

Third Quarter 2017

Management's Discussion and Analysis of Financial Condition and Results of Operations

Introduction

This Management's Discussion and Analysis ("MD&A") provides a review of the results of operations, financial condition and cash flows of Aeterna Zentaris Inc. for the nine months ended September 30, 2017. In this MD&A, "Aeterna Zentaris", the "Company", "we", "us", "our" and the "Group" mean Aeterna Zentaris Inc. and its subsidiaries. This discussion should be read in conjunction with the information contained in the Company's unaudited condensed interim consolidated financial statements and the accompanying notes thereto as at September 30, 2017 and for the three and nine months ended September 30, 2017 and 2016. Our condensed interim consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") applicable to the preparation of interim financial statements, including IAS 34, *Interim Financial Reporting*.

All amounts in this MD&A are presented in US dollars, except for share, option and share purchase warrant information, or as otherwise noted.

Company Overview

We are a specialty biopharmaceutical company engaged in developing and commercializing novel pharmaceutical therapies. We are engaged in drug development activities and in the promotion of products for others.

We recently completed two Phase 3 studies of internally developed compounds: Macrilen™, potentially the first United States ("US") Food and Drug Administration (the "FDA")-approved drug to be used in conjunction with the evaluation of adult growth hormone deficiency ("AGHD"), and Zoptrex™, in the indication for advanced, recurrent endometrial cancer. In addition, we currently co-promote two products: Saizen® [somatropin (rDNA origin) for injection], a recombinant human growth hormone supplement, on behalf of EMD Serono, Inc., the US and Canadian biopharmaceutical businesses of Merck KGaA of Darmstadt, Germany ("EMD Serono"); and APIFINY®, the first non-prostate-specific-antigen ("PSA") blood test for use in evaluating and managing the risk of prostate cancer, on behalf of Armune BioScience, Inc. ("Armune").

We also continue to seek opportunities to in-license and acquire products for US commercialization. Our goal is to become a growth-oriented specialty biopharmaceutical company by pursuing successful development and commercialization of our product portfolio, achieving successful commercial presence and growth, while consistently delivering value to our shareholders, employees and the medical providers and patients who will benefit from our products. We are also looking into out-licensing opportunities for Macrilen™.

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

About Forward-Looking Statements

This document contains forward-looking statements made pursuant to the safe-harbor provision of the US Securities Litigation Reform Act of 1995, which reflect our current expectations regarding future events. Forward-looking statements may include, but are not limited to statements preceded by, followed by, or that include the words "expects," "believes," "intends," "anticipates," and similar terms that relate to future events, performance, or our results. Forward-looking statements involve known risks and uncertainties, many of which are discussed in this MD&A, while others are discussed under the caption "Key Information - Risk Factors" in our most recent Annual Report on Form 20-F filed with the relevant Canadian securities regulatory authorities in lieu of an annual information form and with the US Securities and Exchange Commission ("SEC"). Such statements include, but are not limited to, statements about the timing of, and prospects for, regulatory approval and commercialization of our product candidates, statements about the status of our efforts to establish a commercial operation and to obtain the right to promote or sell products that we did not develop and estimates regarding our capital requirements and our needs for, and our ability to obtain, additional financing. Other additional forward-looking statements may include with respect to: (i) our ability to obtain necessary

approvals from the relevant regulatory authorities to enable us to use the desired brand names for our products; (ii) the impact of securities class action litigation, the litigation involving two former officers of the Company, or other litigation on our cash flow, results of operations and financial position; and (iii) 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.

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™ and the continued availability of funds and resources to successfully launch the product in the event the FDA approves Macrilen™, the rejection or non-acceptance of the NDA by one or more regulatory authorities and, more generally, uncertainties related to the regulatory process, the ability of the Company to efficiently commercialize Macrilen™, the degree of market acceptance of Macrilen™ in the event it is approved for commercialization by the FDA, 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.

About Material Information

This MD&A includes information that we believe to be material to investors after considering all circumstances. We consider information and disclosures to be material if they result in, or would reasonably be expected to result in, a significant change in the market price or value of our securities, or where it is likely that a reasonable investor would consider the information and disclosures to be important in making an investment decision.

The Company is a reporting issuer under the securities legislation of all of the provinces of Canada, and our securities are registered with the SEC. The Company is therefore required to file or furnish continuous disclosure information, such as interim and annual financial statements, MD&A, proxy or information circulars, annual reports on Form 20-F, material change reports and press releases with the appropriate securities regulatory authorities. Copies of these documents may be obtained free of charge upon request from the Company's Corporate Secretary or on the Internet at the following addresses: www.aezsinc.com, www.sedar.com and www.sec.gov.

Key Developments

Product Development

Macrilen™ (macimorelin)

Macrilen™, a ghrelin receptor agonist, is a novel orally-active small molecule that stimulates the secretion of growth hormone. Macrilen™ has been granted orphan drug designation by the FDA for the evaluation of growth hormone deficiency. We own the worldwide rights to this novel patented compound. Macrilen™ is our proposed trade name for macimorelin. The proposed trade name is subject to approval by the FDA. On September 25, 2017, the FDA rejected the Company's proposed trade name Macrilen™, due to orthographic similarities and overlapping product characteristics. Subsequently, on October 11, 2017 the Company appealed the FDA's decision rejecting the proposed trade name Macrilen™. On October 30, 2017, the FDA granted a user fee goal date of January 9, 2018 for the use of the proposed trade name, Macrilen™. On December 16, 2016, we were advised by the European Medicines Agency ("EMA") that Macrilen™ was rejected as the proposed invented name for macimorelin because of its similarity to the names of other medicines. We appealed this decision.

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

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

On February 13, 2017, we announced that, following a comprehensive review of the data obtained from the confirmatory Phase 3 clinical trial of Macrilen™ for the evaluation of AGHD using the ITT as a comparator, we concluded that Macrilen™ demonstrated performance supportive of FDA registration consideration. The press release in which we made such announcement set forth the facts on which our conclusion was based.

On March 7, 2017, we announced that the Pediatric Committee ("PDCO") of the EMA agreed to our Pediatric Investigation Plan ("PIP") for Macrilen™ and agreed that we may defer conducting the PIP until after we file a Marketing Authorization Application ("MAA") seeking marketing authorization for the use of Macrilen™ for the evaluation of adult growth hormone deficiency. The decision will permit us to file an MAA substantially earlier than if we were required to complete the PIP before filing.

On March 30, 2017, we announced that, following our meeting with the FDA on March 29, 2017, we intended to file an NDA seeking approval of Macrilen™ for the evaluation of AGHD. The announcement also indicated that during our meeting with the FDA, the FDA stated that the clinical studies performed with respect to Macrilen™ address the prior deficiencies mentioned in the November 2014 complete response letter and that this conclusion paved the way for re-submission by us of an NDA for Macrilen™. While indicating that the conclusions regarding the performance of Macrilen™ are review issues subject to an examination of the complete data set, the FDA indicated that the summary data submitted by us prior to the meeting appear to support the propositions advanced by us. Most importantly, the FDA specified the additional statistical analysis of existing data that would be required to further support our conclusions.

On June 30, 2017, we announced that we had resubmitted an NDA to the FDA seeking approval of Macrilen™. We believe it has the potential to rapidly become the new standard for assessing AGHD, displacing the ITT and capturing the majority of the market quickly following commercial launch. We anticipate successful FDA approval and, as a result, we continue to build our commercial organization and infrastructure in preparation for the earliest possible launch of Macrilen™. Our focus is to be prepared to launch the product in the first quarter of 2018.

On July 18, 2017, we announced that we had been notified by the FDA that our NDA seeking approval of Macrilen™ for the evaluation of AGHD had been accepted as a complete response to the FDA's November 5, 2014 Complete Response Letter and granted a Prescription Drug User Fee Act ("PDUFA") date of December 30, 2017.

Zoptrex™ (zoptarelin doxorubicin)

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.

The following paragraphs describe recent key developments with respect to Zoptrex™ :

- 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™ 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™ as compared to patients treated with doxorubicin. The results of the study are not supportive to pursue regulatory approval. Based on this outcome, we do not anticipate conducting clinical trials of Zoptrex™ with respect to any other indications. We also discontinued the development of AEZS-138/Disorazol Z, as it was based on the same concept as Zoptrex™.

Commercial Operations

Our U.S. commercial operations consist of 9 full-time sales representatives and a single person sales-management staff in the US. The sales representatives are employed by a contract sales organization and provide services to us pursuant to our contract with the contract sales organization while we employ the sales-management staff. We do not intend to renew this contract, which expires on November 9, 2017. Our sales force currently co-promotes two products that are owned by others: EMD Serono, Inc. (Saizen[®]) and Armune BioScience, Inc. (APIFINY[®]).

Effective on November 3, 2017, we terminated the employment of Jude Dinges, our Senior Vice President and Chief Commercial Officer. A search is underway for Mr. Dinges' replacement.

Our sales force currently co-promotes two products that are owned by others: Saizen[®] and APIFINY[®].

Saizen[®]

On May 8, 2015, we announced that we had entered into a promotional services agreement with EMD Serono, allowing us to promote Saizen[®] [somatotropin (rDNA origin) for injection] to designated medical professionals in specified US territories. Saizen[®] is a recombinant human growth hormone registered in the US for the treatment of pediatric growth hormone deficiency and AGHD. Under this agreement, we were promoting Saizen[®] to designated pediatric endocrinologists and we were receiving commissions based on new, eligible patient starts on Saizen[®] above an agreed-upon base line. This agreement was amended in December 2016. The EMD Serono agreement, as amended, provides that we will promote Saizen[®] in specific agreed-upon US territories to both adult and pediatric endocrinologists in consideration for a sales commission that is based upon new, eligible patient starts, without any baseline. On September 13, 2017, we provided our notice of termination to EMD Serono. The termination will be effective on December 13, 2017.

APIFINY[®]

During the fourth quarter of 2015, we signed a co-marketing agreement with Armune BioScience, Inc. ("Armune") with respect to APIFINY[®], the only cancer-specific, non-PSA blood test for the evaluation of the risk of prostate cancer. On April 27, 2016, we announced that we had entered into a new co-marketing agreement with Armune pursuant to which we acquired the exclusive right to promote APIFINY[®] throughout the United States, effective as of June 1, 2016. In August 2016, we announced that we had expanded the promotion of APIFINY[®] to Florida, following Armune's receipt of a clinical laboratory license from the state.

Corporate Activities

Restructuring Program

In July 2017, our subsidiary located in Germany and its Works Council approved a restructuring program (the "Restructuring Program"), which is being rolled out as a consequence of the negative Phase 3 clinical trial results of Zoptrex[™] announced on May 1, 2017 and the related impact on our product pipeline. This is also part of the continued strategy to transition Aeterna Zentaris into a commercially operating specialty biopharmaceutical organization. The goal of the Restructuring Program is to reduce to a minimum our R&D activities and is expected to result in the termination of approximately 25 employees of the German subsidiary.

We expect to commence implementing the Restructuring Program before the end of the year, with staff departures expected to be completed over a period of approximately 18 months. Total restructuring costs associated with the Restructuring Program was recorded during the three-month period ended September 30, 2017, and includes severance payments, onerous lease provision, and other directly related costs, and have been recorded as follows in the accompanying consolidated statement of comprehensive loss: \$2,644,000 in research and development ("R&D") costs, \$275,000 in general and administrative expenses ("G&A") expenses and \$196,000 in selling expenses. This estimate may vary as a result of changes in the underlying assumptions applied thereto, including but not limited to, the time needed to sublease the unused premises. Most of the restructuring costs are expected to be paid in the financial year ending December 31, 2018.

Public offerings and related events

On April 1, 2016, we entered into an "At-the-Market" ("ATM") sales agreement under which we were 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 \$10.0 million (the "April 2016 ATM Program"). The April 2016 ATM Program provided that common shares were to be sold at market prices prevailing at the time of sale and, as a result, prices varied. Between April 1, 2016 and March 24, 2017, we issued approximately 1.7 million common shares at an average issuance price of \$3.52 per share.

On March 28, 2017, we commenced a new ATM offering pursuant to our prior ATM Sales Agreement under which we were able, at our discretion, 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 approximately 600,000 common shares at an average issuance price of \$2.97 per share.

On April 27, 2017, we entered into a new ATM Sales Agreement (the "New ATM Sales Agreement" or "April 2017 ATM Program"), 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 approximately \$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 November 8, 2017, we issued approximately 1.8 million common shares at an average issuance price of \$2.08 per share under the New ATM Sales Agreement.

Class action lawsuit

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

On September 14, 2015, the Court dismissed the lawsuit, but granted the plaintiffs leave to amend. In dismissing the lawsuit, the court affirmed that the plaintiffs had failed to state a claim. On October 14, 2015, the plaintiffs filed a second amended complaint. We subsequently filed a motion to dismiss, because we believed that the second amended complaint also failed to state a claim. On March 2, 2016, the Court issued an order granting our motion to dismiss the complaint in part and denying it in part. The Court dismissed certain of our current and former officers from the lawsuit. The Court allowed the claim that we misrepresented and omitted material facts from our public statements during the Class Period to proceed against us and our former CEO who departed in 2013, while dismissing such claims against other current and former officers. The Court also allowed a claim for "controlling person" liability to proceed against certain current and former officers.

The lawsuit is currently in discovery. Plaintiffs have filed a motion for class certification, but the Court has not issued a ruling on whether a class will be certified. During the second quarter of 2016, we exceeded the deductible amount applicable to this claim. Therefore, we believe that most of the costs for our defense in future periods will be borne by the insurers who provide directors' and officers' liability insurance to us, subject to our policy limits.

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

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Strategic Review Committee

On July 20, 2017, we announced that the Board of Directors had established a special committee of independent directors (the “Strategic Review Committee”) to develop, consider, investigate and exercise independent oversight relating to potential strategic alternatives to maximize potential future growth and stakeholder value of the Company, including continuing to execute on our existing business plan and/or considering and recommending changes to our management and governance.

On August 8, 2017, we announced that the Strategic Review Committee has engaged a consulting firm and a financial advisor to assist in its efforts. The Strategic Review Committee retained these firms in part to validate the commercial potential of Macrilen™ in order to determine the best means of maximizing value, which includes evaluating and recommending modes of distribution including entering into partnerships or building an internal sales force, raising capital including through an investment from a strategic partner, or selling some or all of the company and its assets. The Board of Directors and the Strategic Review Committee will also consider certain enhancements that have been under discussion at the Board of Directors for the last several months. These include ensuring that the Board of Directors has the commensurate mix of skills and experience to guide the Company in the execution of its business plan and has individuals who reflect a diversity of backgrounds including gender diversity. The Board has also discussed formally adopting a director share ownership requirement to ensure an even greater level of alignment with shareholders. Currently, Board of Directors compensation is split between cash and stock options, a best practice the Board of Directors adopted some time ago. There can be no assurance that evaluation of strategic alternatives will result in any transaction being pursued, entered into or consummated.

Contingency

In late July 2017, we terminated for cause the employment agreement of Mr. David A. Dodd, the former President and Chief Executive Officer and we also terminated the employment of Mr. Philip A. Theodore, the former Senior Vice President, Chief Administrative Officer, General Counsel and Corporate Secretary. All outstanding stock options held by both former officers were cancelled effective as of their respective termination dates, in accordance with the provisions of our Stock Option Plan.

On August 3, 2017, we announced that we had filed a lawsuit against both Messrs. Dodd and Theodore for damages suffered by us for breach of confidence and/or breach of fiduciary duty in an amount to be determined prior to trial. We are also seeking, among other things, an injunction to prevent both Messrs. Dodd and Theodore (i) from continuing to use our confidential and proprietary information without authorization and (ii) from mounting a proxy contest that will be premised upon the breaches of fiduciary and statutory duties and breaches of confidence alleged in the lawsuit. We engaged external counsel to conduct an internal investigation related to this lawsuit, which is still ongoing.

In August 2017, Mr. Dodd filed a lawsuit in the Court of Common Pleas of South Carolina against us for damages of approximately \$1.7 million. He is also requesting that all of his outstanding stock options vest effective upon his termination date. We cannot predict at this time the final outcome or potential losses, if any, with respect to this lawsuit.

In October 2017, the Dodd lawsuit in the Court of Common Pleas of South Carolina was removed to the Federal Court in South Carolina.

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Condensed Interim Consolidated Statements of Comprehensive Loss Information

<i>(in thousands, except share and per share data)</i>	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
	\$	\$	\$	\$
Revenues				
Sales commission and other	122	105	406	319
License fees	119	164	339	288
	<u>241</u>	<u>269</u>	<u>745</u>	<u>607</u>
Operating expenses				
Research and development costs	4,124	4,512	10,178	11,876
General and administrative expenses	1,665	1,631	5,420	5,390
Selling expenses	1,652	1,829	4,643	5,219
	<u>7,441</u>	<u>7,972</u>	<u>20,241</u>	<u>22,485</u>
Loss from operations	<u>(7,200)</u>	<u>(7,703)</u>	<u>(19,496)</u>	<u>(21,878)</u>
Gain (loss) due to changes in foreign currency exchange rates	169	(64)	430	326
Change in fair value of warrant liability	(2,617)	1,687	2,700	4,682
Other finance income	17	25	54	131
Net finance (costs) income	<u>(2,431)</u>	<u>1,648</u>	<u>3,184</u>	<u>5,139</u>
Net loss	<u>(9,631)</u>	<u>(6,055)</u>	<u>(16,312)</u>	<u>(16,739)</u>
Other comprehensive (loss) income:				
Items that may be reclassified subsequently to profit or loss:				
Foreign currency translation adjustments	(400)	(62)	(1,192)	(301)
Items that will not be reclassified to profit or loss:				
Actuarial gain (loss) on defined benefit plans	—	(400)	635	(2,622)
Comprehensive loss	<u>(10,031)</u>	<u>(6,517)</u>	<u>(16,869)</u>	<u>(19,662)</u>
Net loss per share (basic and diluted)	<u>(0.61)</u>	<u>(0.61)</u>	<u>(1.13)</u>	<u>(1.68)</u>
Weighted average number of shares outstanding:				
Basic and Diluted	<u>15,803,080</u>	<u>9,951,573</u>	<u>14,457,421</u>	<u>9,938,980</u>

2017 compared to 2016

Revenues

Sales commission and other were \$122,000 and \$406,000 for the three and nine months ended September 30, 2017 compared to \$105,000 and \$319,000 for the same periods in 2016, and thus increased in 2017 as compared to 2016. The increase is mainly due to the fact that the expanded contract with APIFINY[®] is only effective since June 1, 2016.

License fees were \$119,000 and \$339,000 for the three and nine months ended September 30, 2017, as compared to \$164,000 and \$288,000 for the same periods in 2016. The increase is explained by the amortization of the up-front payment received in connection with one of the out-licensing agreements that we entered into in the third quarter of 2016 for Zoptrex[™].

The Company currently has deferred revenues as at September 30, 2017 of \$652,000 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. The Company will continue to defer the revenue associated with these arrangements until it is notified by its Zoptrex[™] licensees as to whether they intend to stop the development of Zoptrex[™] in the various territories for which the Company may have ongoing obligations to perform under the relevant agreements. In the event the Company is notified by one or all its Zoptrex[™] licensees that the Company's continuing involvement is no longer required, then part or all the remaining carrying amount of deferred revenues will be recognized in the relevant period as income.

Operating Expenses

R&D costs were \$4.1 million and \$10.2 million for the three and nine months ended September 30, 2017, compared to \$4.5 million and \$11.9 million for the same periods in 2016. R&D costs decreased for the three-month and nine-month periods ended September 30, 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 Restructuring Program.

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

<i>(in thousands)</i>	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
	\$	\$	\$	\$
Third-party costs	475	3,504	4,475	8,596
Employee compensation and benefits	2,409 *	717	4,046 *	2,379
Facilities rent and maintenance	1,225 **	224	1,625 **	641
Other costs ***	15	67	32	260
	<u>4,124</u>	<u>4,512</u>	<u>10,178</u>	<u>11,876</u>

* Includes a provision for restructuring in the amount of \$1.6 million.

** Includes a provision for restructuring in the amount of \$1.0 million.

*** Includes mainly depreciation, amortization, impairment, reversal of impairment, gain on disposal of equipment and operating foreign exchange losses.

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The following table summarizes third-party R&D costs, by product candidate, incurred by the Company during the three and nine-month periods ended September 30, 2017 and 2016.

<i>(in thousands, except percentages)</i>	Three months ended September 30,				Nine months ended September 30,			
	2017		2016		2017		2016	
	\$	%	\$	%	\$	%	\$	%
Zoptrex™	(211)	(44.4)	2,094	59.8	2,584	57.7	5,289	61.5
Macrilen™	605	127.4	1,184	33.8	1,708	38.2	2,758	32.1
Other	81	17.1	226	6.4	183	4.1	549	6.4
	475	100.0	3,504	100.0	4,475	100.0	8,596	100.0

Third-party costs attributable to Zoptrex™ decreased during the three and nine months ended September 30, 2017, as compared to the same period in 2016, mainly due to the fact that 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 September 30, 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™ decreased during the three and nine months ended September 30, 2017, as compared to the same period in 2016. This is mainly due to the fact that 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 cost incurred in the third quarter of 2017 are explained mainly by the close out costs as well as additional analysis required by the FDA.

Excluding the impact of foreign exchange rate fluctuations, we now expect that we will incur overall R&D costs of between \$11.0 million and \$13.0 million for the year ended December 31, 2017, including an amount of \$2.6 million recorded in connection with our Restructuring Program discussed above. Most of the restructuring costs are expected to be paid in the financial year ending December 31, 2018. The increase compared to the previous guidance is mainly explained by the onerous lease provision.

G&A expenses were \$1.7 million and \$5.4 million for both the three and nine-month periods ended September 30, 2017, as compared to \$1.6 million and \$5.4 million for the same periods in 2016. The G&A expenses are in-line with expectations.

Excluding the impact of foreign exchange rate fluctuations and the recording of transaction costs related to potential financing activities (not currently known or estimable), we now expect that G&A expenses will range between \$8.0 million and \$9.0 million in 2017. This includes an amount of approximately \$275,000 to recorded in connection with our Restructuring Program discussed above, and higher legal costs.

Selling expenses were \$1.7 million and \$4.6 million for the three and nine months ended September 30, 2017, as compared to \$1.8 million and \$5.2 million for the same periods in 2016. Selling expenses for the three and nine months ended September 30, 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 reduction in the number of sales representatives from 20 to 13 since February 2017. In July 2017, we further reduced the number of sales representative to 10 and we reduced our headcount by one sales manager. Following the creation of the Strategic Review Committee, the Board of Directors is currently evaluating its options to be ready to promote Macrilen™ quickly following the expected approval.

Based on currently available information, we still expect selling expenses to range between \$6.0 million and \$7.0 million in 2017. This includes an amount of approximately \$200,000 recorded in connection with our Restructuring Program discussed above.

Net finance (costs) income was \$(2.4) million and \$3.2 million for the three and nine months ended September 30, 2017, as compared to \$1.6 million and \$5.1 million, for the same periods in 2016. The decrease in finance income is mainly attributable to the change in fair value recorded in connection with our warrant liability. Such change in fair value results from the periodic "mark-to-market" revaluation, via the application of option pricing models, of outstanding share purchase warrants. The closing price of our common shares, which, on the NASDAQ, fluctuated from \$0.84 to \$3.65 during the nine-month period ended September 30, 2017, compared to \$2.67 to \$4.40 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 nine months ended September 30, 2017 was \$9.6 million and \$16.3 million (or \$0.61 and \$1.13 per share), as compared to a net loss of \$6.1 million and \$16.7 million (or \$0.61 and \$1.68 per share) for the same periods in 2016. The increase in net loss for the three-month period ended September 30, 2017 is mainly explained by the change in fair value of the warrant liability due to the increase in the share price since June 30, 2017. However, the loss per share during the same period remained stable due to the increase in the weighted average number of shares due to a share issuance done in November 2016 and ATM issuances done in 2017. The increase in the weighted average number of shares also explains the decrease in the loss per share for the nine-month period.

Quarterly Consolidated Results of Operations Information

(in thousands, except for per share data)

	Three months ended			
	September 30, 2017	June 30, 2017	March 31, 2017	December 31, 2016
	\$	\$	\$	\$
Revenues	241	243	261	304
Loss from operations	(7,200)	(6,679)	(5,617)	(7,598)
Net loss	(9,631)	(2,550)	(4,131)	(8,220)
Net loss per share (basic and diluted)*	(0.61)	(0.18)	(0.31)	(0.71)

(in thousands, except for per share data)

	Three months ended			
	September 30, 2016	June 30, 2016	March 31, 2016	December 31, 2015
	\$	\$	\$	\$
Revenues	269	96	242	102
Loss from operations	(7,703)	(7,184)	(6,991)	(9,858)
Net loss	(6,055)	(7,008)	(3,676)	(10,018)
Net loss per share (basic and diluted)*	(0.61)	(0.71)	(0.37)	(1.46)

* 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 a number of 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™.

Condensed Interim Consolidated Statement of Financial Position Information

	As at September 30, 2017	As at December 31, 2016
	\$	\$
Cash and cash equivalents ¹	12,173	21,999
Trade and other receivables and other current assets	802	744
Restricted cash equivalents	377	496
Property, plant and equipment	154	204
Other non-current assets	9,032	8,216
Total assets	22,538	31,659
Payables and other current liabilities	2,665	3,745
Provision for restructuring costs	2,452	33
Current portion of deferred revenues	479	426
Warrant liability	3,419	6,854
Non-financial non-current liabilities ²	15,478	14,389
Total liabilities	24,493	25,447
Shareholders' (deficiency) equity	(1,955)	6,212
Total liabilities and shareholders' (deficiency) equity	22,538	31,659

1. Approximately \$1.0 million and \$1.5 million were denominated in EUR as at September 30, 2017 and December 31, 2016, respectively, and approximately \$1.7 million and \$3.7 million were denominated in Canadian dollars as at September 30, 2017 and December 31, 2016, respectively.

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

The decrease in cash and cash equivalents as at September 30, 2017, as compared to December 31, 2016, is due to the net cash used in operating activities including variations in components of our working capital. The decrease was partially offset by the net proceeds generated by various issuances of common shares under our April 2016, March 2017 and April 2017 ATM Programs.

The decrease in restricted cash is mainly explained by the decrease of the pledge amount in connection with our corporate credit card program.

The increase in other non-current assets as at September 30, 2017, as compared to December 31, 2016, is mainly due to the increase in goodwill, which is explained by the increase in the EUR/USD foreign exchange rate.

The decrease in payables and other current liabilities is mainly explained by the decrease in trade accounts payable due to payments made to the contract research organization that was responsible for the clinical trials of our two compounds.

The increase in the restructuring provision is explained by the Restructuring Program that was approved in July 2017.

The decrease in our warrant liability from December 31, 2016 to September 30, 2017 is mainly due to a net fair value revaluation gain of \$2.7 million, which was recorded pursuant to our periodic "mark-to-market" revaluation of the underlying outstanding warrants. The revaluation gain is mainly explained by the decrease of the price of our common shares during the period. The remaining variance is explained by the exercise of some Series A Warrants in July 2017.

The increase in non-financial non-current liabilities from December 31, 2016 to September 30, 2017 is mainly due to the increase in the EUR/USD foreign exchange rate offset by a slight increase in the discount rate used to estimate our employee future benefits obligation.

The decrease in shareholders' equity as at September 30, 2017, as compared to December 31, 2016, is attributable primarily to the recording of a net loss for the nine-month period, partially offset by the net proceeds generated by various issuances of common shares under our April 2016, March 2017 and April 2017 ATM Programs.

Financial Liabilities, Obligations and Commitments

We are 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 September 30, 2017 are as follows:

	<u>Minimum lease payments</u>	<u>Minimum sublease receipts</u>	<u>Service and manufacturing</u>
	\$	\$	\$
Less than 1 year	698	(202)	910
1 - 3 years	623	(56)	148
4 - 5 years	182	—	—
Total	<u>1,503</u>	<u>(258)</u>	<u>1,058</u>

During the three months ended September 30, 2017, we recorded an onerous lease provision as part of the Restructuring Program. Therefore, a significant amount of future lease payments have been recorded in the balance sheet as part of the restructuring provision. In addition, we signed an amendment to its lease in South Carolina to reduce the duration from October 2019 to the end of January 2018.

Outstanding Share Data

As at November 8, 2017, we had 16,440,760 million common shares issued and outstanding, as well as 715,806 stock options outstanding. Share purchase warrants outstanding as at November 8, 2017 represented a total of 3,417,840 equivalent common shares.

Capital Disclosures

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

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

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

Liquidity, Cash Flows and Capital Resources

Our operations and capital expenditures have been financed through certain transactions impacting our cash flows from operating activities, public equity offerings and issuances under various ATM programs.

While we had \$12.2 million of cash and cash equivalents as at September 30, 2017, we believe that our cash and cash resources will not be sufficient to fund operations for the next twelve months unless our expenditures are reduced or further financing is obtained. Our ability to continue as a going concern is dependent upon raising additional financing through equity, debt and/or other non-dilutive funding and partnerships. There can be no assurance that we will have sufficient capital to fund our ongoing operations or the development or commercialization of our product candidates without future financings. There can be no assurance that additional financing will be available on acceptable terms or at all. We are currently pursuing financing alternatives that may

include equity, debt, and non-dilutive financing alternatives, including co-development through potential collaborations, strategic partnerships or other transactions with third parties. If we are unable to obtain additional financing when required, we may have to substantially reduce or eliminate planned expenditures or we may be unable to continue our operations. These uncertainties cast substantial doubt as to our ability to meet our obligations as they come due and, accordingly, the appropriateness of the use of accounting principles applicable to a going concern. Our ultimate success, our ability to raise additional financing, whether through equity, debt or other sources of funding and, consequently, to continue as a going concern, is also dependent upon obtaining FDA approval for Macrilen™. The FDA granted a PDUFA date of December 30, 2017.

On April 27, 2017, we entered into a new ATM Sales Agreement, and filed with the SEC a 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 approximately \$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, 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 November 8, 2017, we issued approximately 1.8 million common shares at an average issuance price of \$2.08 per share under the New ATM Sales Agreement.

The variations in our liquidity by activity are explained below.

<i>(in thousands)</i>	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Cash and cash equivalents - Beginning of period	<u>13,931</u>	<u>26,169</u>	<u>21,999</u>	<u>41,450</u>
Cash flows from operating activities:				
Net cash used in operating activities	(5,534)	(5,699)	(18,386)	(20,879)
Cash flows from financing activities:				
Net cash provided by financing activities	3,518	519	8,030	563
Cash flows from investing activities:				
Net cash provided by (used in) investing activities	121	(263)	167	(305)
Effect of exchange rate changes on cash and cash equivalents	137	326	363	223
Cash and cash equivalents - End of period	<u>12,173</u>	<u>21,052</u>	<u>12,173</u>	<u>21,052</u>

Operating Activities

Cash used in operating activities totaled \$5.5 million and \$18.4 million for the three and nine months ended September 30, 2017, as compared to \$5.7 million and \$20.9 million for the same periods in 2016. The decrease in cash used in operating activities for the three and nine months ended September 30, 2017, as compared to the same periods in 2016, is mainly due to lower operating expenses.

We still expect net cash used in operating activities to range from \$24.0 million to \$26.0 million for the year ending December 31, 2017. The timing of the termination notices, that will be given to employees as part of the Restructuring Program, will have an impact on the net cash used in operating activities. Management's intention is to postpone most of the severance payments in the fiscal year 2018. This guidance may vary significantly in future periods and it can also be significantly impacted by ongoing business development initiatives.

Financing Activities

Cash flows from financing activities totaled \$3.5 million and \$8.0 million for the three and nine months ended September 30, 2017, as compared to \$0.5 million and \$0.6 million for the same periods in 2016. The increase is mainly due to net proceeds received from the issuance of common shares under our April 2016, March 2017 and April 2017 ATM Programs during the first nine months of 2017.

Critical Accounting Policies, 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 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, 2016 and 2015 and for the years ended December 31, 2016, 2015 and 2014.

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 us is included in note 4 to our audited annual consolidated financial statements for the year ended December 31, 2016 and in note 3 to our condensed interim consolidated financial statements as at and for the period ended September 30, 2017.

Outlook for 2017

Product Development

Macrilen™

On July 18, 2017, we announced that we had been notified by the FDA that our NDA seeking approval of Macrilen™ for the evaluation of AGHD has been accepted as a complete response to the FDA's November 5, 2014 Complete Response Letter and that Macrilen™ had been granted a PDUFA date of December 30, 2017. We anticipate successful FDA approval and, as a result, we continue to build our commercial organization and infrastructure in preparation for the earliest possible launch of Macrilen™. Our focus is to be prepared to launch Macrilen™ in the US in the first quarter of 2018.

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

Third Quarter MD&A - 2017

Commercial Operations

Saizen[®]

On September 13, 2017, we provided our notice of termination to EMD Serono. The termination will be effective on December 13, 2017. We do not believe that the termination of the Saizen[®] services agreement will have a significant effect on company operations.

APIFINY[®]

During the fourth quarter of 2015, we signed a co-marketing agreement with Armune. On April 27, 2016, we announced that we had entered into a new co-marketing agreement with Armune pursuant to which we acquired the exclusive right to promote APIFINY[®] throughout the United States, effective as of June 1, 2016. Armune continues to pursue agreements with national and regional laboratories.

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

We will continue to record commission revenues in relation to our promotional services agreement for Saizen[®] until its termination and our co-marketing agreement with Armune. As for license fee revenues, we may in future periods recognize deferred revenues relating to our various licensing and technology transfer arrangements with our licensees for Zoptrex[™] in various territories earlier than previously anticipated depending on the level of our continued involvement with Zoptrex[™] in the future, which will in turn depend on whether our Zoptrex[™] licensees continue their own development programs of Zoptrex[™] in their territories and the nature and scope of our ongoing obligations under such arrangements.

Excluding the impact of foreign exchange rate fluctuations, we now expect that we will incur overall R&D costs of between \$11.0 million and \$13.0 million for the year ended December 31, 2017, including an amount of \$2.6 million recorded in connection with our Restructuring Program discussed above. Most of the restructuring costs are expected to be paid in the financial year ending December 31, 2018. The increase compared to the previous guidance is mainly explained by the onerous lease provision.

Based on currently available information, we still expect selling expenses to range between \$6.0 million and \$7.0 million during the year ending December 31, 2017.

Excluding the impact of foreign exchange rate fluctuations and the recording of transaction costs related to potential financing activities (not currently known or estimable), we now expect that G&A expenses will range between \$8.0 million and \$9.0 million in 2017. This includes an amount of approximately \$275,000 to be recorded in connection with our Restructuring Program discussed above, and higher legal costs.

We still expect net cash used in operating activities to range from \$24.0 million to \$26.0 million for the year ending December 31, 2017. The timing of the termination notices, that will be given to employees as part of the Restructuring Program, will have an impact on the net cash used in operating activities. Management's intention is to postpone most of the severance payments in the fiscal year 2018. This guidance may vary significantly in future periods and it can also be significantly impacted by ongoing business development initiatives.

The preceding outlook with regard to our revenue, operating expenditures and cash flow expectations excludes any consideration of any potential strategic commercial initiatives in connection with our efforts to expand our commercial operations in the US or elsewhere. In addition, the outlook could be affected by any transactions or other decisions approved by the Strategic Review Committee. As such, the guidance presented in this MD&A is subject to revision based on new information that is not currently known or available.

Financial Risk Factors and Other Instruments

The nature and extent of our exposure to risks arising from financial instruments, including credit risk, liquidity risk and market risk (share price risk) and how we manage those risks are described in note 12 to our condensed interim consolidated financial statements as at and for the nine months ended September 30, 2017.

Related Party Transactions and Off-Balance Sheet Arrangements

As at September 30, 2017, all related party transactions were eliminated upon consolidation.

As at September 30, 2017, we did not have any interests in special purpose entities or any other off-balance sheet arrangements.

Risk Factors and Uncertainties

An investment in our securities involves a high degree of risk. In addition to the other information included in this MD&A and in the related unaudited condensed interim consolidated financial statements, investors are urged to carefully consider the risks described under the caption "Risk Factors and Uncertainties" in our most recent Annual Report on Form 20-F for the year ended December 31, 2016 as updated in the "Risk Factors and Uncertainties" section of our MD&A for the first quarter of 2017, for a discussion of the various risks that may materially affect our business. Investors should also consider the following risk factors which may materially affect our business:

Healthcare reform measures could hinder or prevent the commercial success of our product candidates and adversely affect our business.

The business prospects and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of healthcare. The U.S. government and other governments have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services, including our product candidates, both in the U.S. and internationally, as well as the amount of reimbursement available from governmental agencies and other third party payers. If reimbursement for our product candidates is substantially less than we expect, our revenue prospects could be materially and adversely impacted.

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

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

We may not obtain necessary approvals from the relevant regulatory authorities to enable us to use the desired brand names for our products.

Even if we are successful in our trademark registrations, the FDA and regulatory authorities in other countries have their own process for drug nomenclature and their own views concerning appropriate proprietary names. The FDA and other regulatory authorities also have the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. No assurance can be given that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future. On December 16, 2016, we learned that the EMA had rejected the “Macrilen™” as the proposed invented name for macimorelin. We intend to appeal the EMA’s determination. The loss, abandonment, or cancellation of any of our trademarks or trademark applications could negatively affect the success of the product candidates to which they relate.

Litigation pertaining to former officers of the Company

In late July 2017, we terminated for cause the employment of Mr. David A. Dodd, the former President and Chief Executive Officer of the Company and we also terminated the employment of Mr. Philip A. Theodore, the former Senior Vice President, Chief Administrative Officer, General Counsel and Corporate Secretary of the Company. All outstanding stock options held by both former officers were cancelled effective as of their respective termination dates, in accordance with the provisions of our stock option plan.

On August 3, 2017, we announced that we had filed a lawsuit against both Messrs. Dodd and Theodore for damages suffered by us for breach of confidence and/or breach of fiduciary duty in an amount to be determined prior to trial. We are also seeking, among other things, an injunction to prevent both Messrs. Dodd and Theodore from: (i) continuing to use our confidential and proprietary information without authorization; and (ii) mounting a proxy contest that will be premised upon the breaches of fiduciary and statutory duties and breaches of confidence alleged in the lawsuit. We engaged external counsel to conduct an internal investigation related to this lawsuit, which is still ongoing.

In August 2017, Mr. Dodd filed a lawsuit in the Court of Common Pleas of South Carolina against us for damages of approximately \$1.7 million. He is also requesting that all of his outstanding stock options vest effective upon his termination date. We cannot predict at this time the final 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 or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, legal fees and costs incurred in connection with such activities may be significant and we could, in the future, be subject to judgments or enter into settlements of claims for significant monetary damages. A decision adverse to our interests could result in the payment of substantial damages and could have a material adverse effect on our cash flow, results of operations and financial position.

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

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.

We have established a Strategic Review Committee to develop, consider, investigate and exercise oversight relating to potential strategic alternatives to maximize potential future growth and stakeholder value of the Company, including continuing to execute on our existing business plan and/or considering and recommending changes to our management and governance. The Strategic Review Committee has retained a consulting firm and a financial advisor to assist in its efforts, in part to validate the commercial potential of Macimorelin in order to determine the best means of maximizing value, which includes evaluating and recommending modes of distribution including entering into partnerships or building an internal sales force, raising capital including through an investment from a strategic partner, or selling some or all of the Company and its assets. There can be no assurance that the evaluation of strategic alternatives will result in any transaction or any specific changes being pursued, entered into or consummated.

The risks and uncertainties not presently known to us or that we currently deem immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment.

Our most recent Annual Report on Form 20-F was filed with the relevant Canadian securities regulatory authorities in lieu of an annual information form at www.sedar.com and with the SEC at www.sec.gov, and investors are urged to consult such risk factors.

Changes in Internal Controls over Financial Reporting

There have been no changes in our internal control over financial reporting during the three-month period ended September 30, 2017 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.