial year ended December 31, 2017: €1.000 = U.S.\$1.198 and CAN\$1.000 = U.S.\$0.797; for the financial year ended December 31, 2016: €1.000 = U.S.\$1.110 and CAN\$1.000 = U.S.\$0.754.

#### 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 three Outside Directors, each of whom is independent, namely Ms. Carolyn Egbert (Chair), Mr. Juergen Ernst and Ms. Robin Smith Hoke.

#### Retainers

Our Outside Directors are paid an annual retainer, the amount of which depends on the position held on the Board. Annual retainers are paid on a quarterly basis to our Outside Directors. Each Outside Director is paid the equivalent value of the payment in his or her home currency, net of any withholdings or deductions required by applicable law. Members of the Strategic Review Committee (the "SRC") were granted a monthly retainer in the amount of U.S. \$7,500 from July 2017 up to and including January 2018, Ms. Egbert and Mr. Ernst deferred payment of their SRC retainers to 2018.

Type of Compensation	Annual Retainer for the year 2018	Monthly Retainer for January 2018
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	-
SRC Chair Retainer	-	7,500
SRC Member Retainer	-	7,500

All Directors are reimbursed for travel and other out-of-pocket expenses incurred in attending Board or committee meetings.

## Outstanding Awards

The following table shows all awards outstanding to each Outside Director as at December 31, 2018:

Name	Option-based Awards					Share-based Awards		
	Issuance Date	Number of Securities Underlying Unexercised Options	Option Exercise Price	Option Expiration Date	Value of Unexercised In-the-money Options <sup>(1)</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 <sup>(2)</sup>
	(mm-dd-yyyy)	(#)	(\$)	(mm-dd-yyyy)	(\$)	(mm-dd-yyyy)	(#)	(\$)
Cardiff, Michael	05-10-2016	20,000	3.48	05-09-2023	—	—	—	—
	12-06-2016	7,850	3.45	12-06-2023	—	—	—	—
	08-15-2017	60,000	2.05	08-15-2024	53,400	—	—	—
Egbert, Carolyn	—	—	—	—	—	05-08-2018	23,000	67,620
	05-10-2016	10,000	3.48	05-09-2023	—	—	—	—
	12-06-2016	7,850	3.45	12-06-2023	—	—	—	—
Ernst, Juergen	08-15-2017	60,000	2.05	08-15-2024	53,400	—	—	—
	—	—	—	—	—	05-08-2018	23,000	67,620
	05-10-2016	10,000	3.48	05-09-2023	—	—	—	—
Smith Hoke, Robin	12-06-2016	7,850	3.45	12-06-2023	—	—	—	—
	08-15-2017	60,000	2.05	08-15-2024	53,400	—	—	—
	—	—	—	—	—	05-08-2018	23,000	67,620
Limoges, Gérard	05-10-2016	10,000	3.48	05-09-2023	—	—	—	—
	12-06-2016	7,850	3.45	12-06-2023	—	—	—	—
	08-15-2017	60,000	2.05	08-15-2024	53,400	—	—	—
Norton, Brent	—	—	—	—	—	05-08-2018	23,000	67,620
	—	—	—	—	—	05-08-2018	23,000	67,620
Pollack, Jonathan	—	—	—	—	—	05-08-2018	23,000	67,620

Value of unexercised in-the-money options" at financial year-end is calculated based on the difference between the (1) closing prices of the Common Shares on the NASDAQ on the last trading day of the fiscal year (December 31, 2018) of \$2.94 and the exercise price of the options, multiplied by the number of unexercised options.

(2) The Company used the closing price of its Common Shares on the NASDAQ as at the last trading day of the fiscal year (December 31, 2018) of \$2.94

See "Summary of the Stock Option Plan" for more details on the Company's second amended and restated stock option plan adopted by the Board on March 29, 2016 and ratified by the shareholders on May 10, 2016 ("Stock Option Plan") and see "Summary of Long-Term Incentive Plan" for more details on the Company's long-term incentive plan adopted by the Board of Directors on March 27, 2018, and ratified by the shareholders on May 8, 2018 ("Long-Term Incentive Plan").

## Total Compensation of Outside Directors

The table below summarizes the total compensation paid to our Outside Directors during the financial year ended December 31, 2018 (all amounts are in U.S. dollars). Our Outside Directors are generally paid in their home currency, Messrs. Cardiff, Limoges, Norton and Pollack were paid in Canadian dollars. Mses. Egbert and Smith Hoke were paid in U.S. dollars and Mr. Ernst was paid in euros.

Name	Fees earned <sup>(1)</sup>	Share-based Awards <sup>(2)</sup>	Option-based Awards	Non-Equity Incentive Plan Compensation	Pension Value	All Other Compensation	Total
	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)
Cardiff, Michael	53,555	41,170	—	—	—	—	94,725
Egbert, Carolyn <sup>(3)</sup>	177,500	41,170	—	—	—	—	218,670
Ernst, Juergen	51,065	41,170	—	—	—	—	92,235
Smith Hoke, Robin	27,879	41,170	—	—	—	—	69,049
Limoges, Gérard	67,500	41,170	—	—	—	—	108,670
Norton, Brent	29,176	41,170	—	—	—	—	70,346
Pollack, Jonathan	29,176	41,170	—	—	—	—	70,346

In respect of our financial year ended December 31, 2018, we paid an aggregate amount of \$450,577 to all of our (1) Outside Directors for services rendered in their capacity as directors, excluding reimbursement of out-of-pocket expenses and the value of share-based awards and option-based awards granted in 2018.

(2) Amounts shown represent the value of the DSUs on the grant date (\$1.79). The value of one DSU on the grant date is the closing price of one Common Share on the NASDAQ on the last trading day preceding the date of grant.

(3) Ms. Egbert was awarded a cash bonus in the amount of \$75,000.

## Compensation of Executive Officers

The following is disclosure of information related to the compensation that we paid to our "Named Executive Officers" during 2018. For the 2018 year, our "Named Executive Officers" were as follows:

• Mr. Michael V. Ward, who currently serves as President and Chief Executive Officer as an employee;

• Mr. James Clavijo, who served as Chief Financial Officer as an employee from March 5, 2018 to September 24, 2018;

• Ms. Leslie Auld, who currently serves as Senior Vice President, Chief Financial Officer as an independent contractor from September 24, 2018; and

• Dr. Richard Sachse, who served as Senior Vice President and Chief Scientific and Chief Medical Officer until June 14, 2018, Mr. Brian Garrison, who currently serves as Senior Vice President, Global Commercial Operations, and Eckhard Guenther, who currently serves as Vice President, Alliance Management, who were our three most highly compensated executive officers (other than our Chief Executive Officer and our current and former Chief Financial Officer) during 2018.

## Compensation Discussion &amp; 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.

#### 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, including stock options, previously granted under our second amended and restated stock option plan adopted by the Board on March 29, 2016 and ratified by the shareholders of Aeterna on May 10, 2016 (the "Stock Option Plan"), and presently granted under the Company's long-term incentive plan adopted by the Board on March 27, 2018 and ratified by the shareholders of Aeterna on May 8, 2018 (the "Long-Term Incentive 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; 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 is based exclusively on the Long Term Incentive Plan, which permits the issuance of a number of equity-based awards based on the contribution of the officers and their responsibilities. The Board adopted a policy regarding stock option grants in December 2014, 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. Since the adoption of the Long-Term Incentive Plan in 2018, we have broadened the types of equity-based awards which we may issue beyond stock options (to include, among other types, restricted stock units, deferred share units and others).

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 up to an annual maximum amount of \$11,200 for employees 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 NGCC did not repeat or update the benchmarking process in 2014 - 2018 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, annually reviews and assesses the Company's current compensation program and makes appropriate adjustments, if any.

In June 2018, the NGCC retained Bowers Consulting LLC ("Bowers"), an independent compensation consulting firm, to assist the NGCC in analyzing the Corporation's director and executive compensation. The Corporation paid fees to Bowers in the amount of \$5,400.

#### 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 long-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 long-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 equity-based awards) 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 equity-based awards, 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 equity-based awards) 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 equity-based awards 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 behavior.

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 and other equity-based awards issued pursuant to our Stock Option Plan or Long-Term Incentive Plan are not derivative securities for this purpose.

#### 2018 Compensation

**Base Salary.** The primary element of our compensation program is base salary. Our view is that a competitive base salary is a necessary element for retaining qualified executive officers. 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.** The Board, based on the NGCC's recommendation, adopted the following performance objectives for 2018:

Goal		Result
Commercialization of Macrilen™ (macimorelin) in Europe and ROW	Assuming EMA approval, develop strategy and implementation plan for commercialization through the out-licensing of Macrilen™ (macimorelin) for Europe and ROW	The Board developed and approved a strategy to out-license macimorelin for the ROW, but the Corporation did not secure acceptable ROW agreements in 2018. The Corporation subsequently (in 2019) engaged Torreyia to assist in identifying and executing upon such opportunities.
Commercialization of Macrilen™ (macimorelin) in Europe and ROW	Successfully execute the board-approved strategy and implementation plan.	Not completed. The Board approved a strategy and implementation plan to pursue commercialization opportunities for macimorelin for the ROW and to implement non-macimorelin related opportunities. The Corporation explored several potential opportunities, but none resulted in a transaction that was acceptable to the Corporation.
Commercialization of Macrilen™ (macimorelin) in United States and Canada	Deploy all effective resources to ensure timely EMA approval of Macrilen™ (macimorelin). Provide effective support to Strongbridge in its commercialization efforts to ensure Macrilen™ (macimorelin) is timely marketed in 2018.	Completed. EMA approval of macimorelin was obtained in January 2019 based on the work of the Corporation during 2018.
Commercialization of Macrilen™ (macimorelin) in United States and Canada	Ensure effective clinical studies are in place to obtain approval of pediatric indication of Macrilen™ (macimorelin).	Not completed. The Corporation provided support, but efforts were slowed due to Strongbridge's sale of its license rights to Novo Nordisk A/S in December 2018.
Commercialization of Macrilen™ (macimorelin) in United States and Canada	Manage costs and control expenses to maximize cash conservation.	In progress. The Corporation is collaborating with Novo Nordisk (and previously with Strongbridge) and is providing appropriate activities with respect to the ongoing clinical studies that are required to obtain approval for the pediatric indication of Macrilen™.
Commercialization of Macrilen™ (macimorelin) in United States and Canada	Provide cash forecast by month on a 24-month projection.	In progress. The Corporation is focused on cost-savings and cash conservation. To this end, the Corporation reduced operating costs in both Germany and the United States in 2018. This continues to be an important objective in 2019.
Improve operations	Ensure effective and efficient use of resources and personnel.	The Corporation remains focused on aligning essential personnel, both in Germany and the United States, with the Corporation's strategy and improving cost-effectiveness. In 2018, this included the termination of employment of certain employees.
Long-Term Equity Compensation	Ensure that performance milestones for key managers align with and support CEO milestones.	The Corporation remains focused on aligning essential personnel, both in Germany and the United States, with the Corporation's strategy and improving cost-effectiveness. In 2018, this included the termination of employment of certain employees.
Long-Term Equity Compensation		Completed.

The Board approved an award of 50,000 stock options at an exercise price of \$1.46, to Mr. Ward on April 2, 2018 in accordance with the Stock Option Plan. The Board approved an award of 100,000 stock options at an exercise price of \$2.11, to Mr. Ward on June 22, 2018, in accordance with the Long-Term Incentive Plan.

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.

There were 628,685 options outstanding under the Stock Option Plan representing approximately 3.82% of all issued and outstanding Common Shares on March 29, 2019. The proposed number of Common Shares issuable pursuant to the Long-Term

Incentive Plan is fixed at 11.4% of the issued and outstanding Common Shares at any given time less the number of Common Shares issuable pursuant to stock options granted at such time under the Stock Option Plan. See below for a complete description of the Long-Term Incentive Plan. The Company does not intend on issuing any new stock options under the Stock Option Plan, and instead will issue any future stock options under the Long-Term Incentive Plan.

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 person eligible to receive grants under the Stock Option Plan (each a "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 ten-day period, all rights of the Participant to such options or to the exercise of same (to the extent not already exercised) shall automatically terminate and have no further force or effect whatsoever. "Closing Date" is defined to mean (x) the closing date of the amalgamation, merger, consolidation, sale or license transaction in the case of clause (i) above; (y) the first expiry date of the takeover bid on which each of the offeror's conditions are either satisfied or waived in the case of clause (ii) above; or (z) the date on which it is publicly announced that holders of greater than 50% of our then outstanding Common Shares have tendered their Common Shares to a takeover bid in the case of clause (iii) above.

The Stock Option Plan provides that the following amendments may be made to the plan 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.

#### Summary of the Long-Term Incentive Plan

The purpose of the Long-Term Incentive Plan is to (i) promote our long-term financial interests and growth by attracting and retaining management and other personnel and key service providers with the training, experience and ability to enable them to make a substantial contribution to the success of our business; (ii) motivate management personnel by means of growth-related incentives to achieve long-range goals; and (iii) further the alignment of interests of participants with those of our shareholders through opportunities for increased share ownership in the Company.

The NGCC is the administrator of the Long-Term Incentive Plan (the “Administrator”). At any time, the Board may serve as the Administrator of the Long-Term Incentive Plan, in lieu of, or in addition, to the NGCC. Except as provided otherwise under the Long-Term Incentive Plan, the Administrator has plenary authority to grant awards pursuant to the terms of the Long-Term Incentive Plan to eligible individuals, determine the types of awards and the number of shares to be covered by the awards, establish the terms and conditions for awards and take all other actions necessary or desirable to carry out the purpose and intent of the Long-Term Incentive Plan.

Participation in the Long-Term Incentive Plan is generally open to all officers, employees and other individuals, including Outside Directors. However, any individual whose services to the Company or any of its subsidiaries are limited to capital-raising transactions, or the promotion and maintenance of a market for the Company securities, are ineligible to participate in the Long-Term Incentive Plan. Prospective officers, employees and other service providers who have accepted offers to provide services to the Company may also participate in the Long-Term Incentive Plan. The Long-Term Incentive Plan enables the grant of stock options, stock appreciation rights, stock awards, stock unit awards, performance shares, cash-based performance units and other stock-based awards, each of which may be granted separately or in tandem with other awards.

The maximum number of Common Shares issuable under the Long-Term Incentive Plan is fixed at 11.4% of the issued and outstanding Common Shares at any given time, less the number of Common Shares issuable pursuant to stock options granted at such time under the Stock Option Plan. There were 261,000 awards outstanding under the Long-Term Incentive Plan representing approximately 1.59% of all issued and outstanding Common Shares on March 26, 2019. See above for a complete description of the Stock Option Plan.

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 no single participant may hold options to purchase, from time to time, more than 5% of our issued and outstanding Common Shares.

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 Long-Term Incentive Plan, within any one-year period, cannot exceed \$100,000 valued on a Black-Scholes basis and as determined by the NGCC; and the aggregate number of securities issuable to all of our Outside Directors entitled to receive a benefit under the Long-Term Incentive Plan, within any one-year period, under all of our security-based compensation arrangements, cannot exceed 1% of its issued and outstanding securities.

Except as provided below or within an award agreement, each award granted under the Long-Term Incentive Plan (other than a performance unit that cannot be paid in shares) will be subject to a minimum vesting period or minimum restriction period as follows: (i) each stock option or SAR will be subject to a minimum vesting period of 12 months from the date of grant, (ii) each award of stock, stock units, performance shares, performance units payable in shares and other stock-based awards (“Full Value Awards”) granted to non-employee directors will be subject to a minimum restriction period of 12 months from the date of grant, and (iii) each Full Value Award granted to a participant other than a non-employee director will be subject to a minimum restriction period of 12 months from the date of grant if vesting of or lapse of restrictions on such award is based on the satisfaction of performance goals and a minimum restriction period of 36 months from the date of grant, applied in either pro rata installments or a single installment, if vesting of or lapse of restrictions on such award is based solely on the participant’s satisfaction of specified service requirements with us (provided that no such Full Value Awards will vest or have its restrictions lapse during the first 12 months following the date of grant). If the grant of a performance award is conditioned on satisfaction of performance goals, the performance period must not be less than 12 months’ duration, but no additional minimum restriction period need apply to such award. The minimum vesting period or minimum restriction period will not apply in the case of death or disability of a participant or in the event of a change in control. Awards that result in the issuance of an aggregate of up to 5% of the share pool under the Long-Term Incentive Plan may be granted without regard to such minimum vesting period or minimum restriction period.

Awards granted under the Long-Term Incentive Plan shall not be subject in any manner to alienation, anticipation, sale, transfer, assignment, pledge, or encumbrance, except as otherwise determined by the Administrator; provided, however, that this restriction shall not apply to the Common Shares received in connection with an award after the

date that the restrictions on transferability of such shares set forth in the applicable award agreement have lapsed. Except as provided in the applicable award agreement or otherwise determined by the Administrator, and subject to the minimum vesting period or minimum restriction period described above, upon termination of service (as defined in the Long-Term Incentive Plan):

- Stock options or stock appreciation rights shall be forfeited, to the extent stock options or stock appreciation rights are not vested and exercisable;

- During the applicable restriction period, restricted stock and any accrued but unpaid dividends that are at that time subject to restrictions shall be forfeited; and
- During the applicable deferral period or portion thereof to which forfeiture conditions apply, or upon failure to satisfy any other conditions precedent to the delivery of common shares or cash to which RSUs, performance shares or performance units relate, all performance shares, performance units and RSUs and any other accrued but unpaid dividend equivalents with respect to such RSUs that are then subject to deferral or restriction shall be forfeited.

In the event of a change in control (as defined in the Long-Term Incentive Plan) of the Company, outstanding awards will terminate upon the effective time of the change in control unless provision is made for the continuation, assumption or substitution of awards by the surviving or successor entity or its parent. Unless an award agreement says otherwise, the following will occur with respect to awards that terminate in connection with a change in control of the Company:

- stock options and SARs, whether vested or unvested, will become fully exercisable and holders of these awards will be permitted immediately before the change in control to exercise them;
- restricted stock and RSUs with time-based vesting (i.e., not subject to achievement of performance goals) will become fully vested immediately before the change in control, and RSUs will be settled as promptly as is practicable in accordance with applicable law; and
- restricted stock, RSUs, performance shares, and performance units that vest based on the achievement of performance goals will become fully vested and earned based on the target performance level as to the performance goals, such that 100% of the target award is earned as of the date of the change of control; and the RSUs and performance units will be settled as promptly as is practicable in accordance with applicable law.

The Long-Term Incentive Plan will terminate on the earlier of (i) the earliest date as of which all awards granted under the Long-Term Incentive Plan have been satisfied in full or terminated and no shares approved for issuance under the Long-Term Incentive Plan remain available to be granted under new awards, or (ii) the tenth anniversary of date the Long-Term Incentive Plan, as amended and restated, is approved by our shareholders.

The Administrator may amend, alter or discontinue the Long-Term Incentive Plan, but no amendment, alteration or discontinuation will be made that would materially impair the rights of a participant with respect to a previously granted award without his or her consent, except such an amendment made to comply with applicable law or rule of any securities exchange or market on which our Common Shares are listed or admitted for trading or to prevent adverse tax or accounting consequences to the Company or the participant. In no event, however, will an amendment be made without the approval of our shareholders to the extent such amendment would (i) materially increase the benefits accruing to participants under the Long-Term Incentive Plan, (ii) increase the number of shares that may be issued under the Long-Term Incentive Plan or to a participant, (iii) materially expand the eligibility for participation in the Long-Term Incentive Plan, (iv) eliminate or modify the prohibition on repricing of stock options and SARs, (v) lengthen the maximum term or lower the minimum exercise price or base price permitted for stock options and SARs, (vi) modify the prohibition on the issuance of reload or replenishment options, (vii) amend the amendment provisions in the Long-Term Incentive Plan, or (viii) amend the Long-Term Incentive Plan to remove or exceed the 10% insider participation limit.

#### Outstanding Option-Based Awards and Share-Based Awards

The following table shows all awards outstanding to our Named Executive Officers as of December 31, 2018:

Name	Option-based Awards					Share-based Awards		
	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)	(\$)	(#)	(\$)	
Auld, Leslie	—	—	—	—	—	—	—	
Clavijo, James <sup>(3)</sup>	—	—	—	—	—	—	—	
Garrison, Brian	11/17/2015	500	116.00	11/17/2022	—	—	—	
	12/21/2015	3,000	4.58	12/21/2022	—	—	—	
	12/06/2016	2,500	3.45	12/06/2023	—	—	—	
Guenther, Eckhard	12/21/2015	5,000	4.58	12/21/2022	—	—	—	
	11/08/2016	398	3.50	11/08/2023	—	—	—	
	12/06/2016	10,000	3.45	12/06/2023	—	—	—	
Sachse, Richard <sup>(4)</sup>	—	—	—	—	—	—	—	
Ward, Michael V.	08/15/2017	150,000	2.05	08/15/2024	133,500	—	—	
	04/02/2018	50,000	1.46	04/02/2025	74,000	—	—	
	06/22/2018	100,000	2.11	06/22/2025	83,000	—	—	

(1) The number of securities underlying unexercised options represents all awards outstanding at December 31, 2018.

"Value of unexercised in-the-money options" at financial year-end is calculated based on the difference between (2) the closing price of the Common Shares on the NASDAQ on the last trading day of the fiscal year (December 31, 2018) of \$2.94 and the exercise price of the options, multiplied by the number of unexercised options.

Mr. Clavijo ceased to be Chief Financial Officer on September 24, 2018. All outstanding stock options held by Mr. (3) Clavijo were cancelled effective as of his termination date in accordance with the provisions of the Stock Option Plan.

Dr. Sachse's employment was terminated effective June 14, 2018. All outstanding stock options held by Dr. Sachse (4) were cancelled in accordance with the provisions of the Stock Option Plan.

There were no share-based awards outstanding to our Named Executive Officers at December 31, 2018.

#### 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, 2018:

Name	Option-based awards	Share-based awards	Non-equity incentive plan compensation	Value
	Value vested during the year <sup>(1)</sup>	Value vested during the year	earned during the year	
	(\$)	(\$)	(\$)	
Auld, Leslie	—	—	—	
Clavijo, James	—	—	—	
Garrison, Brian	3,074	—	35,000	

Guenther, Eckhard	12,299	—	—
Sachse, Richard	—	—	120,000
Ward, Michael V.	—	—	35,000

Represents the aggregate dollar value that would have been realized if the options had been exercised on the (1) 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, 2018, 2017 and 2016. All amounts in the table below are in U.S. dollars. All cash amounts paid to Messrs. Ward, Clavijo and Garrison were paid in U.S. dollars, Ms. Auld's cash payments were made in Canadian dollars and Dr. Sachse and Mr. Guenther's cash payments were made in euros.

## SUMMARY COMPENSATION TABLE

Name and principal position	Years	Salary	Share based awards	Option based awards (1)	Non-equity incentive plan compensation			Total compensation
					Annual incentive plan	Long-term incentive plans	Pension Value	
		(\$)	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)
Ward, Michael V. President and Chief Executive Officer	2018	325,000	—	227,241	35,000	—	—	587,241
	2017	121,461	—	242,495	—	—	—	363,956
	2016	—	—	—	—	—	—	—
Clavijo, James <sup>(2)</sup> Former Chief Financial Officer	2018	190,574	—	130,240	—	—	137,500	458,314
	2017	—	—	—	—	—	—	—
	2016	—	—	—	—	—	—	—
Auld, Leslie Senior Vice President, Chief Financial Officer	2018	62,385	—	—	—	—	—	62,385
	2017	—	—	—	—	—	—	—
	2016	—	—	—	—	—	—	—
Sachse, Richard <sup>(4)</sup> Former Senior Vice President, Chief Scientific Officer and Chief Medical Officer	2018	403,297	—	—	—	—	—	403,297
	2017	222,000	—	—	120,000	—	37,067	379,067
	2016	222,000	—	257,000	55,500	—	37,067	571,567
Garrison, Brian Senior Vice President, Global Commercial Operations	2018	235,015	—	3,550	35,000	—	—	273,565
	2017	—	—	—	—	—	—	—
	2016	—	—	—	—	—	—	—
Guenther, Eckhard Vice President, Alliance Management	2018	191,242	—	—	13,154	—	3,298	207,694
	2017	155,318	—	—	—	—	2,970	158,288
	2016	152,510	—	27,797	—	—	2,851	183,158

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
November 9, 2016	\$3.50	80.35%
December 6, 2016	\$3.45	80.57%
December 16, 2016	\$3.80	80.68%
August 15, 2017	\$2.05	78.86%
April 2, 2018	\$1.46	77.57%
June 22, 2018	\$2.11	80.86%

Mr. Clavijo received a severance payment of \$137,500 following the date that he ceased to be the Chief Financial Officer on September 24, 2018. All outstanding stock options held by Mr. Clavijo were cancelled in accordance with the provisions of the Stock Option Plan.

We maintained a reinsured benevolent fund (Rückgedeckte Unterstützungskasse), which is a type of private defined contribution pension plan, for Dr. Sachse. We contributed 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 (3) amount of Dr. Sachse's salary that exceeds the monthly limit. Dr. Sachse also contributed 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, 2018, 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
\$133,639	\$12,258	\$145,897

#### 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 our incentive plans.

Mr. Ward's total earnings during the financial year ended December 31, 2018 was \$360,000 including an incentive bonus in the amount of \$35,000.

For the financial year ended December 31, 2018, the Board approved an award of 50,000 stock options at an exercise price of \$1.46, to Mr. Ward on April 2, 2018, in accordance with the Stock Option Plan. The Board approved an award of 100,000 stock options at an exercise price of \$2.11, to Mr. Ward on June 22, 2018, in accordance with the Long-Term Incentive 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. See "Long-Term Equity Compensation Plan of Executive Officers - Summary of the Long-Term Incentive Plan", for a complete description of the Long-Term Incentive Plan.

#### Pension, retirement or similar benefits

As at December 31, 2018, the Company and its subsidiaries had accrued pension, retirement or similar benefits obligations amounting to \$13.1 million. See note 18 - 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.

#### Standing 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 11.3 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), Brent Norton, and Jonathan Pollack.

## 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. 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 and Robin Smith Hoke.

## D. Employees

As at December 31, 2018, we had a total of 22 active employees, of which 18 are based in Frankfurt, Germany. The remaining four employees are based in the United States and our CFO is based in Toronto, Canada. Our employees are engaged in the following activities: (i) 12 are engaged in research and development, regulatory affairs and quality assurance; (ii) four are involved in commercial operations and business development; and (iii) 6 are involved in various administrative functions, including finance and accounting. We do not employ any sales representatives. Under the German Restructuring Plan started in 2017, 14 employees left our German subsidiary in 2018 (22 were terminated in 2017, three of them left in 2017, 14 of them left in 2018. Five of the employees who were terminated in 2017 were re-employed in 2018). The Managing Director of the German site was replaced during 2018. We have agreements with our employees covering confidentiality, loyalty, non-competition and assignment of all intellectual property rights developed during the employment period.

## E. Share ownership

The table below sets forth information as of March 29, 2019 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
Auld, Leslie	—	—	—	—
Cardiff, Michael <sup>(3)</sup>	—	—	87,850	87,850
Clavijo, James <sup>(4)</sup>	—	—	—	—
Egbert, Carolyn	1,920	*	77,850	5,951
Ernst, Juergen	1,348	*	77,850	5,951
Garrison, Brian	—	—	6,000	—
Guenther, Eckhard	—	—	15,398	6,801
Hoke Smith, Robin	—	—	—	—
Limoges, Gérard	1,200	*	77,850	5,951
Norton, Brent	—	*	—	—
Pollack, Jonathan	—	*	—	—
Sachse, Richard <sup>(5)</sup>	—	—	—	—
Teifel, Michael	—	—	30,350	13,451
Ward, Michael V.	—	—	—	—
Total	4,468	*	373,148	125,955

\*Less than 1%

(1) Based on 16,440,760 Common Shares outstanding as at December 31, 2018.

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

(3) Mr. Cardiff resigned from the Board for personal reasons in March 2019. At such time, the Board amended the Stock Option Plan to accelerate vesting of Mr. Cardiff's stock options. His stock options will remain exercisable until the seventh business day following the end of the current blackout period, following which time any unexercised options of Mr. Cardiff will be forfeited and cancelled.

(4) Mr. Clavijo ceased to be the Company's Chief Financial Officer on September 24, 2018. All outstanding stock options held by Mr. Clavijo were cancelled effective as of his termination date in accordance with the provisions of the Stock Option Plan.

(5) Dr. Sachse employment was terminated effective June 14, 2018. All outstanding stock options held by Dr. Sachse were cancelled in accordance with the provisions of 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 29, 2019, no individual or entity, other than as set out below, 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 (to whom we refer as our major shareholders). The ownership percentages reflected below are based on 16,440,760 Common Shares outstanding as of March 26, 2019. The shareholders listed below do not have any different voting rights from any of our other shareholders. We know of no arrangements that would, at a subsequent date, result in a change of control of the Company.

Beneficial Owner	No. of Common Shares	Percentage
J. Goldman & Co., L.P.	997,494	6.067201%
J. Goldman Capital Management, Inc.		
Jay G. Goldman <sup>1</sup>		

<sup>1</sup> Based solely on a Schedule 13G, dated February 11, 2019, filed by J. Goldman & Co., L.P. (“JGC”), J. Goldman Capital Management, Inc. (“JGCM”) and Jay G. Goldman (“JGG”) with the SEC. As indicated in that statement, JGC, JGCM, and JGG possess shared voting and dispositive power with respect to all of such Common Shares, all of which are beneficially owned by J. Goldman Master Fund, L.P.

Changes in Percentage Ownership by Major Shareholders

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We had no major shareholders in 2016 or 2017. During 2018, the above listed major shareholders became major shareholders due to the acquisition of over 5% of our outstanding Common Shares.

United States Shareholders

Based on a review of the information provide to us by our transfer agent, as at March 7, 2019, there were thirteen holders of record of our Common Shares, of which two were registered with an address in the United States holding in the aggregate approximately 99.8% of our outstanding Common Shares. We believe that the number of beneficial owners of our Common Shares is substantially greater than the number of record holders, because the overwhelming majority of our Common Shares are held in broker "street names."

B. Related party transactions

Other than employment agreements and indemnification agreements with our management, there are no related party transactions.

C. Interests of experts and counsel

Not required.

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 Offer 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:

	NASDAQTSX			
	(US\$)		(CAN\$)	
	High	Low	High	Low
2018	3.87	1.19	5.10	1.53
2017	3.65	0.84	4.81	1.13
2019				
First quarter <sup>1</sup>	4.27	3.03	5.70	4.12
2018				
Fourth quarter	3.87	1.30	5.10	1.69
Third quarter	2.03	1.60	2.69	2.10
Second quarter	2.62	1.19	3.34	1.53
First quarter	2.41	1.46	3.01	1.89
2017				
Fourth quarter	2.70	1.87	3.48	2.38
Third quarter	2.87	0.98	3.57	1.28
Second quarter	3.35	0.84	4.50	1.13
First quarter	3.65	2.45	4.81	3.24

(1) Up to and including March 28, 2019.

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 required.

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 17, 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 impose any mandatory retirement requirements for directors.

The directors are elected by a majority of the votes cast at the annual meeting at which an election of directors is required, to hold office until the election of their successors, except in the case of resignations or if their offices become vacant by death or otherwise. Subject to the provisions of 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 29, 2019, there were approximately 16.4 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 held by them. The holders of Second Preferred Shares are entitled to preference and priority to any participation of holders of Common Shares or shares of any other class of shares of our share capital ranking junior to the Second Preferred Shares with respect to dividends and, in the event of our liquidation, the distribution of our property upon our dissolution or winding-up, or the distribution of all or part of our assets among the shareholders, to an amount equal to the value of the consideration paid in respect of such shares outstanding, as credited to our issued and paid-up share capital, on an equal basis, in proportion to the amount of their respective claims in regard to such shares held by them.

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

#### Warrants

For a description of our Warrants, see note 17 - warrant liability, to the audited consolidated financial statements included in Item 18 of this Annual Report on Form 20-F.

#### 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.

#### Amended and Restated Shareholder Rights Plan

The Board of Directors of the Corporation approved a shareholder rights plan of the Corporation on March 29, 2016, which was approved, ratified and confirmed by the shareholders at the annual and special meeting of shareholders of the Corporation on May 10, 2016 (the "Existing Rights Plan"). The Existing Rights Plan was implemented to ensure, to the extent possible, that all shareholders of the Corporation are treated fairly in connection with any take-over offer or other acquisition of control of the Corporation.

Pursuant to the terms of the Existing Rights Plan, the Existing Rights Plan will expire upon the termination of the Meeting unless shareholders ratify its continued existence. The Board of Directors reviewed the terms of the Existing Rights Plan for conformity

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with current Canadian securities laws, as well as the evolving practices of public corporations in Canada, with respect to shareholder rights plan design and has made some minor amendments thereto as a result.

The Board of Directors determined it appropriate and in the best interests of the shareholders to continue the Existing Rights Plan and approved the amended and restated shareholder rights plan (the "Rights Plan") on March 26, 2019.

The Rights Plan will take effect immediately upon receipt of approval of the shareholders of the Corporation at the annual and special meeting of shareholders scheduled to be held on May 8, 2019.

If the Rights Plan is approved by the shareholders, the Existing Rights Plan will be amended as set forth below: the provisions in which future shareholder approval is required to ratify the continued existence of the Rights Plan will be revised to specify that such events will occur at every third annual meeting of the shareholders subsequent to the annual meeting of shareholders whereby the Rights Plan is initially approved, as well as the addition of certain provisions in respect of the effective date of the plan to give effect to the fact that the Rights Plan is in effect a continuation of the Existing Rights Plan;

the definition of "Acquiring Person" will exclude Convertible Security Acquisitions (as defined below);

the definition of "Beneficial Owner", "Beneficial Ownership" and "Beneficially Own" will:

exclude securities that may be acquired pursuant to any agreement related to an amalgamation, merger, arrangement, business combination or other similar transaction (statutory or otherwise, but for greater certainty not including a Take-over Bid) that is conditional upon shareholder approval prior to such Person acquiring such securities; and include securities which are subject to a lock-up or similar agreement to tender or deposit them into any Take-over Bid made by such Person or made by any Affiliate or Associate of such Person or made by any other person acting jointly or in concert with such Person, other than Permitted Lock-up Agreements;

"Convertible Security Acquisitions" will be defined to mean an acquisition of Voting Shares by a Person upon the purchase, exercise, conversion or exchange of Convertible Securities, where such Convertible Securities are acquired or received by such Person pursuant to a Permitted Bid Acquisition, an Exempt Acquisition or a Pro Rata Acquisition; "Market Price" will be defined to mean the average of the daily closing price per security on the 20 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;

the definition of "Permitted Lock-Up Agreement" will be added (as described below); and

certain other amendments of a non-substantive, "housekeeping" nature have been made to provide for greater clarity and consistency.

Other than the amendments as described above, the Rights Plan is substantially similar to the Existing Rights Plan.

#### Objectives and Background of the 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 Rights Plan. A draft of the Rights Plan is available at the following websites: [www.zenataris.com](http://www.zenataris.com), [www.sedar.com](http://www.sedar.com) and [www.sec.gov](http://www.sec.gov).

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 20 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  
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
2. 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 Permitted 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 Permitted 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%).

A Permitted 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 Permitted 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 Permitted Lock-up Agreement be made available to us and the public. The definition of Permitted Lock-up Agreement also provides that under a Permitted 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;
  - b) then only if at the close of business on the date Common Shares (and/or "Convertible Securities", as defined in the Rights Plan) are first taken up or paid for under such take-over bid, outstanding Common Shares and Convertible Securities held by shareholders other than any other Acquiring Person, the bidder, the bidder's affiliates or associates, persons acting jointly or in concert with the bidder and any employee benefit plan, deferred



profit-sharing plan, stock participation plan or trust for the benefit of our employees or the employees

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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;

the take-over bid must allow Common Shares and/or Convertible Securities to be deposited or tendered pursuant to 4. 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 that qualified as a Competing Permitted Bid, including any acquisition of Common Shares and/or Convertible Securities made before such take-over bid ceased to be a Competing Permitted Bid, will not be a "Permitted Bid Acquisition" (as defined in the Rights Plan).

#### Waiver and Redemption

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

The Board may, with the approval of a majority of Independent Shareholders (or, after the Separation Time has occurred, holders of rights, other than rights which are void pursuant to the provisions of the Rights Plan or which, prior to the Separation Time, are held otherwise than by Independent Shareholders), at any time prior to the occurrence of a Flip-in Event which has not been waived, elect to redeem all, but not less than all, of the then outstanding rights at a price of CAN\$0.00001 each, appropriately adjusted as provided in the Rights Plan (the "Redemption Price").

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

#### Amendment to the Rights Plan

The Rights Plan may be amended to correct any clerical or typographical error or to make such changes as are required to maintain the validity of the Rights Plan as a result of any change in any applicable legislation, regulations or rules thereunder, without the approval of the holders of the Common Shares or rights. Prior to the Separation Time,

we may, with the prior consent of the holders of Common Shares, amend, vary or delete any of the provisions of the Rights Plan in order to effect any changes which the Board, acting in good faith, considers necessary or desirable. We may, with the prior consent of the holders of rights, at any time after the Separation Time and before the Expiration Time, amend, vary or delete any of the provisions of the Rights Plan.

#### Protection Against Dilution

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

#### Fiduciary Duty of Board

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

#### Exemptions for Investment Advisors

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

#### Term

The Rights Plan will expire on the earlier of (i) the Termination Time; and (ii) the Close of Business on the date on which the annual meeting of the Corporation to be held in 2022 and at every third annual meeting of the Corporation thereafter (each such annual meeting being a “Reconfirmation Meeting”) occurs and at which the Rights Plan is not reconfirmed or presented for reconfirmation as contemplated in the Rights Plan (the “Expiration Time”).

#### 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 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

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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 Innovation, Science and Economic Development Canada.

As of February 2, 2019, the threshold for review of a direct acquisition of control of a non-cultural Canadian business by a World Trade Organization member country investor that is not a state-owned enterprise is an enterprise value of assets that exceeds CAN\$1.045 billion. For “trade agreement investors” that are not state-owned enterprises (as defined in the Investment Act), which as of March 2019 include investors ultimately controlled by nationals of Australia, Chile, Colombia, EU member states, Honduras, Japan, Korea, Mexico, New Zealand, Panama, Peru, Singapore, the United States or Vietnam, the threshold for review of a direct acquisition of control of a non-cultural Canadian business is an enterprise value of assets that exceeds C\$1.568 billion. The enterprise value review thresholds for both World Trade Organization member countries and trade agreement investors are indexed to annual GDP growth and are adjusted accordingly each year. 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 or a trade agreement investor, including a U.S. investor, would be reviewable only if the enterprise value of our assets exceeds the specified threshold for review.

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

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

- the acquisition of our Common Shares by a person in the ordinary course of that person's business as a trader or dealer in securities;
- the acquisition or control of us in connection with the realization of security granted for a loan or other financial assistance and not for any purpose related to the provisions of the Investment Act, if the acquisition is subject to approval under the Bank Act, the Cooperative Credit Associations Act, the Insurance Companies Act or the Trust and Loan Companies 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 "Amended and Restated 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.

#### License and Assignment Agreement

On January 16, 2018, the Company, through AEZS Germany, entered into a license and assignment agreement (the "License and Assignment Agreement") with Strongbridge, to carry out development, manufacturing, registration and commercialization of Macrilen™ (macimorelin) in the United States and Canada.

The Company received a cash payment of \$24,000,000 from Strongbridge, and, for as long as Macrilen™ (macimorelin) is patent-protected, the Company will be entitled to a 15% royalty on net sales up to \$75,000,000 and an 18% royalty on net sales above \$75,000,000. Following the end of patent protection in U.S. or Canada for Macrilen™ (macimorelin),



the Company will be entitled to a 5% royalty on net sales in that country. In addition, the Company will also receive one-time payments from Strongbridge following the first achievement of the following commercial milestone events: \$4,000,000 on achieving \$25,000,000 annual net sales,

\$10,000,000 on achieving \$50,000,000 annual net sales,  
\$20,000,000 on achieving \$100,000,000 annual net sales,  
\$40,000,000 on achieving \$200,000,000 annual net sales, and  
\$100,000,000 on achieving \$500,000,000 annual net sales.

Upon approval by the FDA of a pediatric indication for Macrilen™ (macimorelin), the Company will receive a one-time milestone payment of \$5,000,000 from the licensee.

The licensee will fund 70% of the costs of a pediatric clinical submitted for approval to the EMA and FDA to be run by the Company with customary oversight from a joint steering committee. The joint steering committee will be comprised of four persons, two of whom will be appointed by each of Strongbridge and the Company.

The License and Assignment Agreement will expire at the end of a defined royalty period in each of the U.S. and Canada (the "Territory"), at which time the license that the Company granted will become irrevocable, fully paid-up, perpetual and royalty-free in such country. The licensee has the right to terminate the License and Assignment Agreement if there is a safety concern related to Macrilen™ (macimorelin), withdrawal of regulatory approval for Macrilen™ (macimorelin) in the U.S. believed to be permanent, two hundred and seventy (270) days' prior written notice, or if the Company commits a material breach of any term of the License and Assignment Agreement that it fails to cure within 90 days after receiving written notice of the breach. The Company has the right to terminate the License and Assignment Agreement if the licensee commits a material breach of any term of the License and Assignment Agreement that it fails to cure within 90 days after receiving written notice of the breach. If the breach relates to Canada then the Company shall only have the right to terminate the License and Assignment Agreement in relation to Canada. If the breach relates to the United States, then the Company shall have the right to terminate the License and Assignment Agreement in its entirety.

The License and Assignment Agreement contains customary provisions related to, among other things, confidentiality and non-disclosure, representations and warranties, indemnity and dispute resolution. The License and Assignment Agreement is governed by the laws of the State of New York, United States.

The License and Assignment Agreement is incorporated by reference as Exhibit 4.3 to this Annual Report on Form 20-F.

Effective December 19, 2018, Strongbridge sold its rights to Macrilen™ (macimorelin) in Canada and the United States to Novo and Novo will fund Strongbridge's Macrilen™ (macimorelin) field organization as a contract field force to promote the product in the United States for up to three years.

#### Sinopharm Agreements

On December 1, 2014, we entered into an exclusive master collaboration agreement ("Master Collaboration Agreement"), a technology transfer and technical assistance agreement ("Tech Transfer Agreement") and a license agreement ("Sinopharm License Agreement") with Sinopharm A-Think Pharmaceuticals Co., Ltd. ("Sinopharm") for the development, manufacture and commercialization of Zoptrex™ in all human uses, in the People's Republic of China, including Hong Kong and Macau (collectively, the "Sinopharm 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 Sinopharm Territory. Furthermore, we will be entitled to royalties on future net sales of Zoptrex™ in the Sinopharm Territory. Sinopharm will be responsible for the development, production, registration and commercialization of Zoptrex™ in the Sinopharm Territory.

Sinopharm is required to use commercially reasonable efforts to develop, manufacture and commercialize Zoptrex™ in the Sinopharm Territory, in order to maximize the net sales derived from Zoptrex™ during the royalty term of the Sinopharm License Agreement. In particular, Sinopharm is required to use commercially reasonable efforts to: (i) develop Zoptrex™ for the indication of endometrial cancer in the Sinopharm 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 Sinopharm Territory following successful completion of all appropriate clinical studies; (iii) make the first commercial sale of Zoptrex™ in the Sinopharm Territory within a specified period of time following the approval of

Zoptrex™ for endometrial cancer; (iv) maintain an adequate sales force and provide for relevant staff to manage the pre- and post-launch activities required to commercialize Zoptrex™ in the Sinopharm Territory; and (v) seek to maximize sales of Zoptrex™ in the Sinopharm Territory. Sinopharm's failure to use commercially reasonable efforts to develop, manufacture and commercialize Zoptrex™ would be a material breach of the Sinopharm License Agreement.

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

The Sinopharm 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 Sinopharm 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 Sinopharm 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 Sinopharm License Agreement if Sinopharm commits a material breach of any term of the Sinopharm 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 Sinopharm 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 Sinopharm License Agreement is governed by the laws of Hong Kong.

We do not anticipate significant revenues from the Sinopharm License Agreement in the future other than the amortization of the remaining deferred revenue.

The Master Collaboration Agreement, the Sinopharm License Agreement and the Tech Transfer Agreement are incorporated by reference as Exhibits 4.9, 4.10 and 4.11 to this Annual Report on Form 20-F.

#### Employment and Service Agreements

We had, or one of our subsidiaries had, entered into an employment agreement and, in some cases, a change of control agreement with each of our Named Executive Officers. We terminated Dr. Sachse's employment on January 17, 2018, effective June 14, 2018, and terminated Mr. Clavijo's employment on September 24, 2018.

The employment and change of control agreements of Mr. Ward, the employment and change of control agreements of Mr. Clavijo and the consulting agreement of Ms. Auld described below are filed as Exhibits 4.4, 4.5, 4.6, 4.7 and 4.8 to this Annual Report on Form 20-F.

#### Michael Ward

We entered into an employment agreement and a change of control agreement with Michael V. Ward, Chief Executive Officer, effective as of October 1, 2017 (the "Employment Agreement"). The Employment Agreement provides that we will pay Mr. Ward (the "Executive") an initial base salary of \$250,000 and an annual cash 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. Additionally, the Executive 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. Under the terms of the Employment Agreement, Mr. Ward's base salary increased to \$325,000, upon approval of Macrilen™ (macimorelin) by the FDA, effective as of December 11, 2017.

The Employment Agreement provides that if there is a "separation from service" within the meaning of Section 409A of the U.S. Internal Revenue Code of 1986, as amended, as a result of (i) termination of the Executive's employment

by us without "Cause" or (ii) the Executive resigns for "Good Reason," then the Executive will be entitled to receive severance payments in the amount equal to at least eighteen (18) months of his then base salary paid in equal installments over one (1) year, and conditional upon the Executive executing a full and general Release and complying with certain non-compete and confidentiality agreements. The Executive has no right to receive a cash bonus or any other form of remuneration.

The Executive shall not, for a period equal to one year following his termination of employment with us, directly or indirectly,

compete with us in a business in the development and commercialization of substantially similar endocrine therapies and oncology treatments; 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 applies in those geographic areas in the United States, Canada and Europe in which the same or substantially similar endocrine therapies and oncology treatment are developed and commercialized by us.

Pursuant to the Employment Agreement, the Executive is also entitled to receive certain payments in lieu of and not in addition to any severance payments provided under the Employment Agreement (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 eighteen (18) months of the Executive's then annual base salary, (ii) an amount equivalent to eighteen (18) months of the Executive's annual bonus, if any, which he would have received in the year immediately prior to the year the Change of Control occurred, and (iii) an amount equivalent to eighteen (18) months of the then monthly premium to provide the group medical benefits to the any earned retention bonus, and (iv) an amount equivalent to eighteen (18) months of the then annual cost monthly premium to provide the other benefits to which he is entitled, or our cost to purchase coverage under COBRA for such benefits, whichever is applicable. group medical benefits Executive, his spouse and dependents determined by utilizing the applicable COBRA premium rates for the month the Executive's employment terminates. The Change of Control Payment is subject to applicable statutory withholdings. Any outstanding stock options to acquire our stock shall, in such circumstances, become fully exercisable, vested and non-forfeitable on the date the Executive's employment terminates following a Change of Contract during the term of the agreement. The payments are conditional on the Executive executing a full and general Release.

For the purposes of the Employment Agreement:

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, during the term of the change of control 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 during the term of the change of control 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, or (ii) if the Executive commits an act of serious misconduct or willful or gross negligence in the performance of his duties.

Termination of employment by the Executive for "Good Reason" means the occurrence, without the Executive's express written consent, of any of the following acts: (i) a material reduction of the Executive's base salary as in effect on the date of his Employment Agreement or as same may be increased from time to time, and (ii) any material and sustained reduction in the Executive's duties and responsibilities as Chief Executive Officer and the Board has been provided with notice and fails to cure the situation within thirty (30) days following receipt of notice.

James Clavijo

We entered into an employment agreement and a change of control agreement with Mr. James Clavijo, Chief Financial Officer. Mr. Clavijo left the Company in September 2018, at which time, he received a severance payment in accordance with his employment agreement.

Leslie Auld

We entered into a consulting agreement with Leslie Auld, Senior Vice President, Chief Financial Officer, effective as of September 24, 2018 (the "Consulting Agreement"). The Consulting Agreement provides that Ms. Auld (the "Consultant") will perform specified services for us for up to 120 hours per month. The Consultant will be paid \$150 per hour (plus HST) (the "base fees") for these services. Additionally, the Consultant will be paid for up to eight (8) hours of travel time per round trip, at a rate of \$150 per hour.

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The Consulting Agreement may be terminated by either party for convenience, upon thirty (30) days written notice. The Consulting Agreement may also be terminated by us upon the material breach or default of any provision of the Consulting Agreement by the Consultant, immediately upon the Consultants death or upon the parties' mutual agreement. In the event of termination, the Consultant will be entitled to receive any outstanding base fees and reimbursement for incurred expenses to the effective date of termination.

The Consulting Agreement provides the Consultant indemnifies us from and against any and all claims, costs, liabilities, damages, charges and expenses arising out of the Consulting Agreement or the services, including in respect of misclassification.

The table below shows estimated incremental payments triggered pursuant to termination of employment of our Named Executive Officers who remained employed on December 31, 2018. The amounts shown are in U.S. dollars.

Name	Termination Provisions Value (\$) <sup>(1) (2)</sup>
Auld, Leslie	0
Garrison, Brian	0
Guenther, Eckhard	94,800
Ward, Michael V.	487,500

(1) The termination values assume that the triggering event took place on the last business day of our financial year-end (December 31, 2018).

(2) Value of earned/unused vacation, if applicable, and amounts owing for expense reimbursement are not included as they are not considered as "incremental" payments made in connection with termination of employment.

#### 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, or does not deal at arm's length for purposes of the Tax Act with a corporation resident in Canada that is or becomes, as part of a transaction or series of transactions or events that includes the acquisition of the Common Shares, 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 a foreign currency 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 or is deemed to carry 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) the 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 U.S. for purposes of the Convention and entitled to the benefits of the Convention (a "U.S. holder") is generally limited to 15% of the gross amount of the dividend (or 5% in the case of a U.S. 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. Canadian holders should consult their own tax advisors for advice as to whether an election under subsection 39(4) of the Tax Act is available and/or advisable in their particular circumstances.

#### 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 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 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.

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

The following discussion is a summary of the material U.S. federal income tax consequences applicable to the ownership and disposition of Common Shares by a U.S. Holder (as defined below), but does not purport to be a complete analysis of all potential U.S. federal income tax effects. This summary is based on the Internal Revenue Code of 1986, as amended (the "Code"), U.S. Treasury regulations promulgated thereunder, 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 U.S. federal income taxation that may be relevant to particular U.S. Holders in light of their specific circumstances (for example, U.S. Holders subject to the alternative minimum tax or the Medicare contribution tax on net investment income under the Code) or to holders that may be subject to special rules under U.S. federal income tax law, including:

- dealers in stocks, securities or currencies;
- securities traders that use a mark-to-market accounting method;
- banks and financial institutions;
- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- tax-exempt organizations;
- retirement plans, individual plans, individual retirement accounts and tax-deferred accounts;
- partnerships or other pass-through entities for U.S. federal income tax purposes and their partners or members;
- persons holding Common Shares as part of a hedging or conversion transaction straddle or other integrated or risk reduction transaction;
- persons who or that are, or may become, subject to the expatriation provisions of the Code;
- persons whose functional currency is not the U.S. dollar; and
- direct, indirect or constructive owners of 10% or more of the total combined voting power of all classes of our voting stock or 10% or more of the total value of shares of all classes of our 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, U.S. 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. U.S. Holders of warrants should consult their tax advisors with regard to the U.S. 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 U.S. Holders. In addition, this discussion is limited to U.S. Holders holding Common Shares as capital assets. For purposes of this summary, "U.S. Holder" means a beneficial holder of Common Shares who or that for U.S. federal income tax purposes is:

- an individual citizen or resident of the United States;
- a corporation or other entity classified as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (a) a court within the United States is able to exercise primary supervision over the administration of such trust and one or more "U.S. persons" (within the meaning of the Code) have the authority to control all substantial decisions of the trust, or (b) a valid election is in effect to be treated as a U.S. person for U.S. federal income tax purposes.

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

**U.S. 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 quarterly value of its assets is attributable to assets which produce passive income or are held for the production of passive income. Passive income generally includes dividends, interest, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income.

The Company believes it was a PFIC for the 2015 taxable year but not for the 2016, 2017 and 2018 taxable years. 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 2018 or any future taxable year. U.S. 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 U.S. Holder owns Common Shares, the U.S. Holder, absent certain elections (including the mark-to-market and QEF elections described below), will generally be subject to adverse rules (regardless of whether the Company continues to be classified as a PFIC) with respect to (i) any "excess distributions" (generally, any distributions received by the U.S. Holder on the Common Shares in a taxable year that are greater than 125% of the average annual distributions received by the U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period for the Common Shares) and (ii) any gain realized on the sale or other disposition of the Common Shares.

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

U.S. Holders can avoid the adverse rules described above in part by making a mark-to-market election with respect to the Common Shares, provided that the Common Shares are "marketable". The Common Shares will be marketable if they are "regularly traded" on a "qualified exchange" or other market within the meaning of applicable U.S. Treasury regulations. For this purpose, 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 U.S. Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year an amount equal to the excess, if any, of the fair market value of the U.S. Holder's Common Shares at the close of the taxable year over the U.S. Holder's adjusted tax basis in the Common Shares. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted tax basis in the Common Shares over the fair market value of the Common Shares at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains previously included in income. A U.S. Holder that makes a mark-to-market election generally will adjust such U.S. Holder's tax basis in the Common Shares to reflect the amount included in gross income or allowed as a deduction because of such mark-to-market election. Gains from an actual sale or other disposition of the Common Shares will be treated as ordinary income, and any losses incurred

on a sale or other disposition of the Common Shares will be treated as ordinary losses to the extent of any net mark-to-market gains previously included in income.

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



If the Company is classified as a PFIC, a U.S. Holder of Common Shares will generally be treated as owning stock owned by the Company in any direct or indirect subsidiaries that are also PFICs and will be subject to similar adverse rules with respect to distributions to the Company by, and dispositions by the Company of, the stock of such subsidiaries. A mark-to-market election is not permitted for the shares of any subsidiary of the Company that is also classified as a PFIC. U.S. 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 U.S. Holders with the information that such U.S. Holders are required to report under the QEF rules. However, there can be no assurance that the Company will satisfy the record keeping requirements or provide the information required to be reported by U.S. Holders.

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

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

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

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

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

In addition, if the Company is a PFIC, U.S. 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 U.S. federal income tax or information returns) relating to their ownership of Common Shares.

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.

#### 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 U.S. federal income tax purposes), before reduction for any Canadian withholding tax paid with respect thereto, will generally be taxable to a U.S. Holder as foreign source dividend

income, and generally will not be eligible for the dividends received deduction generally allowed to corporations. Distributions in excess of current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in the Common Shares and thereafter as capital gain. The Company does not, however, intend to calculate its earnings and profits under U.S. federal income tax principles. Therefore, U.S. Holders should expect that any distribution from the Company generally will be treated for U.S. federal income tax purposes as a dividend. U.S. Holders

should consult their own tax advisors with respect to the appropriate U.S. federal income tax treatment of any distribution received from the Company.

Dividends paid to non-corporate U.S. 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 U.S. Holder at the special reduced rates normally applicable to long-term capital gains, provided that certain conditions are satisfied. (including a minimum holding period requirement). The Company believes it was not a PFIC for the 2018 taxable year. However, no assurance can be provided that the Company will not be classified as a PFIC for 2019 and, therefore, no assurance can be provided that a U.S. Holder will be able to claim a reduced rate for dividends paid in 2019 or 2020 (if any).

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

Subject to certain limitations, a U.S. Holder will generally be entitled, at the election of the U.S. Holder, to a credit against its U.S. federal income tax liability, or a deduction in computing its U.S. federal taxable income, for Canadian income taxes withheld by the Company. This election is made on a year-by-year basis and applies to all foreign taxes paid (whether directly or through withholding) by a U.S. Holder during a year. For purposes of the foreign tax credit limitation, dividends paid by the Company generally will constitute foreign source income in the "passive category income" basket. The foreign tax credit rules are complex and U.S. 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 U.S. Holder in a U.S. dollar amount calculated by reference to the exchange rate in effect on the date the U.S. Holder (actually or constructively) receives the dividend, regardless of whether such Canadian dollars are actually converted into U.S. dollars at that time. If the Canadian dollars received are not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a tax basis in the Canadian dollars equal to their U.S. dollar value on the date of receipt. Gain or loss, if any, realized on a sale or other disposition of the Canadian dollars will generally be U.S. source ordinary income or loss to a U.S. Holder.

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

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

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

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

#### Information Reporting and Backup Withholding

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

information reporting or backup withholding tax requirements described herein. U.S. Holders should consult their tax advisors as to their qualification for exemption from backup withholding tax and the procedure for establishing an exemption.

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

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

F. Dividends and paying agents

Not required.

G. Statement by experts

Not required.

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](http://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](http://www.sedar.com). This material includes our Management Information Circular for our annual meeting of shareholders to be held on May 8, 2019 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, 2018 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](http://www.sedar.com)) and on EDGAR ([www.sec.gov](http://www.sec.gov)).

I. Subsidiary information

Not required.

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 payables, accrued liabilities, and provision for restructuring costs.

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, market risk (share price risk) and foreign exchange 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 financial assets at amortized cost 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, 2018 trade accounts receivable for an amount of approximately \$197 were with four counterparties of which \$55 was past due and impaired and impaired amounts were fully reserved and not a part of the balance .

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. On this basis, as at December 31, 2018, the Company has provided for all outstanding and unpaid amounts relating to its operations before its licensing of Macrilen™(macemorelin). The licensee has paid all amounts owing within 90 days of invoicing.

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 23 - Capital disclosures of our financial statements included in this Form 20-F, 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 as further discussed in note 2 - Assessment of liquidity and management's plans. 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.

On December 20, 2017, the FDA granted marketing approval for Macrilen™ (macimorelin) to be used in the diagnosis of patients with AGHD. On January 16, 2018, the Company, through AEZS Germany entered into the License and Assignment Agreement. The License and Assignment Agreement will contribute to fulfilling the Company's future obligations.

(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, as further described in note 17 of our financial statements included in this Form 20-F as it applies to its outstanding share purchase warrants. The 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 income (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 ranged from \$1.19 to \$3.87 during the year ended December 31, 2018.

If variations in the market price of our common shares of -30% and +30% were to occur, the impact on the Company's net income related to the warrant liability held at December 31, 2018 would be as follows:

(in thousands)	Carrying amount	-30%	+30%
	\$	\$	\$
Warrant liability	3,634	1,792	(1,504)
Total impact on net income – (decrease) / increase		1,792	(1,504)
Foreign currency risk			

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





Item 12. Description of Securities Other than Equity Securities

A. Debt securities

Not required.

B. Warrants and rights

Not required.

C. Other securities

Not required.

D. American depositary shares

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

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

None.

Item 15. Controls and Procedures

Under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures as at December 31, 2018. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective as at December 31, 2018.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with 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 acquisition, use or disposition of Company assets that could have a material effect on the financial statements.

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

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria established in Internal Control – Integrated Framework: 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management has concluded that our internal control over financial reporting was effective as at December 31, 2018.

#### Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting during the year ended December 31, 2018 that 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.

In accordance with Securities and Exchange Commission's rules regarding non-accelerated filers, this Annual Report on Form 20-F does not include an attestation report of the Company's independent registered public accounting firm regarding the Company's internal control over financial reporting.

#### Item 16A. Audit Committee Financial Expert

Our Board has determined that we have at least one audit committee financial expert (as defined in paragraph (b) of Item 16A to Form 20-F). The name of the audit committee financial expert is Mr. Gérard Limoges, FCPA, FCA, the Audit Committee's Chairman. In accordance with Item 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 current members of the Audit Committee are Messrs. Brent Norton and Jonathan Pollack, 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 December 16, 2017, the Board adopted a "Code of Conduct and Business Ethics", which replaced the then existing Code of Ethical Conduct as of January 1, 2018. The Code of Conduct and Business Ethics expanded on the previous Code of Ethical Conduct to provide additional details of expected conduct of all employees and directors of the Company, including specific obligations the Company and its employees has as a member of the healthcare industry. 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.zentaris.com](http://www.zentaris.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, Summerville, South Carolina 29486.

#### Item 16C. Principal Accountant Fees and Services

(All amounts are in U.S. dollars)

##### (a) Audit Fees

During the financial years ended December 31, 2018 and 2017, the Company's principal accountant, PricewaterhouseCoopers LLP, billed \$563,558 and \$506,309, 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, 2018 and 2017, the Company's principal accountant, PricewaterhouseCoopers LLP, billed \$37,663 and \$113,430, 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, 2018 and 2017, the Company's principal accountants, PricewaterhouseCoopers LLP billed \$36,224 and \$5,426, respectively, for services related to tax compliance, tax planning and tax advice.

(d) All Other Fees

During the financial years ended December 31, 2018 and 2017, 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, 2018 and 2017, 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, 2018, 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.

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**PART III**

**Item 17 Financial Statements**

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

**Item 18. Financial Statements**

The financial statements appear on pages 95 to 137.

Aeterna Zentaris Inc.

Consolidated Financial Statements

As at December 31, 2018 and December 31, 2017 and for the years ended

December 31, 2018, 2017 and 2016

(presented in thousands of U.S. dollars)

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Report of Independent Registered Public Accounting Firm  
To the Board of Directors and Shareholders of  
Aeterna Zentaris Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Aeterna Zentaris Inc. and its subsidiaries (the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of changes in shareholders’ (deficiency) equity, comprehensive income (loss) and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

“/s/PricewaterhouseCoopers LLP”

Toronto, Ontario, Canada  
March 28, 2019

We have served as the Company’s auditor since 1993.





Aeterna Zentaris Inc.  
Consolidated Statements of Financial Position  
(in thousands of US dollars)

	December 31, 2018	December 31, 2017
	\$	\$
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents (note 7)	14,512	7,780
Trade and other receivables (note 8)	294	221
Inventory (note 9)	240	554
Prepaid expenses and other current assets (note 10)	1,210	826
Total current assets	16,256	9,381
Restricted cash equivalents (note 11)	418	381
Property, plant and equipment (note 12)	65	101
Deferred tax assets (note 20)	—	3,479
Identifiable intangible assets (note 13)	62	90
Other non-current assets	—	150
Goodwill (note 14)	8,210	8,613
Total Assets	25,011	22,195
<b>LIABILITIES</b>		
Current liabilities		
Payables and accrued liabilities (note 15)	2,966	2,814
Provision for restructuring and other costs (note 16)	887	2,469
Income taxes (note 22)	1,669	—
Current portion of deferred revenues (note 6)	74	486
Total current liabilities	5,596	5,769
Deferred revenues (note 6)	258	55
Warrant liability (note 17)	3,634	3,897
Employee future benefits (note 18)	13,205	14,229
Non-current portion of provision for restructuring and other costs (note 16)	411	1,028
Total liabilities	23,104	24,978
<b>SHAREHOLDERS' EQUITY (DEFICIENCY)</b>		
Share capital (note 19)	222,335	222,335
Other capital (note 19)	89,342	88,772
Deficit	(309,781	) (314,161 )
Accumulated other comprehensive income	11	271
Total shareholders' equity (deficiency)	1,907	(2,783 )
Total liabilities and shareholders' equity	25,011	22,195
Commitments and contingencies (note 27)		

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

Aeterna Zentaris Inc.

Consolidated Statements of Changes in Shareholders' (Deficiency) Equity

For the years ended December 31, 2018, 2017 and 2016

(in thousands of US dollars, except share data)

	Common shares (number of) <sup>1</sup>	Share capital \$	Other capital \$	Deficit \$	Accumulated other comprehensive income \$	Total \$
Balance - January 1, 2018	16,440,760	222,335	88,772	(314,161)	271	(2,783)
Net income	—	—	—	4,187	—	4,187
Other comprehensive income (loss):						
Foreign currency translation adjustments	—	—	—	—	(260)	(260)
Actuarial gain on defined benefit plans (note 18)	—	—	—	193	—	193
Comprehensive loss	—	—	—	4,380	(260)	4,120
Share-based compensation costs	—	—	570	—	—	570
Balance - December 31, 2018	16,440,760	222,335	89,342	(309,781)	11	1,907

<sup>1</sup> Issued and paid in full.

	Common shares (number of) <sup>1</sup>	Share capital \$	Pre-funded warrants \$	Other capital \$	Deficit \$	Accumulated other comprehensive income (loss) \$	Total \$
Balance - January 1, 2017	12,917,995	213,980	—	88,590	(298,059)	1,701	6,212
Net loss	—	—	—	—	(16,796)	—	(16,796)
Other comprehensive income (loss):							
Foreign currency translation adjustments	—	—	—	—	—	(1,430)	(1,430)
Actuarial gain on defined benefit plans (note 18)	—	—	—	—	694	—	694
Comprehensive loss	—	—	—	—	(16,102)	(1,430)	(17,532)
Share issuances pursuant to the exercise of pre-funded warrants (note 19)	301,343	977	—	—	—	—	977
Share issuances in connection with "at-the-market" drawdowns (note 19)	3,221,422	7,378	—	—	—	—	7,378
Share-based compensation costs	—	—	—	182	—	—	182
Balance - December 31, 2017	16,440,760	222,335	—	88,772	(314,161)	271	(2,783)

<sup>1</sup> Issued and paid in full.

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

Aeterna Zentaris Inc.

Consolidated Statements of Changes in Shareholders' (Deficiency) Equity

For the years ended December 31, 2018, 2017 and 2016

(in thousands of US dollars, except share data)

	Common shares (number of) <sup>1</sup>	Share capital	Pre-funded warrants	Other capital	Deficit	Accumulated other comprehensive income (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 18)	—	—	—	—	(1,479)	—	(1,479)
Comprehensive loss	—	—	—	—	(26,438)	569	(25,869)
Share issuances in connection with a public offering (note 19)	1,150,000	3,377	—	—	—	—	3,377
Pre-funded warrant issuances in connection with a public offering (note 19)	—	—	2,789	—	—	—	2,789
Share issuances pursuant to the exercise of pre-funded warrants (note 19)	950,000	2,789	(2,789)	—	—	—	—
Share issuances in connection with "at-the-market" drawdowns (note 19)	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>1</sup> Issued and paid in full.

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

Aeterna Zentaris Inc.  
Consolidated Statements of Comprehensive Income (Loss)  
For the years ended December 31, 2018, 2017 and 2016  
(in thousands of US dollars, except share and per share data)

	Years Ended December 31,		
	2018	2017	2016
	\$	\$	\$
Revenues			
License fees (note 6)	24,325	458	497
Product sales (note 6)	2,167	—	—
Royalty income (note 6)	184	—	—
Sales commission and other	205	465	414
Total revenues	26,881	923	911
Cost of sales	2,104	—	—
Gross income	24,777	923	911
Operating expenses (note 20)			
Research and development costs	2,932	10,704	16,495
General and administrative expenses	8,894	8,198	7,147
Selling expenses	3,109	5,095	6,745
Total operating expenses	14,935	23,997	30,387
Income (loss) from operations	9,842	(23,074)	(29,476)
Settlements (note 27)	(1,400)	—	—
Gain (loss) due to changes in foreign currency exchange rates	656	502	(70)
Change in fair value of warrant liability (note 17)	263	2,222	4,437
Other finance income	278	75	150
Net finance income (costs)	1,197	2,799	4,517
Income (loss) before income taxes	9,639	(20,275)	(24,959)
Income tax (expense) recovery (note 22)	(5,452)	3,479	—
Net income (loss)	4,187	(16,796)	(24,959)
Other comprehensive income (loss):			
Items that may be reclassified subsequently to profit or loss:			
Foreign currency translation adjustments	(260)	(1,430)	569
Items that will not be reclassified to profit or loss:			
Actuarial gain (loss) on defined benefit plans	193	694	(1,479)
Comprehensive income (loss)	4,120	(17,532)	(25,869)
Net income (loss) per share (basic) (note 26)	0.25	(1.12)	(2.41)
Net income (loss) per share (diluted) (note 26)	0.24	(1.12)	(2.41)
Weighted average number of shares outstanding (note 26)			
Basic	16,440,760	14,958,704	10,348,879
Diluted	17,034,812	14,958,704	10,348,879

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

Aeterna Zentaris Inc.  
Consolidated Statements of Cash Flows  
For the years ended December 31, 2018, 2017 and 2016  
(in thousands of US dollars)

	Years ended December 31,		
	2018	2017	2016
	\$	\$	\$
Cash flows from operating activities			
Net income (loss) for the year	4,187	(16,796)	(24,959)
Items not affecting cash and cash equivalents:			
Change in fair value of warrant liability (note 17)	(263 )	(2,222 )	(4,437 )
Provision for restructuring and other costs (note 16)	(136 )	3,083	(8 )
Recapture of inventory previously written off	—	(643 )	—
Depreciation, amortization and impairment (notes 12 and 13)	58	94	280
Deferred income taxes (note 22)	3,479	(3,479 )	—
Share-based compensation costs	570	182	1,082
Employee future benefits (note 18)	316	246	382
Amortization of deferred revenues (note 6)	(609 )	(458 )	(345 )
Foreign exchange (gain) loss on items denominated in foreign currencies	(652 )	(553 )	87
Gain on disposal of property, plant and equipment	(9 )	(136 )	(1 )
Other non-cash items	35	(19 )	(83 )
Transaction cost allocated to warrants issued (note 19)	—	—	56
Changes in operating assets and liabilities (note 21)	(151 )	(2,212 )	(1,064 )
Net cash provided by/(used in) operating activities	6,825	(22,913)	(29,010)
Cash flows from financing activities			
Proceeds from issuances of common shares, warrants (including pre-funded warrants), net of cash transaction costs of \$nil, \$250 and \$1,107 in 2018, 2017, and 2016, respectively (note 19)	—	7,788	9,924
Proceeds from warrants exercised (note 19)	—	242	—
Net cash provided by financing activities	—	8,030	9,924
Cash flows from investing activities			
Purchase of property, plant and equipment (note 12)	(9 )	(4 )	(66 )
Proceeds for disposals of property, plant and equipment (note 12)	24	161	2
Change in restricted cash equivalents	(50 )	150	(250 )
Net cash provided by (used in) investing activities	(35 )	307	(314 )
Effect of exchange rate changes on cash and cash equivalents	(58 )	357	(51 )
Net change in cash and cash equivalents	6,732	(14,219)	(19,451)
Cash and cash equivalents – beginning of year (note 6)	7,780	21,999	41,450
Cash and cash equivalents – end of year (note 6)	14,512	7,780	21,999

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

Aeterna Zentaris Inc.

Notes to Consolidated Financial Statements

As at December 31, 2018 and December 31, 2017 and for the years ended December 31, 2018, 2017 and 2016 (tabular amounts in thousands of US dollars, except share/option/warrant/DSU and per share/option/warrant/DSU data and as otherwise noted)

## 1 Business overview

### Summary of business

Aeterna Zentaris Inc. ("Aeterna Zentaris" or the "Company") is a specialty biopharmaceutical company which is commercializing novel pharmaceutical therapies. On December 20, 2017, the United States Food and Drug Administration ("FDA") granted marketing approval for Macrilen™ (macimorelin) to be used in the diagnosis of patients with adult growth hormone deficiency ("AGHD"). On January 16, 2018, the Company, through Aeterna Zentaris GmbH, entered into a license and assignment agreement with Strongbridge Ireland Limited ("Strongbridge") to carry out development, manufacturing, registration, regulatory and supply chain services for the commercialization of Macrilen™ (macimorelin) in the United States and Canada (the "License and Assignment Agreement"). Effective December 19, 2018, Strongbridge sold the United States and Canadian rights to Macrilen™ to Novo Nordisk ("Novo").

### 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 1155 Rene-Levesque Blvd. West, 41<sup>st</sup> Floor, Montreal, Quebec H3B 3V2, Canada and its principal place of business is 315 Sigma Drive, Summerville, South Carolina 29486. The Company's common shares are listed on both the Toronto Stock Exchange (the "TSX") and on the NASDAQ Capital Market (the "NASDAQ").

### Basis of presentation

#### (a) Statement of compliance

These consolidated financial statements as at December 31, 2018 and December 31, 2017 and for the years ended December 31, 2018, 2017 and 2016 have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The accounting policies in these consolidated financial statements are consistent with those of the previous financial year except for the adoption of those standards in 2018 (note 4) and are consistent with the previous quarter.

These consolidated financial statements were approved by the Company's Board of Directors on March 29, 2019.

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 4 - 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.





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(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") which is U.S. dollars for the Company and its U.S. subsidiary, Aeterna Zentaris, Inc. and Euro ("EUR") for its German subsidiaries.

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 (deficiency).

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 income (loss).

2 Assessment of liquidity and management's plans

Since inception, the Company has incurred significant expenses in its efforts to develop and commercialize products. Consequently, the Company has incurred operating losses and negative cash flow from operations historically and in each of the last several years except for the year ended December 31, 2018 when the Company earned revenue from the sale of a license for the adult indication of Macrilen<sup>TM</sup> (macimorelin) in the United States and Canada (note 6). As at December 31, 2018, the Company had an accumulated deficit of \$310 million.

The Company has \$14,512 of cash and cash equivalents as at December 31, 2018, and management believes it has sufficient liquidity to meet its current obligations of \$5,596 and continue its planned level of expenses for at least, but not limited to the next twelve months from the date of issuance of these consolidated financial statements. The Company is focused on managing its operating expenses, and has the discretion to limit research and development costs, administrative expenses and capital expenditures in order to maintain its liquidity, until such time that additional sources of funding can be obtained. The Company's principal focus is on the licensing and development of Macrilen<sup>TM</sup> (macimorelin) and it currently does not have any other approved product. In January 2018, the Company signed a license and assignment agreement with Strongbridge Ireland Ltd., which as of December 19, 2018 is a wholly-owned subsidiary of Novo Nordisk A/S ("Novo"), to carry out development, manufacturing, registration and commercialization of Macrilen<sup>TM</sup> (macimorelin) in the U.S. and Canada (the "License and Assignment Agreement") (see note 6). Consistent with Strongbridge, Novo is funding 70% of the pediatric clinical trial submitted to the EMA and FDA, the Company's sole development priority.

On March 12, 2019, the Company announced that its board of directors has formed a special committee of independent directors (the "Special Committee") to review strategic options available to the Company. The Special Committee has approved the engagement by the Company of a financial advisor that is working with management to assist the Special Committee and the board of directors in considering a wide range of transactions (including opportunities for the license of Macrilen<sup>TM</sup> (macimorelin) outside of the United States and Canada, or other monetization transactions relating to Macrilen<sup>TM</sup> (macimorelin)). Management has evaluated whether material uncertainties exist relating to events or conditions as described in Note 4 and has considered the following in making that critical judgment.

The Company's current operating budget and cash flows from operating activities in 2019 are expected to decline compared with 2018, however, the Company believes it will experience an increase in its royalty income, which, when combined with its forecasted cash flows, the Company believes will provide sufficient liquidity to finance operations and meet its commitments for at least, but not limited to, twelve months from the date of approval of these financial statements.

3 Summary of significant accounting policies

The accounting policies set out below have been applied consistently to all years presented in these consolidated financial statements except for the adoption of those standards in 2018 (note 4) and have been applied consistently by all Group entities.

Cash and cash equivalents

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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.

Inventories

Inventories are valued at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method for all inventories. The Company's policy is to write down inventory that has become obsolete and inventory that has a cost basis in excess of its expected net realizable value. Increases in the reserve are recorded as charges in cost of product sales. For product candidates that have not been approved by the FDA, inventory used in clinical trials is written down at the time of production and recorded as research and development ("R&D") costs. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the clinical trial. All direct manufacturing costs incurred after approval are capitalized into inventory.

Restricted cash equivalents

Restricted cash equivalents are comprised of bank deposits, related to a guarantee for a long-term operating lease 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 33 <sup>1</sup> / <sub>3</sub> %
Leasehold improvements	Straight-line	Remaining lease term

Depreciation expense, which is recorded in the consolidated statement of comprehensive income (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 income (loss), is allocated to the appropriate functional expense categories to which the underlying identifiable intangible assets relate.

Goodwill

Goodwill is recognized as the fair value of the consideration transferred including the recognized amount of any non-controlling interest in the acquiree, less the fair value of the net identifiable assets acquired and liabilities assumed, as of the acquisition date. Subsequent to initial recognition, goodwill is measured at cost less accumulated impairment losses. Goodwill acquired in business combinations is allocated to groups of cash generating units ("CGU") that are expected to benefit from the synergies of the combination.

Impairment of assets



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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 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 income (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 will 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 income (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.

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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 comprehensive income (loss), 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 income (loss) in subsequent periods.

For defined contribution plans, expenses are recorded in the consolidated statement of comprehensive income (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 income (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"); "Financial assets at amortized cost"; "Financial liabilities at "FVTPL"; and "Financial liabilities at amortized cost".

Financial assets at FVTPL: Financial assets carried at FVTPL are initially recorded at fair value and transaction costs are expensed in the statement of comprehensive income (loss). Realized and unrealized gains and losses arising from changes in the fair value of the financial assets held at FVTPL are included in the statement of comprehensive income (loss) in the period in which they arise.

Financial liabilities at FVTPL: These financial liabilities are initially recognized at fair value, and transaction costs directly attributable to issuing the warrants are expensed in the statement of comprehensive income (loss). Financial liabilities that are required to be measured at FVTPL have all fair value movements, excluding those related to changes in the credit risk of the liability which are recorded in other comprehensive income (loss), recognized in the statement of comprehensive income (loss).

Financial assets at fair value through other comprehensive income (FVTOCI): Investments in equity instruments at FVTOCI are initially recognized at fair value plus transaction costs. Subsequently they are measured at fair value, with gains and losses arising from changes in fair value recognized in other comprehensive income (loss) in the period in which they arise.

Financial assets at amortized cost: A financial asset is measured at amortized cost if the objective of the business model is to hold the financial asset for the collection of contractual cash flows, and the asset's contractual cash flows are comprised solely of payments of principal and interest. They are classified as current assets or non-current assets based on their maturity date, and are initially recognized at fair value and subsequently carried at amortized cost less any impairment.

Impairment of financial assets at amortized cost: The Company recognizes a loss allowance for expected credit losses on financial assets that are measured at amortized cost.

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The following table shows the classification of the Company's financial assets/liabilities under IFRS 9 Financial Instruments ("IFRS 9") and the previous classifications under IAS 39:

Financial asset/liability	IFRS 9 Classification	IAS 39 Classification
Cash and cash equivalents	Amortized cost	Loans and receivables
Trade and other receivables	Amortized cost	Loans and receivables
Restricted cash and cash equivalents	Amortized cost	Loans and receivables
Warrant liability (derivative)	FVTPL	FVTPL
Payable and accrued liabilities	Amortized cost	Other financial liabilities
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.

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

License fees

License fees representing non-refundable payments received at the time of executing the license agreements. The Company's promise to grant a license provides its customer with either a right to access the Company's intellectual property ("IP") or a right to use the Company's IP. Revenue from a license that provides a customer the right to use the Company's IP is recognized at a point in time when the transfers to the licensee is completed and the license period begins. Revenue from a license that provides access to the Company's IP over a license term is considered to be a performance obligation satisfied over time and, therefore, revenue is recognized over the term of the license arrangement.

Royalty and milestone income

Royalty income earned through a license is recognized when the underlying sales have occurred. Milestone income is recognized at the point in time when it is highly probable that the respective milestone event criteria are met, and the risk of reversal of revenue recognition is remote. Other revenue also includes revenue from activities such as manufacturing or





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other services rendered, to the extent such revenue is not recorded under net sales, and is recognized when control transfers to the third party and the related performance obligations are satisfied.

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 income (loss) or directly in equity is also recognized directly in other comprehensive income (loss) 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 the 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.

Net income (loss) per share

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

Diluted net income (loss) per share is calculated based on the weighted average number of common shares outstanding during the year, plus the effects of dilutive common share equivalents, such as stock options and share purchase warrants.

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This method requires that diluted net income (loss) per share be calculated using the treasury stock method, as if all common share equivalents had been exercised at the beginning of the reporting period, or period of issuance, as the case may be, and that the funds obtained thereby were used to purchase common shares of the Company at the average trading price of the common shares during the period.

#### 4 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.

##### Accounting for the Macrilen License and Assignment Agreement

See the performance obligations further described in note 6 - Licensing arrangements.

##### 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 selection of the most appropriate 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 17 - Warrant liability and 19 - Share and other capital.

##### Impairment of goodwill and identifiable intangible assets

The annual impairment assessment related to goodwill requires to estimate the recoverable amount, which has been determined using value in use model. The Company also concluded that there was only one CGU as management monitors goodwill and identifiable intangible assets on an overall entity basis. Future events 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 18 - Employee future benefits.

##### 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



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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 22 - Income taxes. .

5 Recent accounting pronouncements

Accounting standards adopted in 2018

IFRS 9 Financial instruments

IFRS 9 replaces the provisions of IAS 39 Financial Instruments: Recognition and Measurement ("IAS 39") that relate to the recognition, classification and measurement of financial assets and financial liabilities, de-recognition of financial instruments, impairment of financial assets and hedge accounting.

The Company's financial assets are mainly comprised of cash and cash equivalents, trade and other receivables, and restricted cash equivalents, which are classified and accounted for under IFRS 9 at amortized cost. Financial liabilities are mainly comprised of payables and accrued liabilities, which are accounted for at amortized cost, and the warrant liability, which is a derivative that is accounted for at fair value through profit and loss (FVTPL).

The impairment of financial assets, including trade and other receivables, is now assessed using the simplified method of the expected credit loss model: previously, the incurred loss model was used. Applying the expected credit loss model has not had a significant impact on the value of the financial assets.

The Company applied the modified retrospective method upon adoption of IFRS 9 on January 1, 2018. This method requires the recognition of the cumulative effect of initially applying IFRS 9 to retained earnings (deficit) and not to restate prior years. The application of this new standard resulted in changes in accounting policies but has no impact on opening deficit.

IFRS 15 Revenue from contracts with customers

Effective January 1, 2018, the Company has adopted IFRS 15 Revenue from Contracts with Customers ("IFRS 15"). This new standard was applied using a modified retrospective approach. The adoption of IFRS 15 did not have a significant impact on the timing or measurement of the Company's revenue and no adjustment to the opening balance of deficit as at January 1, 2018 has been recorded as result of adopting IFRS 15.

The impacts of adoption of the new standard are summarized below:

The Company's revenue consists of licensing fees representing non-refundable payments received at the time of executing the license agreement, which are recognized as revenue upon execution of the license agreements when the Company has no significant future performance obligation and collectability of the fees is probable. Under IFRS 15, the Company determines whether the Company's promise to grant a license provides its customer with either a right to access the Company's IP or a right to use the Company's IP. Revenue from a license that provides a customer the right to use the Company's IP is recognized at a point in time when the transfer to the licensee is completed and the license period begins. Revenue from a license that provides access to the Company's IP over a license term is considered to be a performance obligation satisfied over time and, therefore, revenue is recognized over the term of the license arrangement.

Revenue consists also of royalty income from the out-licensing of IP, which is recognized as earned and from manufacturing and other services, where revenue is recognized when control transfers to the third party and the Company's performance obligations are satisfied. The adoption of IFRS 15 did not significantly change the timing or amount of revenue recognized from these manufacturing and other services arrangements, nor did it change accounting for these royalty arrangements, as the standard's royalty exception is applied for IP licenses.



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Furthermore, the Company receives milestone payments related to the out-licensing of IP. IFRS 15 resulted in the following changes in timing and amount of revenue recognized under these arrangements. In January 2018, the Company received \$24.0 million of which \$23.6 million was recognized in the consolidated statements of comprehensive income (loss) and \$0.4 million was deferred to the consolidated statements of financial position and is being amortized until June 2023 when we expect to commence product sales for the pediatric indication. Under IAS 18, the full \$24.0 million would have been deferred to the consolidated statements of financial position and would have been amortized to the consolidated statements of comprehensive income (loss) evenly until October 2027, representing the expiry date of the underlying patents.

The Company applied the modified retrospective method upon adoption of IFRS 15 on January 1, 2018. This method requires the recognition of the cumulative effect of initially applying IFRS 15 to deficit and not to restate prior years. The application of this new standard effective January 1, 2018 had no impact on opening deficit.

Accounting standards not yet adopted

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 that this new standard may have on the Company's consolidated financial statements.

In June 2017, IFRIC 23, "Uncertainty over Income Tax Treatment" ("IFRIC 23"), was issued. IFRIC 23 provides guidance on how to value uncertain income tax positions based on the probability of whether the relevant tax authorities will accept the company's tax treatments. A company is to assume that a taxation authority with the right to examine any amounts reported to it will examine those amounts and will have full knowledge of all relevant information when doing so. IFRIC 23 is effective for annual periods beginning on or after January 1, 2019. The adoption of this interpretation is not expected to have a significant impact on the Company's consolidated financial statements.

In June 2015, the IASB published ED/2015/5 Remeasurement on a Plan Amendment, Curtailment or Settlement/Availability of a Refund from a Defined Benefit Plan (Proposed amendments to IAS 19 and IFRIC 14) combining two issues submitted separately to the IFRS Interpretations Committee into a single package of narrow-scope amendments to IAS 19 Employee Benefits and IFRIC 14 IAS 19 - The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interaction. However, in April 2017 the IASB decided to pursue the amendments to IAS 19 and in September 2017 confirmed it would do so despite putting off the amendments to IFRIC 14. The amendments in Plan Amendment, Curtailment or Settlement (Amendments to IAS 19) are: (i) if a plan amendment, curtailment or settlement occurs, it is now mandatory that the current service cost and the net interest for the period after the remeasurement are determined using the assumptions used for the remeasurement and (ii) amendments have been included to clarify the effect of a plan amendment, curtailment or settlement on the requirements regarding the asset ceiling. An entity applies the amendments to plan amendments, curtailments or settlements occurring on or after the beginning of the first annual reporting period that begins on or after 1 January 2019. The adoption of these amendments is not expected to have a significant impact on the Company's consolidated financial statements.

6 Licensing arrangements

Macrilen License and Assignment Agreement

On January 16, 2018, the Company through Aeterna Zentaris GmbH entered into a license and assignment agreement (the "License and Assignment Agreement") with Strongbridge to carry out development, manufacturing, registration, regulatory and supply chain services for the commercialization of Macrilen™ (macimorelin) in the United States and



Canada, which provides for (i) the "right to use" license relating to the Adult Indication; (ii) the sale of the right to acquire a license of a future FDA-approved Pediatric Indication; (iii) Strongbridge has agreed to fund 70% of the costs of a pediatric clinical trial submitted for approval to the EMA and FDA to be run by the Company with customary oversight from a joint steering committee; and (iv) for an Interim Supply Arrangement.

(i) Adult Indication

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Aeterna Zentaris Inc.

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Under the terms of the License and Assignment Agreement, and for as long as Macrilen™ (macimorelin) is patent-protected, the Company will be entitled to a 15% royalty on annual net sales up to \$75.0 million and an 18% royalty on annual net sales above \$75.0 million. Following the end of patent protection in United States or Canada for Macrilen™ (macimorelin), the Company will be entitled to a 5% royalty on net sales in that country. In addition, the Company will also receive one-time payments ranging from \$4.0 million to \$100.0 million upon the achievement of commercial milestones going from \$25.0 million annual net sales up to \$500.0 million annual net sales.

In January 2018, the Company received a cash payment of \$24.0 million from Strongbridge and on July 23, 2018, Strongbridge launched product sales of Macrilen™ (macimorelin) in the United States.

(ii) Pediatric Indication

Upon approval by the FDA of a pediatric indication for Macrilen™ (macimorelin), the Company will receive a one-time milestone payment of \$5.0 million. This amount will be recognized once it is probable that it will be received.

Transaction price

Analysis of the total discounted cash flows of both the \$24.0 million payment and the \$5.0 million payment upon FDA approval of the Pediatric Instance demonstrates that 84% of the future revenue streams would be derived from the Adult Indication and 16% from the Pediatric Indication. On a relative fair value basis, the Company has allocated the transaction price to the performance obligations resulting in \$23.6 million being allocated to the Adult Indication and being recognized as license fee revenue in the consolidated statements of comprehensive income (loss) effective January 2018, and \$400 being allocated to the right to a future Pediatric Indication, which is recognized as deferred revenue on the consolidated statements of financial position and amortized monthly beginning January 2018 into the consolidated statements of comprehensive income (loss).

(iii) PIP study

During 2018, the Company invoiced Strongbridge \$358 as its share of the costs incurred by the Company under the PIP. The Company considers the funding arrangement under the PIP to be a collaboration arrangement under IFRS 11 and has accounted for the invoicing as a reduction of costs incurred during the period. This amount is presented in the consolidated statement of financial position as trade and other receivables and has been fully collected.

(iv) Interim Supply Arrangement

The Company has agreed under the License and Assignment Agreement to supply ingredients for the manufacture of Macrilen™ (macimorelin) during an interim period at a price that is set 'at cost', without any profit margin. The Company believes the stand-alone selling price of the manufacturing ingredients to be their cost, as that approximates the amount at which Strongbridge would be able to procure those same goods with other suppliers. During 2018, the Company invoiced \$2,167 and has received payment in full of these invoices. These items are presented in the consolidated statements of comprehensive income (loss) as product sales and cost of goods sold.

Novo purchase of Strongbridge License Agreement

Effective December 19, 2018, Strongbridge sold the entity which owned the License and Assignment Agreement for the United States and Canadian rights to Macrilen™ to Novo .

Zoptrex™ License Agreements

On July 1, 2016, the Company entered into a license agreement (the "Cyntec License Agreement") with Cyntec Co., Ltd. ("Cyntec"), an affiliate of Orient EuroPharma Co., Ltd. ("OEP") for Zoptrex™ (zoptarelin doxorubicin) for the initial indication of endometrial cancer. Under the terms of the Cyntec License Agreement, the Company was paid a nonrefundable

upfront cash payment (the "License Fee") of EUR 0.5 million in consideration for the license to Cyntec of the Company's intellectual property related to Zoptrex™ and the grant to Cyntec of the right to commercialize Zoptrex™ in a territory



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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™ 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™ using quantities of the active pharmaceutical agreement purchased from the Company pursuant to the Supply Agreement.

On December 1, 2014, the Company entered into an exclusive master collaboration agreement ("Master Collaboration Agreement"), a technology transfer and technical assistance agreement ("Tech Transfer Agreement") and a license agreement ("Sinopharm License Agreement") with Sinopharm A-Think Pharmaceuticals Co., Ltd. ("Sinopharm") for the development, manufacture and commercialization of Zoptrex™ in all human uses, in the People's Republic of China, including Hong Kong and Macau (collectively, the "Sinopharm Territory"). Under the terms of the TTA, Sinopharm made a one-time, non-refundable payment (the "Transfer Fee") of \$1,000 to the Company in consideration for the transfer of technical documentation and materials, know-how and technical assistance services. Additionally, pursuant to the Sinopharm License Agreement, the Company is 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 is entitled to royalties on future net sales of Zoptrex™ in the Sinopharm Territory. The Company has 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.

The Company 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.

At December 31, 2017, the Company had deferred revenues net of amortization of \$541 relating to non-refundable upfront payments and, due to events that occurred in 2017, the Company does not anticipate development of Zoptrex™ under the licensing agreements. In the first quarter of 2018, the Company recognized this amount as revenue.

7 Cash and cash equivalents

	December	
	31,	
	2018	2017
	\$	\$
Cash on hand and balances with banks	3,501	7,099
Interest-bearing deposits with maturities of three months or less	11,011	681
	14,512	7,780

8 Trade and other receivables

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	December 31, 2018 2017	
	\$	\$
Trade accounts receivable (net of allowance for doubtful accounts of \$55 (2017 - \$5))	142	20
Value added tax	49	186
Other receivables	103	15
	294	221

See note 24 - Financial instruments and financial risk management for discussion of credit losses.

9 Inventory

	December 31, 2018 2017	
	\$	\$
Finished goods	—	554
Work in process	240	—
	240	554

The Company recognized \$2,087 of inventory costs as cost of sales in the consolidated statement of comprehensive income (loss) for the year ended December 31, 2018 (2017 - nil).

10 Prepaid expenses and other current assets

	December 31, 2018 2017	
	\$	\$
Prepaid insurance	832	410
Prepaid inventory	175	87
Other	203	329
	1,210	826

11 Restricted cash equivalents

The Company had restricted cash equivalents amounting to \$418 at December 31, 2018 and \$381 at December 31, 2017. These balances consist of certificates of deposit that are used as collateral for corporate credit cards and leases.

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Notes to Consolidated Financial Statements

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## 12 Property, plant and equipment

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

	Cost				Total
	Equipment	Furniture and fixtures	Computer equipment	Leasehold improvements	
	\$	\$	\$	\$	\$
At January 1, 2017	3,919	19	737	37	4,712
Additions	2	—	2	—	4
Disposals / Retirements	(2,160)	—	(43)	—	(2,203)
Impact of foreign exchange rate changes	507	—	94	5	606
At December 31, 2017	2,268	19	790	42	3,119
Additions	1	—	8	—	9
Disposals / Retirements	(758)	—	(137)	—	(895)
Reclassifications	11	(11)	—	—	—
Impact of foreign exchange rate changes	(64)	(1)	(24)	(2)	(91)
At December 31, 2018	1,458	7	637	40	2,142
	Accumulated depreciation				Total
	Equipment	Furniture and fixtures	Computer equipment	Leasehold improvements	
	\$	\$	\$	\$	\$
At January 1, 2017	3,799	2	692	15	4,508
Disposals / Retirements	(2,135)	—	(43)	—	(2,178)
Depreciation expense	50	2	30	18	100
Impact of foreign exchange rate changes	496	—	90	2	588
At December 31, 2017	2,210	4	769	35	3,018
Disposals / Retirements	(752)	—	(137)	—	(889)
Depreciation expense	19	1	14	1	35
Impact of foreign exchange rate changes	(63)	—	(22)	(2)	(87)
At December 31, 2018	1,414	5	624	34	2,077

## Carrying amount

	Equipment	Furniture and fixtures	Computer equipment	Leasehold improvements	Total
	\$	\$	\$	\$	\$
At December 31, 2017	58	15	21	7	101
At December 31, 2018	44	2	13	6	65

Depreciation of \$35 (\$100 in 2017 and \$112 in 2016) is presented in the consolidated statement of comprehensive income (loss) as follows: \$20 (\$69 in 2017 and \$80 in 2016) in R&D costs, \$10 (\$10 in 2017 and \$11 in 2016) in general and administrative ("G&A") expenses and \$5 (\$21 in 2017 and \$21 in 2016) in selling expenses.

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## 13 Identifiable intangible assets

Identifiable intangible assets with finite useful lives consist entirely of in-process R&D costs, patents and trademarks with such assets expected to be fully amortized by 2021. Changes in the carrying value of the Company's identifiable intangible assets with finite useful lives are summarized below.

	Year ended December 31, 2018			Year ended December 31, 2017		
	Cost	Accumulated amortization	Carrying value	Cost	Accumulated amortization	Carrying value
Balances – Beginning of the year	\$ 34,246	\$ (34,156 )	\$ 90	\$ 30,032	\$ (29,962 )	\$ 70
Additions	—	—	—	—	—	—
Impairment (loss) reversal*	—	—	—	—	44	44
Recurring amortization expense*	—	(23 )	(23 )	—	(38 )	(38 )
Impact of foreign exchange rate changes	(1,603 )	1,598	(5 )	4,214	(4,200 )	14
Balances – End of the year	32,643	(32,581 )	62	34,246	(34,156 )	90

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

## 14 Goodwill

The change in carrying value is as follows:

	Cost	Accumulated impairment loss	Carrying amount
At January 1, 2017	\$ 7,553	\$ —	\$ 7,553
Impact of foreign exchange rate changes	1,060	—	1,060
At December 31, 2017	8,613	—	8,613
Impact of foreign exchange rate changes	(403 )	—	(403 )
At December 31, 2018	8,210	—	8,210

Management's evaluation of impairment in goodwill is based on estimates that are derived from our licensee's projected sales of Macrilen for 2019 (both units and selling price), annual revenue growth rate, growth in operating expenses, the effect of future costs of the pediatric development program (the "PIP") and discount rate for generating the Company's net present value. There was no impairment assessed at December 31, 2018.

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and as otherwise noted)

15 Payables and accrued liabilities

	December	
	31,	
	2018	2017
	\$	\$
Trade accounts payable	1,282	1,222
Accrued research and development costs	26	127
Salaries, employment taxes and benefits	183	390
Financing of insurance premiums (a)	738	—
Other accrued liabilities	737	1,075
	2,966	2,814

(a) Represents financing of the Company's 2019 insurance premiums, carrying interest at 6.5% and repayable in eight equal monthly installments commencing January 31, 2019.

16 Provision for restructuring and other costs

In the third quarter of 2017, Aeterna Zentaris GmbH, and its Works Council approved a restructuring program (the "2017 German Restructuring"), which was rolled out as a consequence of the negative Phase 3 clinical trial results of Zoptrex™ and the related impact on the product pipeline. This was also part of the continued strategy to transition into a commercially operating specialty biopharmaceutical organization focused on the development and commercialization of Macrilen™ (macimorelin), including through out-licensing arrangements and pursuing in-licensing opportunities. The changes in the Company's provision for restructuring and other costs can be summarized as follows:



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	Other provision	Cetrotide contracts	2017 Restructuring: onerous lease	German Restructuring: severance	2017 German Restructuring: Total
		\$	\$	\$	\$
January 1, 2017	158	574	—	—	732
Provision recognized	—	—	1,113	2,002	3,115
Utilization of provision	(152 )	(145 )	(19 )	(138 )	(454 )
Change in the provision	—	(20 )	10	(41 )	(51 )
Unwinding of discount and impact of foreign exchange rate changes	3	64	104	(16 )	155
December 31, 2017	9	473	1,208	1,807	3,497
Provision recognized	—	317	—	—	317
Utilization of provision	(9 )	(222 )	(467 )	(1,202 )	(1,900 )
Change in the provision	—	—	(21 )	(432 )	(453 )
Unwinding of discount and impact of foreign exchange rate changes	—	(21 )	(57 )	(85 )	(163 )
December 31, 2018	—	547	663	88	1,298
Less: current portion	—	(136 )	(663 )	(88 )	(887 )
Non-current portion	—	411	—	—	411
17 Warrant liability					

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

	Years ended December 31,		
	2018	2017	2016
	\$	\$	\$
Balance – Beginning of the year	3,897	6,854	10,891
Share purchase warrants issued during the year (note 19)	—	—	400
Share purchase warrants exercised during the year	—	(735 )	—
Change in fair value of share purchase warrants	(263 )	(2,222 )	(4,437 )
Balance - End of the year	3,634	3,897	6,854

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

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	Years ended December 31,		2016		Weighted average exercise price (\$)
	2018	2017	2016	2016	
	Number	Number	Number	Number	Weighted average exercise price (\$)
Balance – Beginning of the year	3,417,840	3,779,245	2,842,309	2,842,309	11.30
Issued (note 19)	—	—	945,000	945,000	4.70
Exercised	—	(331,730 )	—	—	—
Expired (note 19)	(25,996 )	(29,675 )	(8,064 )	(8,064 )	4.23
Balance – End of the year	3,391,844	3,417,840	3,779,245	3,779,245	9.66

\* A portion of the Series A warrants was exercised using the cashless feature. Therefore, the total number of equivalent shares issued was 301,343.

The following table summarizes the share purchase warrants outstanding and exercisable as at December 31, 2018:

Exercise price (\$)	Number	Weighted average remaining contractual life (years)
1.07	115,844	1.19
4.70	945,000	1.34
7.10	2,331,000	1.96
	3,391,844	1.76

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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 warrants outstanding as at December 31, 2018. 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 24 - 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) (c)	Expected dividend yield (d)
March 2015 Series A Warrants (e)	115,844	2.94	1.07	2.58 %	81.81 %	1.19	0.00 %
December 2015 Warrants	2,331,000	2.94	7.10	2.47 %	122.00 %	1.96	0.00 %
November 2016 Warrants (f)	945,000	2.94	4.70	2.56 %	78.95 %	1.34	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.

(d) The Company has not paid dividends and it does not intend to pay dividends in the foreseeable future.

For the March 2015 Series A Warrants, the inputs and assumptions applied to the Black-Scholes option pricing (e) 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 19 - Share and other capital).

For the November 2016 Warrants, the Company reduced the fair value of these warrants to take into consideration (f) the fair value of the \$10 call option, which was also calculated using the Black-Scholes pricing model. (see note 19 - Share and other capital).

#### 18 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:

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	Pension benefit plans			Other benefit plans		
	Years ended December 31,			Years ended December 31,		
	2018	2017	2016	2018	2017	2016
	\$	\$	\$	\$	\$	\$
Balances – Beginning of the year	14,145	13,197	12,375	84	217	281
Current service cost	66	107	87	6	14	13
Interest cost	224	237	282	1	3	—
Actuarial (gain) loss arising from changes in financial assumptions	(193 )	(694 )	1,479	19	(115)	—
Benefits paid	(492 )	(485 )	(399 )	(2 )	(66 )	(60 )
Impact of foreign exchange rate changes	(650 )	1,783	(627 )	(3 )	31	(17 )
Balances – End of the year	13,100	14,145	13,197	105	84	217
Amounts recognized:						
In net loss	(290 )	(344 )	(369 )	(26 )	98	(13 )
In other comprehensive income (loss)	843	(1,089)	(852 )	3	(31 )	17

The cumulative amount of actuarial net losses recognized in other comprehensive income (loss) as at December 31, 2018 is \$4,084(\$4,277 as at December 31, 2017 and \$4,971 as at December 31, 2016).

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

	Pension benefit plans			Other benefit plans		
	Years ended December 31,			Years ended December 31,		
Actuarial assumptions	2018	2017	2016	2018	2017	2016
	%	%	%	%	%	%
Discount rate	1.90	1.70	1.60	1.90	1.70	1.60
Pension benefits increase	1.80	1.80	1.80	1.80	1.80	1.80
Rate of compensation increase	2.00	2.00	2.00	2.00	2.00	2.00

The calculation of the pension benefit obligation is sensitive to the discount rate assumption. Effective January 1, 2018, management determined that the discount rate assumption should be adjusted from 1.7% to 1.9% 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:

	2018	2017	2016
Retiring at the end of the reporting period:			
Male	20	20	20
Female	24	24	24
Retiring 20 years after the end of the reporting period:			
Male	28	22	22
Female	31	26	26

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The most recent actuarial reports give effect to the pension and post-employment benefit obligations as at December 31, 2018. The next actuarial reports are planned for December 31, 2019.

In accordance with the assumptions used as at December 31, 2018, undiscounted defined pension benefits expected to be paid, in Euro, are as follows:

	\$
2019	453
2020	458
2021	463
2022	468
2023	476
Thereafter	13,658
	15,976

The weighted average duration of the defined benefit obligation is 15.3 years.

Total expenses for the Company's defined contribution plan in its German subsidiary amounted to approximately \$75 for the year ended December 31, 2018 (\$119 for 2017 and \$129 for 2016).

If variations in the following assumptions had occurred during 2018, the impact on the Company's pension benefit obligation of \$13,100 as at December 31, 2018 would have been as follows:

Assumption	Increase	Decrease
Change interest rate by 0.25%	(467 )	498
Change salary rate by 0.25%	19	(17 )
Change pension by 0.25%	372	(355 )
Change mortality by 1 year	464	(463 )

19 Share and other 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.

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

April 2016 ATM Program

On April 1, 2016, the Company entered into an ATM sales agreement (the "April 1, 2016 ATM Program"), under which the Company was 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 April 2016 ATM Program provides that common shares were to be sold at market prices prevailing at the time of sale and, as a result, prices varied.

Between April 1, 2016 and March 24, 2017, the Company issued a total of 1,706,968 common shares under the April 2016 ATM Program at an average issuance price of \$3.52 per share for aggregate gross proceeds of \$6.0 million less cash transaction costs of \$190 and previously deferred financing costs of \$225.

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#### March 2017 ATM Program

On March 28, 2017, the Company commenced a new ATM offering pursuant to its existing ATM Sales Agreement, dated April 1, 2016, under which the Company was able, at its discretion, from time to time, to sell up to a maximum of 3 million common shares through ATM issuances on the NASDAQ, up to an aggregate amount of \$9.0 million (the "March 2017 ATM Program"). The common shares were to be sold at market prices prevailing at the time of the sale of the common shares and, as a result, sale prices varied.

Between March 28, 2017 and April 18, 2017, the Company issued a total of 597,994 common shares under the March 2017 ATM Program at an average issuance price of \$2.97 per share for aggregate gross proceeds of \$1,780,000 less cash transaction costs of \$55 and previously deferred financing costs of \$65.

#### April 2017 ATM Program

On April 27, 2017, the Company entered into a New ATM Sales Agreement and filed with the Securities and Exchange Commission (the "SEC") a prospectus supplement (the "April 2017 ATM Prospectus Supplement" or "April 2017 ATM Program") related to sales and distributions of up to a maximum of 2.24 million common shares through ATM issuances on the NASDAQ, up to an aggregate amount of \$6.9 million under the New ATM Sales Agreement. The common shares will be sold at market prices prevailing at the time of the sale of the common shares and, as a result, prices may vary. The New ATM Sales Agreement and the April 2017 ATM Program superseded and replaced the March 2017 ATM Program, which itself superseded and replaced the April 2016 ATM Program. The April 2017 ATM Prospectus Supplement supplements the base prospectus included in the Company's Shelf Registration Statement on Form F-3, as amended (the "2017 Shelf Registration Statement"), which was declared effective by the SEC on April 27, 2017. The 2017 Shelf Registration Statement allowed the Company to offer up to \$50 million of common shares and is effective for a three-year period.

Between May 30, 2017 and December 31, 2017, the Company issued a total of 1,805,758 common shares under the April 2017 ATM Program at an average issuance price of \$2.08 per share for aggregate gross proceeds of \$3,761,000 less cash transaction costs of \$115 and previously deferred financing costs of \$285. Because of these issuances, the exercise price of the Series A warrants issued in March 2015 was adjusted to \$1.07 pursuant to the anti-dilution provisions contained in such warrants.

#### Public offerings

##### November 2016 Offering

On November 1, 2016, the Company completed a registered direct offering of 2.1 million 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 \$7.6 million, less cash transaction costs of \$1.0 million, and previously deferred transactions costs of \$27. 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 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 17 - 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,

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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.

The pre-funded warrants were offered in the November 2016 Offering to the investor because the purchase of Units would have resulted in the investor beneficially owning more than an "initial beneficial ownership limitation" of 4.9% of the Company's 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 was allocated to the warrant liability, \$3,239 was allocated to the pre-funded warrants, and the balance of \$3,921 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 was allocated to the warrant liability and immediately recognized in general and administrative expenses in the consolidated statement of comprehensive income (loss), an amount of \$544 was allocated to share capital and an amount of \$450 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.

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 that may be issued from time to time. The Rights Plan was approved, ratified and confirmed by the Company's shareholders at its annual meeting of shareholders held on May 10, 2016.

The Board of Directors reviewed the terms of the Existing Rights Plan for conformity with current Canadian securities laws, as well as the evolving practices of public corporations in Canada, with respect to shareholder rights plan design and has made some minor amendments thereto as a result. The Board of Directors determined it appropriate and in the best interests of the shareholders to continue the Rights Plan and approved the amended and restated rights plan (the "Rights Plan") on March 26, 2019. The Rights Plan will take effect immediately upon receipt of approval of the shareholders of the Corporation at the annual and special meeting of shareholders scheduled to be held on May 8, 2019.

Other capital

The Company accounts for costs associated with share-based compensation from security grants under its long-term incentive plan and stock option plans as other capital in its consolidated statements of changes in shareholders' equity (deficiency) and as general and administrative expenses in its consolidated statements of comprehensive income (loss).

Long-term incentive plan

At the 2018 annual and special meeting of shareholders, the Company's shareholders approved the adoption of the 2018 long-term incentive plan (the "LTIP"), which allows the Board of Directors to issue up to 11.4% of the total issued and outstanding common shares at any given time to eligible individuals at an exercise price to be determined by the Board of Directors at the time of the grant, subject to a ceiling, as stock options, stock appreciation rights, stock awards, stock units, performance shares, performance units, and other stock-based awards. This LTIP replaces the stock option plan (the "Stock Option Plan") for its directors, senior executives, employees and other collaborators who



provide services to the Company. 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 10 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.

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During 2018, the Company granted Deferred Share Units (DSU) and stock options. The following tables summarize the activity under the LTIP and, previously, the Stock Option Plan:

	Years ended December 31,						
	2018	2017		2016			
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	712,415	4.66	966,539	7.23	272,874	25.88	
Granted	426,000	1.74	390,000	2.05	713,573	3.47	
Forfeited	(249,599)	3.23	(643,271)	6.02	(10,034)	99.22	
Cancelled	—	—	—	—	(9,874)	157.11	
Expired	—	—	(853)	704.88	—	—	
Balance – End of period	888,816	3.66	712,415	4.66	966,539	7.23	
Years ended December 31,							
Canadian dollar-denominated stock options	Number	2018		2017		2016	
		Weighted average exercise price (CAN\$)	Weighted average exercise price (CAN\$)	Weighted average exercise price (CAN\$)	Weighted average exercise price (CAN\$)	Weighted average exercise price (CAN\$)	Weighted average exercise price (CAN\$)
Balance – Beginning of the year	1,503	605.84	1,858	820.27	3,787	845.46	
Forfeited	(104)	668.65	—	—	(1,028)	967.63	
Cancelled	—	—	—	—	(901)	758	
Expired	(530)	367.70	(355)	1,728.15	—	—	
Balance – End of the year	869	743.56	1,503	605.84	1,858	820.27	
Total US\$ share-based awards as at December 31, 2018							
Exercise price (US\$)	Number	Weighted average remaining contractual life (years)	Weighted average exercise price (US\$)				
1.46 to 1.79	211,000	8.62	1.71				
1.80 to 2.11	490,000	6.41	2.06				
2.12 to 3.50	157,148	4.75	3.46				
3.51 to 4.58	26,000	3.97	4.58				
4.59 to 1,044.00	4,668	2.77	260.87				
	888,816	6.55	3.66				

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Total exercisable US\$ share-based awards as at December 31, 2018			
Exercise price (US\$)	Number	Weighted average remaining contractual life (years)	Weighted average exercise price (US\$)
1.46 to 1.79	161,000	9.35	1.79
1.80 to 2.11	130,000	5.62	2.05
2.12 to 3.50	104,774	4.75	3.46
3.51 to 4.58	26,000	3.97	4.58
4.59 to 1,044.00	4,668	2.77	260.87
	426,442	6.68	5.29

CAN\$ options outstanding and exercisable as at December 31, 2018			
Exercise price (CAN\$)	Number	Weighted average remaining contractual life (years)	Weighted average exercise price (CAN\$)
570.00 to 741.00	428	0.94	570.00
741.01 to 912.00	441	1.87	912.00
	869	1.41	743.56

As at December 31, 2018, the total compensation cost related to unvested US Dollar stock options not yet recognized amounted to \$198 (\$444 in 2017). This amount is expected to be recognized over a weighted average period of 1.15 years (1.38 years in 2017).

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.

Fair value input assumptions for US dollar-denominated grants

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, 2018	2017
Expected dividend yield	(a) 0.00 %	0.00 %
Expected volatility	(b) 129.23 %	137.60 %
Risk-free annual interest rate	(c) 2.51 %	1.53 %
Expected life (years)	(d) 3.60	3.26
Weighted average share price	\$1.74	\$2.05

Weighted average exercise price	\$1.74	\$2.05
Weighted average grant date fair value	\$1.39	\$1.62

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- (a) The Company has not paid dividends and it does not intend to pay dividends in the foreseeable future.
- (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.
- (c) Based on United States Treasury Government Bond interest rates with a term that is consistent with the expected life of the stock options.
- (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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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 24 - Financial instruments and financial risk management.

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and as otherwise noted)

## 20 Operating expenses

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

	Years ended December		
	31, 2018	2017	2016
	\$	\$	\$
Key management personnel compensation <sup>(1)</sup>			
Salaries and short-term employee benefits	2,388	2,081	2,430
Consultants fees	62	—	—
Termination benefits	356	—	—
Post-employment benefits	147	59	78
Share-based compensation costs	462	87	1,051
	3,415	2,227	3,559
Other employees compensation:			
Salaries and short-term employee benefits	1,325	3,584	3,574
Termination benefits (note 16)	—	1,806	—
Post-employment benefits	275	441	500
Share-based compensation costs	108	95	31
	1,708	5,926	4,105
Professional fees	6,421	7,153	7,157
Insurance	1,303	949	870
Third-party R&D	498	3,758	11,796
Contracted sales force	256	22	14
Travel	256	831	1,185
Marketing services	176	698	5
Laboratory supplies	139	2	30
Other goods and services	342	162	160
Leasing costs, net of sublease receipts of \$121 in 2018, \$359 in 2017 and \$345 in 2016 <sup>(2)</sup>	344	2,247	1,131
Transaction costs related to share purchase warrants	—	—	56
Depreciation and amortization	60	138	195
Impairment (reversal) losses	—	(44)	85
Operating foreign exchange (gains) losses	17	(72)	39
	9,812	15,844	22,723
	14,935	23,997	30,387

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

<sup>(2)</sup> Leasing costs also include changes in the onerous lease provision (note 16 - provisions for restructuring and other costs), other than attributable to the unwinding of the discount.

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



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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.

## 21 Supplemental disclosure of cash flow information

	Years ended December		
	31,		
	2018	2017	2016
	\$	\$	\$
Changes in operating assets and liabilities:			
Trade and other receivables	(95 )	158	228
Inventory	314	—	—
Prepaid expenses and other current assets	448	(343 )	(45 )
Other non-current assets	150	39	(233 )
Payables and accrued liabilities	(586 )	(1,080)	(199 )
Taxes payable	1,669	—	—
Deferred revenues	400	—	555
Provision for restructuring and other costs (note 16)	(1,957)	(435 )	(911 )
Employee future benefits (note 18)	(494 )	(551 )	(459 )
	(151 )	(2,212)	(1,064)

## 22 Income taxes

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

	Years ended December		
	31,		
	2018	2017	2016
	\$	\$	\$
Current tax (expense) recovery	—	—	—
Deferred tax:			
Origination and reversal of temporary differences	(4,003)	6,395	9,199
Adjustments in respect of prior years	742	(149 )	36
Change in unrecognized tax assets	(2,191)	(2,767)	(9,235)
Income tax (expense) recovery	(5,452)	3,479	—

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

	Years ended		
	December 31,		
	2018	2017	2016
Combined Canadian federal and provincial statutory income tax rate	26.7%	26.8%	26.9%



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	Years ended December 31,		
	2018	2017	2016
	\$	\$	\$
Income tax (expense) recovery based on combined statutory income tax rate	(2,574)	5,434	6,714
Change in unrecognized tax assets	(1,963)	(2,701)	(9,235)
Change in unrecognized tax assets related to OCI	(188 )	(228 )	436
Share issuance costs	(40 )	164	224
Permanent difference attributable to the use of local currency for tax reporting	792	(71 )	(30 )
Change in enacted rates used	(58 )	(358 )	(16 )
Permanent difference attributable to net change in fair value of warrant liability	70	595	1,194
Share-based compensation costs	(152 )	(49 )	(291 )
Difference in statutory income tax rate of foreign subsidiaries	(917 )	768	972
Adjustments in respect of prior years	(372 )	(149 )	36
Other	(50 )	74	(4 )
	(5,452)	3,479	—

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.

Income (loss) before income taxes

Income (loss) before income taxes is attributable to the Company's tax jurisdictions as follows:

	Years ended December 31,		
	2018	2017	2016
	\$	\$	\$
Germany	16,297	(13,950)	(19,179)
Canada	(5,504 )	(5,592 )	(5,659 )
United States	(1,154 )	(733 )	(121 )
	9,639	(20,275)	(24,959)

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

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	December 31,	
	2018	2017
	\$	\$
Deferred tax assets		
Current:		
Operating losses carried forward	—	3,479
Non-current:		
Operating losses carried forward	764	696
Intangible assets	3,646	4,812
	4,410	8,987
Deferred tax liabilities		
Current:		
Deferred revenues	38	—
Restricted cash	153	—
Payables and accrued liabilities	95	—
	286	—
Non-current:		
Property, plant and equipment	3	5
Deferred revenues	4,074	5,316
Other	47	187
	4,124	5,508
	4,410	5,508
Deferred tax assets (liabilities), net	—	3,479
Significant components of unrecognized deferred tax assets are as follows:		
	December 31,	
	2018	2017
	\$	\$
Deferred tax assets		
Current:		
Deferred revenues and other provisions	649	584
	649	584
Non-current:		
Deferred revenues	—	—
Operating losses carried forward	81,731	82,421
SR&ED Pool	9,148	9,167
Unused tax credits	5,894	8,019
Employee future benefits	2,048	2,296
Property, plant and equipment	448	407
Share issuance expenses	467	841
Other	241	335
	99,977	103,486
Unrecognized deferred tax assets	100,626	104,070



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As at December 31, 2018, 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	7,880	6,494
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	10,418	10,452
2036	10,592	10,592
2037	7,343	7,343
2038	6,557	6,557
	65,562	64,161

The Company has estimated non-refundable R&D investment tax credits of approximately \$5,894 which can be carried forward to reduce Canadian federal income taxes payable and which expire at dates ranging from 2019 to 2038. 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 \$205,343 in Germany (EUR 173,733) for which there is no expiry date, and to \$3,322 in the United States, which expire as follows:

	United States
	\$
2028	369
2029	178
2034	151
2035	447
2036	195
2037	709
2038	1,273
	3,322

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.

### 23 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, G&A expenses and working capital requirements.

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Over the past several years, the Company has raised capital via public equity offerings and issuances under various ATM sales programs as its primary source of liquidity, as discussed in note 19 - Share and other 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.

#### 24 Financial instruments and financial risk management

Financial assets (liabilities) as at December 31, 2018 and December 31, 2017 are presented below.

December 31, 2018	Financial assets at amortized cost	Financial liabilities at FVTPL	Financial liabilities at amortized cost	Total
	\$	\$	\$	\$
Cash and cash equivalents (note 7)	14,512	—	—	14,512
Trade and other receivables (note 8)	245	—	—	245
Restricted cash equivalents (note 11)	418	—	—	418
Payables and accrued liabilities (note 15)	—	—	(2,940 )	(2,940 )
Provision for restructuring and other costs (note 16)	—	—	(1,298 )	(1,298 )
Warrant liability (note 17)	—	(3,634 )	—	(3,634 )
	15,175	(3,634 )	(4,238 )	7,303
December 31, 2017	Financial assets at amortized cost	Financial liabilities at FVTPL	Financial liabilities at amortized cost	Total
	\$	\$	\$	\$
Cash and cash equivalents (note 7)	7,780	—	—	7,780
Trade and other receivables (note 8)	35	—	—	35
Restricted cash equivalents (note 11)	381	—	—	381
Payables and accrued liabilities (note 15)	—	—	(2,687 )	(2,687 )
Provision for restructuring and other costs (note 16)	—	—	(3,497 )	(3,497 )
Warrant liability (note 17)	—	(3,897 )	—	(3,897 )
	8,196	(3,897 )	(6,184 )	(1,885)

#### Fair value

As discussed in note 17 - Warrant liability, 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.

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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 and provision for restructuring and other costs 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.

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, market risk (share price risk) and foreign exchange 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 financial assets at amortized cost 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. Once there are indicators that there is no reasonable expectation of recovery, such financial assets are written off but are still subject to enforcement activity.

As at December 31, 2018, trade accounts receivable for an amount of approximately \$197 were with four counterparties of which \$55 was past due or impaired and fully provided for (2017 - \$25 with three counterparties and \$5 past due or impaired and fully provided for). The licensee is obligated to pay its quarterly royalties, 60 days after quarter-end.

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. On this basis, as at December 31, 2018, the Company has provided for all outstanding and unpaid amounts relating to its operations before its licensing of Macrilen™(macemorelin). The licensee has paid all amounts owing within 90 days of invoicing.

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 23 - 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 as further discussed in note 2 - Assessment of liquidity and management's plans. 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.

(c) Market risk



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#### 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 as further described in note 15 as it applies to its outstanding share purchase warrants. The 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 income (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 ranged from \$1.19 to \$3.87 during the year ended December 31, 2018.

If variations in the market price of our common shares of -30% and +30% were to occur, the impact on the Company's net income related to the warrant liability held at December 31, 2018 would be as follows:

	Carrying amount	-30%	+30%
	\$	\$	\$
Warrant liability	3,634	1,792	(1,504)
Total impact on net income – (decrease) / increase		1,792	(1,504)

#### (d) Foreign exchange risk

Entities using the Euro as their functional currency

The Company is exposed to foreign exchange risk due to its investments in foreign operations whose functional currency is the Euro. As at December 31, 2018, if the US dollar had increased or decreased by 10% against the Euro, with all variables held constant, net income for the year ended December 31, 2018 would have been lower or higher by approximately \$1,134 (2017 - \$1,087).

#### 25 Segment information

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

#### Geographical information

Revenues by geographical area are detailed as follows:

	Years ended December 31,		
	2018	2017	2016
	\$	\$	\$
Ireland	24,910	—	—
United States	1,416	452	410
China	275	262	249
Singapore	—	—	101
British Virgin Islands	280	206	100
Other	—	3	51
	26,881	923	911

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:



## Aeterna Zentaris Inc.

## Notes to Consolidated Financial Statements

As at December 31, 2018 and December 31, 2017 and for the years ended December 31, 2018, 2017 and 2016 (tabular amounts in thousands of US dollars, except share/option/warrant/DSU and per share/option/warrant/DSU data and as otherwise noted)

	December 31,	
	2018	2017
	\$	\$
Germany	8,599	12,552
United States	153	102
Canada	3	160
	8,755	12,814

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

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,		
	2018	2017	2016
	\$	\$	\$
Company 1	26,127	—	—
Company 2	—	—	20
Company 3	275	262	249
Company 4	—	323	222
Company 5	—	129	167
Company 6	—	—	101
Company 7	280	206	100

## 26 Net income (loss) per share

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

	Years ended December 31,		
	2018	2017	2016
	\$	\$	\$
Net income (loss)	4,187	(16,796 )	(24,959 )
Basic weighted average number of shares outstanding	16,440,760	14,958,704	10,348,879
Diluted weighted average number of shares outstanding	17,034,812	14,958,704	10,348,879
Items excluded from the calculation of diluted net income (loss) per share because the exercise price was greater than the average market price of the common shares or due to their anti-dilutive effect			
Stock options	889,685	713,918	968,397
Share purchase warrants	3,391,844	3,417,840	3,779,245

Net income (loss) per share is calculated by dividing net income (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

Aeterna Zentaris Inc.

Notes to Consolidated Financial Statements

As at December 31, 2018 and December 31, 2017 and for the years ended December 31, 2018, 2017 and 2016 (tabular amounts in thousands of US dollars, except share/option/warrant/DSU and per share/option/warrant/DSU data and as otherwise noted)

share purchase warrants are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal, and thus "in the money" 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.

#### 27 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, 2018 are as follows:

	Minimum lease payments	Minimum sublease receipts	Service and manufacturing	Total
	\$	\$	\$	\$
Less than 1 year	408	(117 )	2,180	2,471
1 - 3 years	533	(24 )	—	509
4 - 5 years	60	—	—	60
More than 5 years	5	—	—	5
Total	1,006	(141 )	2,180	3,045

#### 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.

#### Securities class action lawsuit

The Company and certain of its current and former officers are defendants in a class-action lawsuit pending in the U.S. District Court for the District of New Jersey, brought on behalf of shareholders of the Company. The lawsuit alleges 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™ (macimorelin) and the prospects for the approval of the Company's New Drug Application for the product by the FDA. The plaintiffs represent a class comprised of purchasers of the Company's common shares during the Class Period and seek damages, costs and expenses and such other relief as determined by the Court. The Company considers the claims that have been asserted in the lawsuit to be without merit and is vigorously defending against them. The Company cannot, however, predict at this time the outcome or potential losses, if any, with respect to this lawsuit.

#### Other lawsuits

In late July 2017, the Company terminated for cause the employment agreement of Mr. David A. Dodd, the former President and Chief Executive Officer and it also terminated the employment of Mr. Philip A. Theodore, the former Senior Vice President, Chief Administrative Officer, General Counsel and Corporate Secretary. On August 3, 2017, the Company filed a lawsuit against both Messrs. Dodd and Theodore for damages suffered by the Company for breach of confidence and/or breach of fiduciary duty in an amount to be determined prior to trial. On December 21, 2017, Messrs. Dodd and Theodore brought a counterclaim against the Company and its Chair, Carolyn Egbert, in the amount of CAN\$6.0 million alleging, among other things, that defamatory statements were made against Messrs. Dodd and Theodore. On December 21, 2018, the matter was amicably resolved with the Company agreeing to make a payment to Mr. Dodd in the amount of \$775. The parties consider their contractual relationship as having been terminated.

Cogas Consulting, LLC ("Cogas") filed a lawsuit against the Company in state court in Fulton County, Georgia on February 2, 2018. The lawsuit was removed to federal court in Georgia. In the lawsuit, Cogas alleged that its

employee (and sole shareholder) John Sharkey was entitled to a "success fee" commission on the Strongbridge License Agreement. Cogas was

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Aeterna Zentaris Inc.

Notes to Consolidated Financial Statements

As at December 31, 2018 and December 31, 2017 and for the years ended December 31, 2018, 2017 and 2016 (tabular amounts in thousands of US dollars, except share/option/warrant/DSU and per share/option/warrant/DSU data and as otherwise noted)

claiming damages in the form of a lost commission on the transaction. Cogas claims its commission is 5% on payments the Company receives within the first three years after January 14, 2018 including 5% of the \$24.0 million Strongbridge already paid the Company, plus 5% of any royalty Strongbridge pays the Company through January 17, 2021. On November 5, 2018, the matter was amicably resolved with the Company agreeing to make a payment to Cogas in the amount of \$625. The parties now consider their contractual relationship as having been terminated.

28 Reclassification on comparative figures

To consolidate the presentation of similar items, during 2018, the Company reclassified certain of its prior year comparative balance sheet items as follows:

Prepaid expenses and other current assets

The semi-finished goods inventory of \$87 that was classified as inventory as at December 31, 2017 has been reclassified to prepaid expenses and other current assets as at December 31, 2018.

Provision for restructuring and other costs

The current portion of onerous contract provisions of \$173 that was classified as payables and accrued liabilities as at December 31, 2017 has been reclassified to provision for restructuring and other costs as at December 31, 2018.

The full balance of provisions, comprising \$310 of onerous contract provisions and \$718 of non-current portion of provision for restructuring costs, as at December 31, 2017 has been reclassified to provision for restructuring and other costs at December 31, 2018.

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)
- 2.2 Draft (subject to approval at Shareholders meeting) Amended and Restated Shareholder Rights Plan Agreement between the Registrant and Computershare Trust Company of Canada, as Rights Agent, dated as of [May 8], 2019
- 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 2018 Long-Term Incentive Plan of the Registrant (incorporated by reference to Exhibit 4.7 of the Registrant's Form S-8 filed with the Commission on May 8, 2018)
- 4.3 License and Assignment Agreement, dated January 16, 2018 by and between Aeterna Zentaris GmbH and Strongbridge Ireland Limited (incorporated by reference to Exhibit 99.2 of the Registrant's report on Form 6-K furnished to the Commission on January 19, 2018)
- 4.4 Employment Agreement dated October 1, 2017 between Michael Ward and the Registrant (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2017 filed with the Commission on March 28, 2018)
- 4.5 Change of Control Agreement dated October 1, 2017 between Michael Ward and 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, 2017 filed with the Commission on March 28, 2018)
- 4.6 Employment Agreement dated March 5, 2018 between James Clavijo and 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, 2017 filed with the Commission on March 28, 2018)
- 4.7 Change of Control Agreement dated March 5, 2018 between James Clavijo and the Registrant (incorporated by reference to Exhibit 4.6 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2017 filed with the Commission on March 28, 2018)
- 4.8 Independent Contractor Agreement dated September 18, 2018 between Leslie Auld and the Registrant
- 4.9 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)
- 4.10 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)
- 4.11 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)
- 4.12

- Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 99.1 of the Registrant's report on Form 6-K furnished to the Commission on October 21, 2016)  
At Market Issuance Sales Agreement dated April 27, 2017 between the Registrant and H.C. Wainwright & Co. LLC (incorporated by reference to Exhibit 99.1 of the Registrant's report on Form 6-K furnished to the Commission on April 28, 2017)
- 4.13 Subsidiaries of the Registrant
- 8.1 Code of Conduct and Business Ethics 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, 2017 filed with the Commission on March 28, 2018)
- 11.1 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)
- 11.2 Audit Committee Charter of the Registrant (incorporated by reference to Exhibit 11.3 of the Registrant's Annual Report on Form 20-F for the financial year ended December 31, 2014 filed with the Commission on March 17, 2015)
- 11.3
- 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 Registered Public Accounting Firm
101. INS XBRL Instance Document

- 101. SCH XBRL Taxonomy Extension Schema
- 101. CAL XBRL Taxonomy Extension Schema Calculation Linkbase
- 101. DEF XBRL Taxonomy Extension Schema Definition Linkbase
- 101. LAB XBRL Taxonomy Extension Schema Label Linkbase
- 101. PRE XBRL Taxonomy Extension Schema Presentation Linkbase

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SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

AETERNA ZENTARIS INC.

/s/ Michael V. Ward

Michael V. Ward  
President and Chief Executive Officer

Date: March 29, 2019

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