



**Management's Discussion & Analysis of  
Acerus Pharmaceuticals Corporation  
For the three and twelve months ended December 31, 2018**

The following management's discussion and analysis ("MD&A") of the financial condition and results of the operations of Acerus Pharmaceuticals Corporation and its wholly owned subsidiaries (the "Company", "Acerus", "we" or "our") constitutes management's review of the factors that affected our financial and operating performance for the three and twelve months ended December 31, 2018. This MD&A is dated March 4, 2019 and should be read in conjunction with the audited consolidated financial statements and accompanying notes for the year ended December 31, 2018.

The annual audited consolidated financial statements were prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board and are presented in thousands of United States ("U.S.") dollars except for per share amounts and unless otherwise noted. For more detailed information regarding certain forward-looking statements contained herein, please see the note regarding "Forward-looking Statements". The results of the operations, business prospects and financial condition of the Company will be affected by, among others, the "Risk Factors" set out in our Annual Information Form dated March 4, 2019 available at [www.sedar.com](http://www.sedar.com).

Our ability to realize our assets and meet our obligations as they come due is dependent on successfully commercializing our existing products, bringing new products and technologies to market and achieving future profitable operations, the outcome of which cannot be predicted at this time. Furthermore, we will require additional funds, either from commercial sales of both existing and future products, commercial transactions and investors, to continue the development, commercialization and launch of additional products. These circumstances lend significant doubt as to our ability to meet our obligations as they come due and, accordingly, the ultimate appropriateness of the use of accounting principles applicable to a going concern.

We have assessed our ability to continue as a going concern and concluded that in order to complete our planned product development and commercialization programs, capital will be required. This assessment included taking into account the impact of a potential shortage of certain strengths of Estrace® in 2019, failing to meet projected revenues or other budgeted targets, all of which could lead us to potentially violate its debt financial covenants. Our ability to accomplish our strategic plans is dependent upon earning sufficient revenues from existing products, bringing new products and technologies to market, achieving future profitable operations and possibly obtaining additional financing, executing other strategic initiatives that could provide cash flows, or alternatively curtailing expenditures. There are no assurances that any of these initiatives will be successful. Factors within and outside our control could have a significant bearing on our ability to obtain additional financing.

**Forward-looking statements**

This MD&A contains forward-looking information. This forward-looking information is not based on historical facts but rather on our expectations regarding the future growth of the Company and our respective results of operations, performance and business prospects and opportunities. Forward-looking information may include financial and other projections, as well as statements regarding future plans, objectives or economic performance, or the assumptions underlying any of the foregoing. This MD&A uses words such as "believe", "expect", "would", "will", "expects", "anticipates", "intends", "estimates", or similar expressions to identify forward-looking information. Such forward-looking information reflects our current beliefs based on information currently available to us.

These forward-looking statements are subject to important assumptions and the Company has also made certain macroeconomic and general industry assumptions in the preparation of such forward-looking statements. While the Company considers these factors and assumptions to be reasonable based on information currently available, there can be no assurance that actual results will be consistent with these forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Acerus business, or developments in the Company's industry, to differ materially from the anticipated results, performance, achievements or developments expressed or implied by such forward-looking statements. Risks related to forward-looking statements include, among other things: the ability of the Company to continue as a going concern; the Company's limited operating history; the Company's ability to meet future capital requirements; the fluctuating operating results of the Company; the degree of market acceptance of the Company's products; risks relating to generic competition for the

Company's products; extensive government regulation; risks associated with debt financing; marketing and distribution risks; manufacturing-related risks; supplier risks; risks relating to the supply of raw materials; publication of adverse clinical trial results; risks related to unexpected product safety or efficacy concerns; risks relating to promotional activities; risks associated with the cost and reimbursement of the Company's products; risks related to reliance on data obtained from IQVIA; intellectual property risks, including the uncertainty of intellectual property protection, risks associated with licensed patent rights and the risk of third party claims of infringement; risks related to disputes regarding ownership or inventorship of products and technologies; risks associated with trade secrets; risks related to the performance of services by third parties; risks associated with the public market and volatility associated with the Company's shares; risk of potential third-party liability; risks relating to clinical testing conducted by the Company; regulatory approval related matters; risks related to certain minimum payment obligations; a dependence on key personnel; risk of potential dilution of shareholders; risks associated with potential future acquisition activities; risks associated with the expiry of inventory; risks relating to the valuation of intangible assets; risks associated with returns, allowances and chargebacks; risks relating to the ability of the Company to expand its operations; competition risks; risks associated with technological change; foreign exchange risk; concentration risk; risks associated with certain indemnity obligations; tax-related risks; risks relating to the Company's ability to generate ancillary additional revenue; and risks relating to securities analyst coverage of the Company.

Risks related to forward-looking statements include those risks referred to in our filings with the Canadian Securities regulators, including risks described in our Annual Information Form dated March 4, 2019 under the heading "Risk Factors". Actual results, performance or achievement could differ materially from that expressed in, or implied by, any forward-looking information in this MD&A, and, accordingly, investors should not place undue reliance on any such forward-looking information. Further, any forward-looking information speaks only as of the date on which such statement is made and we undertake no obligation to update any forward-looking information to reflect the occurrence of unanticipated events, except as required by law. New factors emerge from time to time and the importance of current factors may change from time to time and it is not possible for us to predict all such factors, changes in such factors and to assess in advance the impact of each such factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking information contained in this MD&A.

### **Description of business**

The consolidated financial statements represent the consolidated accounts of Acerus (incorporated in Ontario, Canada) and its wholly-owned subsidiaries, Acerus Labs Inc. ("ALI") (incorporated in Ontario), Acerus Biopharma Inc. ("ABI") (formerly named Acerus Pharmaceuticals SRL ("SRL")) (incorporated in Ontario), and Acerus Pharmaceuticals (Barbados) Inc. ("APBI") (incorporated in Barbados). On November 6, 2017, ABI migrated jurisdiction of incorporation, corporate law residence, and tax residence from Barbados to Ontario, Canada. APBI was dissolved on February 26, 2018. The head office, principal address and records office of the Company are located in Mississauga, Ontario, Canada. The Company's registered address is 2486 Dunwin Drive, Mississauga, Ontario, L5L 1J9.

We are a Canadian-based specialty pharmaceutical company focused on the development, manufacture, marketing and distribution of branded products with a primary focus in the field of men's and women's health. We commercialize our products via our own salesforce in Canada, and through a global network of licensed distributors in the U.S. and other territories.

We currently have three marketed products: Estrace<sup>®</sup>, a product for the symptomatic relief of menopausal symptoms, is commercialized in Canada; Natesto<sup>®</sup>, the first and only testosterone nasal gel for testosterone replacement therapy in adult males diagnosed with hypogonadism, is commercialized in Canada and the U.S.; and UriVarx<sup>®</sup>, a Natural Health Product that helps reduce symptoms of hyperactive bladder such as daytime urinary frequency, urgency and nocturia. UriVarx<sup>®</sup> was recently approved by Health Canada and is offered over-the-counter to Canadians dealing with such symptoms. Also, Natesto<sup>®</sup> has been licensed for distribution in 69 additional countries worldwide. Marketing approvals in jurisdictions outside of North America are expected to take place over the course of the coming years. In June 2018, South Korea's Ministry of Food and Drug Safety (MFDS) approved Natesto<sup>®</sup> for the treatment of hypogonadism. Our pipeline includes six innovative products: Stendra<sup>®</sup>, a new chemical entity PDE5 inhibitor for the treatment of erectile dysfunction, which has been approved by the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EU EMA") and is commercialized in the U.S. under the trade name Stendra<sup>®</sup> and in the European Union ("EU") under the trade name Spedra<sup>®</sup>; Lidbree<sup>™</sup> (formerly referred to as Shact<sup>™</sup>), a short acting lidocaine formulation delivered through a proprietary device into the vaginal mucosal tissue; Elegant<sup>™</sup> Vaginal Moisturizer, which provides comfort to women suffering from vaginal dryness, and Elegant<sup>™</sup> pH, which is a pH balanced vaginal product; Gynoflor<sup>™</sup>, an ultra-low dose vaginal estrogen combined with a probiotic, for which the Company received a Notice of Deficiency-Withdrawal Letter for its New Drug Submission on January 24, 2019; and Tefina<sup>™</sup> a clinical stage product aimed at addressing a significant unmet need for women with female sexual dysfunction. Finally, Acerus is working on expanding its product portfolio by leveraging its proprietary delivery systems, patents and formulation expertise. As such, Acerus has a number of products in various stages of development. One of these projects relates to cannabinoids (whether synthetic or naturally derived cannabinoids) to be delivered intranasally to patients, which may have multiple possible therapeutic applications (the

“Cannabinoids Initiative”). Acerus has filed patent applications on the Cannabinoids Initiative, achieved first dosing of subjects in a Phase I clinical trial testing a proprietary intranasal formulation of nasal tetrahydrocannabinol (“THC”) – rich cannabis oil in healthy volunteers, is working to initiate other pharmacokinetic clinical trials and is evaluating potential commercialization pathways including partnering transactions or Acerus-led approaches.

For further information please see the Annual Information Form dated March 4, 2019 and our other filings available on SEDAR at [www.sedar.com](http://www.sedar.com).

### **Key products and developments**

#### Natesto®

We have entered into the following license, development and supply agreements for Natesto®:

<b>Date</b>	<b>Company</b>	<b>Territory</b>	<b>Terms</b>
April 22, 2016	Aytu BioScience Inc. (“Aytu”)	United States	<ul style="list-style-type: none"> <li>• Non-refundable upfront payments totaling \$8.0 million</li> <li>• Sales-based milestones that could potentially total \$37.4 million</li> <li>• Tiered supply price per unit</li> </ul>
December 15, 2016	Hyundai Pharm Co., Ltd (“Hyundai”)	South Korea	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>
June 5, 2017	Therios Healthcare (“Therios”)	Saudi Arabia, United Arab Emirates, and Egypt	<ul style="list-style-type: none"> <li>• Fixed supply price per unit</li> </ul>
June 14, 2017	medac Gesellschaft für Klinische Spezialpräparate mbH (“medac”)	15 European countries: Germany, United Kingdom, France, Italy, Czech Republic, Slovakia, Spain, Sweden, Finland, Denmark, Norway, Poland, Austria, Netherland and Belgium	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval and sales-based milestone payments</li> <li>• Tiered supply price per unit</li> </ul>
See additions on October 31, 2018			
October 17, 2017	Eu Hwa Pte LTD. (“EU”)	Thailand, Malaysia/Brunei, Singapore, Vietnam, Philippines, Hong Kong/Macau and one other small South East Asian country	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>
November 23, 2017	Apsen Farmacêutica (“Apsen”)	Brazil	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>
April 9, 2018	Producto Científicos, S.A. de C.V (“Carnot Laboratorios”)	Mexico and 18 Central and Latin American countries (Argentina, Columbia, Peru, Chile, Ecuador, Guatemala, El Salvador, Nicaragua, Honduras, Panama, Costa Rica, Cuba, Dominican Republic, Venezuela, Bolivia, Uruguay, Paraguay and Haiti)	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>
October 31, 2018	medac	Amended to include all existing European Union Member states and the United Kingdom, Norway, Liechtenstein, Iceland, Turkey,	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• All other terms as per the original agreement</li> </ul>

*Buyout of all obligations under the Mattern License Agreement*

On May 17, 2018, we entered into an agreement with Mattern Pharma AG (“Mattern”) to buy out all of our obligations (the “Buyout”) under the Amended and Restated Intellectual Property Rights and Product Development Agreement, dated December 21, 2013 (as amended) (“License Agreement”), including all of our future royalty payment obligations.

Under the License Agreement, we owed royalties on upfronts, milestones and revenues from products, including Natesto<sup>®</sup>, covered by the License Agreement, including minimum annual royalty payments of \$5.0 million if gross product sales are \$75.0 million or greater, or \$2.5 million if gross product sales are below \$75.0 million, starting in fiscal 2018 and ending in 2024. Pursuant to the Buyout, with the payment of \$7.5 million, all of our material obligations owed to Mattern are suspended, but Mattern’s obligations to us remain in force. Under the Buyout, among other rights, we receive a perpetual, fully-paid, irrevocable license to all of Mattern’s patents and know-how for the products covered by the License Agreement. We will pay the \$7.5 million in the following instalments: \$750 was paid in July 2018, \$1,750 was paid in September 2018, \$625 on January 17, 2019, \$2,025 by April 20, 2019 which includes a \$150 deferral fee, and \$2,500 by January 20, 2020. We recorded an expense of \$6.7 million in May 2018 representing the fair value of the \$7.5 million obligations under the Buyout at that date. The fair value was estimated by discounting the payments using a rate of 14.75%.

The Buyout also includes a covenant not to sue and a waiver from Mattern, which will become irrevocable upon payment of the last instalment to Mattern. The Buyout will remain in full force and effect as long as the License Agreement is in force. In the event of a payment default, following a grace period, the Buyout automatically terminates and the License Agreement’s obligations become binding on Acerus again. In such an event, all monies paid by Acerus pursuant to the Buyout, with the exception of the first instalment, can be offset against monies that would otherwise be owed to Mattern under the License Agreement.

*Natesto<sup>®</sup>*

On February 1, 2018, we received notice from Quebec’s National Institute for Excellence in Health and Social Services (INESSS) of a positive recommendation to the Health Minister for the inclusion of Natesto<sup>®</sup> on the list of medications of the Régie de l’assurance maladie du Québec. Natesto<sup>®</sup> was listed on February 1, 2018.

In June 2018, South Korea’s Ministry of Food and Drug Safety (MFDS) approved Natesto<sup>®</sup> for the treatment of hypogonadism.

*Estrace<sup>®</sup>*

On January 11, 2019, we announced an anticipated shortage of certain doses of Estrace<sup>®</sup> on the Drug Shortages Canada website in relation to supply issues arising from our contract manufacturer. A shortage of Estrace<sup>®</sup> may accelerate erosion of Estrace<sup>®</sup> sales due to the presence of the third-party generic. As such, we determined that the intangible asset related to Estrace<sup>®</sup> had been impaired by \$2.6 million. The intangible asset was written down to its recoverable amount using a value-in-use discounted cash flow method. Key assumptions included the discount rate of 16.9%, estimated cash flows and declines in revenue on the assumption that the contract manufacturer’s license is reinstated by June 2019 and the Company receives its next shipment of Estrace<sup>®</sup> by September 2019.

*Gynoflor<sup>TM</sup>*

We entered into a license and supply agreement with Medinova AG on April 6, 2016, a Swiss pharmaceutical company, that grants exclusive rights to commercialize Gynoflor<sup>TM</sup> in Canada. On February 28, 2017, we submitted a NDS to Health Canada to obtain marketing approval for the product in Canada. Currently, there are no approved estriol + lactobacillus products on the Canadian market.

On December 24, 2017, we received a Notice of Deficiency (“NOD”). In its notice, Health Canada requested additional technical information on Gynoflor<sup>TM</sup> in order to complete its assessment of the product. Acerus officially responded to the NOD on April 11, 2018, focusing only on the vaginal atrophy indication and expects to receive a decision from Health Canada in the first half of 2019. On January 24, 2019 we received a Notice of Deficiency-Withdrawal Letter (“Notice”) for its Gynoflor<sup>TM</sup> New Drug Submission. We have decided not to file a Request for Reconsideration of the Notice and have informed our licensor, Medinova AG (“Medinova”), that further studies will be needed in order for Gynoflor<sup>TM</sup> to be approvable by Health Canada. Under the agreement with Medinova, neither the Company nor Medinova is obligated to conduct such further studies. If no further studies are conducted, then we will not resubmit the Gynoflor<sup>TM</sup> dossier to Health Canada at this time. Acerus and Medinova will continue to work on areas of possible further collaboration.

### Elegant™ franchise

On December 20, 2017, we entered into a license, development and supply agreement with Viramal Limited (“Viramal”), a London-based specialty pharmaceutical company, that grants us exclusive rights to commercialize the Elegant™ franchise in Canada. The Elegant™ franchise comprises Elegant™ Vaginal Moisturizer, which provides comfort to women suffering from vaginal dryness, and Elegant™ pH, which is a pH balanced vaginal product. Elegant™ Vaginal Moisturizer and Elegant™ pH are over-the-counter products. Under the terms of the license, development and supply agreement, we will pay Viramal a regulatory milestone payment upon receiving marketing approval in Canada, as well as milestone payments based on achieving sales targets. Viramal will oversee the manufacturing of Elegant™ and will receive a supply price for the product.

### UriVarx®

On January 8, 2018 we entered into an exclusive distributor and license agreement with Innovus Pharmaceuticals, Inc. (“Innovus”), that grants us the exclusive rights to commercialize UriVarx® in Canada. UriVarx® is a Natural Health Product (NHP) that helps reduce symptoms of hyperactive bladder such as daytime urinary frequency, urgency and nocturia. The product was recently approved by Health Canada and is offered over-the-counter to Canadians dealing with such symptoms. Under the terms of the exclusive distributor and license agreement, we paid an upfront payment at signing and will pay milestone payments based on the achieving certain sales targets. Innovus will oversee the manufacturing of UriVarx® and will receive a supply price for the product.

### Stendra®

On March 27, 2018 we entered into an exclusive distributor and license agreement with Metuchen Pharmaceuticals LLC (“Metuchen”), a privately-held specialty pharmaceutical company, granting us the exclusive rights to commercialize Stendra® in Canada. Stendra® is a new chemical entity targeting the large and growing Erectile Dysfunction (“ED”) market. Under the terms of the sublicense agreement, Metuchen will receive regulatory milestone payments upon Acerus filing a New Drug Submission (“NDS”) with Health Canada and upon Acerus receiving marketing approval in Canada. Metuchen will also receive milestone payments based on Acerus achieving sales targets. Metuchen will oversee the manufacturing of Stendra® and will receive a supply price for the product comprised of a transfer price and royalties on net sales of the product.

### Lidbree™

On May 29, 2018 we entered into an exclusive agreement to commercialize Pharmanest AB’s (“Pharmanest”) Short Acting Lidocaine Product (“Lidbree™”), a pain relief drug device combination in Canada. Under the terms of the license agreement, Pharmanest received an upfront and regulatory milestone payments when we receive marketing approval in Canada. Pharmanest will also receive milestone payments based on the Company achieving sales targets. Pharmanest will oversee the manufacturing of Lidbree™ and will receive a tiered supply price for the product based on a percentage on net sales of the product.

### Corporate Update

#### Long-term debt financing

On October 12, 2018, we entered into a senior secured term loan credit facility with SWK Funding LLC (“SWK”) for up to \$11.0 million (“New Facility”). An initial tranche of \$9.0 million of the New Facility was received at closing, with the remaining \$2.0 million of the New Facility becoming available on or before March 31, 2019 upon satisfaction of certain future conditions.

The New Facility bears interest at a rate per annum equal to the greater of (a) the three-month London Inter-Bank Offered Rate (“LIBOR”) or (b) 1.50%, with such base rate being capped at no greater than 4.25%, plus an applicable margin of 10.50%. The New Facility matures on October 11, 2023 and is interest-only for the first two years of the term. Under the terms of the agreement, we will have the option to prepay the loan prior to the maturity date subject to the payment of certain prepayment fees. The terms of the agreement also contain customary financial covenants. The proceeds from the New Facility was used primarily to (i) repay the amount outstanding under the Quantius credit facility, including a prepayment penalty and royalty retirement fee; (ii) retire the Endo promissory note; and (iii) for ongoing general working capital.

As part of the transaction, SWK received an origination fee representing a low single digit percentage of the maximum facility amount and will receive a final payment representing a single digit percentage of the principal amount actually advanced under the facility. Acerus has also issued 5,331,563 common share purchase warrants (the “Warrants”) to SWK as partial consideration for the New Facility. Each Warrant entitles SWK to purchase one common share of Acerus at an exercise price of CDN\$0.40 per common share, expires on October 11, 2023 and has a cashless exercise feature. Following the second anniversary of the issuance of the Warrants, we

can cause SWK to exercise the Warrants prior to their expiry date if the closing price of our common shares on the TSX is at or above CDN\$0.80 per share for a period of at least 21 consecutive trading days.

#### *Endo – Promissory note*

On October 11, 2018, the promissory note and outstanding accrued interest was repaid in full and the note was extinguished.

#### *Quantius Inc. credit facility*

The Quantius credit facility was subsequently extinguished on October 12, 2018 with the payment of principal, accrued interest pre-payment penalty and royalty retirement fee.

### **Factors affecting results from operations**

#### **Revenue and cost of sales**

Our product revenues reflect the sales of Estrace<sup>®</sup>, Natesto<sup>®</sup> and UriVarx<sup>®</sup> net of chargebacks, discounts and other price adjustments. License and other revenue mainly consist of upfront payments and milestone payments received from license and supply agreements. Cost of sales reflect the cost of finished goods which include manufacturing, distribution, warehousing costs, the amortization of the Estrace<sup>®</sup> product rights intangible asset and royalty expenses for Natesto<sup>®</sup>.

#### **Research and development expenses**

Our research and development (“R&D”) expenses consist primarily of project specific costs, namely: project management, clinical studies, laboratory analysis, new product submissions, formulation development and packaging design costs as well as milestone obligations based on the achievement of specific development, regulatory milestones on or before specific dates. Research and development expenses also include salary, benefits and share-based compensation for R&D management and staff and amortization of intangible assets, leasehold improvements, and manufacturing and laboratory assets.

Our R&D activities focus on clinical research and development, including but not limited to internal and external activities associated with advancing product candidates towards obtaining regulatory approval for marketing in various jurisdictions.

#### **Selling, general and administrative expenses**

Our selling, general and administrative costs mainly consist of salary, benefits, and share-based compensation for non-R&D executive management and other staff, professional fees, public company related costs, selling expenses, office expenses and amortization of leasehold improvements and equipment used for administrative purposes.

#### **Other expenses**

Other expenses consist of interest expense, accretion expense, amortization of deferred financing fees, fair value adjustment to the derivative financial instruments, foreign exchange gains and losses, interest income and a gain on extinguishment of payables. The foreign exchange gains and losses on the intercompany receivables and payables have been major components of the net financing costs as the receivables and payables are denominated in U.S. dollars and are held by the parent company in its functional currency, Canadian dollar, and thus the foreign exchange gain/loss does not eliminate on consolidation.

#### **Foreign currency**

For ABI, its functional currency is the U.S. dollar. For Acerus and ALI (and APBI prior to dissolution), a majority of the revenue and expenses are in Canadian dollars (functional currency) and are translated into U.S. dollar (reporting currency) for consolidated reporting. Accordingly, the results of operations are impacted by fluctuations in the U.S. dollar exchange rate. The Canadian legal entities’ statement of (loss)/income and comprehensive (loss)/income, which are recorded in Canadian dollars, were translated to U.S. dollars at the average exchange rate of \$0.7718 and \$0.7700 respectively for the year ended December 31, 2018 and 2017. Similarly, the Canadian entities’ statement of financial position which is recorded in Canadian dollars was translated into U.S. dollars at the period-end spot rates of \$0.7330 and \$0.7971 at December 31, 2018 and 2017 respectively.

## Taxation

Canada and Barbados have laws related to various taxes imposed by national/federal, provincial and municipal authorities. Applicable taxes include a value added tax (“VAT”) and harmonized sales tax (“HST”), corporate income tax, payroll taxes and other taxes. The VAT and HST taxes that are payable on goods and services billed and purchased are 19.6% in Europe and 13% in Canada, respectively. These may be recoverable due to input tax credits. The corporate income tax rate in Canada is 26.5% in 2018 and 2017. On November 6, 2017, ABI migrated jurisdiction of incorporation, corporate law residence, and tax residence from Barbados to Canada. APBI was dissolved on February 26, 2018.

## Select consolidated financial information

The following table sets forth selected consolidated data for the years ended December 31, 2018, 2017 and 2016 as follows:

	2018	2017	2016
Statement of operations data			
Product revenue	\$ 7,043	\$ 5,348	\$ 7,013
Licensing revenue	334	1,187	-
Operating (loss)/income	(16,542)	(6,861)	(4,364)
Net Loss	(18,786)	(8,623)	(6,204)
Basic and diluted net (loss)/earnings per common share	\$ (0.08)	\$ (0.04)	\$ (0.03)
Balance sheet data:			
Total assets	\$ 16,824	\$ 22,254	\$ 29,716
Long-term debt	8,287	4,569	6,449

\*Licensing and other revenue has been restated as a result of the adoption of IFRS 15 Revenue from contracts with customers. See note 3(b) in the consolidated statements for the year ending December 31, 2018 for more information regarding the restatement as a result of a change in accounting policy.

The fluctuations in reported results during these periods resulted primarily from the following factors:

- The fluctuation in product revenue balances are mainly due to the timing of inventory shipments to Aytu, increasing Natesto<sup>®</sup> sales in Canada and the U.S., offset by declining Estrace<sup>®</sup> sales.
- Operating expenses have increased over the period due to additional personnel to support the growth of the Company, additional selling expenses related to the launch of Natesto<sup>®</sup> Canada (Q4 2016) and UriVarx<sup>®</sup> (Q1 2018) and filing fees and expenses related to new products in the Company’s pipeline.
- In 2018 we extinguished the CDN\$5.0 million debt from Quantius Inc. and the remainder of the promissory note to Endo with proceeds from the SWK credit facility of \$9.0 million.
- In 2018 we also impaired the Estrace<sup>®</sup> intangible asset by \$2.6 million due to an anticipated shortage of certain doses of the product caused by an issue with our contract manufacturer.

## Review of operating results – the year ended December 31

### Revenue and gross profit

	2018	2017	Change \$	Change %
Revenue				
Product revenue	\$ 7,043	\$ 5,348	\$ 1,695	32 %
Licensing and other revenue	334	1,187	(853)	(72)%
	7,377	6,535	842	13 %
Cost of goods sold	3,644	3,263	381	12 %
Royalty buyout	6,680	-	6,680	n/a
Gross margin	\$ (2,947)	\$ 3,272	\$ (6,219)	(190)%

Product revenue increased from \$5.3 million for the year ended December 31, 2017 to \$7.0 million for the year ended December 31, 2018. The increase in product revenue is primarily a result of higher Natesto<sup>®</sup> sales in the U.S. and Canada and the introduction of UriVarx<sup>®</sup> revenues in Q1 2018. The increased sales in the U.S. are primarily due to a higher number of inventory shipments to our U.S. partner, Aytu, for Natesto<sup>®</sup>. Natesto<sup>®</sup> revenue from the U.S. is expected to fluctuate between periods based on the timing of large

and potentially non-regular inventory orders. These orders may impact both quarterly and annual revenue figures, and the related variance compared to prior periods, as a large order may comprise a relatively large portion of the period's total revenues until inventory purchases become regular and/or second-tier revenues from Aytu's sales become a larger portion of U.S. revenues. As a result, changes in revenues on a period-to-period basis may not provide a clear indication of actual sales trends for the U.S. market. We continue to see steady growth in the Natesto® Canadian market as various marketing initiatives come to fruition.

There was a slight decline in Estrace® sales which were \$3.8 million for the year ended December 31, 2018 versus \$4.4 million for the same prior year period due to the continued pressure from a generic.

Licensing and other revenues are primarily dependent on the timing of out-licensing transactions and the achievement of milestones.

Cost of goods sold for the year ended December 31, 2018 was \$3.6 million compared to \$3.3 million in fiscal 2017. Gross margins were impacted by revenue from shipments of Natesto® inventory, which is sold to Aytu at a contractual supply price with a small margin. When Aytu sells the product, we then receive an additional top-up revenue that has no related cost of goods. We expect to continue to see fluctuations in the gross margin depending on the relative proportion of revenue from inventory shipment and top-up revenue. During Q2 2018 we expensed \$6.7 million of expense related to the Mattern Buyout.

#### *Operating expenses*

	2018		2017		Change \$	Change %
Operating expenses						
Research and development	\$	2,398	\$	2,166	\$ 232	11 %
Selling, general and administrative		11,197		7,967	3,230	41 %
	\$	13,595	\$	10,133	\$ 3,462	34 %

#### *Research and development*

Research and development expenses have increased by \$0.2 million for the year ended December 31, 2018 versus fiscal 2017. Clinical trial expense increased by \$0.1 million mainly due to costs associated with the various Natesto® studies, including the cardiovascular trial in the U.S. and cannabinoid trial costs. Product development and professional fees increased by \$0.2 million due to fees related to the filing or preparation of filing of various pipeline products. This was offset by a \$0.1 million decrease in amortization of intangible assets due to the extension of the expected life of certain assets.

Given the nature of our business and product pipeline, we expect to continue to incur research and development expenses in the future. Research and development expenditures may increase if we initiate further clinical studies and as we incur regulatory costs to get product approvals in Canada as well as to support our distribution partners as they file for approval outside Canada and the U.S. In June 2018, South Korea's MFDS approved Natesto® for the treatment of hypogonadism. In addition, formulation optimization and product development costs may be incurred for products utilizing other in-licensed or in-housed developed technologies in the future.

#### *Selling, general and administrative*

Selling, general and administrative expenses increased by \$3.2 million over the prior year. Expenses in 2018 include an impairment charge of \$2.6 million for the Estrace® intangible due to an anticipated shortage of certain doses of the product. The anticipated shortage is due to a supply issue with our contract manufacturer. A shortage of Estrace® may accelerate erosion of Estrace® sales due to the presence of the third-party generic. Fiscal 2017 included an expense of \$1.1 million related to severance for a member of the executive team. Adjusting for this factor, salaries and benefits increased by \$1.2 million over the prior year. This increase is mainly due to additional personnel, including the onboarding of the sales team in Q4 2017 and severance fees for a member of the executive team. Selling expenses increased by \$0.2 million due to the increased activities related to Natesto® and the launch of UriVarx®. Professional fees and business development fees increased by \$0.1 million and \$0.3 million, respectively, over the prior year due to increased consulting fees related to additional business activities and vacant personnel positions. Office and sundry expenses have increased by \$0.1 million and over the prior year mainly due to the increase in personnel and related recruiting fees.

*Other expenses*

	2018	2017	Change \$	Change %
Other expenses/(income)				
Interest on long-term debt and other financing costs	\$ 1,773	\$ 380	\$ 1,393	367 %
Interest income	(12)	(21)	9	43 %
Foreign exchange loss	1,029	1,521	(492)	(32)%
Change in fair value of derivative financial instruments	(380)	156	(536)	344 %
Gain on extinguishment of payables	(195)	(321)	126	39 %
	\$ 2,215	\$ 1,715	\$ 500	29 %

The \$1.4 million increase in interest on long-term debt and other financing costs for the year ended December 31, 2018 over the prior year period is mainly due to the accelerated amortization of the financing fees and royalty accrual due to the early retirement of the Quantius credit facility in October 2018. Interest expense also includes \$0.5 million in accretion expense related to the accrual of the long-term Mattern Buyout.

The decrease in foreign exchange loss is due to the fluctuation in the Canadian/U.S. exchange rate and the decrease in the inter-company loan balances, for which the foreign exchange loss does not eliminate on consolidation.

The change in fair value of derivative financial instruments is due to the addition of warrants issued as part of the SWK facility and the fluctuation of the share price in relation to the exercise price of the warrants issued.

The gain on extinguishment of payables relates to the reversal of reserves previously taken.

**Select quarterly information**

The following table highlights selected unaudited consolidated financial data for each of the eight most recent quarters that, in management's opinion, have been prepared on a basis consistent with the unaudited condensed interim consolidated financial statements for the three and twelve months ended December 31, 2018. The selected financial information presented below reflects all adjustments, consisting primarily of normal recurring adjustments which are, in the opinion of management, necessary for a fair presentation of results for the interim periods. These results are not necessarily indicative of results for any future period and you should not rely on these results to predict future performance.

	Three months ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Statement of operations data				
Product revenue	\$ 1,884	\$ 1,583	\$ 1,952	\$ 1,624
Licensing and other revenue**	184	-	150	-
Cost of goods sold	811	777	1,029	1,027
Royalty Buyout/Minimum royalty	-	-	4,266	2,414
Research and development	571	751	604	472
Selling, general & administrative expense	5,024	2,159	2,231	1,783
Finance costs, net	686	765	382	382
Net loss**	(5,051)	(2,871)	(6,410)	(4,454)
Basic and diluted net loss per common share**	\$ (0.02)	\$ (0.01)	\$ (0.03)	\$ (0.02)

\*\*Licensing and other revenue have been restated as a result of the adoption of IFRS 15 Revenue from contracts with customers. See note 3(b) in the consolidated statements for the year ending December 31, 2018 for more information regarding the restatement as a result of a change in accounting policy.

	Three months ended			
	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
Statement of operations data				
Product revenue	\$ 1,779	\$ 1,360	\$ 1,194	\$ 1,015
Licensing and other revenue**	600	-	584	-
Cost of goods sold	1,328	661	636	638
Research and development	674	367	402	723
Selling, general & administrative expense	3,070	1,793	1,483	1,621
Finance costs, net	(914)	1,402	863	364
Net loss**	(1,826)	(2,863)	(1,606)	(2,331)
Basic and diluted net loss per common share**	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)

\*\*Licensing and other revenue have been restated as a result of the adoption of IFRS 15 Revenue from contracts with customers. See note 3(b) in the consolidated statements for the year ending December 31, 2018 for more information regarding the restatement as a result of a change in accounting policy.

The fluctuations in reported results during these periods resulted primarily from the following factors:

- With Natesto<sup>®</sup> sales ramping in both Canada and the U.S. (including inventory purchases) and revenues from UriVarx<sup>®</sup>, product revenue grew quarter over quarter in the first half of 2018. We saw a modest increase in product revenues in Q3 2018 and a substantial increase in Q4 2018 after we adjust the Q2 2018 figures for the inventory shipment to Aytu. The slight decrease in Estrace<sup>®</sup> revenues over the prior year due to the continued pressure from a generic are offset by the growth in Natesto Canada product revenues and Natesto U.S. tier-two product revenues.
- In Q1 2018, we expensed the minimum royalty obligation of \$2.4 million on Natesto<sup>®</sup> sales. In Q2 2018 the Buyout with Mattern was finalized and the minimum royalty obligation of \$2.4 million was reversed. However, we accrued \$6.7 million, the discounted value of the \$7.5 million Mattern Buyout in Q2 2018.
- Research and development expense fluctuates depending on timing of regulatory activities and level of product development activities. Fiscal 2018 reflects increased spending on clinical trials related to Natesto<sup>®</sup>, including the cardiovascular trial in the U.S. and cannabinoid trial costs.
- Selling, general and administrative expenses have increased in 2018 over the prior quarters mainly due to the on-boarding of the sales team in Q4 2017, increased selling expenses related to Natesto<sup>®</sup> and UriVarx<sup>®</sup> and increased professional fees and business development costs due to increased business activities and consulting fees.
- An impairment charge of \$2.6 million was taken in Q4 2018 related to the Estrace<sup>®</sup> intangible due to an anticipated shortage of certain doses of the product. The anticipated shortage is a result of supply issues arising from our contract manufacturer. A shortage of Estrace<sup>®</sup> may accelerate erosion of Estrace<sup>®</sup> sales due to the presence of the third-party generic.
- Net finance costs fluctuations over the quarters are mainly due to foreign exchange gain/loss on translation of the U.S. dollar denominated intercompany receivable and payable with the parent company into Canadian dollar, and lower interest expense due to the repayment of the debt owed to MidCap in Q1 2017, offset by the interest from the Quantius credit facility obtained in Q4 2017 and accelerated recognition of the related deferred financing fees as the Quantius credit facility was extinguished in October 2018. Net financing fees also reflect the cost of the new SWK credit facility for \$9.0 million.

## Review of operating results – Fourth quarter

The following table presents selected financial information (including certain non-IFRS measures, as noted) for the three months ended December 31, 2018 and 2017, which were derived from the consolidated financial statements for the respective periods:

	Three months ended, December 31, 2018	Three months ended, December 31, 2017 Restated*
<b>Revenue</b>		
Product revenue	\$ 1,884	\$ 1,779
Licensing and other revenue	184	600
	2,068	2,379
Cost of goods sold	811	1,328
<b>Gross margin</b>	<b>1,257</b>	<b>1,051</b>
<b>Expenses</b>		
Research and development	571	674
Selling, general and administrative	5,024	3,070
<b>Total operating expenses</b>	<b>5,595</b>	<b>3,744</b>
Operating loss	(4,338)	(2,693)
<b>Other expenses/(income)</b>		
Interest on long-term debt and other financing costs	497	85
Interest income	-	(3)
Foreign exchange loss	676	(930)
Change in fair value of derivative financial instruments	(292)	255
Gain on extinguishment of payables	(195)	(321)
<b>Total other expenses</b>	<b>686</b>	<b>(914)</b>
Loss for the period before income taxes	(5,024)	(1,779)
Income tax expense	27	47
<b>Net loss for the period</b>	<b>(5,051)</b>	<b>(1,826)</b>
Other comprehensive income, net of income tax		
Foreign currency translation adjustment	102	(1,064)
<b>Total comprehensive loss for the period</b>	<b>(4,949)</b>	<b>(2,890)</b>
<i>*See note 3(b) within the consolidated financial statements for the year ended December 31, 2018 for details regarding the restatement as a result of change in accounting policy.</i>		
Loss per common share		
Basic and diluted net loss per common share	\$ (0.02)	\$ (0.01)
Weighted average common shares outstanding		
Basic	235,317,848	213,118,645
Diluted	235,317,848	213,118,645

### Revenue and gross profit

	Three months ending December 31,			
	2018	2017	Change \$	Change %
Revenue				
Product revenue	\$ 1,884	\$ 1,779	\$ 105	6 %
Licensing and other revenue	184	600	(416)	(69)%
	2,068	2,379	(311)	(13)%
Cost of goods sold	811	1,328	(517)	(39)%
Gross margin	\$ 1,257	\$ 1,051	\$ 206	20 %

Product revenues increased from \$1.8 million for the three months ended December 31, 2017 to \$1.9 million for the same 2018 period. While Natesto<sup>®</sup> sales in Canada and the US tier-two revenues increased, we saw a \$0.2 million decrease in Estrace<sup>®</sup> net revenue from Q4 2017 due to continued pressure from a generic. Furthermore, Q4 2018 saw revenues from UriVarx<sup>®</sup> which was launched in Q1 2018 and as such does not have a comparable revenue figure in 2017. The higher Natesto<sup>®</sup> product revenue in Q4 2018 over the same prior year period was mainly due to a higher Canadian market share and greater tier-two revenues (as defined below) received from Aytu, offset by the lack of an inventory shipment in Q4 2018 versus one shipment in Q4 2017 to Aytu.

Revenues from the sale of Natesto<sup>®</sup> in the U.S. are earned in two steps: 1) at a contractual supply price reflecting cost of goods sold plus a nominal margin when the product is delivered to the marketing partner (tier-one); and 2) an additional top-up amount is earned based on a tiered pricing schedule when the marketing partner recognizes the sale of product (tier-two). As such, the gross margin earned for tier-one revenues are nominal with a bulk of the gross margins being recognized when tier-two revenues are earned. Depending on the mix of tier-one and tier-two, gross margins can fluctuate substantially.

Cost of goods sold for the three months ended December 31, 2018 was \$0.8 million compared to \$1.3 million for the same prior year period. Gross margins for Q4 2017 are lower because of the inventory shipment to Aytu during the period which is sold at a nominal margin.

### Operating expenses

	Three months ending December 31,			
	2018	2017	Change \$	Change %
Operating expenses				
Research and development	\$ 571	\$ 674	\$ (103)	(15)%
Selling, general and administrative	5,024	3,070	1,954	64 %
	\$ 5,595	\$ 3,744	\$ 1,851	49 %

### Research and development

Research and development for the three months ended December 31, 2018 remained consistent with the same prior year period. Increases in product development expenses for Natesto<sup>®</sup> are offset by lower clinical trial costs due to the timing of work being done and lower salary and benefits due to the timing recognition of certain expenses.

As stated previously, given the nature of our business and product pipeline, we expect to continue to incur research and development expenses in the future. Research and development expenditures may increase if we initiate further clinical studies and as we incur regulatory costs to get product approvals in Canada as well as to support our distribution partners as they file for approval outside Canada and the U.S. In addition, formulation optimization and product development costs may be incurred for products utilizing other in-licensed or in-house developed technologies in the future.

### Selling, general and administrative

Selling, general and administrative expenses increased by \$2.0 million for the three months ended December 31, 2018 over the same prior year period. Expenses in 2018 include an impairment charge of \$2.6 million for the Estrace<sup>®</sup> intangible due to an anticipated shortage of certain doses of the product. The anticipated shortage is due to a supply issue with our contract manufacturer. A shortage of Estrace<sup>®</sup> may accelerate erosion of Estrace<sup>®</sup> sales due to the presence of the third-party generic. Despite the additional personnel in 2018 and the onboarding of the sales team in Q4 2017, salaries, benefits and share-based compensation for the three months ended December 31, 2018 decreased by \$0.3 million and \$0.2 million respectively versus the same 2017 period. The decrease is mainly due to the accrual of severance costs for a member of the executive team in Q4 2017 of \$1.1 million, offset by severance costs in Q4 2018 of \$0.4 million. Selling expenses decreased by \$0.1 million due to the timing of activities related to Natesto<sup>®</sup> and UriVarx<sup>®</sup>. Office and sundry expenses also decreased by \$0.1 million of the prior year period mainly due to personnel recruiting fees recognized in Q4 2017.

### Other expenses

	Three months ending December 31,			
	2018	2017	Change \$	Change %
Other expenses/(income)				
Interest on long-term debt and other financing costs	\$ 497	\$ 85	\$ 412	485 %
Interest income	-	(3)	3	100 %
Foreign exchange (gain)/loss	676	(930)	1,606	(173)%
Change in fair value of derivative financial instruments	(292)	255	(547)	215 %
Gain on extinguishment of payables	(195)	(321)	126	39 %
	<u>\$ 686</u>	<u>\$ (914)</u>	<u>\$ 1,600</u>	<u>(175)%</u>

The \$0.4 million increase in interest on long-term debt and other financing costs for the three months ended December 31, 2018 over the same prior year period is mainly due to \$0.2 million in accretion expense related to the accrual of the long-term Mattern Buyout and the interest and relating financing costs associated with a higher outstanding long-term debt balance and the acceleration of the deferred financing costs related with the extinguishment of the Quantius credit facility.

The increase in foreign exchange loss is due to the fluctuation in the Canadian/U.S. exchange rate and the decrease in the inter-company loan balances, for which the foreign exchange loss does not eliminate on consolidation.

The change in fair value of derivative financial instruments is due to the addition of warrants issued as part of the SWK facility and the fluctuation of the share price in relation to the exercise price of the warrants issued.

The gain on extinguishment of payables relates to the reversal of reserves previously taken.

### Financial position

The following table presents a summary of our financial position:

	December 31,		Change \$	Change %
	2018	2017		
Working capital (total current assets less total current liabilities)	\$ 1,959	\$ 3,996	\$ (2,037)	(51)%
Non-current assets	9,200	14,048	(4,848)	(35)%
Long-term obligations	11,230	4,355	6,875	158 %
Shareholders' equity	(71)	13,689	(13,760)	(101)%

### Working capital

The approximately \$2.0 million decrease in working capital from December 31, 2017 to December 31, 2018 reflects the following:

- \$2.5 million increase in accrued liabilities, mainly due to the \$4.7 million accrual related to the Mattern Buyout, of which \$2.2 million is recorded as a long-term liability.
- \$0.4 million decrease in trade and other receivables due to timing of sale and collections.
- \$0.3 million decrease in licensing fee receivable due to the collection of outstanding amounts.
- \$0.5 million decrease in inventory mainly due to the sale of product offset by lower purchases made in the year.

This is offset by:

- \$0.7 million increase in cash due to \$6.1 million being used in operating activities, \$0.2 million used in the acquisition of product rights and fixed assets and \$0.3 million exchange loss on cash, offset by \$7.4 million from financing activities.
- \$1.0 million decrease in the current portion of long-term debt due to the extinguishment of the Endo promissory note and Quantius credit facility and the timing of principal payments associated with the SWK credit facility.

### Non-current assets

Non-current assets consist of property and equipment, and intangible assets. Property and equipment mainly consist of office, lab and manufacturing equipment, fixtures, and leasehold improvements. Intangible assets consist of technology, patents and product rights. The \$0.2 million decrease in property and equipment from December 31, 2017 to December 31, 2018 is primarily due to depreciation and amortization expense and impact of foreign exchange offset by \$0.1 million in additions.

At December 31, 2018 manufacturing equipment with a net book value of \$0.7 million was held off-site by a third party (\$0.8 million at December 31, 2017).

Intangible assets decreased due to amortization expense of \$1.7 million, impairment charge of \$2.6 million and \$0.8 million foreign exchange effect on the Canadian balance of intangible assets offset by the \$0.5 million addition of the intangible asset related to the UriVarx<sup>®</sup>, Stendra<sup>™</sup> and Lidbree<sup>™</sup> product rights. Expenses in 2018 include an impairment charge of \$2.6 million for the Estrace<sup>®</sup> intangible due to an anticipated shortage of certain doses of the product due to supply issues with our contract manufacturer. A shortage of Estrace<sup>®</sup> may accelerate erosion of Estrace<sup>®</sup> sales due to the presence of the third-party generic.

#### *Long-term obligations*

Long-term obligations consist of long-term portion of the Mattern Buyout, long-term debt, derivative financial instruments and deferred lease inducement.

On October 11, 2018, the Endo promissory note and outstanding accrued interest was repaid in full and the note was extinguished.

The Quantius credit facility was subsequently extinguished on October 12, 2018 with payments of principal, accrued interest prepayment penalty and royalty retirement fee.

On October 12, 2018, we entered into a senior secured term loan credit facility with SWK for up to \$11.0 million. An initial tranche of \$9.0 million of the New Facility was received at closing, with the remaining \$2.0 million of the New Facility becoming available upon satisfaction of certain future conditions. The proceeds from the New Facility was used primarily to (i) repay the amount outstanding under the Quantius Facility, including a prepayment penalty and royalty retirement fee; (ii) retire the Endo promissory note; and (iii) for ongoing general working capital. As of December 31, 2018, we had \$9.0 million outstanding on the credit facility.

#### *Shareholders' equity*

We are authorized to issue an unlimited number of common shares. As at December 31, 2018, we had 235,384,262 common shares issued and outstanding, 31,951,001 warrants outstanding and exercisable for 31,951,001 common shares, 17,763,346 outstanding stock options with a weighted average exercise price of CDN\$0.18.

The \$13.8 million decrease in shareholders' equity from December 31, 2017 to December 31, 2018 is primarily due to \$18.8 million in net loss, offset by the \$0.2 million foreign currency translation adjustment, \$0.4 million in share-based compensation, \$1.4 million increase in warrants and \$3.0 million increase in share capital.

On June 28, 2018, we closed an offering, under which we issued 22,041,705 units at a price of CDN\$0.30 per unit, which included 2,875,005 units in connection with the exercise in full of the over-allotment option granted to the Underwriters of the offering. Each unit is comprised of one common share and one common share purchase warrant of the Company. Each warrant shall entitle the holder thereof to purchase one additional common share of the Company at an exercise price of CDN \$0.40 at any time up to 24 months following closing of the offering. On closing, the Underwriter received cash commission equal to 7% of the gross proceeds from the sale of Units and compensation options entitling it to purchase 1,542,919 Common Shares at a price of CDN \$0.30 within 24 months of closing. The proceeds from this transaction were used to fund ongoing general working capital as well as pay the \$1.8 million tranche in the Buyout.

The gross proceeds have been segregated into their common share and warrant components based on their relative fair values of CDN\$4.6 million and CDN\$2.0 million respectively. The common share and warrant components are shown net of transaction costs of CDN\$0.7 million and CDN\$0.3 million respectively. The fair value of the warrants was based on a Black-Scholes model, with the residual amounts of the net proceeds being allocated to the value of the common shares. The fair value of the warrants, CDN\$0.09 per warrant, was based on a Black-Scholes model using the following variables: an expected life of 2 years; a risk-free rate of 1.95%; a volatility rate of 86%; and an exercise price of CDN\$0.40. The fair value of the broker warrants, CDN\$0.11 per warrant, was based on a Black-Scholes model using the following variables: an expected life of 2 years; a risk-free rate of 1.95%; a volatility rate of 86%; and an exercise price of CDN\$0.30.

## Liquidity and capital resources

### Liquidity risk

As detailed in the long-term obligations section above, as at December 31, 2018, there is \$9.0 million of principal outstanding on the SWK credit facility. On October 12, 2018, we entered into a senior secured term loan credit facility with SWK for up to \$11.0 million. An initial tranche of \$9.0 million of the new facility was received at closing, with the remaining \$2.0 million of the new facility becoming available on or before March 31, 2019, upon satisfaction of certain future conditions. The terms of the agreement also contain customary financial covenants. A portion of the proceeds from the new facility was used to retire the Endo and Quantius facilities.

Liquidity risk is the risk that we may encounter difficulties in meeting our financial liability obligations as they become due. We have planning and budgeting processes in place to help determine the funds required to support our normal operating requirements on an ongoing basis. Since inception, we have financed our cash requirements primarily through issuances of equity securities and long-term debt. We control liquidity risk through management of working capital, cash flows, and sourcing of funding.

The purpose of liquidity management is to ensure that there is sufficient cash to meet all of our financial commitments and obligations as they come due. The audited consolidated financial statements for the year ended December 31, 2018 have been prepared on a going concern basis, which assert that we have the ability in the near term to continue to realize our assets and discharge our liabilities and commitments. Our ability to do this is dependent on successfully commercializing our existing products, bringing new products and technologies to market and achieving future profitable operations, the outcome of which cannot be predicted at this time. Furthermore, we will require additional funding, either from commercial sales of our existing products, commercial transactions or investors, to continue the development and commercialization of additional products. These circumstances lend significant doubt as to our ability to meet our obligations as they come due and, accordingly, the ultimate appropriateness of the use of accounting principles applicable to a going concern. There are no assurances that any of these initiatives will be successful. Factors within and outside the Company's control could have a significant bearing on its ability to obtain additional financing.

### Cash flows

Cash flows from/(used in):	2018	2017	Change \$	Change %
Operating activities	\$ (6,131)	\$ 99	\$ (6,230)	(6,293)%
Financing activities	7,350	(2,433)	9,783	402 %
Investing activities	(245)	10	(255)	(2,550)%
Exchange (loss)/gain on cash	(301)	281	(582)	(207)%
Net increase/(decrease) in cash	\$ 673	\$ (2,043)	\$ 2,716	133 %

At December 31, 2018 we had a cash balance of \$3.8 million, which is a \$0.7 million decrease from December 31, 2017.

The cash outflow from operating activities for the year December 31, 2018 is a result of a \$18.8 million net loss, offset by \$6.8 million in non-cash expenses and net \$5.9 million inflow from working capital. The net inflow from working capital is largely due to the Mattern Buyout accrual. In the prior year comparable period, the inflow from operating activities was mainly driven by the receipt of \$4.0 million upfront payment from Aytu offset by the \$8.6 million net loss, \$3.9 million in non-cash expenses, and \$0.7 million of funds from working capital.

The cash from financing activities in the year ended December 31, 2018 is mainly a result of the \$4.4 million net proceeds from issuance of common shares and warrants, \$10.2 million of proceeds from debt issuance, offset by \$0.7 million in interest and financing fees paid and \$6.6 million in principal debt payments. A portion of the proceeds from the SWK credit facility was used to retire the Endo and Quantius facilities. Cash used in financing for the year ended December 31, 2017 was an outflow of \$2.4 million mainly due to the extinguishment of the senior financing, and principal paid on the promissory note and \$0.7 million in interest and financing fees paid, offset by the \$2.4 million received as part of the Quantius credit facility.

Cash used in investing activities for the year ended December 31, 2018 is related to the purchase of the Canadian product rights of UriVarx® and Lidbree™ and the purchase of laboratory equipment.

### Capital expenditures

Our 2018 capital expenditures primarily related to our investment in laboratory assets.

### Off-balance sheet arrangements

We have operating leases for the right to use office equipment and laboratory facilities in our Canadian head office. There are no other off-balance sheet arrangements.

We have a lease agreement for a 10,000 sq. ft. facility in Canada that expires in June 2025.

	December 31, 2018
No later than 1 year	\$ 165
Later than 1 year and no later than 5 years	718
Later than 5 years	269
	<u>\$ 1,152</u>

### Contractual obligations and commitments

As of December 31, 2018, and in normal course of business, we have the following obligations to make future payments, representing contracts and other commitments that are known and committed.

	Less than 3 months	3-6 months	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years	Total
Accounts payable and accrued liabilities	\$ 5,407	\$ 101	\$ 123	\$ 2,800	\$ -	\$ 8,431
Purchase commitments	-	99	343	699	3,157	4,298
Long-term debt (principal and interest)	299	303	612	1,217	11,724	14,155
As at December 31, 2018	<u>\$ 5,706</u>	<u>\$ 503</u>	<u>\$ 1,078</u>	<u>\$ 4,716</u>	<u>\$ 14,881</u>	<u>\$ 26,884</u>

On October 12, 2018, we entered into a senior secured term loan credit facility with SWK for up to \$11.0 million. An initial tranche of \$9.0 million of the new facility was received at closing, with the remaining \$2.0 million of the new facility becoming available on or before March 31, 2019, upon satisfaction of certain future conditions. The new facility bears interest at a rate per annum equal to the greater of (a) the three-month London Inter-Bank Offered Rate (“LIBOR”), or (b) 1.50%, with such base rate being capped at no greater than 4.25%, plus an applicable margin of 10.50%. The new facility matures on October 11, 2023 and is interest-only for the first two years of the term. Under the terms of the agreement, we will have the option to prepay the loan prior to the maturity date subject to the payment of certain prepayment fees. The terms of the agreement also contain customary financial covenants.

We have accrued the full value of the Mattern Buyout under accrued liabilities. The Buyout has been discounted at a rate of 14.75%. The Buyout will remain in full force and effect as long as the License Agreement is in force. In the event of a payment default, following a grace period, the Buyout automatically terminates and the License Agreement’s obligations become binding on Acerus again. In such an eventuality, all monies paid by Acerus pursuant to the Buyout, with the exception of the first instalment, can be offset against monies that would otherwise be owed to Mattern under the License Agreement.

In relation to the pulmonary and nasal dry powder delivery technology, there is a milestone payment of \$2.0 million due upon FDA approval for each product up to a maximum of \$8.0 million (see note 5(b) of the December 31, 2018 consolidated financial statements) for products submitted for approval by ABI itself.

The Company may be required to make certain regulatory or sales based milestone payments as part of many of their in-licensing agreements as described in notes 5(e)(f)(g) and (h) in the consolidated financial statements ended December 31, 2018.

## Related party transactions

Key management includes our directors and executive officers. The remuneration of directors and key members of management and professional fees paid or payable to firms affiliated with a current director of ABI and the interim CEO for the three and twelve months ended December 31, 2018 and 2017 were as follows:

	For the three months ended		For the year ended	
	December 31,		December 31,	
	2018	2017	2018	2017
Short-term compensation of key management and directors	\$ 328	\$ 244	\$ 1,512	\$ 1,432
Termination benefits	366	1,061	366	1,061
Share-based compensation	90	339	370	550
Professional fees paid or payable to firms affiliated with directors & officers	-	115	189	116
	\$ 784	\$ 1,759	\$ 2,437	\$ 3,159

These transactions are in the normal course of operations.

Executive employment agreements allow for total additional payments of approximately \$1,542 if a change in control occurs, \$1,493 if all are terminated without cause, and \$nil if all are terminated with cause.

As at December 31, 2018, Acerus held a \$2,073 receivable (\$7,188 payable as at December 31, 2017) from its wholly owned subsidiary ABI. The payable is non-interest bearing, due on demand and eliminates upon consolidation except for the foreign exchange gain of \$152 for the year ended December 31, 2018 (loss of \$1,677 for the year ended December 31, 2017) that has been recorded in the consolidated statement of income loss.

## Dividends

We intend to re-invest future earnings to finance our growth and therefore do not intend to pay dividends in the foreseeable future. Any subsequent decision to pay dividends is at the discretion of the Board of Directors and will depend on our financial position, operating results, capital requirements and other factors deemed relevant by the Board of Directors.

## Financial instruments

As at December 31, 2018, our financial instruments consisted of cash, trade and other receivables, accounts payable and accrued liabilities, long-term debt, and derivative financial instrument. The derivative financial instrument is measured at fair value with any changes recognized through the consolidated statement of (loss)/income and comprehensive (loss)/income and is classified as Level 2. Cash, trade and other receivables, accounts payable and accrued liabilities are measured at amortized costs and their fair values approximate carrying values due to their short-term nature except for the Buyout payable. The Buyout payable has been discounted using a current interest rate and accordingly its carrying value approximates fair value.

The long-term debt is measured at amortized cost. At December 31, 2018 the fair value of the long-term debt approximates its face value of \$9.0 million. The fair values are based on cash flows discounted using a rate based on the borrowing rate and are within Level 3 of the fair value hierarchy.

## Currency risk

We are exposed to currency risk related to the fluctuation of foreign exchange rates. We are exposed to currency risk through our net assets denominated in US dollars, Euros, and the British Pound.

	December 31, 2018		
	USD	EUR	GBP
Cash	\$ 231	\$ -	\$ -
Trade and other receivables	301	-	-
Accounts payable and accrued liabilities	(670)	(243)	(8)
Long-term debt	(9,000)	-	-
	\$ (9,138)	\$ (243)	\$ (8)

Based on the above net exposure at December 31, 2018, and assuming that all other variables remain constant, a 5% appreciation or depreciation of the U.S. dollar against the other currencies would have resulted in the following impact on net (loss)/income:

## US Dollar

Net income effect:

	US	EUR	GBP	Total
Appreciate 5%	\$ 435	\$ (12)	\$ (1)	\$ 422
Depreciate 5%	(481)	12	1	(468)

### Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company has an interest rate of LIBOR + 10.50% per annum with a LIBOR floor rate of 1.5% and the rate being capped at no greater than 4.25% for the SWK credit facility.

A 0.5% appreciation in the present LIBOR rate would lead to an increase of \$173 of interest payments for the life of the loan. A 0.5% depreciation in the present LIBOR rate would lead to a decrease of \$173 of interest payments required for the life of the loan.

### Credit risk

Credit risk is the risk of a financial loss if a customer or counterparty to a financial instrument fails to meet its contractual obligation. Financial instruments that potentially expose us to significant concentrations of credit risk consist of cash, and trade and other receivables. Our investment policies are designed to mitigate the possibility of deterioration of principal, enhance our ability to meet our liquidity needs and provide high returns within those parameters. Cash is on deposit with a Canadian chartered bank located in Canada.

We monitor the collectability of trade and other receivables and estimates on allowance for doubtful accounts. We have concentration risk, as approximately 51% of our trade receivables are due from three pharmaceutical wholesalers in Canada and 29% from an out-licensing partner.

As at December 31, 2018, the allowance for doubtful accounts was \$nil. Allowance for doubtful accounts is minimal because there has not been a significant change in credit quality and all amounts are considered recoverable.

### Market risk

The change in fair value of our derivative liability, which is measured at fair value through profit and loss ("FVTPL"), results from the periodic "mark-to-market" revaluation. The valuation is impacted, among other inputs, by the market price of our common shares. As a result, the change in fair value of the derivative liability, which is reported through the consolidated statement of (loss)/income and comprehensive (loss)/income, has been and may continue in future periods to be materially affected most notably by changes in our common share price.

Assuming that all other variables remain constant, a 5% appreciation or depreciation of our share price would have resulted in an \$18 decrease and \$18 increase in net loss respectively (\$28 increase and \$28 decrease in net income at December 31, 2017).

### Accounting pronouncements

The accounting policies applied are consistent with the significant accounting policies used in the preparation of the audited annual consolidated financial statements for the year ended December 31, 2018. These policies have been consistently applied to all periods presented except for the adoption of IFRS 15 and IFRS 9 on January 1, 2018.

A number of new or amended standards became applicable for the 2018 reporting period and we had to change our accounting policies and make retrospective adjustments as a result of adopting IFRS 15 Revenue from Contracts with Customers.

The impact of the adoption of these standards and the new accounting policies are disclosed in the note below. The other standards did not have any impact on our accounting policies and did not require retrospective adjustments.

Other new standards and amendments to standards and interpretations have not been applied in preparing these consolidated financial statements. None of these standards are expected to have a significant effect on our consolidated financial statements, except for the following set out below:

## **Impact of changes and updates to accounting policies**

### IFRS 16 Leases

The new standard brings most leases on-balance sheet, eliminating the distinction between operating and finance leases. Lessor accounting remains largely unchanged and the distinction between operating and finance leases is retained. The new standard is effective for annual reporting periods beginning on or after January 1, 2019 with earlier application permitted for entities that apply IFRS 15 *Revenue from Contracts with Customers*. We are currently quantifying the impact of adoption and is assessing transitional implementation options.

IFRS 16 will result in almost all leases being recognized on the balance sheet by lessees, as the distinction between operating and financing leases is removed. Under the new standard, an asset (the right to use the leased item) and a financial liability to pay rentals are recognized. The only exceptions are short-term and low-value leases.

The following standards have been adopted on January 1, 2018:

### IFRS 9 Financial Instruments

In July 2014, the IASB issued IFRS 9 Financial Instruments to replace IAS 39 “*Financial Instruments: Recognition and Measurement*”. The new standard uses a principle-based approach for the classification and measurement of financial assets: amortized cost and fair value. Additional amendments include a single “expected loss” impairment method and a substantially reformed approach to hedge accounting. This standard is effective for annual periods beginning on or after January 1, 2018. Our financial assets primarily consist of trade receivables. The adoption of IFRS 9 was applied on a retrospective basis on January 1, 2018 without restatement of comparatives and did not have a significant effect on the valuation of our financial assets.

### IFRS 15 Revenue from Contracts with Customers

We adopted IFRS 15 *Revenue from Contracts with Customers* on January 1, 2018 which resulted in changes in accounting policies and adjustments to the amounts recognized in the financial statements. In accordance with the transition provisions in IFRS 15, we have adopted the new rules retrospectively and have restated comparatives for the 2017 fiscal year.

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

- Our product revenue is from the sale of goods where control transfers to the customer and our performance obligations are satisfied. The adoption of IFRS 15 did not significantly change the timing or amount of revenue recognized under these arrangements.
- License and other revenue mainly consist of upfront and milestone payments received from license and supply agreements. In our review of out-licensing agreements, we concluded that the license is distinct from other goods and services in the contracts. The license provides the partner with the right to use our intellectual property. Previously, the upfront payments were recorded as deferred revenue and amortized as income over the life of the contracts. Under IFRS 15, the upfront revenue is recognized when control transfers to the licensee and the license period begins. For milestone payments, there has been no change in the recognition criteria, income is recognized at the point in time when it is highly probable that the milestone event criteria are met, and the risk of reversal of revenue recognition is remote.

The following tables show the adjustments recognized for each individual line item. Line items that were not affected by the changes have not been included. As a result, the sub-totals and totals disclosed cannot be recalculated from the numbers provided.

	<b>January 1, 2017 As originally presented</b>	<b>IFRS 15</b>	<b>January 1, 2017 Restated</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
<b>Current liabilities</b>			
Current portion of deferred revenue	1,006	(1,006)	-
<b>Total current liabilities</b>	<b>8,467</b>	<b>(1,006)</b>	<b>7,461</b>
Deferred revenue	6,198	(6,198)	-
<b>Total liabilities</b>	<b>17,515</b>	<b>(7,204)</b>	<b>10,311</b>
<b>Shareholders' equity</b>			
Accumulated other comprehensive loss	(15,931)	(439)	(16,370)
Deficit	(134,111)	7,643	(126,468)
<b>Total shareholders' equity</b>	<b>12,201</b>	<b>7,204</b>	<b>19,405</b>
<b>Total liabilities &amp; shareholders' equity</b>	<b>\$ 29,716</b>	<b>\$ -</b>	<b>\$ 29,716</b>

	<b>December 31, 2017 As originally presented</b>	<b>IFRS 15</b>	<b>January 1, 2018 Restated</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
<b>Current liabilities</b>			
Current portion of deferred revenue	1,206	(1,206)	-
<b>Total current liabilities</b>	<b>5,416</b>	<b>(1,206)</b>	<b>4,210</b>
Deferred revenue	6,567	(6,567)	-
<b>Total liabilities</b>	<b>16,338</b>	<b>(7,773)</b>	<b>8,565</b>
<b>Shareholders' equity</b>			
Accumulated other comprehensive loss	(14,091)	39	(14,052)
Deficit	(142,825)	7,734	(135,091)
<b>Total shareholders' equity</b>	<b>5,916</b>	<b>7,773</b>	<b>13,689</b>
<b>Total liabilities &amp; shareholders' equity</b>	<b>\$ 22,254</b>	<b>\$ -</b>	<b>\$ 22,254</b>

	<b>December 31, 2017 As originally presented</b>	<b>IFRS 15</b>	<b>December 31, 2017 Restated</b>
<b>REVENUE</b>			
Licensing and other fees	1,096	91	1,187
Total revenue	6,444	91	6,535
Gross margin	3,181	91	3,272
<b>LOSS BEFORE INCOME TAXES</b>	<b>(8,667)</b>	<b>91</b>	<b>(8,576)</b>
<b>NET LOSS</b>	<b>\$ (8,714)</b>	<b>\$ 91</b>	<b>\$ (8,623)</b>
<b>OTHER COMPREHENSIVE LOSS, NET OF INCOME TAX</b>			
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Foreign currency translation adjustment	1,840	478	2,318
<b>TOTAL COMPREHENSIVE LOSS FOR THE YEAR</b>	<b>\$ (6,874)</b>	<b>\$ 569</b>	<b>\$ (6,305)</b>

## **Critical accounting estimates**

In preparing our consolidated financial statements, we are required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results may differ from these estimates. Estimates are based on our best knowledge of current events and actions that we may undertake in the future. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and any future periods are affected.

### Going concern

The audited consolidated financial statements for the year ended December 31, 2018 were prepared using IFRS applicable to a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business as they come due for the foreseeable future. Our ability to realize our assets and meet our obligations as they come due is dependent on successfully commercializing our existing products, bringing new products and technologies to market and achieving future profitable operations, the outcome of which cannot be predicted at this time. Furthermore, we will require additional funding, either from commercial sales of our existing products, commercial transactions or investors, to continue the development and commercialization of additional products. These circumstances lend significant doubt as to our ability to meet our obligations as they come due and, accordingly, the ultimate appropriateness of the use of accounting principles applicable to a going concern.

### Revenue recognition

Product revenue is recorded at the invoiced amount less estimated accruals for product returns, discounts, chargebacks and other price adjustments. These contract liabilities with respect to Estrace<sup>®</sup>, Natesto<sup>®</sup> and UriVarx<sup>®</sup> are presently based on historical levels and are recognized as a reduction of revenue. While such experience has allowed for reasonable estimates in the past, history may not always be an accurate indicator of future events. Management will monitor these contract liabilities and make adjustments when it believes actual results may differ from established contract liabilities.

License and other revenue mainly consists of upfront payments and milestone payments received in license and supply agreements. Management, in its review of out-licensing agreements, uses significant judgement to determine if the license is distinct from other goods and services in the contract and if the license provides the partner with the right to use or the right to access the Company's intellectual property. Management makes their decision by reviewing contracts and through discussions with internal and external personnel to determine the substance of the agreements.

### Fair value of derivative financial instruments

The fair values of derivative financial instruments that are not traded in an active market are determined using valuation techniques. We use our judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at the end of each reporting period. Additional information is disclosed in note 14 of our December 31, 2018 consolidated financial statements.

### Clinical trial expenses

Clinical trial expenses are accrued based on estimates of the services received and efforts expended pursuant to contracts with clinical research organizations (CROs), consultants and other vendors. In the normal course of business, we contract third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements vary from contract to contract, are subject to negotiation and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrolment of patients or the completion of portions of the clinical trial or similar conditions. We accrue and expense clinical trial activities based upon estimates of the proportion of work completed over the life of the individual clinical trial and patient enrolment rates in accordance with agreements established with CROs and clinical trial sites. We determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

### Share based payments

The compensation expense related to share-based payments is determined using the Black-Scholes option pricing model. The significant variables and estimates used in the model are volatility, dividend yield, expected option life, and risk-free interest rate. In addition, management also applies an estimated forfeiture rate. Additional information is disclosed in note 20 of our December 31, 2017 consolidated financial statements.

### Income taxes

We are subject to income taxes in different jurisdictions and therefore use judgment to determine the provision for income taxes. Management makes estimates and takes tax filing positions and it is uncertain whether certain estimates and tax filing positions will be sustained upon examination by applicable tax authorities. Provisions for uncertain tax positions are recorded based on management's estimate of the most likely outcome. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred income tax assets and liabilities in the period in which such determination is made.

### **Non-IFRS financial measures**

The non-IFRS measures included in this MD&A are not recognized measures under IFRS and do not have a standardized meaning prescribed by IFRS and may not be comparable to similar measures presented by other issuers. When used, these measures are defined in such terms as to allow the reconciliation to the closest IFRS measure. These measures are provided as additional information to complement those IFRS measures by providing further understanding of our results of operations from our perspective. Accordingly, they should not be considered in isolation nor as a substitute for analysis of our financial information reported under IFRS. Despite the importance of these measures to management in goal setting and performance measurement, we stress that these are non-IFRS measures that may be limited in their usefulness to investors.

We use non-IFRS measures, such as EBITDA and Adjusted EBITDA to provide investors with a supplemental measure of our operating performance and thus highlight trends in our core business that may not otherwise be apparent when relying solely on IFRS financial measures. We also believe that securities analysts, investors and other interested parties frequently use non-IFRS measures in the valuation of issuers. We also use non-IFRS measures in order to facilitate operating performance comparisons from period to period, prepare annual operating budgets, and to assess our ability to meet our future debt service, capital expenditure and working capital requirements.

The definition and reconciliation of EBITDA and Adjusted EBITDA used and presented by the Company to the most directly comparable IFRS measures follows below:

### **EBITDA and Adjusted EBITDA**

EBITDA is defined as net (loss)/income adjusted for income tax, depreciation of property and equipment, amortization of intangible assets, interest on long-term debt and other financing costs, interest income, and changes in fair values of derivative financial instruments. Management uses EBITDA to assess the Company's operating performance.

Adjusted EBITDA is defined as EBITDA adjusted for, as applicable, licensing and other revenue, royalty expenses associated with triggering events, Buyout, milestones, share based compensation, impairment of intangible asset, foreign exchange (gain)/loss and gain on extinguishment of payables. We use Adjusted EBITDA as a key metric in assessing our business performance when we compare results to budgets, forecasts and prior years. Management believes Adjusted EBITDA is a good alternative measure of cash flow generation from operations as it removes cash flow fluctuations caused by extraordinary and non-recurring items, including changes in working capital. A reconciliation of net (loss)/income to EBITDA (and Adjusted EBITDA) is set out below.

	For the three months ended		For the year ended	
	December 31,		December 31,	
	2018	2017	2018	2017
Net (loss)	\$ (5,051)	\$ (1,823)	\$ (18,786)	\$ (8,623)
Adjustments:				
Income tax expense	27	47	29	47
Amortization of intangible assets	394	406	1,694	1,781
Depreciation of property and equipment	47	66	240	264
Interest on long-term debt and other financing costs*	497	85	1,773	380
Interest income	-	(3)	(12)	(21)
Change in fair value of derivative	(292)	255	(380)	156
<b>EBITDA</b>	<b>\$ (4,378)</b>	<b>\$ (967)</b>	<b>\$ (15,442)</b>	<b>\$ (6,016)</b>
Licensing and other revenue	(184)	(603)	(334)	(1,187)
Royalty expense/Buyout	-	-	6,680	-
Share based compensation	112	372	449	589
Foreign exchange loss/(gain)	676	(930)	1,029	1,521
Gain on extinguishment of payables	(195)	-	(195)	-
Impairment loss on intangible asset	2,641	-	2,641	-
<b>Adjusted EBITDA</b>	<b>\$ (1,328)</b>	<b>\$ (2,128)</b>	<b>\$ (5,172)</b>	<b>\$ (5,093)</b>

\* This figure includes interest expense and the amortization of deferred financing costs and accretion expense related to our outstanding debts.

### Management's responsibility for financial reporting

#### *Disclosure controls and procedures and internal controls over financial reporting*

As at December 31, 2018 management has disclosure controls and procedures ("DCP") that provide reasonable assurance that information required to be disclosed by the Company in its filings under Canadian securities legislation is recorded, processed, summarized and reported in a timely manner. The system of DCP includes, among other things, the Company's Corporate Disclosure and Whistleblower policies and Code of Conduct, the review and approval procedures of the Disclosure Committee and continuous review and monitoring procedures by senior management.

As at December 31, 2018 management has designed internal controls over financial reporting ("ICFR") within the Company in order to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with IFRS. These controls were designed based on the framework established by Internal Control - Integrated Framework: 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Due to its inherent limitations, ICFR may not prevent or detect misstatements. In addition, the design of any system of control is based upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all future events, no matter how remote, or that the degree of compliance with the policies or procedures may not deteriorate. Accordingly, even effective ICFR can only provide reasonable, not absolute, assurance of achieving the control objectives for financial reporting.

#### *Changes in internal controls over financial reporting*

There have been no changes to the Company's internal controls over financial reporting during the year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.

An evaluation of the design and effectiveness of the Company's DC&P and ICFR has been conducted by management, under the supervision of the Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Based on this evaluation, the CEO and CFO have concluded that, as of December 31, 2018, the Company's disclosure controls and procedures and internal control over financial reporting, as defined by National Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings, are operating effectively.

## **Litigation**

### ***Shenk Litigation***

In November 2013, each of the Acerus, SRL (predecessor of ABI) and APBI (which has since been dissolved) were served with a third party claim by Valeant Pharmaceuticals International, Inc. and Valeant International (Barbados) SRL (collectively, the "Valeant Parties"). The third party claim seeks certain contribution and indemnity, and damages relating to an underlying claim advanced against the Valeant Parties by Mr. Reiner Schenk. Mr. Schenk asserts that, inter alia, the Valeant Parties breached certain obligations owing to him under a confidentiality agreement in 2005 and 2006, and that he is accordingly owed certain damage amounts. Mr. Schenk had originally included Acerus, SRL and APBI as party to his action in 2011 but promptly discontinued his claims against such parties. Each of the Loan Parties believes that the claim of Mr. Schenk, and the related third party claim by the Valeant Parties, is in each case without merit. We have defended the third-party claim, denying any liability to Valeant. It is expected that a date for trial will be set in the near future, although there is currently no fixed date by which a trial date must be set.

## **Subsequent Events**

### ***Gynoflor™***

On January 24, 2019 we received a Notice of Deficiency-Withdrawal Letter ("Notice") for its Gynoflor™ New Drug Submission. We have decided not to file a Request for Reconsideration of the Notice and have informed our licensor, Medinova AG ("Medinova"), that further studies will be needed in order for Gynoflor™ to be approvable by Health Canada. Under the agreement with Medinova, neither the Company nor Medinova is obligated to conduct such further studies. If no further studies are conducted, then we will not resubmit the Gynoflor™ dossier to Health Canada at this time. Acerus and Medinova will continue to work on areas of possible further collaboration.

## **Additional information**

Additional information about Acerus, including the Company's Annual Information Form, is available in documents filed by the Company with Canadian securities regulatory authorities and made available on the System for Electronic Document Analysis and Retrieval at [www.sedar.com](http://www.sedar.com).