



**Management's Discussion & Analysis of  
Acerus Pharmaceuticals Corporation  
For the three and nine months ended September 30, 2019**

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 nine months ended September 30, 2019. This MD&A is dated November 13, 2019 and should be read in conjunction with the unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2019, together with the notes and audited consolidated financial statements for the year ended December 31, 2018.

The unaudited condensed interim consolidated financial statements were prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board applicable to the preparation of interim financial statements including International Accounting Standards 34: Interim Financial Reporting 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, and meet the amended minimum threshold for consolidated unencumbered liquid assets required to be maintained by the Company in December 2019 and January 2020, additional capital will be required. In addition, the anticipated shortage of certain strengths of Estrace® in 2019 and the manufacturing process change in Natesto® that resulted in Health Canada requiring the submission of a Supplemental New Drug Submission ("SNDS") before the product can be re-introduced to the Canadian market could result in the Company failing to meet projected revenues or other budgeted targets, which could result in the Company violating its debt financial covenants within the next twelve months. 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; risks relating to the conduct of its commercial partners; 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 unaudited condensed interim 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") (incorporated in Ontario) and Acerus Pharmaceuticals (Barbados) Inc. ("APBI") (incorporated in Barbados). 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.

Acerus Pharmaceuticals Corporation is a Canadian-based specialty pharmaceutical company focused on the commercialization and development of innovative prescription products that improve patient experience, with a primary focus in the field of men's health. The Company commercializes its products via its own salesforce in Canada, and through a global network of licensed distributors in the U.S. and other territories

We currently have two marketed products: Estrace<sup>®</sup>, a product for the symptomatic relief of menopausal symptoms, is commercialized in Canada; and Natesto<sup>®</sup>, the first and only testosterone nasal gel for testosterone replacement therapy in adult males diagnosed with hypogonadism, is commercialized in Canada, the U.S and South Korea. UriVarx<sup>®</sup>, a Natural Health Product that helps reduce symptoms of hyperactive bladder such as daytime urinary frequency, urgency and nocturia was commercialized in Canada by Acerus until June 1, 2019 when a mutual termination agreement was entered into with Innovus.

Natesto<sup>®</sup> has also 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. On June 14, 2018, we reported that South Korea's Ministry of Food and Drug Safety (MFDS) approved Natesto<sup>®</sup> for the treatment of hypogonadism. On July 10, 2019 we announced that Hyundai officially launched the commercialization of Natesto<sup>®</sup>. On August 2, 2019, we announced a voluntary recall and replacement of Natesto<sup>®</sup> in the Canadian and South Korean markets as several batches were found to be non-conforming during long-term stability studies. The expectation at that time was that the product would be re-manufactured and re-introduced by the end of October of 2019.

On November 1, 2019, we announced that Health Canada had indicated that the minor modifications made to the manufacturing process to address the earlier non-conforming issue required a supplemental new drug submission. The result of this decision is that Natesto® will not be available in the Canadian and South Korean markets until January 2021 (assuming that Health Canada takes the full time needed for their review). At this time, the current supply of Natesto® to the US is not affected by this situation.

Our pipeline includes five innovative products: Lidbree™ (formerly referred to as Shact™), a short acting lidocaine formulation delivered through a proprietary device into the vaginal mucosal tissue; avanafil 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® and in the European Union (“EU”) under the trade name Spedra®; Elegant™ Vaginal Moisturizer, which provides comfort to women suffering from vaginal dryness, Elegant™ pH, which is a pH balanced vaginal product; and Tefina™ 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. One of the projects we have under development 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 and achieved first positive results from dosing of subjects in a Phase I clinical trial test with a proprietary intranasal formulation of nasal tetrahydrocannabinol THC – rich cannabis oil in healthy volunteers. We are actively looking at potential partnering transactions for these initiatives.

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> <li>• See note below on Amended and Restated agreement signed Q3 2019</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, Australia, New Zealand, South Africa and Israel.	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• All other terms as per the original agreement</li> </ul>

In June 2018, South Korea’s Ministry of Food and Drug Safety (MFDS) approved Natesto® for the treatment of hypogonadism. On February 27, 2019 we announced making the first shipment of Natesto® to South Korea. On July 10, 2019 we announced that Hyundai officially launched the commercialization of Natesto®.

On August 2, 2019, we announced that we will voluntarily replace certain Natesto® lots released in the Canadian and South Korean markets, which is expected to cause temporary shortages in those markets. We have identified four commercial lots of Natesto® released in the Canadian and South Korean markets that were found to be non-conforming during long-term stability studies, even though such lots were fully in-specification at the time of release. This post-release non-conformity is not harmful to the patient, but may result in difficulties in dispensing.

We made minor modifications to the manufacturing process that appear to have resolved the previously identified issues and have produced a batch of Natesto® (the “Revised Batch”). While we believed the changes would have been classified by Health Canada as level III, thereby requiring only an annual notification update to Health Canada and allowing for product to be released in Q4-2019, Health Canada, after much deliberation, classified the modifications as level I, requiring the submission of a SNDS prior to the release of the Revised Batch in the Canadian market. In the event that Health Canada utilizes the full regulatory allotted time for reviewing a SNDS, we would expect the Revised Batch to be released in the Canadian Market in Q1-2021. We continue to work with Health Canada to facilitate an expeditious review of the SNDS and minimize market disruptions.

At this time, the current supply of Natesto® to the United States is not affected by this situation. We are working with our South Korean partner to determine whether the Revised Batch can be released in the South Korean market and, if so, under what timeframes.

We had previously impaired inventory by \$0.3 million and accrued \$0.5 million related to replacing products, discounts and potential returns due to the issue described above. However, due to the additional delays, the Company reversed the previous accruals related to discounts and replacement of product and has accrued \$0.7 million for returns in the current quarter.

#### *Co-promote Natesto® in the U.S.*

We entered into an amended and restated licensing agreement with Aytu in July 2019, which, upon closing, will move the partnership from an out-license model to a co-promotion arrangement. Under the terms of the new agreement, Aytu returns the NDA for Natesto® in the U.S. back to Acerus. Going forward we will assume all regulatory and clinical responsibilities and costs for the product in the U.S. We will take on a more expansive role in matters such as U.S. marketing, reimbursement and medical strategy as part of the companies’ joint commercialization committee, and will launch a specialist sales force focused on urologists and endocrinologists (Acerus Sales Channel). Aytu will retain its primary care sales force (Aytu Sales Channel) and will continue to book all product net revenue while serving as the exclusive U.S. supplier of Natesto® to wholesalers, pharmacies and other customers that receive a direct shipment. Financial payments will be based upon a tiered level of net revenue, post cost of goods sold (COGS), based on annual sales performance in the respective Acerus and Aytu Sales Channels.

To establish a high performing commercial footprint in the U.S., we have engaged Syneos Health (NASDAQ: SYNH), a leading integrated biopharmaceutical solutions organization including the industry's largest Contract Commercial Organization (CCO), to be our commercialization partner. Syneos Health has extensive experience in Men's Health and with Natesto®, and offers an end-to-end model that will enable us to rapidly stand up a U.S. commercial team; to scale across all aspects of commercialization, including medical and regulatory affairs, managed markets, marketing and sales; and will provide greater flexibility and effectiveness in resource deployment.

As part of the amended and restated partnership agreement, we did not pay Aytu to regain the marketing authorization for Natesto® in the U.S. The royalty structure currently in place will be replaced with a pay-for-performance incentive structure intended to drive Natesto® revenue growth in both Sales Channels. The revised agreement extends the partnership to the later of 2027, the launch of an FDA approved, AB-rated generic equivalent to Natesto®, or the expiration or invalidation of the last to expire Natesto® patent.

Aytu will now pay us a variable rate commission for sales made in the Acerus Channel as per the following schedule:

- Up to the current status quo of Natesto® net sales (\$0 - \$5.5 million), Acerus will receive a commission equivalent to 25% of net revenue generated;
- For the next \$4.5 million in net revenue (\$5.5 million - \$10.0 million), Acerus will receive a commission equivalent to 50% of net revenue generated; and
- Above \$10.0 million in net revenue, Acerus receives a commission equivalent to the combination of 90% of urologists and endocrinologists related net revenues and 10% of Aytu's sales channel net revenue generated.

Closing is conditioned upon Acerus raising capital, whether by way of equity or debt, of at least \$10.0 million on or before January 29, 2020.

We have begun the process of preparing for the 2020 launch and have incurred costs of \$2.1 million that have been expensed in selling, general and administrative expenses in the nine months ended September 30, 2019. These expenses are discussed in further detail in the Review of Operating Results.

#### *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®, 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: \$0.8 million was paid in July 2018, \$1.8 million was paid in September 2018, \$0.6 million was paid in January 2019, \$2.0 million was paid in April 2019 which included a \$0.2 million deferral fee, and \$2.5 million will be paid by January 20, 2020 (subject to deferral rights). 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.

#### *Estrace®*

On January 11, 2019, we reported an anticipated shortage of certain doses of Estrace® on the Drug Shortages Canada website in relation to supply issues arising from our contract manufacturer. We were notified by our contract manufacturer of a partial manufacturing license suspension at the facility where Estrace® is being produced as a result of an audit by U.K. health authorities. Anticipating a potential shortage of certain strengths of Estrace® over the next six months, we impaired the related intangible asset by \$2.6 million at December 31, 2018. In 2019, we were informed of further delays in lifting the license suspension and as a result, we impaired the asset

by a further \$2.5 million at March 31, 2019. An alternative manufacturer has been identified and we are working towards supply of product in the first half of fiscal 2020.

The intangible asset was written down to its recoverable amount in both 2018 and 2019 using a value-in-use discounted cash flow model. Key assumptions included a pre-tax discount rate of 16.9%, estimated cash flows, projected declines in revenue and for the 2019 model an increased cost of goods related to transferring the product to a different contract manufacturer. In the model, we assumed we would receive product by the second quarter in fiscal 2020 (versus by September 2019 in the 2018 impairment model).

#### Gynoflor™

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™ 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™ 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. 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.

On June 17, 2019, we terminated the license and supply agreement with Medinova.

#### 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 achieving certain sales targets. Innovus will oversee the manufacturing of UriVarx® and will receive a supply price for the product.

We reached a mutual agreement with Innovus to terminate the exclusive distributor and license agreement effective June 1, 2019.

#### avanafil (available in the U.S. under the brand name 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 avanafil in Canada (available in the U.S. under the brand name Stendra®). Avanafil 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 avanafil and will receive a supply price for the product comprised of a transfer price and royalties on net sales of the product.

On March 4, 2019, we announced we filed a NDS for avanafil with Health Canada. The initial screening process by Health Canada was completed in June 2019. The dossier is now in active review by Health Canada.

## 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 payment and a regulatory milestone payment 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

### Private placement

On March 29, 2019 the Company closed a non-brokered private placement of 23,230,772 common shares to certain directors and officers at a price of CDN\$0.195 per common share for gross proceeds of CDN\$4.5 million.

### Long-term debt financing

#### *First Generation Loan*

On July 18, 2019, we entered into a \$5.0 million subordinated secured term loan facility ("the Loan") with First Generation Capital Inc. ("First Generation"), a company affiliated with the Chairman of the Board of Directors of Acerus.

The Loan is subordinated to the existing \$9.0 million facility with SWK and bears interest at a rate per annum equal to the three-month LIBOR, plus an applicable margin of 10.50%. Subject to the terms of the subordination and intercreditor agreement between First Generation and SWK, the Loan is repayable in full on December 31, 2020, is interest-only until maturity with regularly scheduled payments of interest to First Generation being permitted subject to certain conditions related to our market capitalization and aggregate annual revenue, and can be prepaid in full or in part without penalty following repayment in full of indebtedness owing to SWK.

#### *SWK – Credit Facility*

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. As the conditions were not satisfied, we did not draw on the additional \$2.0 million of the New Facility.

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 some of which were amended on June 28, 2019. 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 "Original 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.

On September 30, 2019 we received a waiver letter from SWK waiving the requirement to comply with the Adjusted EBITDA and Aggregate Revenue covenants as at September 30, 2019 contained in the credit agreement.

We also amended the agreement to set the minimum threshold for Consolidated Unencumbered Liquid Assets required for us to maintain. This amount is defined in the agreement as cash adjusted for a certain portion of accounts receivable and payable. This level will be set at (i) \$1.0 million at September 30, 2019; (ii) \$5.0 million at December 15, 2019; (iii) \$4.0 million at December 31, 2019; (iv) \$2.0 million at January 31, 2020, and (v) \$1.0 million at all times after January 31, 2020. In connection with the amendment, we agreed to reprice 5,331,563 outstanding Original Warrants from CDN\$0.40 to CDN\$0.11. In addition, the Original Warrants' expiry date has been extended from October 11, 2023 to September 30, 2024. No other changes were made to the term of the Original Warrants.

On October 3, 2019, the Company issued 1,361,544 common share purchase warrants (the “New Warrants”) to SWK in connection with the amendment. Each New Warrant will entitle SWK to purchase one common share of Acerus at an exercise price of CDN\$0.11 per common share and will expire on September 30, 2024. The terms of the New Warrants will otherwise be identical to those of the Original Warrants. As such, in certain circumstances, we may cause SWK to exercise the New Warrants prior to their expiry date if the closing price of our common shares on the TSX exceeds CDN\$0.80 per share for a period of at least 21 consecutive trading days. The obligation to issue these shares is recorded as a warrant derivative liability on the balance sheet as of September 30, 2019 with a value of \$0.1 million.

#### *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 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. 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 and interest income. 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, the 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 \$0.7523 and \$0.7766 respectively for the nine months ended September 30, 2019 and 2018. 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 \$0.7551 and \$0.7330 at September 30, 2019 and December 31, 2018.

## Taxation

Canada has 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 note in Canada is 26.5% in 2019 and 2018. APBI was dissolved on February 26, 2018.

## 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 nine months ended September 30, 2019 except for the adoption of IFRS 16 *Leases* on January 1, 2019 which was adopted on a modified retrospective basis with no restatement of comparatives as permitted under the specific transitional provisions in the standard. The reclassifications and adjustments arising from the new leasing rules are therefore recognized in the opening balance sheet on January 1, 2019. 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			
	September 30, 2019	June 30, 2019	March 31, 2019	December 31, 2018
<b>Statement of operations data</b>				
Product revenue	\$ (167)	\$ 1,256	\$ 2,165	\$ 1,884
Licensing and other revenue	-	-	-	184
Cost of goods sold	(124)	1,339	632	811
Research and development	622	647	1,038	571
Selling, general & administrative expense	3,184	2,220	4,238	5,024
Finance costs, net	763	253	688	686
Income tax expense	-	-	-	27
Net loss	(4,612)	(3,203)	(4,431)	(5,051)
Basic and diluted net loss per common share	\$ (0.02)	\$ (0.01)	\$ (0.02)	\$ (0.02)

	Three months ended			
	September 30, 2018	June 30, 2018	March 31, 2018	December 31, 2017
<b>Statement of operations data</b>				
Product revenue	\$ 1,583	\$ 1,952	\$ 1,624	\$ 1,779
Licensing and other revenue	-	150	-	600
Cost of goods sold	777	1,029	1,027	1,328
Royalty Buyout/Minimum royalty	-	4,266	2,414	-
Research and development	751	604	472	674
Selling, general & administrative expense	2,159	2,231	1,783	3,070
Finance costs, net	765	382	382	(914)
Income tax expense	2	-	-	47
Net loss	(2,871)	(6,410)	(4,454)	(1,826)

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

- In Q2 2019 we had previously impaired inventory by \$0.3 million and accrued \$0.5 million related to replacing products, discounts and potential returns due to the issue described regarding certain Natesto® lots released in the Canadian and South Korean markets. However, due to the additional delays, the Company reversed the previous accruals related to discounts and replacement of product and has accrued \$0.7 million for returns in Q3 2019 causing negative net sales and cost of goods values for the quarter.
- The fluctuation in product revenue balances are mainly due to the timing of Natesto® inventory shipments to Aytu in the U.S. and declining Estrace® sales offset by increased sales of Natesto® and UriVarx® in Canada. Q1 2019 also reflects a one-time adjustment of \$0.7 million to recognize top-up revenue for the Natesto® units Aytu currently has on hand. Revenues in Q3 2019 reflect the temporary shortage of Natesto® in the Canadian and South Korean markets.

- 2019 research and development expenses include an accrual for the Health Canada NDS filing fees for avanafil and clinical trial expenses related to the cardiovascular trial in the U.S.
- Operating expenses have increased over the period due to additional personnel to support the growth of the Company and additional selling expenses related to Natesto<sup>®</sup> Canada (launched in Q4 2016) and UriVarx<sup>®</sup> (launched in Q1 2018). Q3 2019 operating expenses have significantly increased over prior quarters, reflecting the additional spend in anticipation of the closing of the Amended and Restated License Agreement (“A&R Agreement”) with Aytu to co-promote Natesto<sup>®</sup> in the US.
- 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 and in Q1 2019 by a further \$2.5 million due to an anticipated shortage of certain doses of the product caused by an issue with our contract manufacturer.
- We reached a mutual agreement with Innovus to terminate the exclusive distributor and license agreement for UriVarx effective June 1, 2019. We impaired the intangible asset by a net of \$0.1 million.

### Select consolidated financial information

The following table sets forth selected consolidated data for the three months ended September 30, 2019 and 2018 as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Statement of operations data				
Revenue	\$ (167)	\$ 1,583	\$ 3,254	\$ 5,309
Operating loss	(3,849)	(2,104)	(10,542)	(12,204)
Net Loss	(4,612)	(2,871)	(12,246)	(13,735)
Basic and diluted net loss per common share	\$ (0.02)	\$ (0.01)	\$ (0.05)	\$ (0.06)
Balance sheet data:				
	September 30,	December 31,		
	2019	2018		
Total assets	\$ 13,885	\$ 16,824		
Long-term debt	13,417	8,287		

### Review of operating results – Nine months ended September 30,

#### Revenue and gross profit

	Nine months ending September 30,			
	2019	2018	Change \$	Change %
Revenue				
Product revenue	\$ 3,254	\$ 5,159	\$ (1,905)	(37)%
Licensing and other revenue	-	150	(150)	(100)%
	3,254	5,309	(2,055)	(39)%
Cost of goods sold	1,847	2,833	(986)	(35)%
Royalty buyout	-	6,680	(6,680)	(100)%
Gross margin	\$ 1,407	\$ (4,204)	\$ 5,611	133 %

Revenue decreased from \$5.3 million for the nine months ended September 30, 2018 to \$3.3 million for the same 2019 period. The decrease in product revenue is mainly due to the decrease in Estrace<sup>®</sup> sales due to the presence of a generic and conservation measures taken by management due to the supply issue with our third party contract manufacturer. Revenues were also impacted by higher Tier 1 revenues in the 2018 period due to two shipments of inventory to Aytu and the voluntary recall of Natesto<sup>®</sup> product in Canada and South Korea in 2019. For the nine months ended September 30, 2019 there was an accrual of \$0.7 million to account for additional returns related to the product recall of certain lots of Natesto<sup>®</sup> in the Canadian and South Korean market (see note below). This is offset by a one-time adjustment to recognize top-up revenue for the Natesto<sup>®</sup> units Aytu had on hand in Q1 2019, continued increase in Natesto<sup>®</sup> and UriVarx<sup>®</sup> sales in Canada and additional Tier 2 revenue earned from Natesto<sup>®</sup> in the U.S.

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 Tier 2 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.

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 nine months ended September 30, 2019 were \$1.8 million compared to \$2.8 million for the same prior year period. Current period gross margins are impacted by the one-time top-up revenue adjustment recognized in the first quarter.

On August 2, 2019, we announced that we will voluntarily replace certain Natesto® lots released in the Canadian and South Korean markets, which is expected to cause temporary shortages in those markets. We have identified four commercial lots of Natesto® released in the Canadian and South Korean markets that were found to be non-conforming during long-term stability studies, even though such lots were fully in-specification at the time of release. This post-release non-conformity is not harmful to the patient, but may result in difficulties in dispensing.

We made minor modifications to the manufacturing process that appear to have resolved the previously identified issues and have produced a batch of Natesto® (the “Revised Batch”). While we believed the changes would have been classified by Health Canada as level III, thereby requiring only an annual notification update to Health Canada and allowing for product to be released in Q4-2019, Health Canada, after much deliberation, classified the modifications as level I, requiring the submission of a SNDS prior to the release of the Revised Batch in the Canadian market. In the event that Health Canada utilizes the full regulatory allotted time for reviewing a SNDS, we would expect the Revised Batch to be released in the Canadian Market in Q1-2021. We continue to work with Health Canada to facilitate an expeditious review of the SNDS and minimize market disruptions.

At this time, the current supply of Natesto® to the United States is not affected by this situation. We are working with our South Korean partner to determine whether the Revised Batch can be released in the South Korean market and, if so, under what timeframes.

In Q2 2019, we had previously impaired inventory by \$0.3 million and accrued \$0.5 million related to replacing products, discounts and potential returns due to the issue described above. However, due to the additional delays, the Company reversed the previous accruals related to discounts and replacement of product and has accrued \$0.7 million for returns in the current quarter.

In the nine months ended September 30, 2018, we expensed \$6.7 million related to the Mattern Buyout.

#### *Operating expenses*

	Nine months ending September 30,			
	2019	2018	Change \$	Change %
Operating expenses				
Research and development	\$ 2,307	\$ 1,827	\$ 480	26 %
Selling, general and administrative	9,642	6,173	3,469	56 %
	<u>\$ 11,949</u>	<u>\$ 8,000</u>	<u>\$ 3,949</u>	<u>49 %</u>

#### *Research and development*

Research and development expenses have increased by \$0.5 million for the nine months ended September 30, 2019 versus the same prior year period. Product development and professional fees increased by a net of \$0.2 million mainly due to Health Canada NDS filing fees and related work for avanafil and preparation of filing of various pipeline products. Clinical trial expenses increased by \$0.4 million mainly due to costs associated with the various Natesto® studies, a cardiovascular trial in the U.S. and cannabinoid trial costs. This is offset by a \$0.2 million decrease in salaries and benefits due to changes in bonus accruals and number of employees.

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-housed developed technologies in the future.

#### *Selling, general and administrative*

Selling, general and administrative expenses increased by \$3.5 million over the prior year period. The main increase is due to a \$2.5 million impairment charge to the Estrace® intangible asset due to an anticipated shortage of certain doses of the product caused by an issue with our contract manufacturer. Professional fees and selling costs have increased by \$1.3 million combined mainly due to costs incurred in anticipation of the closing of the A&R Agreement with Aytu, offset by greater expenses in the 2018 period relating to UriVarx® and Natesto® Canada. Selling expenses for Natesto® Canada have decreased significantly in Q3 2019 due to the voluntary recall of certain lots in August 2019. Salaries and benefits increased by \$0.1 million due to increased headcounts and severance accrual offset by adjustments to bonus accruals. The \$0.1 million increase in travel expenses can also be attributed to additional headcounts

and increased activities. This is offset by a \$0.1 million decrease in share-based compensation and a \$0.4 million decrease in business development expenses.

Anticipating a potential shortage of certain strengths of Estrace<sup>®</sup> over the next six months, we impaired the related intangible asset by \$2.6 million at December 31, 2018. In 2019, we were informed of further delays our contract manufacturer would have in producing product. As such, we determined that the intangible asset related to Estrace<sup>®</sup> had been further impaired by \$2.5 million. We are currently working with an alternative manufacturer to produce product.

#### *Other expenses*

	Nine months ending September 30,			
	2019	2018	Change \$	Change %
Other expenses/(income)				
Interest on long-term debt and other financing costs	\$ 1,868	\$ 1,276	\$ 592	46 %
Interest income	(6)	(12)	6	50 %
Foreign exchange (gain)/loss	(94)	353	(447)	(127)%
Change in fair value of derivative financial instruments	(64)	(88)	24	27 %
	\$ 1,704	\$ 1,529	\$ 175	11 %

The \$0.6 million increase in interest on long-term debt and other financing costs for the nine months ended September 30, 2019 over the same prior year period is mainly due to the higher outstanding principal balance of long-term debt (\$14.0 million as at September 30, 2019 versus \$5.0 million as at September 30, 2018), the \$0.2 million deferral fee, \$0.2 million in accretion expense related to the Mattern Buyout agreement and \$0.1 million related to the SWK warrant modification and issuance. The prior year figures were impacted by the accelerated amortization of the Quantius credit facility financing fees and royalty accrual due to the early retirement of the facility in October 2018.

The foreign exchange gain 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 and modification of warrants issued as part of the New Facility and the fluctuation of the share price in relation to the exercise price of the warrants issued.

### **Review of operating results – Three months ended September 30,**

#### *Revenue and gross profit*

	Three months ending September 30,			
	2019	2018	Change \$	Change %
Revenue				
Product revenue	\$ (167)	\$ 1,583	\$ (1,750)	(111)%
Licensing and other revenue	-	-	-	n/a
	(167)	1,583	(1,750)	(111)%
Cost of goods sold	(124)	777	(901)	(116)%
Gross margin	\$ (43)	\$ 806	\$ (849)	(105)%

Product revenue decreased from \$1.6 million for the three months ended September 30, 2018 to negative \$0.2 million for the same 2019 period. The decrease in product revenue is mainly due to the decrease in Estrace<sup>®</sup> sales due to the presence of a generic and conservation measures taken by management due to the supply issue with our third party contract manufacturer. Revenues were also impacted by the voluntary recall of Natesto<sup>®</sup> product in Canada and South Korea in 2019 and the termination of UriVarx sales in June 2019. In Q2 2019, we accrued \$0.1 million in discounts and potential returns due to the recall and \$0.4 million related to cost to replace units in the channel. However, due to the additional delays, in Q3 2019 we reversed this accrual and accrued \$0.7 million for expected returns in the quarter leading to the negative values in both product revenues and cost of goods sold.

Cost of goods sold for the three months ended September 30, 2019 were negative \$0.1 million compared to \$0.8 million for the same prior year period. In the current period, amortization of intangible assets and depreciation of fixed assets accounts for \$0.2 million of the expense in cost of goods sold. The reversal of the \$0.4 million Q2 2019 accrual related to the cost to replace recalled Natesto<sup>®</sup> product, as described above, has led to the negative values in cost of goods sold for the quarter.

### Operating expenses

	Three months ending September 30,			
	2019	2018	Change \$	Change %
Operating expenses				
Research and development	\$ 622	\$ 751	\$ (129)	(17)%
Selling, general and administrative	3,184	2,159	1,025	47 %
	<u>\$ 3,806</u>	<u>\$ 2,910</u>	<u>\$ 896</u>	<u>31 %</u>

### Research and development

Research and development expenses have decreased by \$0.1 million for the three months ended September 30, 2019 versus the same prior year period. The \$0.1 million increase in clinical trial expenses mainly due to costs associated with the various Natesto<sup>®</sup> studies and a cardiovascular trial in the U.S. are offset by \$0.1 million decrease in professional fees and \$0.1 million decrease in salaries and benefits due to changes in bonus accruals and number of employees.

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-housed developed technologies in the future.

### Selling, general and administrative

Selling, general and administrative expenses increased from \$2.2 million for the three months ended September 30, 2018 to \$3.2 million for the same 2019 period. Professional fees and selling costs have increased by \$1.5 million combined mainly due to costs incurred in anticipation of the closing of the A&R Agreement with Aytu, offset by greater expenses in the 2018 period relating to UriVarx<sup>®</sup> and Natesto<sup>®</sup> Canada. Selling expenses for Natesto<sup>®</sup> Canada have decreased significantly in Q3 2019 due to the voluntary recall of certain lots in August 2019. Salaries and benefits decreased by \$0.4 million due to bonus accrual adjustments and decreased headcount. Business development expenses also decreased by \$0.1 million over the prior year period as a result of lower activities.

### Other expenses

	Three months ending September 30,			
	2019	2018	Change \$	Change %
Other expenses/(income)				
Interest on long-term debt and other financing costs	\$ 702	\$ 718	\$ (16)	(2)%
Interest income	(5)	(3)	(2)	(67)%
Foreign exchange (gain)/loss	91	48	43	90 %
Change in fair value of derivative financial instruments	(25)	2	(27)	1,350 %
	<u>\$ 763</u>	<u>\$ 765</u>	<u>\$ (2)</u>	<u>(0)%</u>

The \$0.1 million increase in interest on long-term debt and other financing costs for the three months ended September 30, 2019 over the same prior year period is mainly due to the higher outstanding principal balance of long-term debt (\$14.0 million as at September 30, 2019 versus \$5.0 million as at September 30, 2018) and \$0.1 million in accretion expense related to the Mattern Buyout agreement. The 2018 figures include a royalty accrual expense of \$0.2 million due to the early retirement of the Quantius facility in Q3 2018.

The 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 and modification of warrants issued as part of the New Facility and the fluctuation of the share price in relation to the exercise price of the warrants issued.

## Financial position

The following table presents a summary of our financial position:

	September 30, 2019	December 31, 2018	Change \$	Change %
Working capital (total current assets less total current liabilities)	\$ (896)	\$ 1,959	\$ (2,855)	(146)%
Non-current assets	6,385	9,200	(2,815)	(31)%
Long-term obligations	14,297	11,230	3,067	27 %
Shareholders' equity	(8,808)	(71)	(8,737)	12,306 %

### *Working capital*

The \$2.9 million decrease in working capital from December 31, 2018 to September 30, 2019 reflects the following:

- \$0.8 million decrease in accounts receivable due to timing of sales and collections
- \$0.9 million decrease in inventory mainly due to the sale of related products and a \$0.3 million impairment charge to Canadian Natesto® inventory
- \$2.7 million increase in accrued liabilities mainly due to the timing of expenses and payments, \$2.1 million additional payables due to activities in anticipation of the closing of the A&R Agreement with Aytu and \$0.7 million due to the accruals related to the voluntary product recalls of certain batches of Natesto® in Canada and South Korea.
- \$0.1 million increase in the current portion of lease liability due to the implementation of IFRS 16

This is offset by:

- \$0.3 million increase in cash due to proceeds from a debt issuance of \$5.0 million and a private placement of \$3.4 million offset by \$6.9 million being used in operating activities, \$1.2 million used in other financing activities, \$0.1 million used in the acquisition of product rights and fixed assets and \$0.1 million exchange gain on cash.
- \$0.5 million increase in contract asset mainly due to the one-time adjustment to recognize top-up revenue for the units Aytu currently has on hand.
- \$0.8 million increase in prepaids mainly due to deposits for inventory production

### *Non-current assets*

Non-current assets consist of property and equipment, right of use asset and intangible assets. Property and equipment mainly consist of office, lab and manufacturing equipment, fixtures, and leasehold improvements. Right of use asset relates to the lease on the Canadian facilities. Intangible assets consist of technology, patents and product rights. The \$0.2 million decrease in property and equipment from December 31, 2018 to September 30, 2019 is primarily due to depreciation and amortization expense and impact of foreign exchange.

At September 30, 2019 manufacturing equipment with a net book value of \$0.6 million was held off-site by a third party (\$0.7 million at December 31, 2018).

The addition of the right of use asset relates to the application of the IFRS 16 *Leases* standard on January 1, 2019. The balance reflects the discounted lease payments adjusted for prepaid balances, lease incentives earned, any initial direct costs and any restoration costs. The standard was applied on a modified retrospective basis from January 1, 2019 with no restatement of comparatives as permitted under the specific transitional provisions in the standard.

Intangible assets decreased due to the impairment charge of \$2.5 million related to Estrace® and UriVarx®, amortization expense of \$0.6 million offset by \$0.2 million in additions and foreign exchange effect on the Canadian balance of intangible assets.

### *Long-term obligations*

As at September 30, 2019 long-term obligations consist of long-term debt, derivative financial instruments and lease liability.

As at December 31, 2018 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 extinguished on October 12, 2018 with payments of principal, accrued interest pre-payment penalty and royalty retirement fee.

On September 30, 2019 we received a waiver letter from SWK waiving the requirement to comply with the Adjusted EBITDA and Aggregate Revenue covenants as at September 30, 2019 contained in the credit agreement.

We also amended the agreement to set the minimum threshold for Consolidated Unencumbered Liquid Assets required for us to maintain. This amount is defined in the agreement as cash adjusted for a certain portion of accounts receivable and payable. This level will be set at (i) \$1.0 million at September 30, 2019; (ii) \$5.0 million at December 15, 2019; (iii) \$4.0 million at December 31, 2019; (iv) \$2.0 million at January 31, 2020, and (v) \$1.0 million at all times after January 31, 2020. In connection with the amendment, we agreed to reprice 5,331,563 outstanding Original Warrants from CDN\$0.40 to CDN\$0.11. In addition, the Original Warrants' expiry date has been extended from October 11, 2023 to September 30, 2024. No other changes were made to the term of the Original Warrants. On October 3, 2019, the Company issued 1,361,544 New Warrants to SWK in connection with the amendment. Each New Warrant will entitle SWK to purchase one common share of Acerus at an exercise price of CDN\$0.11 per common share and will expire on September 30, 2024. The terms of the New Warrants will otherwise be identical to those of the Original Warrants. As such, in certain circumstances, we may cause SWK to exercise the New Warrants prior to their expiry date if the closing price of our common shares on the TSX exceeds CDN\$0.80 per share for a period of at least 21 consecutive trading days. The obligation to issue these shares is recorded as a warrant derivative liability on the balance sheet as of September 30, 2019 with a value of \$0.1 million.

On July 18, 2019, we entered into a \$5.0 million subordinated secured term loan facility with First Generation, a company affiliated with the Chairman of the Board of Directors of Acerus. The Loan is subordinated to the existing \$9.0 million facility with SWK and bears interest at a rate per annum equal to the three-month LIBOR, plus an applicable margin of 10.50%. Subject to the terms of the subordination and intercreditor agreement between First Generation and SWK, the Loan is repayable in full on December 31, 2020, is interest-only until maturity with regularly scheduled payments of interest to First Generation being permitted subject to certain conditions related to Acerus' market capitalization and aggregate annual revenue, and can be prepaid in full or in part without penalty following repayment in full of indebtedness owing to SWK. As of September 30, 2019, the Company had \$5.0 million outstanding on the credit facility.

The addition of the lease liability relates to the application of the IFRS 16 *Leases* standard on January 1, 2019. The balance reflects the discounted future lease payments. The standard was applied on a modified retrospective basis from January 1, 2019 with no restatement of comparatives as permitted under the specific transitional provisions in the standard. The deferred lease inducement balances were eliminated with the application of the new standard.

#### *Shareholders' deficiency*

We are authorized to issue an unlimited number of common shares. As at September 30, 2019, we had 261,225,290 common shares issued and outstanding, 23,584,624 warrants outstanding and exercisable for 23,584,624 common shares, 13,354,215 outstanding stock options with a weighted average exercise price of CDN\$0.18.

The \$8.7 million decrease in shareholders' equity from December 31, 2018 to September 30, 2019 is primarily due to \$12.2 million in net loss, \$0.1 million adjustment of IFRS 16 *Leases*, offset by the less than \$0.1 million foreign currency translation adjustment, \$0.2 million in share-based compensation and \$3.7 million increase in share capital which includes a cashless exercise of options of \$0.3 million.

On March 29, 2019 we closed a non-brokered private placement of 23,230,772 common shares to certain directors and officers at a price of CDN\$0.195 per common share for net proceeds of \$3.4 million.

### **Liquidity and capital resources**

#### **Liquidity risk**

As detailed in the long-term obligations section above, as at September 30, 2019, there is \$9.0 million of principal outstanding on the New 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. As we did not satisfy the specified conditions, we were unable to draw on the additional \$2.0 million. The terms of the agreement also contain customary financial covenants some of which were amended on June 28, 2019. A portion of the proceeds from the New Facility was used to retire the Endo and Quantius facilities.

On September 30, 2019 we received a waiver letter from SWK waiving the requirement to comply with the Adjusted EBITDA and Aggregate Revenue covenants as at September 30, 2019 contained in the credit agreement.

We also amended the facility to set the minimum threshold for Consolidated Unencumbered Liquid Assets required for us to maintain and reprice 5,331,563 outstanding Original Warrants currently held by SWK that were issued with the signing of the credit agreement in 2018. The Original Warrants were repriced from CDN\$0.40 to CDN\$0.11. In addition, the Original Warrants' expiry date has been extended from October 11, 2023 to September 30, 2024. No other changes were made to the term of the Original Warrants. On October 3, 2019, the Company issued 1,361,544 New Warrants to SWK in connection with the amendment. See "Long-term obligations" section for more detail.

On July 18, 2019, we entered into a \$5.0 million subordinated secured term loan facility with First Generation, a company affiliated with the Chairman of the Board of Directors of Acerus. The Loan is subordinated to the existing \$9.0 million facility with SWK and bears interest at a rate per annum equal to the three-month LIBOR, plus an applicable margin of 10.50%. Subject to the terms of the subordination and intercreditor agreement between First Generation and SWK, the Loan is repayable in full on December 31, 2020, is interest-only until maturity with regularly scheduled payments of interest to First Generation being permitted subject to certain conditions related to Acerus' market capitalization and aggregate annual revenue, and can be prepaid in full or in part without penalty following repayment in full of indebtedness owing to SWK. As of September 30, 2019, we had \$5.0 million outstanding on the credit facility.

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 unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2019 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 with lenders 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):	For the nine months ended September 30,			
	2019	2018	Change \$	Change %
Operating activities	\$ (6,905)	\$ (5,482)	\$ (1,423)	26 %
Financing activities	7,164	3,888	3,276	(84)%
Investing activities	(108)	(244)	136	(56)%
Exchange (loss)/gain on cash	114	(87)	201	(231)%
Net increase/(decrease) in cash	\$ 265	\$ (1,925)	\$ 2,190	114 %

At September 30, 2019 we had a cash balance of \$4.1 million.

The cash outflow from operating activities for the nine months ended September 30, 2019 is a result of a \$12.2 million net loss offset by \$5.5 million in non-cash expenses and \$0.2 million outflow from working capital. The cash outflow from operating activities for the nine months ended September 30, 2018 are a result of a \$13.7 million net loss, offset by \$3.3 million in non-cash expenses and net \$4.9 million inflow from working capital. The net inflow from working capital is largely due the \$6.7 million Mattern Buyout accrual.

The cash from financing activities for the nine months ended September 30, 2019 are mainly from the issuance of long-term debt of \$5.0 million and the non-brokered private placement which brought in a net of \$3.4 million. This is offset by interest payments of \$1.1 million and principal elements of lease payments of \$0.1 million. The cash used in financing activities in the nine months ended September 30, 2018 is mainly a result of net proceeds of \$4.4 million from issuance of common shares and warrants and \$1.6 million from proceeds of debt, offset by \$1.5 million debt principal payments and \$0.6 million interest and financing fee payments.

Cash used in investing activities for the nine months ended September 30, 2019 are related to the additional milestone payment of \$0.1 million made on filing the NDS for avanafil. Cash used in investing activities for the nine months ended September 30, 2018 is related to the purchase of the Canadian product rights of UriVarx® and the purchase of laboratory equipment.

## Capital expenditures

Our 2019 capital expenditures primarily related to our investment in laboratory assets.

## Contractual obligations and commitments

As of September 30, 2019, 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	6 months - 1 year	Between 1 and 2 years	Between 2 and 5 years	Total
Accounts payable and accrued liabilities	\$ 5,583	\$ 389	\$ 2,500	\$ -	\$ -	\$ 8,472
Purchase commitments	711	-	-	-	-	711
Lease liability (principal and interest)	29	33	66	132	396	656
Long-term debt (principal and interest)	302	299	600	8,857	9,070	19,128
As at September 30, 2019	\$ 6,625	\$ 721	\$ 3,166	\$ 8,989	\$ 9,466	\$ 28,967

Please refer to the “Long-term debt financing” sections for details on the SWK and First Generation loans.

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 nine months ended September 30, 2019 and 2018 were as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Short-term compensation of key management and directors	\$ 208	\$ 572	\$ 768	\$ 1,184
Termination benefits	-	-	363	-
Share-based compensation	51	110	141	280
Interest accrued	128	-	128	-
Professional fees paid or payable to firms affiliated with directors & officers	-	-	-	189
	\$ 387	\$ 682	\$ 1,400	\$ 1,653

These transactions are in the normal course of operations.

Executive employment agreements allow for total additional payments of approximately \$1.3 million if a change in control occurs, \$1.2 million if all are terminated without cause, and \$nil if all are terminated with cause.

As at September 30, 2019, we had a \$6.0 receivable (\$2.1 million receivable as at December 31, 2018) to its wholly owned subsidiary ABI. The receivable is non-interest bearing, due on demand and eliminates upon consolidation except for the foreign exchange gain of \$0.1 million and loss of \$0.1 million for the three and nine months ended September 30, 2019 (gain of \$0.1 million and loss of \$0.3 million for the three and nine months ended September 30, 2018) that has been recorded in the consolidated statement of loss.

As of September 30, 2019, the Company had \$5.0 million outstanding on a subordinated secured term loan facility with First Generation, a company affiliated with the Chairman of the Board of Directors of Acerus. Please see note in “Long-term debt financing” for more details. At September 30, 2019 the Company had \$0.1 million in interest expense and \$0.1 million outstanding in accounts payable related to the loan.

### 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 September 30, 2019, 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 September 30, 2019 the fair value of the long-term debt approximates its face value of \$14.0 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.

	September 30, 2019		
	USD	EUR	GBP
Cash	\$ 3,861	\$ -	\$ -
Trade and other receivables	173	-	-
Intercompany receivable	5,986	-	-
Accounts payable and accrued liabilities	(2,956)	(270)	(15)
Long-term debt	(14,000)	-	-
	\$ (6,936)	\$ (270)	\$ (15)

Based on the above net exposure at September 30, 2019, 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%	\$ 330	\$ (14)	\$ (1)	\$ 315
Depreciate 5%	(365)	14	1	(350)

### 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. We have 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. We have an interest rate of LIBOR + 10.5% per annum for the First Generation Loan.

A 0.5% appreciation in the present LIBOR rate would lead to an increase of \$171 of interest payments for the life of the loan. A 0.5% depreciation in the present LIBOR rate would lead to a decrease of \$171 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 16% of our trade receivables are due from one pharmaceutical wholesaler in Canada and 56% from an out-licensing partner.

As at September 30, 2019, 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 immaterial impact on our net loss.

### 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 16 on January 1, 2019.

We adopted IFRS 16 on a modified retrospective basis from January 1, 2019, with no restatement of comparatives, as permitted under the specific transitional provisions in the standard. The reclassifications and the adjustments arising from the new leasing rules are therefore recognized in the opening balance sheet on January 1, 2019.

On adoption of IFRS 16, we recognized lease liabilities in relation to leases which had previously been classified as operating leases under the principles of IAS 17 *Leases*. These liabilities were measured at the present value of the remaining lease payments excluding renewal options as they are not reasonably certain that the options will be exercised, discounted using our incremental borrowing rate as of January 1, 2019. The weighted average incremental borrowing rate applied to the lease liabilities on January 1, 2019 was 6.25%.

The following is a reconciliation of total operating lease commitments at December 31, 2018 to the lease liabilities recognized at January 1, 2019:

Total operating lease commitments disclosed at December 31, 2018	\$	1,152
Variable lease payments not recognized in lease liability		(357)
Operating lease liabilities before discounting		795
Discounted using incremental borrowing rate		(135)
<b>Total lease liabilities recognized under IFRS 16 at January 1, 2019</b>	<b>\$</b>	<b>660</b>
Of which are:		
Current lease liabilities		78
Non-current lease liabilities		582

The associated right-of-use asset for the property lease was measured on a retrospective basis as if the new rules had always been applied adjusted by the amount of any prepaid or accrued lease payments and deferred lease inducement relating to that lease recognized in the statement of financial position as at December 31, 2018. There were no onerous lease contracts that would have required an adjustment to the right-of-use assets to the date of initial application.

The recognized right-of-use asset relates to the lease on the Canadian facilities. The change in accounting policy affected the following items in the statement of financial position on January 1, 2019:

- Right-of-use assets – increased by \$296
- Prepaid and other assets – decreased by \$26
- Lease liabilities - increased by \$660
- Accrued lease rentals – decreased by \$31
- Deferred lease inducement – decreased by \$300

The net impact on deficit on January 1, 2019 was an increase of \$59. Segment assets for September 30, 2019 increased by \$244 as a result of the change in account policy.

In applying IFRS 16 for the first time, the Company used the following practical expedients permitted by the standard:

- reliance on previous assessments on whether leases are onerous
- elected to account for the payments for short-term leases and leases of low-value assets as an expense in the statement of loss on a straight-line basis over the lease term
- the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

For the three and nine months ended September 30, 2019 depreciation of the right of use asset was \$12 and \$35 respectively. The right of use asset is depreciated on a straight-line basis over the term of the lease.

Right of use asset, January 1, 2019	\$	296
Depreciation of right of use asset		(35)
Foreign exchange effect		9
Right of use asset, September 30, 2019	\$	270

For the three and nine months ended September 30, 2019 finance charges on the lease liability were \$9 and \$28 respectively (included in Interest on long-term debt and other financing costs in the consolidated statement of loss and comprehensive loss) and the expense related to variable lease payments not included in the measurement of lease liabilities was \$13 and \$47 respectively (included in selling, general & administrative expenses in the consolidated statement of loss and comprehensive loss). The lease term matures on June 30, 2025.

Lease liabilities, January 1, 2019	\$	660
Payments		(59)
Foreign exchange effect		18
Lease liabilities, September 30, 2019		619
Current lease liabilities		94
Non-current lease liabilities	\$	525

The lease liability will mature on June 30, 2025. As at September 30, 2019, we had the following obligations to make future payments related to the lease liabilities:

	September 30,
	2019
No later than 1 year	\$ 128
Later than 1 year and no later than 5 years	529
Later than 5 years	72
	729
Finance charges	(110)
Total lease liabilities	\$ 619

Until December 31, 2018, leases of property and equipment were classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) were charged to profit or loss on a straight-line basis over the period of the lease.

From January 1, 2019, leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to comprehensive loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of fixed lease payments.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be determined, the lessee's incremental borrowing rate is used, being the rate that the lessee would have to pay to borrow the funds necessary to obtain an asset of similar value in a similar economic environment with similar terms and conditions. Subsequent to initial measurement, the liability will be reduced for payments made and increased for interest. It is remeasured to reflect any reassessment or modification, or if there are changes in substance fixed payments. When the lease liability is remeasured, the corresponding adjustment is reflected in the right-of-use asset, or comprehensive loss if the right-of-use asset is already reduced to zero.

Right-of-use assets are measured at cost comprising the following:

- The amount of the initial measurement of lease liability
- Any lease payments made at or before the commencement date less any lease incentives received
- Any initial direct costs, and
- Any restoration costs

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in comprehensive loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise IT-equipment.

#### **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 unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2019 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 with lenders 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.

Historically, we recognized revenue for certain partners in two steps: 1) at a contractual supply price when the product is delivered to the marketing partner; and 2) an additional top-up amount is earned based on a pricing schedule when the marketing partner recognizes sales of the product. Variable additional top-up amounts were estimated based on the partner's reported net sales for the period. We previously only recognized the top-up revenue when the partner sold the product as it was unable to reliably estimate its portion of revenue. While we still do this for our South Korean partner, we believe there are sufficient stable historical results to estimate the top-

up revenue earned per unit that is highly probable of not resulting in a significant reversal of cumulative revenue in the future for our U.S. partner. As of January 1, 2019, we will recognize revenue for this partner on delivery of the product as the sum of two items: 1) the contractual supply price when the product is delivered; 2) an estimate of the top-up revenue that is highly probable will be earned when the marketing partner recognizes sale of the product. An adjustment will be made, if required, to the actual top-up revenue earned when the marketing partner recognizes sale of the product. As this change was done in 2019 we made a one-time adjustment to revenue of \$0.7 million to recognize top-up revenue for the units Aytu currently has in inventory.

License and other revenue mainly consist 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 our 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, 2018 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.

#### Lease liability

In determining the lease term, management considers all the facts and circumstances that create an economic incentive to exercise an extension option, or not exercise a termination option. The extension option is only included in the lease term if the lease is reasonably certain to be extended. The assessment is reviewed if a significant event or a significant change in circumstances occurs which affects this assessment and that is within management's control.

The lease payments are discounted using the interest rate implicit in the lease. As that rate could not be determined, management estimated our incremental borrowing rate, being the rate, we would have to pay to borrow the funds necessary to obtain an asset of similar value in a similar economic environment with similar terms and conditions.

### 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 the impact of charges related to a product recall. 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 nine months ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Net (loss)	\$ (4,612)	\$ (2,871)	\$ (12,246)	\$ (13,735)
Adjustments:				
Income tax	-	2	-	2
Amortization of intangible assets	177	447	642	1,300
Depreciation of property and equipment	64	64	191	193
Depreciation of right of use asset	12	-	35	-
Interest on long-term debt and other financing costs*	702	718	1,868	1,276
Interest income	(5)	(3)	(6)	(12)
Change in fair value of derivative	(25)	2	(64)	(88)
<b>EBITDA</b>	<b>\$ (3,687)</b>	<b>\$ (1,641)</b>	<b>\$ (9,580)</b>	<b>\$ (11,064)</b>
Licensing and other revenue	-	-	-	(150)
Royalty expense/Buyout	-	-	-	6,680
Share based compensation	57	111	163	337
Foreign exchange loss/(gain)	91	48	(94)	353
Charges related to product recall	184	-	976	-
Impairment loss on intangible asset	-	-	2,536	-
<b>Adjusted EBITDA</b>	<b>\$ (3,355)</b>	<b>\$ (1,482)</b>	<b>\$ (5,999)</b>	<b>\$ (3,844)</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 September 30, 2019 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 Company's Disclosure Committee and continuous review and monitoring procedures by senior management.

As at September 30, 2019 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 nine months ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.

## **Litigation**

### *Schenk Litigation*

Valeant Pharmaceuticals International, Inc. and Valeant International Bermuda ("Valeant") are defendants in Ontario Superior Court of Justice Action No. CV-11-438382, which claims a declaration that Valeant is contractually obligated to compensate the plaintiff, Reiner Schenk ("Schenk") pursuant to the terms of a contract between Schenk and Biovail Corporation. The main action was commenced by Notice of Action issued on October 31, 2011 and a Statement of Claim was issued on December 14, 2011. Acerus Pharmaceuticals Corporation was named as one of the defendants in the main action, but the action was discontinued as against Acerus on December 14, 2011. On October 29, 2013, Valeant commenced a third party claim against Acerus (among others) claiming contribution, indemnity and other relief over to the full extent that Valeant may be held liable to Schenk, and damages for breach of fiduciary duty, breach of contract and intentional interference with economic relations in any amount for which Valeant is found liable to Schenk. Acerus has defended the third party claim, denying any liability to Valeant. The parties have concluded examinations for discovery and are scheduled to attend a pre-trial conference in February 2020. The trial is scheduled to commence in April 2020 and is anticipated to be two weeks long. As at September 30, 2019, we have not accrued for any potential claims.

### **Additional information**

Additional information about Acerus, including the Company's Annual Information Form dated March 4, 2019, 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).