



**Management's Discussion & Analysis of  
Acerus Pharmaceuticals Corporation  
For the three and twelve months ended December 31, 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 twelve months ended December 31, 2020. This MD&A is dated March 10, 2021 and should be read in conjunction with the annual audited consolidated financial statements and accompanying notes for the year ended December 31, 2020.

The annual audited consolidated financial statements were prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board and are presented in thousands of United States ("U.S.") dollars except for per share amounts and unless otherwise noted. For more detailed information regarding certain forward-looking statements contained herein, please see the note below 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 10, 2021 available at [www.sedar.com](http://www.sedar.com).

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 within the next two quarters. In addition, we expect that the Company will breach its minimum revenue and EBITDA financial covenants as at March 31, 2021 unless a waiver is obtained from our lender. As a result, our long-term debt could become currently due shortly thereafter. 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, obtaining additional financing, and 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. Delays in reintroducing Natesto<sup>®</sup> to the Canadian market, or unsuccessfully executing its US market strategy, could result in the Company failing to meet projected revenues or other budgeted targets which could result in continuing to violate our debt covenants. In addition, factors within and outside our management's control could have a significant bearing on our ability to obtain additional financing. These circumstances cast significant doubt as to our ability to realize our assets, meet our contractual obligations and commitments as they come due and, accordingly, the ultimate appropriateness of the use of accounting principles applicable to a going concern.

**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 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 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 10, 2021 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 over 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 Pharmaceuticals Corporation ("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 currently have one marketed product: Natesto<sup>®</sup>, the first and only testosterone nasal gel for testosterone replacement therapy in adult males diagnosed with hypogonadism. Our primary market is the United States where we commercialize our product with our contract commercial provider Syneos Health ("Syneos"). Natesto<sup>®</sup> has also been licensed for distribution in Canada and in over 60 additional countries worldwide, through a global network of licensed distributors. Marketing approvals in jurisdictions outside of North America are expected to take place over the course of the coming years.

Our active pipeline includes two innovative products: Lidbree<sup>™</sup> (formerly referred to as Shact<sup>™</sup>), a short acting lidocaine formulation delivered through a proprietary device into the vaginal mucosal tissue; 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<sup>®</sup> and in the European Union ("EU") under the trade name Spedra<sup>®</sup>. In addition, Acerus is working on expanding its product portfolio by leveraging its proprietary delivery systems ("TriVair"), patents and formulation expertise. Our focus in 2020 was to secure extended patent applications for TriVair from 2024 to 2037. Patent extensions have been granted in Canada and Japan with extensions in Europe and the USA expected in 2021. We are actively looking at potential partnering transactions for these initiatives with our partner IP Med.

Beyond the active product pipeline, we have product rights to Tefina<sup>™</sup>, a clinical stage product aimed at addressing a significant unmet need for women with female sexual dysfunction.

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

On November 30, 2020, we entered into an asset purchase agreement to a third party to sell our Canadian rights for Estrace®.

For further information please see the Annual Information Form dated March 10, 2021 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®:

<b>Date</b>	<b>Company</b>	<b>Territory</b>	<b>Terms</b>
April 22, 2016	Aytu BioScience Inc. (“Aytu”)	United States	<ul style="list-style-type: none"> <li>• Non-refundable upfront payments totaling \$8.0 million</li> <li>• Sales-based milestones that could potentially total \$37.4 million</li> <li>• Tiered supply price per unit</li> <li>• See note below on Amended and Restated agreement effective July 2019</li> </ul>
December 15, 2016	Hyundai Pharm Co., Ltd (“Hyundai”)	South Korea	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>
June 5, 2017	Therios Healthcare (“Therios”)	Saudi Arabia, United Arab Emirates, and Egypt	<ul style="list-style-type: none"> <li>• Fixed supply price per unit</li> <li>• The agreement was terminated by mutual consent on May 19, 2020</li> </ul>
June 14, 2017	medac Gesellschaft für Klinische Spezialpräparate mbH (“medac”)	15 European countries: Germany, United Kingdom, France, Italy, Czech Republic, Slovakia, Spain, Sweden, Finland, Denmark, Norway, Poland, Austria, Netherland and Belgium	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval and sales-based milestone payments</li> <li>• Tiered supply price per unit</li> </ul>
		See additions on October 31, 2018	
October 17, 2017	Eu Hwa Pte LTD. (“HWA”)	Thailand, Malaysia/Brunei, Singapore, Vietnam, Philippines, Hong Kong/Macau and one other small South East Asian country	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>
November 23, 2017	Apsen Farmacêutica (“Apsen”)	Brazil	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>
April 9, 2018	Producto Científicos, S.A. de C.V (“Carnot Laboratorios”)	Mexico and 18 Central and Latin American countries (Argentina, Columbia, Peru, Chile, Ecuador, Guatemala, El Salvador, Nicaragua, Honduras, Panama, Costa Rica, Cuba, Dominican Republic, Venezuela, Bolivia, Uruguay, Paraguay and Haiti)	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>
October 31, 2018	medac	Amended to include all existing European Union Member states and the United Kingdom, Norway,	<ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• All other terms as per the original agreement</li> </ul>

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Liechtenstein, Iceland, Turkey,  
Australia, New Zealand, South  
Africa and Israel.

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

On August 2, 2019, we announced that we will voluntarily replace certain Natesto<sup>®</sup> lots released in the Canadian and South Korean markets, which is expected to cause temporary shortages in those markets. We identified four commercial lots of Natesto<sup>®</sup> 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 was 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<sup>®</sup>. 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.

As an alternative solution, we procured new API as soon as it became available from our supplier and successfully produced Natesto<sup>®</sup> with the new API using the currently approved manufacturing process. We announced the commercial production of Natesto<sup>®</sup> had resumed on July 28, 2020. The first shipment of this new commercial product to the United States was sent in July 2020. The first shipment of new commercial product to South Korea was sent in December 2020. Canadian market shipments are expected to resume in mid 2021.

On January 10, 2020, we announced that the dossier filed as a Decentralized Procedure in 19 European countries for the approval of Natesto<sup>®</sup> 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. We plan to re-submit the application once the data from the studies is available.

#### *Co-promote Natesto<sup>®</sup> in the U.S.*

We entered into an amended and restated licensing agreement with Aytu in July 2019, which moved the partnership from an out-license model to a co-promotion arrangement. Under the terms of the new agreement, Aytu returned the NDA for Natesto<sup>®</sup> in the U.S. back to Acerus. Accordingly, we have assumed all regulatory and clinical responsibilities and costs for the product in the U.S. We have taken 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 have launched 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<sup>®</sup> 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.

As part of the amended and restated licensing agreement, we did not pay Aytu to regain the marketing authorization for Natesto<sup>®</sup> in the U.S. The royalty structure currently in place was replaced with a pay-for-performance incentive structure intended to drive Natesto<sup>®</sup> 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<sup>®</sup>, or the expiration or invalidation of the last to expire Natesto<sup>®</sup> patent.

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

- Up to the current status quo of Natesto<sup>®</sup> 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 to accelerate the growth of Natesto<sup>®</sup> 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.

In 2019, we also engaged Syneos Health (NASDAQ: SYNH), a leading integrated biopharmaceutical solutions organization including the industry's largest Contract Commercial Organization (CCO), to help us establish a high performing commercial footprint in the U.S. Syneos Health has extensive experience in Men's Health and with Natesto<sup>®</sup>, and offers an end-to-end model that enables rapid deployment of a U.S. commercial team; scale across all aspects of commercialization, including medical and regulatory affairs, managed markets, marketing and sales; and provides greater flexibility and effectiveness in resource deployment. In partnership with Syneos, on July 20, 2020, Acerus announced the launch of its U.S. Specialty sales force initially comprising of 22 sales representatives. As of the current date, 32 Syneos personnel are deployed in sales and commercial operations support.

#### *Buyout of all obligations under the Mattern License Agreement*

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

Under the License Agreement, we owed royalties on upfronts, milestones and revenues from products, including Natesto<sup>®</sup>, covered by the License Agreement, including minimum annual royalty payments of \$5.0 million if gross product sales are \$75.0 million or greater, or \$2.5 million if gross product sales are below \$75.0 million, starting in fiscal 2018 and ending in 2024. Pursuant to the Buyout, with the payment of \$7.5 million, all of our material obligations owed to Mattern are suspended, but Mattern's obligations to us remain in force. Under the Buyout, among other rights, we receive a perpetual, fully-paid, irrevocable license to all of Mattern's patents and know-how for the products covered by the License Agreement. We 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 became irrevocable upon payment of the last instalment to Mattern in April 2020. The Buyout will remain in full force and effect as long as the License Agreement is in force.

#### Estrace<sup>®</sup>

In March 2019 we impaired the product right intangible asset for Estrace<sup>®</sup> by \$2,471 following notification by its contract manufacturer of further delays in lifting the license suspension at the facility where Estrace<sup>®</sup> was being produced following an audit by UK health authorities in 2018 as a continued shortage of Estrace<sup>®</sup> may accelerate erosion of Estrace<sup>®</sup> 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.

On November 30, 2020, we entered into an asset purchase agreement with a third party to sell our Canadian rights to Estrace<sup>®</sup> in exchange for royalty payments based on gross sales of Estrace for up to 5 years ending May 31, 2026. However, PMS is not required to commence commercial sales of Estrace unless certain conditions are satisfied by June 30, 2021. At this time, we anticipate these conditions will be met.

#### avanafil (available in the U.S. under the brand name Stendra<sup>®</sup>)

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<sup>®</sup>). 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.

On April 15, 2020, we received a NOD for its avanafil New Drug Submission. Health Canada 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. We submitted our response to the NOD on November 11, 2020. On December 11, 2020, Health Canada confirmed that the submission had passed screening and was accepted into review. This process may take up to an additional 360 days to complete.

On July 7, 2020, VIVUS, Inc. (“VIVUS”), the licensor of avanafil to Metuchen, announced that it has completed the solicitation of an in-court prepackaged plan of reorganization, under which IEH Biopharma LLC (“IEH”) will take 100% ownership of VIVUS ahead of its July 7, 2020 chapter 11 filing. The Company has communicated with Metuchen and received assurances that the chapter 11 filing will not impact the supply chain for avanafil or access to the intellectual property it has licensed.

#### Lidbree™

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

#### Elegant™ 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 Elegant™ franchise in Canada. The Elegant™ franchise comprises Elegant™ Vaginal Moisturizer, which provides comfort to women suffering from vaginal dryness, and Elegant™ pH, which is a pH balanced vaginal product. Elegant™ Vaginal Moisturizer and Elegant™ pH are over-the-counter products. Under the terms of the license, development and supply agreement, we would pay Viramal a regulatory milestone payment upon receiving marketing approval in Canada, as well as milestone payments based on achieving sales targets. Viramal would oversee the manufacturing of Elegant™ and would receive a supply price for the product.

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

#### Gynoflor™

We entered into a license and supply agreement with Medinova AG on April 6, 2016, a Swiss pharmaceutical company, that grants exclusive rights to commercialize Gynoflor™ in Canada. On February 28, 2017, we submitted a NDS to Health Canada to obtain marketing approval for the product in Canada. At that time, there were 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 decided not to file a Request for Reconsideration of the Notice and informed our licensor, Medinova AG (“Medinova”), that further studies would 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.

We subsequently terminated the license and supply agreement with Medinova on June 17, 2019.

#### 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 approved by Health Canada and 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 and has led to an economic downturn. This disruption, 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 currently foresee adverse effects on our supply chain, collectability of our receivables, or further impairment triggering events in relation to the carrying value of our intangible assets at this time arising from COVID-19. We qualified for and received some financial assistance under the Canada Emergency Wage Subsidy as detailed in note 17 to our audited consolidated financial statements.

Our supply chains and contract manufacturers are still active and are supporting the Company’s efforts to expand its business. Our co-promotion partners in the U.S. are mitigating the limitations on in-person sales calls with alternate virtual strategies.

### Share Capital

On November 24, 2020, we issued 526,600,000 Common Shares, pursuant to the Rights Offering announced on October 20, 2020, for gross proceeds of CDN\$13,165. SWK also became entitled to an increase in the exchange basis of their outstanding warrants to prevent a dilution of their interest as a result of the Rights Offering. The exchange basis was determined at 1.16 to 1. Accordingly, their allotment of the Original Warrants described below, was increased by 853,050 and 217,817 respectively.

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 First Generation Common Share, being a 25% discount to the five-day volume weighted average price of the First Generation 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 was 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 transaction is presented net of \$0.1 million of financing costs.

As of December 31, 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”). Security for the loan comprises a General Security Agreement on all assets, including intellectual property, of Acerus and its wholly-owned subsidiaries. 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 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 were 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 were 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 and were further amended as described below.

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 December 31, 2020, we made a total of \$0.75 million of principal payments to SWK.

On September 29, 2020, the Company received a waiver with regards to the minimum aggregate revenue required for the three-month period ending September 30, 2020. On December 23, 2020, we received a waiver with regards to the minimum aggregate revenue required for the three-month period ending December 31, 2020. We expect that the Company will breach its minimum revenue and EBITDA financial covenants as at March 31, 2021 unless a waiver is obtained from SWK. Also, failing to meet projected revenues or failing to successfully execute other strategic initiatives could result in continuing violations our debt covenants beyond March 31, 2021. As a result, our long-term debt could become currently due shortly thereafter.

At December 31, 2020, we had \$8.25 million outstanding on the credit facility.

#### *Canadian credit facility*

At December 31, 2020, we also had a Canadian Credit facility of \$0.75 million with no expiration date for use only as letters of credit and bank guarantees. At December 31, 2020, \$nil was drawn as standby letters of credit and bank guarantees. At December 31, 2020, we had \$0.75 million available under this facility.

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

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

Our product revenues for the year reflect the sales of Estrace<sup>®</sup> and Natesto<sup>®</sup> net of chargebacks, discounts and other price adjustments. Cost of sales reflect the cost of finished goods which include manufacturing, distribution, warehousing costs, the amortization of the Estrace<sup>®</sup> product rights intangible asset and royalty expenses for Natesto<sup>®</sup>.

Our product revenue reflects sales of Estrace<sup>®</sup> and Natesto<sup>®</sup> recorded at the invoiced amount less estimated accruals for product returns, discounts, chargebacks and other price adjustments. These provisions with respect to product revenues 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. We monitor these provisions and make adjustments when we believe actual results may differ from established reserves.

Revenues for Natesto<sup>®</sup> from 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), we are 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. Our assessment of the estimated future net pricing schedules takes into consideration

both historical gross to net revenue deduction experience as reported by its marketing partners, as well as 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.

### **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 and marketing 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.

### **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 statements 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 consolidated financial information

The following table sets forth selected consolidated data for the years ended December 31, 2020, 2019 and 2018 as follows:

	2020	2019	2018
<b>Statement of operations data</b>			
Product revenue	\$ 1,085	\$ 3,575	\$ 7,043
Licensing revenue	-	193	334
Operating loss	(22,885)	(14,036)	(16,542)
Net loss	(24,424)	(16,129)	(18,786)
Basic and diluted net loss per common share	\$ (0.03)	\$ (0.06)	\$ (0.08)
 <b>Balance sheet data:</b>			
Total assets	\$ 16,982	\$ 15,440	\$ 16,824
Long-term debt	8,019	19,990	8,287

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

- Revenue from the sale of Estrace® declined \$1.1 million in 2020 due to the product supply shortage caused by the interruption of production we previously reported on January 11, 2019. Revenue from the sale of Natesto® declined \$1.0 million attributable to fewer shipments to Aytu in the U.S. and the postponement of reintroducing Natesto® to the Canadian market. Fiscal 2019 also reflects a one-time adjustment of \$0.7 million to recognize top-up revenue for the Natesto® units Aytu currently has on hand. Product revenue declined a further \$0.4 million to \$nil in 2020 versus \$0.4 million in 2019 attributable to the cancellation of the UriVarx® distribution and licensing agreement in June 2019.
- Revenues in 2019 and 2020 were impacted by the voluntary recall of certain batches of Natesto® in Canada and South Korea. On August 2, 2019, we announced a voluntary recall and replacement of Natesto® in the Canadian and South Korean markets as several batches were found to be non-conforming during long-term stability studies. We sourced new API and were able to use our currently approved manufacturing process avoiding a supplemental new drug submission to Health Canada. On July 28, 2020, we announced the commercial production of Natesto had resumed. Shipments of Natesto® resumed in 2020 to the U.S. and South Korean markets. Canadian market shipments are anticipated to resume in mid-2021.
- On January 11, 2019, we reported an anticipated shortage of certain doses of Estrace® on the Drug Shortages Canada website in relation to supply issues arising from our contract manufacturer. On November 30, 2020, we sold our Canadian rights to Estrace to Pharmascience Inc. and will no longer sell this product.
- Operating losses increased \$8.8 million in 2020 over 2019. \$7.5 million of the increase in Operating loss in 2020 versus 2019 is attributable to selling and marketing expenses to implement our Co-promote strategy for Natesto® in the U.S. with Syneos. A further \$2.5 million is attributable to a decline in Gross Margin offset by a decrease of \$0.9 million attributable to non-cash charges year over year for loss on disposal and impairment charges related to intangible assets. Research and development expenditures were also lower by \$0.3 million in 2020 over 2019 attributable to COVID 19 restrictions.
- In 2018 we extinguished the CDN\$5.0 million debt with Quantius Inc. and the remainder of the promissory note to Endo, with proceeds from the SWK credit facility of \$9.0 million. We also took on an additional \$11.5 million of debt from First Generation in fiscal 2019, and subsequently converted this debt to equity in February 2020.

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

### Revenue and gross margin

	December 31, 2020	December 31, 2019	Change \$	Change %
<b>Revenue</b>				
Product revenue	\$ 1,085	\$ 3,575	\$ (2,490)	(70%)
Licensing and other revenue	-	193	\$ (193)	(100%)
	1,085	3,768	\$ (2,683)	(71%)
Cost of goods sold	2,014	2,199	\$ (185)	(8%)
<b>Gross margin</b>	(929)	1,569	\$ (2,498)	(159%)

Revenue decreased from \$3.8 million for the year ended December 31, 2019 to \$1.1 million for the year ended December 31, 2020. Revenue from the sale of Estrace® declined \$1.1 million in 2020 due to the product supply shortage caused by the interruption of production we previously reported on January 11, 2019. Revenue from the sale of Natesto® declined \$1.0 million attributable to fewer shipments to Aytu in the U.S. and the postponement of reintroducing Natesto® to the Canadian market. Product revenue declined a further \$0.4 million year over year due to the termination of our agreement with Innovus effective June 1, 2019 for the distribution and licensing of UriVarx®.

Natesto® revenue from the U.S. is expected to fluctuate between periods based on the timing of large and potentially non-regular inventory orders. These orders may impact both quarterly and annual revenue figures, and the related variance compared to prior periods, as a large order may comprise a relatively large portion of the period's total revenues. This variability will be reduced when inventory purchases become more frequent. As a result, changes in revenues on a period-to-period basis may not provide a clear indication of actual sales trends for the U.S. market.

Licensing and other revenues was earned from out-licensing agreements which expired or were terminated in 2019.

Gross margin decreased from \$1.6 million for the year ended December 31, 2019 to (\$1.0) million for the year ended December 31, 2020. Gross margin from the sales of Estrace® declined \$0.8 million year over year due to the decrease in sales and \$0.5 million of fixed non-cash amortization expense charged to cost of goods sold irrespective of revenue. Gross margin from the sales of Natesto® declined \$1.3 million year over year due to the decrease in sales and due to \$0.7 million in spoilage charges recognized in 2020 for slow moving raw materials. Gross margin declined a further \$0.4 million due the termination of the distribution and licensing agreement for UriVarx®.

#### *Operating expenses*

	Year ended December 31,			
	2020	2019	Change \$	Change %
Operating expenses				
Research and development	\$ 2,526	\$ 2,829	\$ (303)	(11)%
Selling, general and administrative	19,430	12,776	6,654	52 %
	<u>\$ 21,956</u>	<u>\$ 15,605</u>	<u>\$ 6,351</u>	<u>41 %</u>

#### *Research and development*

Research and development expenses decreased by \$0.3 million for the year ended December 31, 2020 versus the year ended December 31, 2019. The decrease is attributable to delays in clinical trials and research due to COVID 19 restrictions.

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

#### *Selling, general and administrative*

Selling, general and administrative expenses increased by \$6.6 million for the year ended December 31, 2020 versus the year ended December 31, 2019. \$7.5 million of the increase is attributable to selling and marketing expenses to implement our Co-promote strategy for Natesto® in the U.S. with Syneos Health offset by a \$0.9 million decrease in non-cash charges year over year for loss on disposal and impairment charges related to intangible assets.

*Other expenses (income)*

	Year ended December 31,			
	2020	2019	Change \$	Change %
Other expenses (income)				
Interest expense and other financing costs	\$ 1,975	\$ 2,532	\$ (557)	(22)%
Interest income	(67)	(17)	(50)	(294)%
Foreign exchange (gain) loss	(112)	(261)	149	(57)%
Change in fair value of derivative financial instruments	(182)	(161)	(21)	(13)%
Gain on remeasurement of lease liability	(75)	-	(75)	n/a
	<u>\$ 1,539</u>	<u>\$ 2,093</u>	<u>\$ (554)</u>	<u>(26)%</u>

The \$0.6 million decrease in interest expense and other financing costs for the year ended December 31, 2020 versus the year ended December 31, 2019 due primarily to the reduction in accretion expense (\$nil in 2020 versus \$0.5 million in 2019) recorded in other financing costs for the buy out of the Mattern license agreement.

The gain on remeasurement of the lease liability arises from the early termination of our premises lease at our Canadian headquarters as of June 30, 2021.

**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 audited consolidated financial statements for the year ended December 31, 2020. The selected financial information presented below reflects all adjustments, consisting primarily of normal recurring adjustments which are, in the opinion of management, necessary for a fair presentation of results for the interim periods. These results are not necessarily indicative of results for any future period and you should not rely on these results to predict future performance.

	Three months ended			
	December 31, 2020	September 30, 2020	June 30, 2020	March 31, 2020
Statement of operations data				
Product revenue	\$ 271	\$ 493	\$ 176	\$ 145
Licensing and other revenue	-	-	-	-
Cost of goods sold	846	743	224	201
Research and development	744	760	400	622
Selling, general & administrative expense	5,617	5,634	4,602	3,577
Finance costs, net	167	404	560	408
Net loss	(7,103)	(7,048)	(5,610)	(4,663)
Basic and diluted net loss per common share	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)

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

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

- The fluctuation in product revenue balances is mainly due to the timing of Natesto<sup>®</sup> inventory shipments to Aytu in the U.S. and declining Estrace<sup>®</sup> sales offset by increased sales of Natesto<sup>®</sup> and UriVarx<sup>®</sup> 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<sup>®</sup> units Aytu currently has on hand. Revenues in Q3 2019 to Q3 2020 reflect the temporary shortage of Natesto<sup>®</sup> in the Canadian and South Korean markets. UriVarx<sup>®</sup> sales were terminated June 1, 2019. Revenues in Q3 2020 reflect a shipment of Natesto<sup>®</sup> 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<sup>®</sup> 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. Q3 2020 cost of goods sold reflects a charge of \$275 for spoilage of slow-moving raw materials. An additional provision for spoilage of \$0.5 million was recognized against Q4 2020 cost of goods sold.
- 2020 research and development expenses reflect a decrease in clinical trial expense due to delays arising from COVID 19 restrictions particularly in the first six months of 2020. 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.
- Selling, general and administrative expenses have increased steadily quarter over quarter between 2020 and 2019 reflecting the additional spend related to the A&R Agreement with Aytu and our agreement with Syneos to co-promote Natesto<sup>®</sup> in the U.S.

## Review of operating results – Fourth quarter

The following table presents selected financial information (including certain non-IFRS measures, as noted) for the three months ended December 31, 2020 and 2019, which were derived from the consolidated financial statements for the respective periods:

	<b>For the three months ended,</b>	
	<b>2020</b>	<b>2019</b>
<b>Revenue</b>		
Product revenue	\$ 271	\$ 321
Licensing and other revenue	-	193
	271	514
Cost of goods sold	846	352
<b>Gross margin</b>	<b>(575)</b>	<b>162</b>
<b>Expenses</b>		
Research and development	744	522
Selling, general and administrative	5,617	3,134
<b>Total operating expenses</b>	<b>6,361</b>	<b>3,656</b>
Operating loss	(6,936)	(3,494)
<b>Other expenses/(income)</b>		
Interest on long-term debt and other financing costs	362	664
Interest income	(2)	(11)
Foreign exchange (gain)/loss	(96)	(167)
Change in fair value of derivative financial instruments	(22)	(97)
Gain on remeasurement of lease liability	(75)	-
<b>Total other expenses</b>	<b>167</b>	<b>389</b>
Loss for the year before income taxes	(7,103)	(3,883)
Income tax expense	-	-
<b>Net loss for the year</b>	<b>(7,103)</b>	<b>(3,883)</b>
Other comprehensive income, net of income tax		
Foreign currency translation adjustment	-	(153)
<b>Total comprehensive loss for the year</b>	<b>(7,103)</b>	<b>(4,036)</b>
Loss per common share		
Basic and diluted net loss per common share	\$ (0.01)	\$ (0.01)
Weighted average common shares outstanding		
Basic and diluted	975,848,903	261,225,290

## Review of operating results – Three months ended December 31,

### Revenue and gross margin

	Three months ending December 31,			
	2020	2019	Change \$	Change %
Revenue				
Product revenue	\$ 271	\$ 321	\$ (50)	(16)%
Licensing and other revenue	-	193	(193)	(100)%
	271	514	(243)	(47)%
Cost of goods sold	846	352	494	140 %
Gross margin	\$ (575)	\$ 162	\$ (737)	(455)%

Product revenue was comparable for the three months ended December 31, 2020 versus the prior period in 2019. Licensing and other revenues was earned from out-licensing agreements all of which expired or were terminated in 2019.

Cost of goods sold for the three months ended December 31, 2020 reflects a charge for spoilage of slow-moving raw materials of \$0.5 million versus \$nil in the prior period in 2019.

### Operating expenses

	Three months ending December 31,			
	2020	2019	Change \$	Change %
Operating expenses				
Research and development	\$ 744	\$ 522	\$ 222	43 %
Selling, general and administrative	5,617	3,134	2,483	79 %
	\$ 6,361	\$ 3,656	\$ 2,705	74 %

### Research and development

Research and development expenses have increased by \$0.2 million for the three months ended December 31, 2020 versus the prior period in 2019 attributable primarily to an increase in non-cash charges for depreciation and share-based compensation.

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

### Selling, general and administrative

Selling, general and administrative expenses increased by \$2.5 million for the three months ended December 31, 2020 versus the prior period in 2019. Most of the increase is attributable to a \$1.6 million non-cash charge for the loss on the sale of our Canadian market rights for Estrace® to Pharmascience Inc. A further \$0.8 million increase is attributable to selling and marketing expenses incurred with Syneos to augmented the co-promotion of Natesto® in the U.S. market in parallel with our current arrangement with Aytu. We expect to maintain this level of quarterly expenditure with Syneos through 2021.

### Other expenses

	Three months ending December 31,			
	2020	2019	Change \$	Change %
Other expenses (income)				
Interest expense and other financing costs	\$ 362	\$ 664	\$ (302)	(45)%
Interest income	(2)	(11)	9	(82)%
Foreign exchange (gain)/loss	(96)	(167)	71	(43)%
Change in fair value of derivative financial instruments	(22)	(97)	75	77 %
Gain on remeasurement of lease liability	(75)	-	(75)	
	<u>\$ 167</u>	<u>\$ 389</u>	<u>\$ (222)</u>	<u>(57)%</u>

The \$0.3 million decrease in interest expense and other financing costs for the three months ended December 31, 2020 over the same prior year period is primarily due to the reduction in accretion expense for the buy out of the Mattern license agreement.

The foreign exchange gain is due to the fluctuation in the Canadian/U.S. exchange rate.

The change in fair value of derivative financial instruments reflects the fluctuation of the share price in relation to the exercise price of the warrants issued.

The gain on remeasurement of the lease liability arises from the early termination of our premises lease at our Canadian headquarters on June 30, 2021.

### Financial position

The following table presents a summary of our financial position:

	December 31,		Change \$	Change %
	2020	2019		
Working capital (total current assets less total current liabilities)	\$ 6,931	\$ 1,726	\$ 5,205	302 %
Non-current assets	2,948	6,205	(3,257)	(52)%
Long-term obligations	6,719	20,762	(14,043)	(68)%
Shareholders' equity	3,160	(12,831)	15,991	(125)%

### Working capital

The \$5.2 million increase in working capital from December 31, 2019 to December 31, 2020 reflects the following:

- \$3.3 million increase in cash attributable to the timing of the Rights Offering in late November 2020.
- \$0.8 million increase in inventory attributable primarily to the build up of Natesto® finished goods and WIP inventory in anticipation of 2021 deliveries.
- \$0.4 million increase in accounts receivable arising from gross to net recoveries from Aytu related to sales of Natesto in the U.S. market.
- \$2.0 million increase due to a reduction in accounts payable and accrued liabilities enabled with the proceeds available from November Rights Offering.

This was offset by:

- \$1.4 million increase in current portion of long-term debt attributable to SWK loan repayments scheduled for 2021.

### 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. At December 31, 2020 manufacturing equipment with a net book value of \$0.4 million was held off-site by a third party (\$0.6 million at December 31, 2019).

The \$3.3 million decrease in non-current assets at December 31, 2020 versus December 31, 2019 reflects the following:

Intangible assets decreased by \$2.0 million to reflect the sale of our Estrace<sup>®</sup> product rights to Pharmascience Inc. and a further \$0.7 million for amortization expense.

The \$0.6 million decrease in right to use asset and property and equipment at December 31, 2020 versus December 31, 2019 comprises \$0.3 million attributable to depreciation expense and \$0.3 million attributable to a reduction to the carrying value of the right to use asset due to the early termination of our Mississauga headquarters premises lease and the resulting remeasurement of the related lease liability.

#### *Lease liability*

The lease liability was reduced by \$0.5 million in December 2020 due to the early termination of our Mississauga headquarters premises lease and the resulting remeasurement of the related lease liability. The remaining lease liability is reflected in current liabilities and will be fully paid by June 30, 2021 coinciding with the lease termination date.

#### *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 29, 2020, the Company received a waiver with regards to the minimum aggregate revenue required for the three-month period ending September 30, 2020. On December 23, 2020, we received a waiver with regards to the minimum aggregate revenue required for the three month period ending December 31, 2020.

At December 31, 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 December 31, 2020, \$nil was drawn as standby letters of credit and bank guarantees and the full \$750 remains available under this facility.

#### *Shareholders’ deficiency*

We are authorized to issue an unlimited number of common shares. Each common share entitles the holder thereof to receive notice of and exercise one vote at all meetings of shareholders. As at December 31, 2020, we had 1,537,588,081 common shares issued and outstanding, and 72,509,507 outstanding stock options with a weighted average exercise price of CDN\$0.06.

The \$16.0 million increase in shareholders’ equity at December 31, 2020 versus December 31, 2019 is primarily due to \$27.8 million in issuance of common shares net of costs, \$11.9 million related to the First Generation debt and interest conversion net of cost, \$0.7 million in stock option expense, offset by a \$24.4 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 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 August 28, 2020, we issued 532,015 common shares at CDN\$0.0531 per share to a vendor in lieu of cash payment.

On November 24, 2020, we issued 526,600,000 Common Shares, pursuant to the Rights Offering announced on October 20, 2020, for gross proceeds of CDN\$13,165. SWK also became entitled to an increase in the exchange basis of their outstanding warrants to prevent a dilution of their interest as a result of the Rights Offering. The exchange basis was determined at 1.16 to 1. Accordingly, their allotment of the Original Warrants described below, was increased by 853,050 and 217,817 respectively.

## Liquidity and capital resources

### Liquidity risk

As detailed in the long-term obligations section above, as at December 31, 2020, there is \$8.25 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. 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. We control liquidity risk through management of working capital, cash flows, and sourcing of funding. 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.

The audited consolidated financial statements for the three months and year ended December 31, 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. 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 within the next two quarters.

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, obtaining additional financing, and 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. For example, delays in reintroducing Natesto<sup>®</sup> to the Canadian market, or unsuccessfully executing on our US market strategy, could result in the Company failing to meet projected revenues or other budgeted targets. In addition, factors within and outside our management's control could have a significant bearing on our ability to obtain additional financing.

### Cash flows

Cash flows from/(used in):	For the year ended December 31,			
	2020	2019	Change \$	Change %
Operating activities	\$ (22,167)	\$ (11,383)	\$ (10,784)	95 %
Financing activities	25,460	13,297	12,163	(91)%
Investing activities	-	(108)	108	(100)%
Exchange gain on cash	-	225	(225)	(100)%
Net increase in cash	\$ 3,293	\$ 2,031	\$ 1,262	(62)%

At December 31, 2020, we had a cash balance of \$9.2 million.

The cash outflow from operating activities for the year ended December 31, 2020 is a result of a \$24.4 million net loss and \$2.8 million outflow from working capital, offset by \$5.0 million in non-cash expenses. The cash outflow from operating activities for the year ended December 31, 2019 is a result of a \$16.1 million net loss and \$1.3 million outflow from working capital, offset by \$6.0 million in non-cash expenses.

The cash inflow from financing activities for the year ended December 31, 2020 are mainly from net proceeds from the issuance of securities of \$27.8 million, offset by interest payments of \$1.4 million, principal payments on long term debt of \$0.8 million and principal

elements of lease payments of \$0.1 million. The cash inflow from financing activities for the year ended December 31, 2019 are mainly from the issuance of long-term debt of \$11.5 million and the non-brokered private placement which brought in a net of \$3.4 million. This is offset by interest payments of \$1.5 million and principal elements of lease payments of \$0.1 million. There was no foreign exchange gain or loss for year ended December 31, 2020 due to the change in functional currency as discussed in the Accounting Pronouncement section of this MD&A.

### Capital expenditures

Our 2020 capital expenditures were \$nil while our 2019 capital expenditures primarily related to our investment in laboratory assets.

### Contractual obligations and commitments

As of December 31, 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	Total
Accounts payable and accrued liabilities	\$ 5,011	\$ 129	\$ 295	\$ -	\$ -	\$ 5,435
Purchase commitments	4,510	4,273	5,878	4,865	-	\$ 19,526
Lease liability (principal and interest)	34	238	-	-	-	\$ 272
Long-term debt (principal and interest)	249	847	1,645	3,062	4,849	10,652
As at December 31, 2020	9,804	5,487	7,818	7,927	4,849	35,885

Purchase commitments reflects \$13.9 million contracted with Syneos Health over the next two years. See previous discussion under *Copromote Natesto® in the U.S.*

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

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, 2020 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(g) and (h) in the consolidated financial statements ended December 31, 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 months and year ended December 31, 2020 and 2019 were as follows:

	For the three months ended December 31,		For the year ended December 31,	
	2020	2019	2020	2019
Short-term compensation of key management and directors	\$ 343	\$ 141	\$ 1,527	\$ 909
Termination benefits	-	-	-	363
Share-based compensation	219	14	628	155
Interest expense (note 14)	-	186	212	314
	\$ 562	\$ 341	\$ 2,367	\$ 1,741

These transactions are in the normal course of operations.

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

As at December 31, 2020, Acerus had a \$10.6 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 for the year ended December 31, 2019). There was no foreign exchange gain or loss in the three months and year ended December 31, 2020 due to a change in functional currency as discussed in the Accounting Pronouncement section of this MD&A.

Please refer to the “Shareholders’ deficiency” section for details on an equity financing and debt-to-equity conversion by First Generation. As a result of these transactions, First Generation’s share ownership increased from 45.1% to 85.8%.

### Dividends

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

### Financial instruments

As at December 31, 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 and comprehensive loss and is classified as Level 2. Cash, trade and other receivables, contract assets, accounts payable and accrued liabilities are measured at amortized costs and their fair values approximate carrying values due to their short-term nature except for the Buyout payable. The Buyout payable has been discounted using a current interest rate and accordingly its carrying value approximates fair value.

The long-term debt is measured at amortized cost. At December 31, 2020 the fair value of the long-term debt approximates its face value of \$8.25 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 British Pounds of the parent company, whose functional currency is the US dollar.

	December 31, 2020		
	CDN	EUR	GBP
Cash	\$ 10,263	\$ -	\$ -
Trade and other receivables	216	55	-
Accounts payable and accrued liabilities	(1,533)	(76)	(65)
Lease liability	292	-	-
	\$ 9,238	\$ (21)	\$ (65)

Based on the above net exposure at December 31, 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%	\$ (346)	\$ (1)	\$ (5)	\$ (352)
Depreciate 5%	382	1	5	388

### 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 and with its affiliated bank located in the U.S.

We monitor the collectability of trade and other receivables and estimates on allowance for doubtful accounts. We have concentration risk with revenues earned from our U.S. out-licensing partner comprising 58% of revenues for the year and 53% of its trade receivables at year end.

As at December 31, 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 are consistent with the significant accounting policies used in the preparation of the audited annual consolidated financial statements for the year ended December 31, 2020. These policies have been consistently applied to all periods presented except as noted below regarding the change in functional currency.

### **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 consolidated financial statements for the year ended December 31, 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. 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 within the next two quarters. In addition, we expect that the Company will breach its minimum revenue and EBITDA financial covenants as at March 31, 2021 unless a waiver is obtained from our lender. 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, obtaining additional financing, and 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. Delays in reintroducing Natesto® to the Canadian market, or unsuccessfully executing its US

market strategy, could result in the Company failing to meet projected revenues or other budgeted targets which could result in continuing to violate our debt covenants. In addition, factors within and outside our management's control could have a significant bearing on our ability to obtain additional financing. These circumstances cast significant doubt as to our ability to realize our assets, meet our contractual obligations and commitments 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 provisions with respect to product revenues 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. We monitor these provisions and make adjustments when it believes actual results may differ from established reserves.

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), we are 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. Our assessment of the estimated future net pricing schedules takes into consideration both historical gross to net revenue deduction experience as reported by its marketing partners, as well as 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.

#### Impairment of non-financial assets

At December 31, 2020, we have an intangible asset with a carrying value of \$1,765 relating to a technology platform ("TriVair") for pulmonary and nasal delivery of pharmaceutical medication that was acquired in 2009. The recoverability of this intangible asset is dependent on successful development and subsequent commercialization of the related products or entering into a potential transaction to license or sell the technology. We have granted a third party exclusive worldwide rights to develop, manufacture and market nasal and pulmonary inhalation devices developed or manufactured using the TriVair technology under a five-year intellectual property right and product development agreement. In return, we are entitled to receive 37% of any upfront fees, payments, or milestone payments on the first partnering transaction entered into by this third party (and 25% on any subsequent partnering transactions) and 15% of all revenues received by this third party in connection with the sale of products developed using the technology to other parties. The third party has the option to extend this agreement by a further five years from the expiry of the term if the total amounts received by us during the initial term are at least \$2,500. No revenues have been received to date. We are required to assess at the end of each year whether there is any indication that this intangible asset 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. This requires a significant amount of judgment. In our view, based on the potential pipeline of applications being developed by the third party, no indicators of impairment have been identified during the current year with respect to this intangible asset.

#### Derecognition of Estrace product right intangible asset and related accrued receivable

We reported an anticipated shortage of Estrace in January 2019 due to supply issues with its contract manufacturer and have since identified an alternative manufacturer and is continuing to work to transfer the manufacture of Estrace® to the new contract manufacturer which is expected to be completed in the first half of 2021. We entered into an asset purchase agreement to sell all of our Estrace® assets (excluding accounts receivable and inventory), effective November 30, 2020, to Pharmascience Inc in exchange for consideration in the form of royalties ranging from 10% to 15% on future Estrace product sales made by Pharmascience Inc over a period of approximately five years ending May 31 2026. If we are not able to meet certain "launch conditions" including the transfer of the manufacturing process to the new contract manufacturer by June 30, 2021, Pharmascience Inc is under no obligation to relaunch the product. If we complete the launch conditions by June 30, 2021, Pharmascience Inc is required to relaunch the product within six months of the launch conditions being met. Otherwise, we have the option to buy back the acquired assets for \$100.

Derecognizing the acquired assets occurs when the buyer obtains control of the assets and has the ability to direct the use of and obtain substantially all of the remaining benefits from the assets. In our judgment, based on the facts and circumstances surrounding this transaction, control of the acquired assets transferred to Pharmascience Inc. on November 30, 2020, notwithstanding the additional performance obligations we are required to complete to fulfil the launch conditions specified in the agreement. As a result, the acquired assets have been derecognized and a loss of \$1,629 recorded on their disposal, assuming disposal proceeds of \$691 and after providing for \$288 of costs expected to be incurred in order to complete the transfer of the manufacturing process to the new contract manufacturer.

The future royalties receivable represents variable consideration and is only included in the disposal proceeds to the extent that it is highly probable that a significant reversal in the amount of cumulative consideration will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Determining the amount of variable consideration to record requires significant judgment and involves significant estimation uncertainty. We applied the expected value method using a probability weighted approach modeling multiple scenarios and assigning probability factors to each scenario to determine this amount, resulting in disposal proceeds of \$691 being recorded which are included in contract assets (note 7). A +/- 10% change in estimated future sales by Pharmascience Inc. using the probability weightings in the model would change the estimated disposal proceeds by \$69. Changes to the probabilities assigned to various scenarios in the model could also impact the resulting disposal proceeds recorded. Additional information is disclosed in note 12 of our December 31, 2020 consolidated financial statements.

#### 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, 2020 consolidated financial statements.

#### Clinical trial expenses

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

#### Share based payments

The compensation expense related to share-based payments is determined using the Black-Scholes option pricing model. The significant variables and estimates used in the model are volatility, dividend yield, expected option life, and risk-free interest rate. In addition, management also applies an estimated forfeiture rate. Additional information is disclosed in note 21 of our December 31, 2020 consolidated financial statements.

#### 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 to EBITDA (and Adjusted EBITDA) is set out below.

	For the three months ended December 31,		For the year ended December 31,	
	2020	2019	2020	2019
Net (loss)	\$ (7,103)	\$ (3,883)	\$ (24,424)	\$ (16,129)
Adjustments:				
Amortization of intangible assets	180	176	717	818
Depreciation of property and equipment	60	63	245	254
Depreciation of right of use asset	13	12	48	47
Interest expense and other financing costs*	362	664	1,975	2,532
Interest income	(2)	(11)	(67)	(17)
Change in fair value of derivative	(22)	(97)	(182)	(161)
<b>EBITDA</b>	<b>\$ (6,512)</b>	<b>\$ (3,076)</b>	<b>\$ (21,688)</b>	<b>\$ (12,656)</b>
Licensing and other revenue	-	(193)	-	(193)
Share based compensation	230	13	654	176
Foreign exchange (gain)	(96)	(167)	(112)	(261)
Gain on remeasurement of lease liability	(75)	-	(75)	-
Charges related to product recall	71	77	-	1,053
Loss on sale of intangible asset	1,629	-	1,629	-
Impairment loss on intangible asset	-	-	-	2,536
<b>Adjusted EBITDA</b>	<b>\$ (4,753)</b>	<b>\$ (3,346)</b>	<b>\$ (19,592)</b>	<b>\$ (9,345)</b>

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

### Management's responsibility for financial reporting

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

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

As at December 31, 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 year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.

An evaluation of the design and effectiveness of the Company's DC&P and ICFR has been conducted by management, under the supervision of the Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Based on this evaluation, the CEO and CFO have concluded that, as of December 31, 2020, the Company's disclosure controls and procedures and internal control over financial reporting, as defined by National Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings, are operating effectively.

### **Litigation**

#### *Schenk Litigation*

Valeant Pharmaceuticals International, Inc. and Valeant International Bermuda ("Valeant") are defendants in Ontario Superior Court of Justice Action No. CV-11-438382, which claims a declaration that Valeant is contractually obligated to compensate the plaintiff, Reiner Schenk ("Schenk") pursuant to the terms of a contract between Schenk and Biovail Corporation. The main action was commenced by Notice of Action issued on October 31, 2011 and a Statement of Claim was issued on December 14, 2011. Acerus Pharmaceuticals Corporation was named as one of the defendants in the main action, but the action was discontinued as against Acerus on December 14, 2011. On October 29, 2013, Valeant commenced a third party claim against Acerus (among others) claiming contribution, indemnity and other relief over to the full extent that Valeant may be held liable to Schenk, and damages for breach of fiduciary duty, breach of contract and intentional interference with economic relations in any amount for which Valeant is found liable to Schenk. Acerus has defended the third-party claim, denying any liability to Valeant. The parties have concluded examinations for discovery and attended a pre-trial conference in February 2020. The trial 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 December 31, 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. The Company alleges that the suspension of Recipharm's manufacturing license in August 2018, in contravention of its contractual obligations to the Company, led to a shortage of Estrace® in Canada. Due to the shortage, Estrace® revenues and the Company's market share has decreased substantially each year since the shortage began. Consequently, the Company has sued Recipharm for, among other things, its loss of profits and loss of market share caused by the shortage. The Company and Recipharm have exchanged pleadings and attended a Case Management Conference on November 20, 2020. The Company anticipates participating in a motion in the first half of 2021 to determine legal issues ahead of trial. As of December 31, 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.

### **Additional information**

Additional information about Acerus, including the Company's Annual Information Form dated March 10, 2021, is available in documents filed by the Company with Canadian securities regulatory authorities and made available on the System for Electronic Document Analysis and Retrieval at [www.sedar.com](http://www.sedar.com).