



**Management's Discussion & Analysis of
Acerus Pharmaceuticals Corporation
For the three and nine months ended September 30, 2020**

The following management's discussion and analysis ("MD&A") of the financial condition and results of the operations of Acerus Pharmaceuticals Corporation and its wholly owned subsidiaries (the "Company", "Acerus", "we" or "our") constitutes management's review of the factors that affected our financial and operating performance for the three and nine months ended September 30, 2020. This MD&A is dated November 2, 2020 and should be read in conjunction with the unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2020, together with the audited consolidated financial statements and accompanying notes for the year ended December 31, 2019.

The unaudited condensed interim consolidated financial statements were prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board applicable to the preparation of interim financial statements including International Accounting Standards 34: Interim Financial Reporting and are presented in thousands of United States ("U.S.") dollars except for per share amounts and unless otherwise noted. For more detailed information regarding certain forward-looking statements contained herein, please see the note regarding "Forward-looking Statements". The results of the operations, business prospects and financial condition of the Company will be affected by, among others, the "Risk Factors" set out in our Annual Information Form dated March 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, to continue the development, commercialization and launch of additional products. These circumstances cast 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 delays in re-introducing Natesto® 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, Symphony 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 associated with the impact of the novel coronavirus ("COVID-19") as a global pandemic and impacts on the economy, workforces, financial markets and supply chain.

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) and Acerus Biopharma Inc. ("ABI") (incorporated in Ontario). 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 with our contract commercial provider Syneos Health ("Syneos") 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 over 60 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 commercial batches specific to these two markets 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 using the same batch of active pharmaceutical ingredient (“API”) 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). As an alternative solution, we procured new API as soon as it became available from its supplier and successfully produced Natesto[®] using the new API and currently approved manufacturing process. On July 28, 2020 we announced the commercial production of Natesto[®] has been resumed. New batches of Natesto[®] have been manufactured utilizing the approved manufacturing process and new batches of testosterone API. The first shipment of this new commercial product was sent to the United States and we anticipate that we will be able to supply South Korea and Canada prior to year end 2020.

Our active pipeline includes two innovative products: Lidbree[™] (formerly referred to as Shact[™]), a short acting lidocaine formulation delivered through a proprietary device into the vaginal mucosal tissue; and 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[®]. In addition, 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.

Beyond the active product pipeline, we have product rights to Tefina[™], a clinical stage product aimed at addressing a significant unmet need for women with female sexual dysfunction. However, we are not actively developing this product given our product focus to a men’s health portfolio.

On September 8, 2020 the license, development and supply agreement with Viramal Limited (“Viramal”), granting the us the exclusive rights to commercialize the Elegant[™] franchise in Canada, was mutually terminated.

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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Fixed supply price per unit • The agreement was terminated by mutual consent on May 19, 2020
June 14, 2017	medac Gesellschaft für	15 European countries: Germany, United Kingdom, France, Italy,	<ul style="list-style-type: none"> • Non-refundable upfront fee

	Klinische Spezialpräparate mbH (“medac”)	Czech Republic, Slovakia, Spain, Sweden, Finland, Denmark, Norway, Poland, Austria, Netherland and Belgium	<ul style="list-style-type: none"> • Milestone payment on regulatory approval and sales-based milestone payments • Tiered supply price per unit
See additions on October 31, 2018			
October 17, 2017	Eu Hwa Pte LTD. (“HWA”)	Thailand, Malaysia/Brunei, Singapore, Vietnam, Philippines, Hong Kong/Macau and one other small South East Asian country	<ul style="list-style-type: none"> • Non-refundable upfront fee • Milestone payment on regulatory approval • Tiered supply price per unit
November 23, 2017	Apsen Farmacêutica (“Apsen”)	Brazil	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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 using the same batch of API that appeared 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.

As an alternative solution, we procured new API as soon as it became available from its supplier and successfully produced Natesto® using the new API and currently approved manufacturing process. On July 28, 2020 we announced the commercial production of Natesto® has been resumed. New batches of Natesto® have been manufactured utilizing the approved manufacturing process and new batches of API. The first shipment of this new commercial product was sent to the United States and we anticipate that we will be able to supply South Korea and Canada prior to the end of 2020.

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 voluntarily 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 voluntarily 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 United 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.

On July 20, 2020 Acerus announced the launch of its U.S. Specialty sales force that will focus on promoting Natesto® within the Acerus Channel.

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 paid 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 paid on 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.

Estrace[®]

In March 2019 we impaired the product right intangible asset for Estrace by \$2,471 following notification by its contract manufacturer of further delays in lifting the license suspension at the facility where Estrace was being produced following an audit by UK health authorities in 2018 as a continued shortage of Estrace may accelerate erosion of Estrace sales due to the presence of a third-party generic. As a result an alternative manufacturer was identified and we began working towards securing a new supply of product for mid 2020. Acerus continues to work with its new third-party contract manufacturer to complete the transfer of the production of Estrace and have the first new batch of Estrace available in the market in the first quarter of 2021. Based on estimated inventory levels in the channel, sales levels, current market and competitive outlook management has determined that the slightly extended timeline would not have a material impact on expected future market share and thus does not represent a further impairment trigger.

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.

On April 15, 2020, we received a NOD for its avanafil New Drug Submission. Health Canada has requested the provision of additional quality information related to the avanafil drug substance in alignment with International Council for Harmonization (ICH) technical guidance adopted by Health Canada. Until this information is provided to Health Canada, the avanafil review process has been halted. We received an extension to November 13, 2020 to respond fully to the NOD. If we are successful in providing the required information, the NDS review process will restart and may take up to 360 days to complete.

LidbreeTM

On May 29, 2018 we entered into an exclusive agreement to commercialize Pharmanest AB’s (“Pharmanest”) Short Acting Lidocaine Product (“LidbreeTM”), 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 LidbreeTM and will receive a tiered supply price for the product based on a percentage on net sales of the product.

ElegantTM franchise

On December 20, 2017, we entered into a license, development and supply agreement with Viramal, a London-based specialty pharmaceutical company, that grants us exclusive rights to commercialize the ElegantTM franchise in Canada. The ElegantTM franchise comprises ElegantTM Vaginal Moisturizer, which provides comfort to women suffering from vaginal dryness, and ElegantTM pH, which is a pH balanced vaginal product. ElegantTM Vaginal Moisturizer and ElegantTM 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 ElegantTM and will receive a supply price for the product.

On September 8, 2020 we terminated the license, development and supply agreement with Viramal.

GynoflorTM

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.

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.

Corporate Update

Impact of COVID-19 pandemic

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus (“COVID-19”) as a global pandemic, which continues to spread throughout Canada and around the world. This contagious disease outbreak and any related adverse public health developments, has adversely affected workforces, economies, and financial markets globally, potentially leading to an economic downturn. This disruption, even temporary, has impacted our operations and overall business by delaying the progress of our research and development programs and selling activities. While there is significant uncertainty, as to the duration and impact of this outbreak, we do not foresee adverse effects on our supply chain, collectability of its receivables, or further impairment triggering events in relation to the carrying value of our intangible asset at this time arising from COVID-19.

Acerus’ supply chains and contract manufacturers are still active and are supporting the Company’s efforts to expand its business. We are making progress in returning Natesto® to the Canadian and South Korean markets.

Share Capital

On August 28, 2020, we issued 532,015 common shares at CDN\$0.0531 per share to a vendor in lieu of cash payment.

On June 28, 2020, 23,584,624 warrants issued in relation to a 2018 bought deal transaction expired. The value of the warrants, \$1.4 million was transferred to contributed surplus.

On February 12, 2020 we announced that we had entered into an agreement with First Generation Capital Inc. (“First Generation”), a company affiliated with the Chairman of the Board of Directors of Acerus, in respect of an equity financing and debt-to-equity conversion by First Generation. 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 the Company of \$18.0 million (the “FGC Private Placement”). The private placement is presented net of \$0.2 million of financing costs. The agreement also included the conversion of the Company’s 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 CDN\$0.053269 per Acerus Common Share (the “Debt Conversion”). The debt conversion is presented net of \$0.1 million of financing costs.

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.

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.

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.

On February 12, 2020 we announced we entered into an agreement with First Generation in respect of an equity financing and debt-to-equity conversion by First Generation. The agreement included the conversion of the Company’s 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 CDN\$0.053269 per Acerus Common Share (the “Debt Conversion”). The debt conversion is presented net of \$0.1 million of financing costs.

As of September 30, 2020, the Company had \$nil outstanding on the loan.

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.

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 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 February 12, 2020, we announced that we entered into an agreement with SWK in respect of an amendment to the New Facility (the "February 2020 SWK Amendment"). The amendment to the New Facility which would, among other things, (i) set the minimum threshold for consolidated unencumbered liquid assets required for us to maintain by at \$1.5 million; (ii) reset the revenue and EBITDA covenants to better reflect the nature of the Company's business at this time compared to the time the New Facility was entered into; (iii) require pre-payment of \$0.75 million of principal in three instalments during 2020 and a commensurate reduction in the amount used to calculate exits fees; (iv) delay the date on which the Company must begin repaying principal from Q1-2021 to Q2-2021; and (v) provide flexibility to the Company 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. We also made a prepayment of \$0.25 million of principal to SWK. This prepayment was the first of the three installments to be made in fiscal 2020. As of September 30, 2020, we made a total of \$0.5 million of principal payments to SWK.

Canadian credit facility

At September 30, 2020, we also had a Canadian Credit facility of \$750, with no expiration date for use only as letters of credit and bank guarantees. At September 30, 2020, \$nil was drawn as standby letters of credit and bank guarantees. At September 30, 2020, we had \$750 available under this facility.

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

Effective January 1, 2020, we changed the functional currency of the Canadian parent and its wholly-owned subsidiary ALI to the United States dollar given the increasing prevalence of the United States dollar-denominating activities of the Company over time. ABI remains consistent in using the United States dollar as its functional currency. The change in functional currency from Canadian dollars to United States dollar is accounted for prospectively from January 1, 2020. The exchange rate used to translate the balance sheet to reflect the change in functional currency on adoption was \$0.77. This results in all of the entities in the consolidated statement having a functional currency and presentation currency as the United States dollar.

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 rate in Canada is 26.5% in 2020 and 2019.

Select quarterly information

The following table highlights selected unaudited condensed interim consolidated financial data for each of the eight most recent quarters that, in management’s opinion, have been prepared on a basis consistent with the unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2020 except for the adoption of IFRS 16 *Leases* on January 1, 2019 which was adopted on a modified retrospective basis with no restatement of comparatives as permitted under the specific transitional provisions in the standard. The reclassifications and adjustments arising from the new leasing rules are therefore recognized in the opening balance sheet on January 1, 2019. The selected financial information presented below reflects all adjustments, consisting primarily of normal recurring adjustments which are, in the opinion of management, necessary for a fair presentation of results for the interim periods. These results are not necessarily indicative of results for any future period and you should not rely on these results to predict future performance.

	Three months ended			
	September 30, 2020	June 30, 2020	March 31, 2020	December 31, 2019
Statement of operations data				
Product revenue	\$ 493	\$ 176	\$ 145	\$ 321
Licensing and other revenue	-	-	-	193
Cost of goods sold	743	224	201	352
Research and development	760	400	622	522
Selling, general & administrative expense	5,634	4,602	3,577	3,134
Finance costs, net	404	560	408	389
Net loss	(7,048)	(5,610)	(4,663)	(3,883)
Basic and diluted net loss per common share	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)

	Three months ended			
	September 30, 2019	June 30, 2019	March 31, 2019	December 31, 2018
Statement of operations data				
Product revenue	\$ (167)	\$ 1,256	\$ 2,165	\$ 1,884
Licensing and other revenue	-	-	-	184
Cost of goods sold	(124)	1,339	632	811
Research and development	622	647	1,038	571
Selling, general & administrative expense	3,184	2,220	4,238	5,024
Finance costs, net	763	253	688	686
Income tax expense	-	-	-	27
Net loss	(4,612)	(3,203)	(4,431)	(5,051)
Basic and diluted net loss per common share	\$ (0.02)	\$ (0.01)	\$ (0.02)	\$ (0.02)

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 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 to Q3 2020 reflect the temporary shortage of Natesto[®] in the Canadian and South Korean markets. UriVarx[®] sales were terminated June 1, 2019. Revenues in Q3 2020 reflect a shipment of Natesto[®] to Aytu, recognition of the potential related top-up revenue, revenue adjustments related to new rebate and trial card programs and an adjustment to previously recognized top-up revenue due to disposal of short-dated product.
- 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.
- 2020 research and development expenses reflect a decrease in clinical trial expense and increased focus on manufacturing process improvements. 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 to Q3 2020 operating expenses have significantly increased over prior quarters, reflecting the additional spend related to the A&R Agreement with Aytu to co-promote Natesto[®] in the US.
- In 2018 we extinguished the CDN\$5.0 million debt from Quantius Inc. and the remainder of the promissory note to Endo with proceeds from the SWK credit facility of \$9.0 million. We also took on an additional \$11.5 million of debt from First Generation Capital in fiscal 2019, which, along with the accrued interest, was converted into common shares in February 2020.
- 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.

Select consolidated financial information

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Statement of operations data				
Revenue	\$ 493	\$ (167)	\$ 814	\$ 3,254
Operating loss	(6,644)	(3,849)	(15,949)	(10,542)
Net Loss	(7,048)	(4,612)	(17,321)	(12,246)
Basic and diluted net loss per common share	\$ (0.01)	\$ (0.02)	\$ (0.02)	\$ (0.05)
Balance sheet data:				
	September 30,	December 31,		
	2020	2019		
Total assets	\$ 15,285	\$ 15,440		
Long-term debt	8,166	19,990		

Review of operating results – nine months ended September 30,

Revenue and gross profit

	Nine months ending September 30,			
	2020	2019	Change \$	Change %
Product revenue	\$ 814	\$ 3,254	\$ (2,440)	(75)%
Cost of goods sold	1,168	1,847	(679)	(37)%
Gross margin	\$ (354)	\$ 1,407	\$ (1,761)	125 %

Product revenue decreased from \$3.3 million for the nine months ended September 30, 2019 to \$0.8 million for the same 2020 period. Revenues in the prior year reflect a one-time adjustment to recognize top-up revenue for the Natesto[®] units Aytu had on hand in Q1 2019. The current period revenues were impacted by the voluntary recall of Natesto[®] product in Canada and South Korea in Q3 2019, the termination of UriVarx sales in June 2019 and 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. In the current period, there was also a \$0.2 million reversal of revenue previously recognized as top-up revenue for the Natesto[®] units Aytu had on hand resulting from these units being disposed of due to short dating. There were also additional accruals for new rebate and trial card programs that started in Q3 2020 in the U.S. market. The prior year figures reflect the accrual for returns related to the product recall of \$0.7 million.

Cost of goods sold for the nine months ended September 30, 2019 were \$1.8 million compared to \$1.2 million for the same 2020 period. In the current period, amortization of intangible assets and depreciation of fixed assets accounts for \$0.5 million of the expense in cost of goods sold and \$0.3 million related to disposed product. Furthermore, under the co-promote agreement with Aytu, product is initially sold to them at actual costs, without a markup. The gross margins for the 2019 period were impacted by a one-time top-up revenue adjustment recognized in the first quarter.

Operating expenses

	Nine months ending September 30,			
	2020	2019	Change \$	Change %
Operating expenses				
Research and development	\$ 1,782	\$ 2,307	\$ (525)	(23)%
Selling, general and administrative	13,813	9,642	4,171	43 %
	\$ 15,595	\$ 11,949	\$ 3,646	31 %

Research and development

Research and development expenses have decreased by \$0.5 million for the nine months ended September 30, 2020 versus the same prior year period. Clinical trial cost decreased by \$0.5 million over the prior year mainly due to decrease in costs associated with the various Natesto[®] studies. The \$0.3 million decrease in salaries and benefits due to changes in bonus accruals and number of employees. This is offset by the net increase of \$0.3 million in product development and professional fees mainly related to Natesto[®] manufacturing process.

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

Selling, general and administrative

Selling, general and administrative expenses increased from \$9.6 million for the nine months ended September 30, 2019 to \$13.8 million for the same 2020 period. The increase is mainly due to a \$6.6 million increase in selling costs, reflecting additional costs incurred related to the A&R Agreement with Aytu to co-promote Natesto® in the US. Share-based compensation increased by \$0.3 million due to timing and amount of issuances, recruiting fees related to new employees of \$0.2 million and business development expenses increased by \$0.1 million due to increased activities. This is offset by a \$0.4 million decrease in salaries and benefits and \$0.1 million decrease in travel costs, which is a result of the decreased headcount in the current period in Canada, offset by the addition of 5 specialty sales representatives and 2 leadership team members in the US. The expenses in 2019 also included a \$2.5 million intangible impairment charged expensed related to Estrace® and UriVarx®.

Other expenses

	Nine months ending September 30,			
	2020	2019	Change \$	Change %
Other expenses/(income)				
Interest expense and other financing costs	\$ 1,613	\$ 1,868	\$ (255)	(14)%
Interest income	(65)	(6)	(59)	(983)%
Foreign exchange (gain)/loss	(16)	(94)	78	(83)%
Change in fair value of derivative financial instruments	(160)	(64)	(96)	(150)%
	<u>\$ 1,372</u>	<u>\$ 1,704</u>	<u>\$ (332)</u>	<u>(19)%</u>

The \$0.3 million decrease in interest on long-term debt and other financing costs for the nine months ended September 30, 2020 over the same prior year period is mainly due to the lower outstanding principal balance of long-term debt throughout the period. This was further impacted by the accretion expenses in the prior year period related to a long-term payable to M&P Patent AG which was extinguished in April 2020.

The foreign exchange gain is due to the fluctuation in the Canadian/U.S. exchange rate and the change in functional currency of the parent company and ALI from Canadian to the U.S. dollar.

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

Review of operating results – Three months ended September 30,

Revenue and gross profit

	Three months ending September 30,			
	2020	2019	Change \$	Change %
Product revenue	\$ 493	\$ (167)	\$ 660	(395)%
Cost of goods sold	743	(124)	867	(699)%
Gross margin	<u>\$ (250)</u>	<u>\$ (43)</u>	<u>\$ (207)</u>	<u>481 %</u>

Product revenue in Q3 2020 reflects a shipment of Natesto® product to Aytu and the related estimated top-up revenue. The current period also reflects the decrease in Estrace® sales due to the presence of a generic and conservation measures taken by management due to the supply issues with our third party contract manufacturer. Cost of goods sold for Q3 2020 was \$0.7 million, reflecting the cost of production of the shipment of Natesto® product to Aytu, \$0.2 million of intangible asset amortization and fixed asset depreciation and \$0.3 million of costs related to disposed product.

In Q2 2019, we accrued \$0.1 million in discounts and potential returns due to the Natesto® product recall in Canada and South Korea, and \$0.4 million related to cost to replace the units in the channel. However, due to additional delays in providing product, in Q3 2019, we reversed this accrual and accrued \$0.7 million for expected returns in the quarter leading to the negative values in both product revenues and cost of goods sold.

Operating expenses

	Three months ending September 30,			
	2020	2019	Change \$	Change %
Operating expenses				
Research and development	\$ 760	\$ 622	\$ 138	22 %
Selling, general and administrative	5,634	3,184	2,450	77 %
	<u>\$ 6,394</u>	<u>\$ 3,806</u>	<u>\$ 2,588</u>	<u>68 %</u>

Research and development

Research and development expenses have increased by \$0.1 million for the three months ended September 30, 2020 versus the same prior year period. Clinical trial cost decreased by \$0.2 million over the prior year mainly due to decrease in costs associated with the various Natesto[®] studies. This is offset by a net increase of \$0.3 million in product development costs and professional fees over the prior year period, reflecting mainly additional costs related to Natesto[®] manufacturing process.

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

Selling, general and administrative

Selling, general and administrative expenses increased from \$3.2 million for the three months ended September 30, 2019 to \$5.6 million for the same 2020 period. The increase is mainly due to a \$2.2 million increase in selling costs reflecting additional costs incurred related to the A&R Agreement with Aytu to co-promote Natesto[®] in the U.S.. Office expenses increased by \$0.2 million mainly due to recruiting fees for new employees. Salaries and benefits increased by \$0.1 million due to bonus reversals made in the prior year and severance payments in the current quarter. Share based compensation also increased by \$0.1 million due to timing and number of issuances. These expenses are offset by a \$0.2 million decrease in professional fees, reflecting consulting costs in the prior year related to the co-promote agreement for Natesto[®].

Other expenses

	Three months ending September 30,			
	2020	2019	Change \$	Change %
Other expenses/(income)				
Interest expense and other financing costs	\$ 385	\$ 702	\$ (317)	(45)%
Interest income	(2)	(5)	3	(60)%
Foreign exchange (gain)/loss	77	91	(14)	(15)%
Change in fair value of derivative financial instruments	(56)	(25)	(31)	(124)%
	<u>\$ 404</u>	<u>\$ 763</u>	<u>\$ (359)</u>	<u>(47)%</u>

Interest on long-term debt and other financing costs decreased by \$0.3 million. The prior year period included accretion expenses related to a long-term payable to M&P Patent AG ("M&P") which was extinguished in April 2020 and also included a higher long-term debt balance.

The foreign exchange gain is due to the fluctuation in the Canadian/U.S. exchange rate and the change in functional currency of the parent company and ALI from Canadian to the U.S. dollar.

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

Financial position

The following table presents a summary of our financial position:

	September 30, 2020	December 31, 2019	Change \$	Change %
Working capital (total current assets less total current liabilities)	\$ 2,249	\$ 1,726	\$ 523	30 %
Non-current assets	5,448	6,205	(757)	(12)%
Long-term obligations	7,673	20,762	(13,089)	(63)%
Shareholders' equity	24	(12,831)	12,855	(100)%

Working capital

The \$0.5 million increase in working capital from December 31, 2019 to September 30, 2020 reflects the following:

- \$1.5 million increase in inventory due to raw material purchases for the production of Natesto[®] and Estrace[®]
- \$1.0 million decrease in accounts payable and accrued liabilities due to the timing and payment of expenses and the extinguishment of the M&P buyout accrual in April 2020
- \$0.3 million increase in trade and other receivables mainly due to the shipment of Natesto[®] product to Aytu in Q3 2020

This is offset by:

- \$1.1 million decrease in cash mainly due to the \$18.0 million private placement in February 2020, offset by funds used in operating and financing activities.
- \$1.1 million increase in the current portion of long-term debt due to the timing of principal payments offset by deferred financing cost.

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, 2019 to September 30, 2020 is primarily due to depreciation and amortization expense.

At September 30, 2020 manufacturing equipment with a net book value of \$0.5 million was held off-site by a third party (\$0.6 million at December 31, 2019).

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 by \$0.5 million due to amortization expense.

Long-term obligations

Long-term obligations consist of long-term debt, derivative financial instruments and lease liability.

Please refer to the “Long-term debt financing” section above for details on the First Generation Loan and SWK facility.

On February 12, 2020 we announced we entered into an agreement with First Generation in respect of an equity financing and debt-to-equity conversion by First Generation. The agreement included the conversion of the Company’s 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 CDN\$0.053269 per Acerus Common Share (the “Debt Conversion”). The debt conversion is presented net of \$0.1 million of financing costs.

On February 12, 2020, we announced that we entered into an agreement with SWK in respect of an amendment to the New Facility (the “February 2020 SWK Amendment”). The amendment to the New Facility which would, among other things, (i) set the minimum threshold for consolidated unencumbered liquid assets required for us to maintain by at \$1.5 million, (ii) reset the revenue and EBITDA covenants to better reflect the nature of the Company’s business at this time compared to the time the New Facility was entered into, (iii) delay the date on which the Company must begin repaying principal from Q1-2021 to Q2-2021; (iv) require pre-payment of \$0.75

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 the Company 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 \$0.1 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. The Company also made a prepayment of \$0.25 million of principal to SWK. This prepayment was the first of the three installments to be made in fiscal 2020. As of September 30, 2020, we made \$0.5 million in principal payments.

On September 28, 2020, we received a waiver with regards to the minimum aggregate revenue required for the three month period ending September 30, 2020.

At September 30, 2020, we also had a Canadian Credit facility of \$750, with no expiration date for use only as letters of credit and bank guarantees. At September 30, 2020, \$nil was drawn as standby letters of credit and bank guarantees. At September 30, 2020, we had \$750 available under this facility.

Lease liability

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. The change in balance from December 31, 2019 reflects principal payments and foreign exchange impacts.

Shareholders' deficiency

We are authorized to issue an unlimited number of common shares. As at September 30, 2020, we had 1,010,988,081 common shares issued and outstanding, and 67,357,689 outstanding stock options with a weighted average exercise price of CDN\$0.06.

On June 28, 2020, 23,584,624 warrants issued in relation to a 2018 bought deal transaction expired. The value of the warrants, \$1.4 million was transferred to contributed surplus.

The \$12.9 million increase in shareholders' equity from December 31, 2019 to September 30, 2020 is primarily due to \$17.8 million in issuance of common shares net of costs, \$11.9 million related to the First Generation debt and interest conversion net of cost, \$0.4 million in stock option expense, offset by a \$17.3 million net loss.

On February 12, 2020 we announced that we had entered into an agreement with First Generation, in respect of an equity financing and debt-to-equity conversion by First Generation. 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 the Company of \$18.0 million. The private placement is presented net of \$0.2 million of financing costs. The agreement also included the conversion of the Company's 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 CDN\$0.053269 per Acerus Common Share. The debt conversion is presented net of \$0.1 million of financing costs.

On August 28, 2020, we issued 532,015 common shares at CDN\$0.0531 per share to a vendor in lieu of cash payment.

Liquidity and capital resources

Liquidity risk

As detailed in the long-term obligations section above, as at September 30, 2020, there is \$8.5 million of principal outstanding on the New Facility. See "Long-term debt financing" section for more detail.

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

The purpose of liquidity management is to ensure that there is sufficient cash to meet all of our financial commitments and obligations as they come due. The unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2020 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, 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

Cash flows from/(used in):	For the nine months ended September 30,			
	2020	2019	Change \$	Change %
Operating activities	\$ (17,091)	\$ (6,905)	\$ (10,186)	148 %
Financing activities	15,988	7,164	8,824	(123)%
Investing activities	-	(108)	108	(100)%
Exchange (loss)/gain on cash	-	114	(114)	(100)%
Net increase/(decrease) in cash	\$ (1,103)	\$ 265	\$ (1,368)	516 %

At September 30, 2020 we had a cash balance of \$4.8 million.

The cash outflow from operating activities for the nine months ended September 30, 2020 is a result of a \$17.3 million net loss off set by \$2.6 million in non-cash expenses and \$2.4 million outflow from working capital. The cash outflow from operating activities for the nine months ended September 30, 2019 are a result of a \$12.2 million net loss, offset by \$5.5 million in non-cash expenses and net \$0.2 million outflow from working capital.

The cash inflow from financing activities for the nine months ended September 30, 2020 are the \$17.8 million proceeds from the First Generation private placement, offset by \$1.2 million in interest and financing fees paid, \$0.1 million paid in financing costs related to the debt conversion, \$0.5 million of principal paid on the SWK facility and \$0.1 million paid for the principal elements of the lease liability. The cash inflow from in financing activities for the nine months ended September 30, 2019 are from a private placement of \$3.4 million, proceeds from long-term debt of \$5.0 million, offset by interest and financing fees paid of \$1.1 million.

Cash used in investing activities for the nine months ended September 30, 2019 are related to the additional milestone payment of \$0.1 million made on filing the NDS for avanafil.

Capital expenditures

Our capital expenditures primarily related to our investment in laboratory assets. For the nine months ended September 30, 2020 there were no capital expenditures.

Contractual obligations and commitments

As of September 30, 2020, 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	\$ 5,767	\$ 20	\$ 631	\$ -	\$ -	\$ -	\$ 6,418
Purchase commitments	643	-	-	-	-	-	643
Lease liability (principal and interest)	33	33	66	131	334	-	597
Long-term debt (principal and interest)	512	249	1,679	3,210	5,589	-	11,239
	6,955	302	2,376	3,341	5,923	-	18,897

Please refer to the “Long-term debt financing” sections for details on the SWK facility.

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(d)(e) and (f) in the unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2020.

Related party transactions

Key management includes our directors and executive officers. The remuneration of directors and key members of management and professional fees paid for the three and nine months ended September 30, 2020 and 2019 were as follows:

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Short-term compensation of key management and directors	\$ 444	\$ 208	\$ 1,184	\$ 768
Termination benefits	-	-	-	363
Share-based compensation	195	51	409	141
Interest expense	-	128	212	128
	\$ 639	\$ 387	\$ 1,805	\$ 1,400

These transactions are in the normal course of operations.

Executive employment agreements allow for total additional payments of approximately \$1.9 million if a change in control occurs, \$1.8 million if all are terminated without cause, and \$nil if all are terminated with cause.

As at September 30, 2020, Acerus had a \$10.5 million receivable (\$6.2 million receivable as at December 31, 2019) from 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 and \$0.1 million for the three and nine months ended September 30, 2019). There was no foreign exchange gain or loss in the three and nine months ended September 30, 2020 due to a change in functional currency as discussed in the Accounting Pronouncement section of this MD&A.

Please refer to the “Long-term debt financing” sections for details on the First Generation debt and related interest expense incurred.

Please refer to “Subsequent Events” sections for details on the Rights Offering and stand by commitment.

Dividends

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

Financial instruments

As at September 30, 2020, 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 September 30, 2020 the fair value of the long-term debt approximates its face value of \$8.5 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 Canadian dollars, Euros, and the British Pounds of the parent whose functional currency is the U.S. dollar.

	September 30, 2020		
	CDN	EUR	GBP
Cash	\$ 201	\$ -	\$ -
Trade and other receivables	175	-	-
Accounts payable and accrued liabilities	(1,789)	(156)	(76)
	\$ (1,413)	\$ (156)	\$ (76)

Based on the above net exposure at September 30, 2020 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:

	CDN	EUR	GBP	Total
Appreciate 5%	\$ 67	\$ (8)	\$ (4)	\$ 55
Depreciate 5%	(74)	8	4	(62)

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.

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 66% of our trade receivables are due from our marketing partner in the U.S. and 16% from two pharmaceutical wholesaler in Canada.

As at September 30, 2020, 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 in these unaudited condensed interim consolidated financial statements are consistent with the significant accounting policies used in the preparation of the annual audited consolidated financial statements for the year ended December 31, 2019 except for as noted below.

Foreign currency translation

Financial Statements

Effective January 1, 2020, we changed the functional currency of the Canadian parent and its wholly-owned subsidiary ALI to the United States dollar. ABI remains consistent in using the United States dollar as its functional currency. The change in functional currency from Canadian dollars to United States dollar is accounted for prospectively from January 1, 2020. The exchange rate used to translate the balance sheet to reflect the change in functional currency on adoption was \$0.77. This results in all of the entities in the consolidated statement having a functional currency and presentation currency as the United States dollar.

Critical accounting estimates

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

Going concern

The unaudited condensed interim consolidated financial statements for the three and nine months ended September 30, 2020 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, 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.

Income taxes

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

Lease liability

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

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

Non-IFRS financial measures

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

We use non-IFRS measures, such as EBITDA and Adjusted EBITDA to provide investors with a supplemental measure of our operating performance and thus highlight trends in our core business that may not otherwise be apparent when relying solely on IFRS financial

measures. We also believe that securities analysts, investors and other interested parties frequently use non-IFRS measures in the valuation of issuers. We also use non-IFRS measures in order to facilitate operating performance comparisons from period to period, prepare annual operating budgets, and to assess our ability to meet our future debt service, capital expenditure and working capital requirements.

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

EBITDA and Adjusted EBITDA

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

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

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Net (loss)	\$ (7,048)	\$ (4,612)	\$ (17,321)	\$ (12,246)
Adjustments:				
Amortization of intangible assets	179	177	537	642
Depreciation of property and equipment	57	64	185	191
Depreciation of right of use asset	11	12	35	35
Interest expense and other financing costs*	385	702	1,613	1,868
Interest income	(2)	(5)	(65)	(6)
Change in fair value of derivative	(56)	(25)	(160)	(64)
EBITDA	\$ (6,474)	\$ (3,687)	\$ (15,176)	\$ (9,580)
Share based compensation	176	57	424	163
Foreign exchange (gain)	77	91	(16)	(94)
Charges related to product recall	-	184	(71)	976
Impairment loss on intangible asset	-	-	-	2,536
Adjusted EBITDA	\$ (6,221)	\$ (3,355)	\$ (14,839)	\$ (5,999)

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

Management's responsibility for financial reporting

Disclosure controls and procedures and internal controls over financial reporting

As at September 30, 2020 management has disclosure controls and procedures ("DCP") that provide reasonable assurance that information required to be disclosed by the Company in its filings under Canadian securities legislation is recorded, processed, summarized and reported in a timely manner. The system of DCP includes, among other things, the Company's Corporate Disclosure and Whistleblower policies and Code of Conduct, the review and approval procedures of the Company's Disclosure Committee and continuous review and monitoring procedures by senior management.

As at September 30, 2020 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 three and nine months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.

Litigation

Schenk Litigation

Valeant Pharmaceuticals International, Inc. and Valeant International Bermuda ("Valeant") are defendants in Ontario Superior Court of Justice Action No. CV-11-438382, which claims a declaration that Valeant is contractually obligated to compensate the plaintiff, Reiner Schenk ("Schenk") pursuant to the terms of a contract between Schenk and Biovail Corporation. The main action was commenced by Notice of Action issued on October 31, 2011 and a Statement of Claim was issued on December 14, 2011. Acerus Pharmaceuticals Corporation was named as one of the defendants in the main action, but the action was discontinued as against Acerus on December 14, 2011. On October 29, 2013, Valeant commenced a third party claim against Acerus (among others) claiming contribution, indemnity and other relief over to the full extent that Valeant may be held liable to Schenk, and damages for breach of fiduciary duty, breach of contract and intentional interference with economic relations in any amount for which Valeant is found liable to Schenk. Acerus has defended the third-party claim, denying any liability to Valeant. The parties have concluded examinations for discovery and attended a pre-trial conference in February 2020. The trial was scheduled to commence in April 2020 and was anticipated to be two weeks long. However, in an effort to reduce the transmission of COVID-19, the Ontario Superior Court suspended all regular operations in March 2020. Accordingly, the trial was adjourned to a later date. The trial is expected to take place in 2021. As of September 30, 2020, the Company has not accrued for any potential claims.

Recipharm Litigation

On June 18, 2020, the Company commenced litigation against Recipharm Limited ("Recipharm"), a wholly-owned subsidiary of Recipharm AB (RECI-B.ST), in the Commercial Court of London. Acerus alleges that the suspension of Recipharm's manufacturing license in August 2018, in contravention of its contractual obligations to Acerus, led to a shortage of Estrace[®] in Canada. Due to the shortage, Estrace[®] revenues and Acerus' market share has decreased substantially each year since the shortage began. Consequently, Acerus has sued Recipharm for, among other things, its loss of profits and loss of market share caused by the shortage. As of September 30, 2020, the Company has not accrued for any potential claims.

In the normal course of business, we may be the subject of litigation claims. While management assesses the merits of each lawsuit and defends itself accordingly, we may be required to incur significant expenses or devote significant resources to defending itself against such litigation.

Subsequent Event

On October 20, 2020, we announced that we will be offering rights (the "Rights Offering") to holders of our common shares ("Common Shares") of record at the close of business on October 27, 2020 (the "Record Date"). Pursuant to the Rights Offering, each holder of Common Shares will receive one transferable right (a "Right") for each Common Share held. Every 1.91984064 Rights will entitle a holder to purchase one Common Share at a price of \$0.025 per common share (the "Subscription Price"). The Rights Offering is expected to raise gross proceeds of approximately \$13.165 million.

The Subscription Price is equal to approximately an 37.97% discount to the volume weighted average trading price of the Common Shares on the Toronto Stock Exchange (the "TSX") for the 5 day period ending October 19, 2020. Based on the 1,010,988,081 Common Shares outstanding as of the date of this news release, a maximum of 526,600,000 Common Shares could be issued pursuant to the Rights Offering, representing 52.09% of the currently issued and outstanding Common Shares. The final number of Common Shares will depend on the actual number of Common Shares issued and outstanding on the Record Date. The Rights Offering will be conducted in Canada, and those in jurisdictions where Acerus may lawfully offer the Rights.

The Rights Offering will include an additional subscription privilege under which holders of Rights who fully exercise their basic subscription privilege will be entitled to subscribe pr rata for additional Common Shares, if available, that were not otherwise subscribed for in the Rights Offering.

The Rights and the Common Shares issuable upon exercise of the Rights will be listed on the TSX. The Rights will be listed for trading on the TSX beginning on October 26, 2020 under the symbol "ASP.RT". Trading in the Rights on the TSX will cease at 12:00 p.m. (Toronto time) on November 24, 2020.

In connection with the Rights Offering, the Company has entered into a standby commitment agreement dated October 19, 2020 (the "Standby Commitment Agreement") with First Generation Capital Inc. (the "Standby Purchaser"), the Company's major shareholder. The Standby Purchaser has agreed, subject to certain terms, conditions and limitations, to purchase such number of Common Shares that are available to be purchased, but not otherwise subscribed for under the Rights Offering, that will result in 100% of the Common Shares being subscribed under the Rights Offering (the "Standby Commitment"). Pursuant to the Standby Commitment, the Company will, subject to the terms of the Standby Commitment Agreement, be guaranteed to issue at least 526,600,000 Common Shares in connection with the Rights Offering for aggregate gross proceeds of \$13.165 million.

As at the date hereof, the Standby Purchaser owns or exercises control or direction over, directly or indirectly, 867,134,176 Common Shares, representing approximately 85.77% of the issued and outstanding Common Shares. Assuming no Acerus shareholders exercise their Rights and the Standby Purchaser acquires 100% of the Common Shares available pursuant to the Rights Offering, the Standby Purchaser would own an aggregate of 1,393,734,176 Common Shares representing approximately 90.64% of the then issued and outstanding Common Shares.

The Standby Purchaser is a "related party" of the Company under Multilateral Instrument 61-101 – Protection of Minority Security Holders in Special Transactions ("MI 61-101") because it exercises control and direction over more than 10% of the issued and outstanding Common Shares. The Rights Offering is not subject to the related party rules under MI 61-101 based on a prescribed exception related to rights offerings.

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.