Management's Discussion & Analysis of
Acerus Pharmaceuticals Corporation
For the three and twelve months ended December 31, 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 twelve months ended December 31, 2019. This MD&A is dated March 3, 2020 and should be read in conjunction with the audited consolidated financial statements and accompanying notes for the year ended December 31, 2019.

The annual audited consolidated financial statements were prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board and are presented in thousands of United States ("U.S.") dollars except for per share amounts and unless otherwise noted. For more detailed information regarding certain forward-looking statements contained herein, please see the note regarding "Forward-looking Statements". The results of the operations, business prospects and financial condition of the Company will be affected by, among others, the "Risk Factors" set out in our Annual Information Form dated March 3, 2020 available at 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, or commercial transactions with lenders or investors (notwithstanding the refinancing completed on February 20, 2020 described in subsequent events note), 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 additional capital will be required. In addition, the shortage of certain strengths of Estrace® in 2020 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; First Generation's significant influence over matters put before the shareholders; 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 or similar providers; 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 securities analyst coverage of the Company; risks related to having limited experience in the U.S. market, risks related to the actions of its commercial partners, risks associated with the costs of complying with U.S. laws and regulations, risks related to controlled substances in the U.S., risks related to U.S. third party payer actions, risks related to U.S. federal coverage and reimbursement policies, risks related to training a U.S. sales force and risks related to evolving tariffs and trade policies between the U.S. and other countries.

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 3, 2020 under the heading "Risk Factors". Actual results, performance or achievement could differ materially from that expressed in, or implied by, any forward-looking information in this MD&A, and, accordingly, investors should not place undue reliance on any such forward-looking information. Further, any forward-looking information speaks only as of the date on which such statement is made and we undertake no obligation to update any forward-looking information to reflect the occurrence of unanticipated events, except as required by law. New factors emerge from time to time and the importance of current factors may change from time to time and it is not possible for us to predict all such factors, changes in such factors and to assess in advance the impact of each such factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking information contained in this MD&A.

Description of business

The consolidated financial statements represent the consolidated accounts of Acerus (incorporated in Ontario, Canada) and its wholly-owned subsidiaries, Acerus Labs Inc. ("ALI") (incorporated in Ontario), Acerus Biopharma Inc. ("ABI") (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. We commercialize our products via its own salesforce in the United States and through a global network of licensed distributors in other territories

We currently have two marketed products: Estrace®, a product for the symptomatic relief of menopausal symptoms, is commercialized in Canada; and Natesto®, the first and only testosterone nasal gel for testosterone replacement therapy in adult males diagnosed with hypogonadism, is commercialized in Canada and the U.S. UriVarx®, 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® has also been licensed for distribution in 68 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® for the treatment of hypogonadism. On July 10, 2019 we announced that Hyundai officially launched the commercialization of Natesto®. On August 2, 2019, we announced a voluntary recall and replacement of Natesto® 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). We currently do not expect the current supply of Natesto® to the U.S. to be 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 3, 2020 and our other filings available on SEDAR at www.sedar.com.

Key products and developments

Natesto®

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

Date	Company	Territory	Terms
April 22, 2016	Aytu BioScience Inc. ("Aytu")	United States	• Non-refundable upfront payments totaling $8.0 million • Sales-based milestones that could potentially total $37.4 million • Tiered supply price per unit • See note below on Amended and Restated agreement ("A&R Agreement") signed Q3 2019
December 15, 2016	Hyundai Pharm Co., Ltd ("Hyundai")	South Korea	• Non-refundable upfront fee • Milestone payment on regulatory approval • Tiered supply price per unit
June 5, 2017	Therios Healthcare ("Therios")	Saudi Arabia, United Arab Emirates, and Egypt	• Fixed supply price per unit
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 See additions on October 31, 2018	• Non-refundable upfront fee • Milestone payment on regulatory approval and sales-based milestone payments • Tiered supply price per unit
October 17, 2017	Eu Hwa Pte LTD. ("HWA")	Thailand, Malaysia/Brunei, Singapore, Vietnam, Philippines,	• Non-refundable upfront fee • Milestone payment on regulatory approval • Tiered supply price per unit

		Hong Kong/Macau and one other small South East Asian country	
November 23, 2017	Apsen Farmacêutica ("Apsen")	Brazil	• Non-refundable upfront fee • Milestone payment on regulatory approval • Tiered supply price per unit
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)	• Non-refundable upfront fee • Milestone payment on regulatory approval • Tiered supply price per unit
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.	• Non-refundable upfront fee • All other terms as per the original agreement

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 the Revised Batch of Natesto®. 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.

We currently do not expect the current supply of Natesto® to the United States to be 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 have expensed $1.1 million for costs related to this voluntary recall.

On January 10, 2020, we announced that the dossier filed as a Decentralized Procedure in 19 European countries for the approval of Natesto® had been withdrawn. The regulatory dossier was filed by our European licensee - medac Gesellschaft für klinische Spezialpräparate mbH ("medac"). The MPA (Swedish Health Authority), the Reference Member State (RMS) for the procedure, has requested that studies be completed, which were not otherwise required in other filings globally (including in Canada and the United States). After consulting with medac, we have mutually agreed to withdraw the application to allow for the completion of the studies. Subsequently it is aimed to re-submit the dossier with additional data.

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 licensing 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.

On December 2, 2019 we announced that we revised our commercial licensing agreement with Aytu Bioscience ("Aytu") to accelerate the growth of Natesto® in the Unitesd States closed and became fully effective as of December 1, 2019. Both parties mutually waived the closing conditions of the revised licensing agreement, including the requirement that we complete a raise of a minimum of $10.0 million on or before the end of January 2020.

To accelerate the launch of our U.S. commercial team, Aytu has agreed to transfer 5 current sales personnel to Acerus as of December 2, 2019. These staff will operate as Acerus employees but they will remain on Aytu's payroll until the earlier of the date on which Acerus is ready to fully assume the personnel or June 30, 2020. Aytu will deduct the costs of these sales personnel from quarterly payments otherwise owed to Acerus under the revised agreement, with a final accounting to be done once per year. Throughout 2020, Acerus will be building out a complete US-based specialty care sales force and other commercial functions, significantly increasing the number of employees working directly on Natesto® in the United States.

We have begun the process of preparing for the 2020 launch and have incurred costs of $3.7 million that have been expensed in selling, general and administrative expenses in the year ended December 31, 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 20, 2019, $2.0 million was paid in April 2019 which included a $0.2 million deferral fee, and $0.6 million was paid January 20, 2020 with the remaining $1.9 million and $0.2 million in deferral fee due April 19, 2020. We recorded an expense of $6.7 million in May 2018 representing the fair value of the $7.5 million obligations under the Buyout at that date. The fair value was estimated by discounting the payments using a rate of 14.75%.

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

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 the we are working towards securing supply of product in fiscal 2020.

A shortage of Estrace® may accelerate erosion of Estrace® sales due to the presence of the third-party generic. The intangible asset was written down to its recoverable amount in both 2018 and 2019 using a value-in-use discounted cash flow model. The most critical assumptions in determining the recoverable amount of this asset are in estimating when replacement product will be available and the impact that the current product shortage will have on our sales level in both the short and longer term due to the presence of the third party generic. Other key assumptions include estimating an appropriate pre tax discount rate reflecting current market assessments of the risks specific to this asset for which future cash flow estimates have not been adjusted, declining revenue growth rates, projected costs of goods sold using an alternative contract manufacturer and working capital requirements.

In the current years impairment model, we assumed we would receive more product to sell by the second quarter in fiscal 2020 (versus by September 2019 in the 2018 impairment model), annual sales would have declined at 12.5% a year absent the stock shortages, and that actual sales will recover to approximately half of the level that would be otherwise have been forecast in the absence of the product shortage by the end of the 5 year forecast period with a 12.5% declining terminal growth rate thereafter. The 2019 impairment model also reflects an increased cost of goods related to transferring the product to a different contract manufacturer. The projected cash flows have been discounted using a pre tax discount rate of 16.9%

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 we 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 granted 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 paid milestone payments based on achieving certain sales targets. Innovus oversaw the manufacturing of UriVarx® and received 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 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 gross proceeds of CDN$4.5 million.

Please see subsequent event note regarding a private placement and refinancing transactions.

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 was repayable in full on December 31, 2020, was 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 could have been prepaid in full or in part without penalty following repayment in full of indebtedness owing to SWK.

On December 18, 2019 we announced that we had amended the Loan to (i) increase the borrowed amount to $11.5 million ("the A&R Loan"), (ii) extend the maturity date to June 30, 2021 and (iii) cap the total amount of interest payable to First Generation under the A&R Loan (including interest paid from the closing of the original $5.0 million subordinated secured term loan facility) to an amount equal to CDN$1.7 million.

The other terms of the A&R Loan remained unchanged from the original facility. The A&R Loan continued to be subordinated to the existing $9.0 million facility with SWK and, subject to the cap on the total interest payable described above, bore interest at a rate per annum equal to the three-month London Inter-Bank Offered Rate, plus an applicable margin of 10.50%. Subject to the terms of the subordination and intercreditor agreement between First Generation and SWK, the A&R Loan was repayable in full on June 30, 2021, continued to be 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 could have been prepaid in full or in part without penalty following repayment in full of indebtedness owing to SWK. The proceeds from the A&R Loan will be used for ongoing general working capital.

Please see subsequent event note regarding a private placement and refinancing transactions.

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 were not able to draw on the additional $2.0 million on March 31, 2019.

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 was interest-only for the first two years of the term. Principal payments thereafter was based on a tiered percentage of net revenue with a cap of $0.6 million per quarter.

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 on maturity representing a single digit percentage of the principal amount actually advanced under the facility. We 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 trades at or above CDN$0.80 per share for a period of at least 21 consecutive trading days.

The proceeds from the New Facility was used primarily to (i) repay the amount outstanding under the Quantius Facility, including a prepayment penalty and royalty retirement fee; (ii) retire the Endo promissory note; and (iii) for ongoing general working capital.

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.

We also amended the debt agreement in September 2019 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. We were in compliance with this covenant at December 31, 2019.

In connection with the amendment, we agreed to reprice the 5,331,563 Original Warrants from CDN$0.40 to CDN$0.11. In addition, the Original Warrants' expiry date was 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, we issued 1,361,544 common share purchase warrants (the "new Warrants") to SWK in connection with the amendment. Each New Warrant entitled SWK to purchase one common share of Acerus at an exercise price of CDN$0.11 per common share and expired 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 issues these share purchase warrants are recorded as a warrant derivative liability on the balance sheet.

On December 16, 2019, we received a waiver letter from SWK ("SWK Waiver") waiving the requirement to comply with the Adjusted EBITDA and Aggregate Revenue covenants as at December 31, 2019 contained in the credit agreement. The amendment agreement also changed the set minimum threshold for Consolidated Unencumbered Liquid Assets required to be maintained by the Company from $1.0 million at all times after January 31, 2020 to $2.0 million.

The waiver of the covenants was contingent on us raising an additional $6.5 million prior to December 23, 2019. In connection therewith, we obtained a commitment letter from First Generation to amend and restate the $5.0 million subordinated secured term loan facility previously entered into on July 19, 2019 between Acerus and First Generation to (i) increase the borrowed amount to $11.5 million, (ii) extend the maturity date to June 30, 2021 and (iii) cap the total amount of interest payable to First Generation under the amended loan (including interest paid from the closing of the original $5.0 million subordinated secured term loan facility) to an amount equal to 9.99% of the market capitalization of our at the time of closing.

Please see subsequent event note regarding the February 2020 SWK Amendment.

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®, Natesto® and UriVarx® 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® product rights intangible asset and royalty expenses for Natesto®.

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 $0.7536 and $0.7718 respectively for the year ended December 31, 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 $0.7699 and $0.7330 at December 31, 2019 and 2018 respectively.

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 consolidated financial information

The following table sets forth selected consolidated data for the years ended December 31, 2019, 2018 and 2017 as follows:

	2019	2018	2017
Statement of operations data			
Product revenue	$ 3,575	$ 7,043	$ 5,348
Licensing revenue	193	334	1,187
Operating (loss)/income	(14,036)	(16,542)	(6,861)
Net Loss	(16,129)	(18,786)	(8,623)
Basic and diluted net (loss)/earnings per common share	$ (0.06)	$ (0.08)	$ (0.04)
Balance sheet data:			
Total assets	$ 15,440	$ 16,824	$ 22,254
Long-term debt	19,990	8,287	4,569

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

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

- The fluctuation in product revenue balances are mainly due to the timing of Natesto® inventory shipments to Aytu in the U.S. and declining Estrace® sales offset by increased sales of Natesto® and UriVarx® in Canada. Fiscal 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 were in 2019 were impacted by the voluntary recall of certain batches of Natesto® in Canada and South Korea. On August 2, 2019, we announced a voluntary recall and replacement of Natesto® in the Canadian and South Korean markets as several batches were found to be non-conforming during long-term stability studies. 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).
- 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.
- Operating (loss) for fiscal 2019 reflects cost cutting measures taken due to the decreased product revenue, an impairment of $2.5 million on the Estrace® intangible asset ($2.6 million in fiscal 2018) and $3.7 million in expenses related to launching a US-based speciality sales force, which will promote Natesto® to urologist and endocrinologist as part of the revised commercial licensing agreement with Aytu.

- In 2018 we extinguished the CDN$5.0 million debt form Quantius Inc. and the remainder of the promissory note to Endo with proceeds from the SWK credit facility of $9.0 million. We also took on an additional $11.5 million of debt from First Generation in fiscal 2019.

Review of operating results – the year ended December 31

Revenue and gross profit

	2019	2018	Change $	Change %
Revenue				
Product revenue	$ 3,575	$ 7,043	$ (3,468)	(49)%
Licensing and other revenue	193	334	(141)	(42)%
	3,768	7,377	(3,609)	(49)%
Cost of goods sold	2,199	3,644	(1,445)	(40)%
Royalty buyout	-	6,680	(6,680)	(100)%
Gross margin	$ 1,569	$ (2,947)	$ 4,516	153 %

Revenue decreased from $7.4 million for the year ended December 31, 2018 to $3.8 million for the same 2019 period. The decrease in product revenue is mainly due to the decrease in Estrace® 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® product in Canada and South Korea in 2019. For the year ended December 31, 2019 there was an accrual of $0.7 million to account for additional returns related to the product recall of certain lots of Natesto® 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® units Aytu had on hand in Q1 2019 and additional Tier 2 revenue earned from Natesto® in the U.S.

Natesto® 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 year ended December 31, 2019 were $2.2 million compared to $3.6 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. Cost of goods also reflects a $0.3 million inventory write off related to that Natesto® Canada voluntary recall.

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 the Revised Batch of Natesto®. 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.

We currently do not expect the current supply of Natesto® to the United States to be 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 the year ended December 31, 2018, we expensed $6.7 million related to the Mattern Buyout.

Operating expenses

	2019	2018	Change $	Change %
Operating expenses				
Research and development	$ 2,829	$ 2,398	$ 431	18 %
Selling, general and administrative	12,776	11,197	1,579	14 %
	$ 15,605	$ 13,595	$ 2,010	15 %

Research and development

Research and development expenses have increased by $0.4 million for the year ended December 31, 2019 versus the same prior year period. Product development and professional fees increased by a net of $0.3 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 $1.6 million over the prior year period. Professional fees and selling costs have increased by $2.8 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. This is offset by $0.5 million decrease in business development costs, reflecting a decrease in activities. There was 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 taken in fiscal 2019 versus a $2.6 million impairment charge taken in fiscal 2018. Higher severance accruals in fiscal 2019 are offset by a decrease in salaries, bonus accrual and headcount leading to a $0.4 million decrease in salaries and benefits and $0.2 million decrease in share-based compensation.

Other expenses

	2019	2018	Change $	Change %
Other expenses/(income)				
Interest on long-term debt and other financing costs	$ 2,532	$ 1,773	$ 759	43 %
Interest income	(17)	(12)	(5)	(42)%
Foreign exchange (gain)/loss	(261)	1,029	(1,290)	(125)%
Change in fair value of derivative financial instruments	(161)	(380)	219	58 %
Gain on extinguishment of payables	-	(195)	195	100 %
	$ 2,093	$ 2,215	$ (122)	(6)%

The $0.8 million increase in interest on long-term debt and other financing costs for the year ended December 31, 2019 over the same prior year period is mainly due to the higher outstanding principal balance of long-term debt ($20.5 million as at December 31, 2019 versus $9.0 million as at December 31, 2018), the $0.2 million deferral fee 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.

Select quarterly information

The following table highlights selected unaudited consolidated financial data for each of the eight most recent quarters that, in management's opinion, have been prepared on a basis consistent with the unaudited condensed interim consolidated financial statements

for the three and twelve months ended December 31, 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			
	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
Statement of operations data				
Product revenue	$ 321	$ (167)	$ 1,256	$ 2,165
Licensing and other revenue	193	-	-	-
Cost of goods sold	352	(124)	1,339	632
Research and development	522	622	647	1,038
Selling, general & administrative expense	3,134	3,184	2,220	4,238
Finance costs, net	389	763	253	688
Net loss	(3,883)	(4,612)	(3,203)	(4,431)
Basic and diluted net loss per common share	$ (0.01)	$ (0.02)	$ (0.01)	$ (0.02)

	Three months ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Statement of operations data				
Product revenue	$ 1,884	$ 1,583	$ 1,952	$ 1,624
Licensing and other revenue	184	-	150	-
Cost of goods sold	811	777	1,029	1,027
Royalty Buyout/Minimum royalty	-	-	4,266	2,414
Research and development	571	751	604	472
Selling, general & administrative expense	5,024	2,159	2,231	1,783
Finance costs, net	686	765	382	382
Income tax expense	27	2	-	-
Net loss	(5,051)	(2,871)	(6,410)	(4,454)
Basic and diluted net loss per common share	$ (0.02)	$ (0.01)	$ (0.03)	$ (0.02)

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, we reversed the previous accruals related to discounts and replacement of product and have 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 up to Q2 2019. 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 and Q4 2019 reflect the temporary shortage of Natesto® in the Canadian and South Korean markets. UriVarx® sales were terminated June 1, 2019.
- 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® Canada (launched in Q4 2016) and UriVarx® (launched in Q1 2018). Q3 2019 and Q4 2019 operating expenses have significantly increased over prior quarters, reflecting the additional spend in anticipation of the closing of the A&R Agreement with Aytu to co-promote Natesto® in the US.
- In 2018 we extinguished the CDN$5.0 million debt form Quantius Inc. and the remainder of the promissory note to Endo with proceeds from the SWK credit facility of $9.0 million. We also took on an additional $11.5 million of debt from First Generation Capital in fiscal 2019.
- In 2018 we also impaired the Estrace® intangible asset by $2.6 million, by a further $2.5 million in Q1 2019 due to an anticipated shortage of certain doses of the product caused by an issue with our contract manufacturer.

Review of operating results – Fourth quarter

The following table presents selected financial information (including certain non-IFRS measures, as noted) for the three months ended December 31, 2019 and 2018, which were derived from the consolidated financial statements for the respective periods:

	For the three months ended, December 31,	
	2019	**2018**
Revenue		
Product revenue	$ 321	$ 1,884
Licensing and other revenue	193	184
	514	2,068
Cost of goods sold	352	811
Royalty buyout	-	-
Gross margin	162	1,257
Expenses		
Research and development	522	571
Selling, general and administrative	3,134	5,024
Total operating expenses	3,656	5,595
Operating loss	(3,494)	(4,338)
Other expenses/(income)		
Interest on long-term debt and other financing costs	664	497
Interest income	(11)	-
Foreign exchange (gain)/loss	(167)	676
Change in fair value of derivative financial instruments	(97)	(292)
Gain on extinguishment of payables	-	(195)
Total other expenses	389	686
Loss for the year before income taxes	(3,883)	(5,024)
Income tax expense	-	27
Net loss for the year	(3,883)	(5,051)
Other comprehensive income, net of income tax		
Foreign currency translation adjustment	(153)	102
Total comprehensive loss for the year	(4,036)	(4,949)
Loss per common share		
Basic and diluted net loss per common share	$ (0.01)	$ (0.02)
Weighted average common shares outstanding		
Basic and diluted	261,225,290	235,262,972
Diluted	261,225,290	235,262,972

Review of operating results – Three months ended December 31,

Revenue and gross profit

	Three months ending December 31,			
	2019	2018	Change $	Change %
Revenue				
Product revenue	$ 321	$ 1,884	$ (1,563)	(83)%
Licensing and other revenue	193	184	9	5 %
	514	2,068	(1,554)	(75)%
Cost of goods sold	352	811	(459)	(57)%
Gross margin	$ 162	$ 1,257	$ (1,095)	(87)%

Product revenue decreased from $1.9 million for the three months ended December 31, 2018 to $0.3 million for the same 2019 period. The decrease in product revenue is mainly due to the decrease in Estrace® 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® product in Canada and South Korea in 2019 and the termination of UriVarx sales in June 2019. Natesto® revenues were also impacted by a one-time adjustment to recognize top-up revenue for the Natesto® units Aytu had on hand in Q1 2019. As such Tier 2 revenue earned from Natesto® in the US recognized in Q4 2019 were lower due to lower units sold, coupled with the fact that a portion of the revenue from the units sold had already been recognized in Q1 2019.

Cost of goods sold for the three months ended December 31, 2019 were $0.4 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 $0.1 million of the expense in cost of goods sold.

Operating expenses

	Three months ending December 31,			
	2019	2018	Change $	Change %
Operating expenses				
Research and development	$ 522	$ 571	$ (49)	(9)%
Selling, general and administrative	3,134	5,024	(1,890)	(38)%
	$ 3,656	$ 5,595	$ (1,939)	(35)%

Research and development

Research and development expenses have decreased by less than $0.1 million for the three months ended December 31, 2019 versus the same prior year period. The $0.1 million decrease in salaries and benefits due to changes in bonus accruals and number of employees was offset by a $0.1 million increase in product development related to Natesto®.

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 decreased from $5.0 million for the three months ended December 31, 2018 to $3.1 million for the same 2019 period. Professional fees and selling costs have increased by $1.4 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 Q4 2019 due to the voluntary recall of certain lots in Q3 2019. Salaries and benefits decreased by $0.5 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 December 31,			
	2019	2018	Change $	Change %
Other expenses/(income)				
Interest on long-term debt and other financing costs	$ 664	$ 497	$ 167	34 %
Interest income	(11)	-	(11)	n/a
Foreign exchange (gain)/loss	(167)	676	(843)	(125)%
Change in fair value of derivative financial instruments	(97)	(292)	195	67 %
Gain on extinguishment of payables	-	(195)	195	(100)%
	$ 389	$ 686	$ (297)	(43)%

The $0.2 million increase in interest on long-term debt and other financing costs for the three months ended December 31, 2019 over the same prior year period is mainly due to the higher outstanding principal balance of long-term debt ($20.5 million as at December 31, 2019 versus $9.0 million as at December 31, 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:

	December 31, 2019	December 31, 2018	Change $	Change %
Working capital (total current assets less total current liabilities)	$ 1,726	$ 1,959	$ (233)	(12)%
Non-current assets	6,205	9,200	(2,995)	(33)%
Long-term obligations	20,762	11,230	9,532	85 %
Shareholders' equity	(12,831)	(71)	(12,760)	17,972 %

Working capital

The $0.2 million decrease in working capital from December 31, 2018 to December 31, 2019 reflects the following:

- $0.9 million decrease in accounts receivable due to the decreased level of sales and timing of collections
- $1.0 million decrease in inventory mainly due to the sale of related products and a $0.3 million impairment charge to Canadian Natesto® inventory
- $1.8 million increase in accounts payable and accrued liabilities mainly due to $1.1 million are payables for activities related to the new A&R Agreement with Aytu, $0.3 million additional interest payable due to a larger long-term debt balance and $0.7 million of accruals related to the voluntary product recalls of certain batches of Natesto® in Canada and South Korea of set by the timing of expenses and payments.
- $0.1 million increase in the current portion of lease liability due to the implementation of IFRS 16

This is offset by:

- $2.0 million increase in cash due to proceeds from a debt issuance of $11.5 million and a private placement of $3.4 million offset by $11.4 million being used in operating activities, $1.6 million used in other financing activities, $0.1 million used in the acquisition of product rights and fixed assets and $0.2 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.
- $1.1 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 December 31, 2019 is primarily due to depreciation and amortization expense and impact of foreign exchange.

At December 31, 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 $0.8 million offset by $0.1 million in additions and $0.2 million foreign exchange effect on the Canadian balance of intangible assets.

Long-term obligations

As at December 31, 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.

We also amended the SWK debt agreement in September 2019 to set the minimum threshold for Consolidated Unencumbered Liquid Assets required to be maintained. This amount is defined in the agreement has cash adjusted for a certain portion of accounts receivable and payable. This level was 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 the 5,331,563 Original Warrants from CDN$0.40 to CDN$0.11. We were in compliance with this covenant at December 31, 2019.

In connection with the amendment, we agreed to reprice the 5,331,563 Original Warrants from CDN$0.40 to CDN$0.11. In addition, the Original Warrants' expiry date was 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, we 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, the Company may cause SWK to exercise the New Warrants prior to their expiry date if the closing price of the Company's 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 share purchase warrants are recorded as a warrant derivative liability on the balance sheet.

On December 16, 2019, we received a waiver letter from SWK ("SWK Waiver") waiving the requirement to comply with the Adjusted EBITDA and Aggregate Revenue covenants as at December 31, 2019 contained in the credit agreement. The amendment agreement also changed the set minimum threshold for Consolidated Unencumbered Liquid Assets required to be maintained by the Company from $1.0 million at all times after January 31, 2020 to $2.0 million.

The waiver of the covenants was contingent on us raising an additional $6.5 million prior to December 23, 2019. In connection therewith, we obtained a commitment letter from First Generation to amend and restate the $5.0 million subordinated secured term loan facility previously entered into on July 19, 2019 between Acerus and First Generation to (i) increase the borrowed amount to $11.5 million, (ii) extend the maturity date to June 30, 2021 and (iii) cap the total amount of interest payable to First Generation under the amended loan (including interest paid from the closing of the original $5.0 million subordinated secured term loan facility) to an amount equal to 9.99% of the market capitalization of our at the time of closing.

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 was subordinated to the existing $9.0 million facility with SWK and bore 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 was repayable in full on December 31, 2020, was 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 could be prepaid in full or in part without penalty following repayment in full of indebtedness owing to SWK.

On December 18, 2019 we amended the Loan to (i) increase the borrowed amount to $11.5 million, (ii) extend the maturity date to June 30, 2021 and (iii) cap the total amount of interest payable to First Generation under the A&R Loan (including interest paid from the closing of the original $5.0 million subordinated secured term loan facility) to an amount equal to CDN$1.7 million.

The other terms of the A&R Loan remain unchanged from the original facility. The A&R Loan will continue to be subordinated to the existing $9.0 million facility with SWK and, subject to the cap on the total interest payable described above, will bear interest at a rate per annum equal to the three-month London Inter-Bank Offered Rate, plus an applicable margin of 10.50%. Subject to the terms of the subordination and intercreditor agreement between First Generation and SWK, the A&R Loan will be repayable in full on June 30, 2021, will continue to be 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. The proceeds from the A&R Loan will be used for ongoing general working capital.

See the subsequent event note on the private placement and refinancing activities that occurred after December 31, 2019.

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 December 31, 2019, we had 261,225,290 common shares issued and outstanding, 23,584,624 warrants outstanding and exercisable for 23,584,624 common shares, 12,866,992 outstanding stock options with a weighted average exercise price of CDN$0.17.

The $12.8 million decrease in shareholders' equity from December 31, 2018 to December 31, 2019 is primarily due to $16.1 million in net loss, $0.1 million adjustment of IFRS 16 Leases, offset by $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 December 31, 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.

We received a waiver letter from SWK waiving the requirement to comply with the Adjusted EBITDA and Aggregate Revenue covenants as at December 31, 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, we 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 was 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.

On December 18, 2019 we amended the Loan to (i) increase the borrowed amount to $11.5 million, (ii) extend the maturity date to June 30, 2021 and (iii) cap the total amount of interest payable to First Generation under the A&R Loan (including interest paid from the closing of the original $5.0 million subordinated secured term loan facility) to an amount equal to CDN$1.7 million. See "Long-term obligations" section for more detail. As of December, 2019, we had $11.5 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 audited consolidated financial statements for the year ended December 31, 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, or commercial transactions with lenders or investors (notwithstanding the refinancing completed on February 20, 2020 described in the subsequent events note), 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 our control could have a significant bearing on its ability to obtain additional financing.

Cash flows

	For the year ended December 31,			
Cash flows from/(used in):	2019	2018	Change $	Change %
Operating activities	$ (11,383)	$ (6,131)	$ (5,252)	86 %
Financing activities	13,297	7,350	5,947	(81)%
Investing activities	(108)	(245)	137	(56)%
Exchange (loss)/gain on cash	225	(301)	526	(175)%
Net increase/(decrease) in cash	$ 2,031	$ 673	$ 1,358	(202)%

At December 31, 2019 we had a cash balance of $5.9 million.

The cash outflow from operating activities for the year ended December 31, 2019 is a result of a $16.1 million net loss offset by $6.0 million in non-cash expenses and $1.3 million outflow from working capital. The cash outflow from operating activities for year ended December 31, 2018 are a result of a $18.8 million net loss, offset by $6.8 million in non-cash expenses and net $5.9 million inflow from working capital. The net inflow from working capital is largely due the $6.7 million Mattern Buyout accrual.

The cash inflow from financing activities for the year ended December 31, 2019 are mainly from the issuance of long-term debt of $11.5 million and the non-brokered private placement which brought in a net of $3.4 million. This is offset by interest payments of $1.5 million and principal elements of lease payments of $0.1 million. The cash used in financing activities in the year ended December 31, 2018 is mainly a result of net proceeds of $4.4 million from issuance of common shares and warrants and $10.2 million from proceeds of debt, offset by $6.6 million debt principal payments and $0.7 million interest and financing fee payments.

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

Capital expenditures

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

Contractual obligations and commitments

As of December 31, 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	Greater than 5 years	Total
Accounts payable and accrued liabilities	$ 4,554	$ 2,120	$ 482	$ -	$ -	$ -	$ 7,156
Purchase commitments	517	212	-	-	-	-	729
Lease liability (principal and interest)	34	34	67	135	404	40	714
Long-term debt (principal and interest)	284	284	576	16,219	8,180	-	25,543
As at December 31, 2019	$ 5,389	$ 2,650	$ 1,125	$ 16,354	$ 8,584	$ 40	$ 34,142

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, 2019 consolidated financial statements) for products submitted for approval by ABI itself.

We 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)(g) and (h) in the consolidated financial statements ended December 31, 2019.

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 December 31, 2019 and 2018 were as follows:

	For the three months ended December 31,		For the year ended December 31,	
	2019	2018	2019	2018
Short-term compensation of key management and directors	$ 141	$ 328	$ 909	$ 1,512
Termination benefits	-	366	363	366
Share-based compensation	14	90	155	370
Interest accrued	186	-	314	-
Professional fees paid or payable to firms affiliated with directors & officers	-	-	-	189
	$ 341	$ 784	$ 1,741	$ 2,437

These transactions are in the normal course of operations.

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

As at December 31, 2019, we had a $6.2 million 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 loss of $0.1 million for year ended December 31, 2019 (gain of $0.1 million for the year ended December 31, 2018) that has been recorded in the consolidated statement of loss.

As of December 31, 2019, we had $11.5 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 December 31, 2019 we had $0.3 million in interest expense and $0.3 million outstanding in accounts payable related to the loan. Please see the subsequent event note for more details on agreements entered into with First Generation subsequent to year end in respect of an equity financing and debt-to-equity conversion.

Dividends

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

Financial instruments

As at December 31, 2019, our financial instruments consisted of cash, trade and other receivables, contract assets, 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, contract assets, accounts payable and accrued liabilities are measured at amortized costs and their fair values approximate carrying values due to their short-term nature except for the Buyout payable. The Buyout payable has been discounted using a current interest rate and accordingly its carrying value approximates fair value.

The long-term debt is measured at amortized cost. At December 31, 2019 the fair value of the long-term debt approximates its face value of $20.5 million.

Currency risk

We are exposed to currency risk related to the fluctuation of foreign exchange rates. We are exposed to currency risk through net assets denominated in US dollars, Euros, and the British Pounds of the parent whose functional currency is the Canadian dollar.

	December 31, 2019		
	USD	EUR	GBP
Cash	$ 5,550	$ -	$ -
Trade and other receivables	52	-	-
Intercompany receivable	6,188	-	-
Accounts payable and accrued liabilities	(2,381)	(34)	(15)
Long-term debt	(20,500)	-	-
	$ (11,091)	$ (34)	$ (15)

Based on the above net exposure at December 31, 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%	$ 528	$ (2)	$ (1)	$ 525
Depreciate 5%	(584)	2	1	(581)

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 Fist Generation Loan.

A 0.5% appreciation in the present LIBOR rate would lead to an increase of $0.1 million of interest payments for the life of the loans. A 0.5% depreciation in the present LIBOR rate would lead to a decrease of $0.1 million of interest payments required for the life of the loans.

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 12% of our trade receivables are due from one pharmaceutical wholesaler in Canada and 30% from an out-licensing partner.

As at December 31, 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, 2019. 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)
Total lease liabilities recognized under IFRS 16 at January 1, 2019	$	660
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 December 31, 2019 increased by $263 as a result of this change in policy.

In applying IFRS 16 for the first time, we 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.

The right of use asset is depreciated on a straight-line basis over the term of the lease.

The lease liability will mature on June 30, 2025. As at December 31, 2019, we had the following obligations to make future payments related to the lease liabilities:

	December 31, 2019
No later than 1 year	$ 135
Later than 1 year and no later than 5 years	539
Later than 5 years	40
	714
Finance charges	(103)
Total lease liabilities	$ 611

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 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 compromising 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 consolidated financial statements for the year ended December 31, 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, or commercial transactions with lenders or investors (notwithstanding the refinancing completed on February 20, 2020 described), 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®, Natesto® and UriVarx® 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.

Revenues for certain of our partners are earned 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 net pricing schedule when the marketing partner recognizes sales of the product. In estimating the total transaction price to be recorded as revenue at the time control passes (on shipment of the products to the marketing partner), management is required to estimate the portion of the additional top-up amount (variable consideration) that is highly probable will not result in a significant reversal in the amount of cumulative revenue once the marketing partner has sold the product and their net pricing schedule is known. Management's assessment of the estimated future net pricing schedules takes into consideration both historical experience as well as our expectations of the future gross to net revenue deductions required by our marketing partners in order to commercialize the sale of our products to meet our collective strategic objectives.

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.

Impairment of non-financial assets

We are required to assess at the end of each reporting period whether there is any indication that its intangible assets may be impaired. If any such indication exists, we are required to estimate the recoverable amount of the intangible asset. Where an impairment exists the asset is written down to its recoverable amount. We assessed that the anticipated shortage of certain doses of Estrace® as a result of being informed by its contract manufacturing partner of further delays in lifting their license suspension was an indicator that this product right intangible asset may be further impaired. The most critical assumptions in determining the recoverable amount of this asset is in estimating when replacement product will be available and the impact that the current product shortage will have on our sales level in both the short and longer term due to the presence of the third party generic. Other key assumptions include estimating an appropriate pre tax discount rate reflecting current market assessments of the risks specific to this asset for which future cash flow estimates have not been adjusted, declining revenue growth rates, projected costs of goods sold using an alternative contract manufacturer and working capital requirements.

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 15 of our December 31, 2019 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 21 of our December 31, 2019 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 December 31,		For the year ended December 31,	
	2019	2018	2019	2018
Net (loss)	$ (3,883)	$ (5,051)	$ (16,129)	$ (18,786)
Adjustments:				
Income tax	-	27	-	29
Amortization of intangible assets	176	394	818	1,694
Depreciation of property and equipment	63	47	254	240
Depreciation of right of use asset	12	-	47	-
Interest on long-term debt and other financing costs*	664	497	2,532	1,773
Interest income	(11)	-	(17)	(12)
Change in fair value of derivative	(97)	(292)	(161)	(380)
EBITDA	$ (3,076)	$ (4,378)	$ (12,656)	$ (15,442)
Licensing and other revenue	(193)	(184)	(193)	(334)
Royalty expense/Buyout	-	-	-	6,680
Share based compensation	13	112	176	449
Foreign exchange loss/(gain)	(167)	676	(261)	1,029
Gain on extinguishment of payables	-	(195)	-	(195)
Charges related to product recall	77	-	1,053	-
Impairment loss on intangible asset	-	2,641	2,536	2,641
Adjusted EBITDA	$ (3,346)	$ (1,328)	$ (9,345)	$ (5,172)

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

Management's responsibility for financial reporting

Disclosure controls and procedures and internal controls over financial reporting

As at December 31, 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 Disclosure Committee and continuous review and monitoring procedures by senior management.

As at December 31, 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 year ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.

An evaluation of the design and effectiveness of the Company's DC&P and ICFR has been conducted by management, under the supervision of the Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Based on this evaluation, the CEO and CFO have concluded that, as of December 31, 2019, the Company's disclosure controls and procedures and internal control over financial reporting, as defined by National Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings, are operating effectively.

Litigation

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 attended 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 December 31, 2019, we have not accrued for any potential claims.

Subsequent Event

Private Placement and Refinancing

On February 12, 2020, we announced that we had entered into agreements with First Generation ("FGC") in respect of an equity financing and debt-to-equity conversion by First Generation and with SWK in respect of an amendment to the New Facility (the "Refinancing Transactions"). First Generation is the Company's largest shareholder of the Company and an entity owned and controlled by Mr. Ian Ihnatowycz, Chairman of the board of directors (the "Board") of the Company. The Refinancing Transactions have been negotiated on an arm's-length basis, including under the supervision of and upon a recommendation by, a special committee of the Board (the "Special Committee") comprised of entirely independent directors unrelated to the parties involved.

The Refinancing Transactions consisted of:

- a private placement to First Generation of 449,148,891 Acerus Common Shares at an offering price of CDN$0.053269 per FGC Common Share, being a 25% discount to the five day volume weighted average price of the FGC Common Shares on the TSX as at January 31, 2020, for aggregate gross proceeds to us of $18.0 million (the "FGC Private Placement");

- the conversion of our outstanding $11.5 million (plus accrued interest of $0.5 million) owing to First Generation under the A&R Loan into approximately 300,081,885 Acerus Common Shares at a conversion price of C$0.053269 per Acerus Common Share (the "Debt Conversion"); and

- an amendment to the New Facility (the "February 2020 SWK Amendment") which would, among other things, (i) set the minimum threshold for consolidated unencumbered liquid assets required to be maintained by us at $1.5 million, (ii) reset the revenue and EBITDA covenants to better reflect the nature of our business at this time compared to the time the New Facility was entered into, (iii) delay the date on which we must begin repaying principal from Q1-2021 to Q2-2021; (iv) require pre-payment of $0.8 million of principal in three instalments during 2020 and a commensurate reduction in the amount used to calculate exits fees; and (v) provide flexibility to us to dispose of non-core assets and retain some of the proceeds of such dispositions for working capital.

As consideration for and in connection with the February 2020 SWK Amendment, we paid SWK an amendment fee of $0.08 million and to amend the exercise price of the 6,693,107 outstanding SWK Warrants and New Warrants, which expire on September 30, 2024, from CDN$0.11 to CDN$0.053269.

On February 21, 2020, we announced the closing of the Refinancing Transactions. We received $18.0 million in gross proceeds from the private placement of 449,148,891 Acerus Common Shares to First Generation and converted $11.5 million (plus accrued interest of $0.5 million) owing to First Generation under the A&R Loan into 300,081,885 Acerus Common Shares. In addition, the February 2020 SWK Amendment became effective. As consideration for and in connection with the SWK Amendment, we paid SWK an amendment fee of $0.08 million and amended the exercise price of the SWK Warrants and New Warrants, which expire on September 30, 2024, from CDN$0.11 to CDN$0.053269. We also made a prepayment of $0.3 million of principal to SWK. This prepayment was the first of the three installments previously announced on February 12, 2020.

Upon closing of these transactions, we have 1,010,456,066 Acerus Common Shares issued and outstanding on a non-diluted basis.

It is expected that we will ask shareholders to approve a share consolidation at our next annual meeting of shareholders.

Additional information

Additional information about Acerus, including the Company's Annual Information Form dated March 3, 2020, 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.