



**Management's Discussion & Analysis of
Acerus Pharmaceuticals Corporation
For the three and twelve months ended December 31, 2021**

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, 2021. This MD&A is dated March 14, 2022 and should be read in conjunction with the annual audited consolidated financial statements and accompanying notes for the year ended December 31, 2021.

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 14, 2022 available at 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 quarter. Our ability to accomplish our strategic plans, including funding the contemplated \$6 million up-front fee on the indirect acquisition of Serenity LLC described below in *Subsequent Events*, 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 as planned in 2022, 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 violating 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 related to the Company's acquisition of Serenity Pharmaceuticals LLC ("Serenity") including: the Company's lack of experience marketing nocturia products; overestimating the market opportunity for Noctiva™; underestimating its costs to market Noctiva™; not having a supply agreement in place to produce Noctiva™; and 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 14, 2022, 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 Suite 205, 7025 Langer Drive, Mississauga, Ontario, L5N 0E8.

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®, 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"). Our previous contract with Aytu Biosciences Inc. ("Aytu") was terminated effective March 31, 2021. Following a transition period that ended on July 31, 2021, we assumed all responsibilities within the U.S. market for services previously contracted to them.

On May 10, 2021, we announced that we had entered into a three-year agreement with Amneal Pharmaceuticals Inc. ("Amneal") to co-promote Natesto® in the United States Endocrinology segment. Amneal will sell Natesto® to their existing Endocrinology targets through June 30, 2024, leveraging their current relationships with Endocrinology health care providers.

Natesto® 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: avanafil a new chemical entity PDE5 inhibitor for the treatment of erectile dysfunction, which has been approved by the U.S. Food and Drug Administration (“FDA”) and the European Medicines Agency (“EU EMA”) and is commercialized in the U.S. under the trade name Stendra® and, in the European Union (“EU”) under the trade name Spedra® and Lidbree™ (formerly referred to as Shact™), a short acting lidocaine formulation delivered through a proprietary device into the vaginal mucosal tissue. In addition, Acerus is working on expanding its product portfolio by leveraging its proprietary delivery systems (“TriVair™”), patents and formulation expertise. Our focus in 2021 was to secure extended patent applications for TriVair™ from 2024 to 2037. Patent extensions have been granted in Canada, Japan and Europe. Patent prosecution for the US market was rejected for a second time in December 2021. A resubmission has been filed but this time separating the claim between Intra nasal and pulmonary. This approach was also necessary for the Japanese approval, which only covers only intranasal applications. See further the discussion below regarding an impairment assessment of the underlying intangible asset. This product is currently licensed to IP Med Inc., who are actively looking for potential technology applications within the US market.

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

On February 28, 2022, we announced we had entered into a definitive agreement (the “Definitive Agreement”) to indirectly acquire Serenity LLC (“Serenity”) and the global rights to its Noctiva™ brand in a combined cash and stock transaction. Noctiva™ is prescribed for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. It is the first US Food and Drug Administration approved therapy for nocturia. The transaction closed on March 7, 2022, following approval of the transaction by the Toronto Stock Exchange. Refer to the “*Subsequent Events*” section for more information.

For further information please see the Annual Information Form dated March 14, 2022 and our other filings available on SEDAR at www.sedar.com.

Key products and developments

Natesto®

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

Date	Company	Territory	Terms
April 22, 2016	Aytu BioScience Inc. (“Aytu”)	United States	<ul style="list-style-type: none"> Non-refundable upfront payments totaling \$8.0 million Sales-based milestones that could potentially total \$37.4 million Tiered supply price per unit Agreement amended and restated agreement effective July 2019 Agreement terminated effective March 31, 2021, with a 120-day transition period ending July 31, 2021
December 15, 2016	Hyundai Pharm Co., Ltd (“Hyundai”)	South Korea	<ul style="list-style-type: none"> Non-refundable upfront fee Milestone payment on regulatory approval Tiered supply price per unit
June 5, 2017	Therios Healthcare (“Therios”)	Saudi Arabia, United Arab Emirates, and Egypt	<ul style="list-style-type: none"> Fixed supply price per unit The agreement was terminated by mutual consent on May 19, 2020
June 14, 2017	medac Gesellschaft für Klinische Spezialpräparate mbH (“medac”)	15 European countries: Germany, United Kingdom, France, Italy, Czech Republic, Slovakia, Spain, Sweden, Finland, Denmark, Norway, Poland, Austria, Netherland and Belgium (See update below on October 31, 2018)	<ul style="list-style-type: none"> Non-refundable upfront fee Milestone payment on regulatory approval and sales-based milestone payments Tiered supply price per unit

October 17, 2017	Eu Hwa Pte LTD. (“HWA”)	Thailand, Malaysia/Brunei, Singapore, Vietnam, Philippines, Hong Kong/Macau and one other small South East Asian country	<ul style="list-style-type: none"> Non-refundable upfront fee Milestone payment on regulatory approval Tiered supply price per unit
November 23, 2017	Apsen Farmacêutica (“Apsen”)	Brazil	<ul style="list-style-type: none"> Non-refundable upfront fee Milestone payment on regulatory approval Tiered supply price per unit
April 9, 2018	Producto Científicos, S.A. de C.V (“Carnot Laboratorios”)	Mexico and 18 Central and Latin American countries (Argentina, Columbia, Peru, Chile, Ecuador, Guatemala, El Salvador, Nicaragua, Honduras, Panama, Costa Rica, Cuba, Dominican Republic, Venezuela, Bolivia, Uruguay, Paraguay and Haiti)	<ul style="list-style-type: none"> Non-refundable upfront fee Milestone payment on regulatory approval Tiered supply price per unit This agreement was terminated by mutual consent on May 18, 2021 upon repayment of the upfront fee.
October 31, 2018	medac	Amended to include all existing European Union Member states and the United Kingdom, Norway, Liechtenstein, Iceland, Turkey, Australia, New Zealand, South Africa and Israel.	<ul style="list-style-type: none"> Non-refundable upfront fee All other terms as per the original agreement
March 30, 2021	Maylen Farma	20 countries in eastern Europe, Central Asia and the Middle East.	<ul style="list-style-type: none"> Milestone payment on regulatory approval Tiered supply price per unit

As reported previously, as of March 31, 2021, all recall obligations related to the previously reported August 2, 2019, voluntary recall and replacement of Natesto® in both the Canadian and South Korean markets have been fulfilled. Specifically, all replacement product committed to our South Korean partner has been shipped and the Canadian market recall final report has been filed to Health Canada. Canadian market shipments are expected to resume in late 2022.

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

Natesto® in the U.S.

On April 1, 2021, we announced the buy back of all remaining U.S. rights for Natesto from Aytu. Under the terms of the Termination and Transition Agreement, we agreed to pay a termination fee of \$7.5 million, to be paid in equal instalments of \$0.25 million over 30 months beginning April 15, 2021. We also agree to repurchase all unsold inventory on hand as of March 31, 2021, the termination date. Aytu continued to support the distribution of Natesto® during a transition period which ended on July 31, 2021. The Termination and Transition Agreement also provides that any expenses claimed during the 120-day transition period attributable to sales made prior to April 1, 2021, are shared in accordance with the previous License and Supply Agreement (as described above). From April 1, 2021, Acerus earns 100% of net revenue on product sales of Natesto® in the US.

On May 10, 2021, we announced that we had entered into a three-year agreement with Amneal Pharmaceuticals Inc. (“Amneal”) to co-promote Natesto® in the United States Endocrinology segment. Under the terms of the agreement, Amneal will sell Natesto® to their existing Endocrinology targets through June 30, 2024, leveraging the current Endocrinology clients of Amneal’s 50+ sales representatives. In compensation for their marketing efforts, Amneal will receive a commission for most of the net profits attributed to Endocrinology targets in the three active promotional years, with Acerus retaining a low double-digit percentage of such profits during the active promotion period. Amneal will also receive a three-year trailing royalty following the active promotion period, with compensation to them decreasing from a majority of net profits to a minority of the net profits. Amneal’s commission for the six month

period ended December 31, 2021 was not material consistent with the anticipated ramp up period to disseminate product knowledge internally and subsequently promote to their existing Endocrinology customers.

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®, 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. In total, 30+ Syneos personnel are currently deployed in sales and commercial operations support. Acerus also employs 4 employees located in the US responsible for the day to day management of our Natesto® business.

During 2021, we were granted an additional patent and listing in the Orange Book extending intellectual property protection on Natesto® in the U.S. to 2034.

Estrace®

On November 30, 2020, we sold all of its Estrace® assets to a third party. We will receive purchase consideration computed as a royalty on sales for a period of approximately five years ending May 31, 2026. An amount of \$691 was initially accrued as a contract asset for the portion of the estimated future royalties receivable being the amount we considered was highly probable of not being subject to a significant reversal when the uncertainty associated with this variable consideration is subsequently resolved. As certain launch conditions were not met by June 30, 2021, including the successful transfer of the manufacturing process by us to a new contract manufacturer, the third party is under no obligation to relaunch the product. Specifically, we have been unable to replicate the production attributes of Estrace with the new contract manufacturer that would support an L3 attestation with Health Canada to qualify the new manufacturer. Therefore, taking into account our reduced confidence level in being able to complete the launch conditions, and timing thereof, and the impact this may have on the third party's decision to relaunch the product, the carrying value was previously reduced to \$nil to reflect our estimate of the amount highly probable of not being subject to a significant reversal when these uncertainties are resolved. An amount of \$288 was accrued at December 31, 2020 to complete the manufacturing transfer of which \$205 remains unspent at December 31, 2021. A launch, assuming launch conditions can be met, is currently indeterminate. Accordingly, a charge of \$150 was recorded in cost of goods sold to reflect our estimate of the net realizable value of raw materials currently held at the new contract manufacturer should we not ultimately be able to complete the manufacturing transfer.

avanafil (available in the U.S. under the brand name Stendra®)

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. In October, 2021, the Company received a Notice of Deficiency from Health Canada related to its avanafil New Drug Submission ("NDS"). Health Canada had previously requested the provision of additional pre-clinical and toxicology data related to the avanafil active pharmaceutical ingredient (API) from the API manufacturer, Sanofi. Sanofi did not provide the available data in a format requested by Health Canada as per the timeline prescribed. As a result, Acerus has had to withdraw the avanafil dossier from the review process. Acerus is working with Petros Pharmaceuticals, the licensor of avanafil to Acerus, and Sanofi to ensure that the information will be provided in a timely manner and to discuss how to apportion the additional regulatory costs incurred as a result of the failure of Sanofi to supply the information to Health Canada. A resubmission is expected to be made to Health Canada during the first quarter of 2022, with the expected introduction of avanafil to the Canadian market occurring in late 2023.

On December 11, 2020, VIVUS, Inc. ("VIVUS"), the licensor of avanafil to Metuchen, announced that it had received approval of its plan of reorganization, under which IEH Biopharma LLC ("IEH") now holds 100% ownership of VIVUS. As set forth in the plan of reorganization, VIVUS will continue to fulfill its supply chain obligations for avanafil and provide 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.

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 introduce new variants 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 financial assistance under the Canada Emergency Wage Subsidy amounting to \$0.1 million for the year ended December 31, 2021 (\$0.2 million for the year ended December 31, 2020).

Our supply chains and contract manufacturers are still active and are supporting the Company’s efforts to expand its business.

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.

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.

On April 30, 2021, we announced closing a \$15 million subordinated secured loan facility ("Loan Facility") with First Generation, a company affiliated with the Chairman of the Board of Directors of the Company. The loan will be made available by way of one or more advances under a secured promissory note. The Loan Facility is subordinated to the existing credit facility with SWK and bears interest at a fixed rate of 8% per annum. Subject to the terms of the subordination and intercreditor agreement between First Generation and SWK, the Loan Facility is repayable in full by December 31, 2024. Prior to December 31, 2024, cash payments of interest or principal repayments are subject to certain exceptions related to the Company's market capitalization and the outstanding amount of the senior facility with SWK. The Loan Facility can be repaid in full or in part without limitation following repayment of the full amount owing to SWK.

On December 13, 2021, we announced we had entered into an amending agreement with First Generation to increase the subordinated loan facility from \$15 million to \$25 million. SWK consented to the \$10 million increase as well as a temporary amendment to reduce the minimum Consolidated Unencumbered Liquid Asset covenant from \$2 million to \$250 until February 1, 2022.

On February 18, 2022, we announced that we had entered into an amending agreement with First Generation to increase the subordinated loan facility from US\$25 million to US\$30.845 million. This increase was made available to the Company by way of a single advance under a secured grid promissory note with First Generation. The proceeds from the Loan Facility increase were used on February 17, 2022, to settle all obligations under the SWK credit facility.

In accordance with IFRS 9 – Financial Instruments, loans must be initially measured at fair value. We have assessed the fair market interest rate attributable to the subordinated loan facility and determined that an interest rate of 14% represents fair value. Accordingly, fair value adjustments amounting to \$3.5 million have been recorded on advances to date. As the loan is from a related party who has a controlling interest in the Company, the resultant gain has been recorded as contributed surplus. A +/- 1% change in the discount rate would change the estimated initial fair value of the loan by +/- \$0.5 million.

As of December 31, 2021, the Company had \$20 million outstanding on the Loan Facility.

SWK – Credit Facility

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.

On March 26, 2021, the Company announced we had entered into an agreement with SWK in respect of an amendment to the New Facility. The amendment (i) increases minimum threshold for consolidated unencumbered liquid assets required to be maintained by the Company from \$1,500 to \$2,000 effective May 15, 2021; (ii) waives the revenue and EBITDA covenants for 2021 and resets them for 2022 to better reflect the nature of the Company's business at this time; (iii) fixed principal repayments at \$600 per quarter; and (iv) requires a pre-payment of \$500 of principal by May 15, 2021. A loss on modification of \$64 was recorded against deferred financing fees as a result of this amendment.

On December 13, 2021, we announced that SWK had consented to amending our agreement with First Generation to increase the subordinated loan facility from \$15 million to \$25 million. SWK also consented to a temporary amendment to reduce the minimum Consolidated Unencumbered Liquid Asset covenant from \$2 million to \$250 until February 1, 2022.

As noted in the *First Generation Loan* section above, on February 18, 2022, we announced that we had settled all obligations under the SWK credit facility effective February 17, 2022. However at December 31, 2021, we had \$6.445 million in principal outstanding on the credit facility, inclusive of a \$495 exit fee due at maturity and we were in compliance with all of our covenants.

Canadian credit facility

At December 31, 2021, 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, 2021, \$nil was drawn as standby letters of credit and bank guarantees with \$0.75 million remaining available under this facility.

Factors affecting results from operations

Revenue and cost of sales

Our product revenues for the year ended December 31, 2021 reflects the sale Natesto® net of deductions for early pay discounts, rebates, co-pay, distribution fees, chargebacks and returns (collectively known as gross to net adjustments). A description of these adjustments is as follows:

- Early pay discounts are granted for payment on mutually agreed terms.
- Rebates represent discounts off the wholesale acquisition cost ("WAC") of product negotiated between the Company and individual Pharmacy Benefit Managers ("PBMs") in return for listing on the PBMs health plan formularies.
- Co-Pay represents the Company's cash discount offered to patients directly to cover the remaining out of pocket costs for the Company's products.
- Distribution fees represent the costs charged by wholesalers for distributing the Company's product throughout North America.
- Charge backs represent discounts off the wholesale acquisition cost of product negotiated between the Company and select wholesalers; notably, large pharmacy chains and government administered benefit plans.
- Returns represents products previously sold subsequently returned to the Company due to product expiry (i.e. short-dated product). The Company's wholesaler agreements provide for an 18-month period for the return of short dated product commencing 6 months before the products expiry date.

Amounts accrued for individual gross to net items are included in Accounts payable and accrued liabilities within current liabilities. These provisions are based on both historical levels and relevant forward-looking information. While such historical experience and forward-looking information has allowed for reasonable estimates in the past, these may not always be accurate indicators of future events. We monitor these provisions quarterly and make adjustments when we believe actual results may differ from established reserves.

Prior to the termination of the license and supply agreement with Aytu on March 31, 2021, we recognized Natesto® revenue on delivery of the product to this marketing partner as the sum of two items: 1) the contractual supply price when the product is delivered; and 2) an estimate of the top-up revenue that is highly probable will not result in a significant reversal in the amount of cumulative revenue earned when the marketing partner recognizes the sale of the product. An adjustment was made, if required, to the actual top-up revenue earned when the marketing partner recognizes the sale of the product. The initial estimate of the top-up revenue, and subsequent adjustments if required, were reflected as a contract asset until it is earned.

Cost of sales reflect the cost of finished goods which include manufacturing, distribution and warehousing costs.

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, or 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 product 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 expenses consist primarily 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.

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. Taxes paid on goods and services purchased are generally recoverable as input tax credits. The corporate income tax rate in Canada is 26.5% in 2021 and is unchanged from 2020.

Select consolidated financial information

	Three months ended December 31,		Year ended December 31,	
	2021	2020	2021	2020
Statement of operations data				
Product revenue	\$ 738	\$ 271	\$ (4,133)	\$ 1,085
Operating loss	(8,198)	(6,936)	(33,666)	(22,885)
Net Loss	(9,023)	(7,103)	(33,817)	(24,424)
Basic and diluted net loss per common share	\$ (0.01)	\$ (0.01)	\$ (0.02)	\$ (0.03)
Balance sheet data:				
	December 31,	December 31,		
	2021	2020		
Total assets	\$ 9,652	\$ 16,982		
Long-term debt	23,290	8,019		

Review of operating results – Year ended December 31, 2021

Revenue and gross margin

	Year ended December 31,			
	2021	2020	Change \$	Change %
Product revenue	\$ 2,121	\$ 1,085	\$ 1,036	95 %
Termination fee	(6,254)	-	(6,254)	n/a
	(4,133)	1,085	(5,218)	(481)%
Cost of goods sold	1,118	2,014	(896)	(44)%
Gross margin	\$ (5,251)	\$ (929)	\$ (4,322)	(465)%

Revenue increased \$1.0 million for the year ended December 31, 2021, versus the prior year in 2020 and is due primarily to the recognition of 100% of the gross margin on Natesto® sales in the US market versus a revenue share in the comparative period under the previous Aytu agreement. This change was effective April 1, 2021, following the termination of our previous agreement with Aytu effective March 31, 2021.

We agreed to pay Aytu a termination fee of \$7,500, payable in equal installments of \$250 over 30 months, in return for buying back all of our rights to Natesto® in the U.S. market. The first installment was paid on April 15, 2021. We recorded a charge against revenue of \$6,204 on March 31, 2021, representing the fair value of the \$7,500 obligation payable. The fair value was estimated by discounting the installment payments using a rate of 17%. A +/- 10% change in the discount rate would change the estimated fair value by +/- \$106. We also paid a fee of \$50 in May 2021 to Carnot Laboratorios to terminate our current agreement.

Despite the increase in product revenue, cost of goods sold decreased by \$0.9 million versus the prior period in 2020, as the comparative period includes a non-cash charge of \$0.5 million for the amortization of the Estrace intangible asset and a \$0.4 million in incremental charges for obsolete and slow-moving raw materials. The Estrace asset was subsequently sold in November 2020 resulting in no equivalent amortization charge in the current year.

Operating expenses

	Year ended December 31,			
	2021	2020	Change \$	Change %
Operating expenses				
Research and development	\$ 6,563	\$ 2,526	\$ 4,037	160 %
Selling, general and administrative	21,852	19,430	2,422	12 %
	\$ 28,415	\$ 21,956	\$ 6,459	29 %

Research and development

Research and development expenses have increased by \$4.0 million for the year ended December 31, 2021, versus the prior year in 2020. \$1.7 million of the increase is attributable to a non-cash impairment charge to reduce the carrying value of the company's TriVair intangible asset to \$nil. We received notice in December 2021 that our TriVair patent application to extend patent protection from 2024 to 2037 for the US market was rejected. Although we resubmitted the patent claim splitting out Intranasal from Pulmonary use, the rejection raises significant uncertainty and further delays regarding our ability to successfully prosecute this patent application for the US market. The inability to extend the patent for the US market has hindered all business development opportunities identified by our business development partner to date. In light of these factors, we have recorded an impairment amounting to the unamortized balance of this intangible asset as at December 31, 2021. The balance of the increase of \$2.3 million is attributable to an increase in clinical trial activities for Natesto® in the U.S. related to the Ambulatory Blood Pressure Monitoring trial (required by the FDA) that was deferred from 2020 due to Covid related restrictions. An increased level of expense is anticipated through the first half of FY2022 in order to complete this trial.

Given the nature of our business and product pipeline, we will continue to incur research and development expenses in the future. Research and development expenditures will increase as we initiate further clinical studies, such as our Ambulatory Blood Pressure Monitoring trial in the U.S. noted above, 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 North America. 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 as well as costs anticipated to develop the next generation of dispenser for Natesto®.

Selling, general and administrative

Selling, general and administrative expenses increased by \$2.4 million for the year ended December 31, 2021, versus the prior year in 2020. However, the prior year reflects a non-cash charge of \$1.6 million of the loss on the sale of Estrace product rights in November 2020. All other expenses increased by \$4.0 million. Of this increase, approximately \$1.7 million is attributable to selling and marketing expenses incurred with Syneos and for increased marketing materials and advertising campaign with a new advertising agency for the promotion of Natesto® in the U.S. market. The full compliment of contracted Syneos resources for sales, sales management, medical liaison and business development resources are now in place. Approximately \$0.6 million of the increase relates to increased professional fees and business development activities (net of the legal fees recovery from Recipharm noted above). Approximately \$0.6 million of the increase relates to non-cash charges for depreciation and share based compensation. An increase of \$0.4 million is attributable to additional full-time staff in support of Natesto® in the US market. A further \$0.7 million of the increase relates to a one-time charge to write off the accrued receivable recorded in Q4 2020 for expected proceeds from the sale of Estrace. Although we remain committed to completing the technology transfer and launch conditions pursuant to the sale agreement, a reassessment of the probability weighted outcomes used to determine the accrued amount no longer supports the original accrual and a full write down was taken in Q2 2021.

Other expenses (income)

	Year ended December 31,		Change \$	Change %
	2021	2020		
Other expenses (income)				
Interest expense and other financing costs	\$ 2,570	\$ 1,975	\$ 595	30 %
Litigation settlement proceeds	(2,328)	-	(2,328)	n/a
Interest income	(8)	(67)	59	88 %
Foreign exchange (gain) loss	(63)	(112)	49	(44)%
Change in fair value of derivative financial instruments	(84)	(182)	98	54 %
Gain on remeasurement of lease liability	-	(75)	75	100 %
Loss on modification of debt	64	-	64	n/a
	\$ 151	\$ 1,539	\$ (1,388)	(90)%

The net \$0.6 million increase in interest expense and other financing costs for the year ended December 31, 2021 over the prior year is due to an increase in interest expense attributable to the new First Generation Loan Facility and accrued interest expense on the Aytu termination fee payable, offset by the reduction in accretion expense for the buy out of the Mattern license agreement, conversion of the previous First Generation interest bearing loan to equity in February 2020, reduced current period interest charges on our debt with SWK due to principal repayments.

The litigation settlement proceeds were received from Recipharm upon acceptance of their offer to settle our claim as previously reported in the *Litigation* section below. A further \$0.4 million was accrued as a recovery of legal expenses and recognized as a reduction of selling, general and administrative expenses in the current year.

The foreign exchange gain is due primarily 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 loss on debt modification arises from the amendment to our debt with SWK described in the “Long-term debt financing” section above.

Review of operating results – Three months ended December 31, 2021

Revenue and gross margin

	Three months ending December 31,		Change \$	Change %
	2021	2020		
Revenue				
Product revenue	\$ 738	\$ 271	\$ 467	172 %
	738	271	467	172 %
Cost of goods sold	393	846	(453)	(54)%
Gross margin	\$ 345	\$ (575)	\$ 920	(160)%

Revenue increased \$0.5 million for the three months ended December 31, 2021, versus the prior period in 2020, reflecting the recognition of 100% of the gross margin on Natesto® sales in the US market versus a revenue share in the comparative period under the previous Aytu agreement. This change was effective April 1, 2021, following the termination of our previous agreement with Aytu effective March 31, 2021.

Cost of goods sold decreased by \$0.5 million versus the prior period in 2020, as the comparative period includes a non-cash charge of \$0.1 million for the amortization of the Estrace intangible asset and a \$0.5 million charge for slow-moving raw materials. The Estrace asset was sold in November 2020 resulting in no equivalent amortization charge in the current period.

Operating expenses

	Three months ending December 31,		Change \$	Change %
	2021	2020		
Operating expenses				
Research and development	\$ 3,309	\$ 744	\$ 2,565	345 %
Selling, general and administrative	\$ 5,234	\$ 5,617	(383)	(7)%
	\$ 8,543	\$ 6,361	\$ 2,182	34 %

Research and development

Research and development expenses have increased by \$2.6 million for the three months ended December 31, 2021, versus the prior period in 2020. \$1.7 million of the increase is attributable to a non-cash impairment charge to reduce the carrying value of the company's TriVair intangible asset to \$nil as noted above. The balance of the increase of \$0.9 million is attributable to an increase in clinical trial activities for Natesto® in the U.S. related to the Ambulatory Blood Pressure Monitoring trial (required by the FDA) that was deferred from 2020 due to Covid related restrictions. An increased level of expense is anticipated through the first half of FY2022 in order to complete this trial.

Given the nature of our business and product pipeline, we will continue to incur research and development expenses in the future. Research and development expenditures will increase as we initiate further clinical studies to differentiate our Natesto® product 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 North America. 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 as well as costs anticipated to develop the next generation of dispenser for Natesto®.

Selling, general and administrative

Selling, general and administrative expenses decreased by \$0.4 million for the three months ended December 31, 2021 versus the prior period in 2020. However, the prior year reflects a non-cash charge of \$1.6 million of the loss on the sale of Estrace product rights in November 2020. All other expenses increased by \$1.2 million of which \$0.7 million reflects increased spend on our contracted sales force and advertising as well as \$0.5 million for additional full time staff, both in support of Natesto® in the US market.

Other expenses (income)

	Three months ending December 31,		Change \$	Change %
	2021	2020		
Other expenses (income)				
Interest expense and other financing costs	\$ 863	\$ 362	\$ 501	138 %
Gain on remeasurement of lease liability	-	(75)	75	(100)%
Interest income	(3)	(2)	(1)	50%
Foreign exchange (gain) loss	8	(96)	104	(108)%
Change in fair value of derivative financial instruments	(43)	(22)	(21)	(95)%
	\$ 825	\$ 167	\$ 658	394 %

The \$0.5 million increase in interest expense and other financing costs is due to the increase in interest bearing debt: notably, the First Generation Loan Facility and accrued interest expense on the Aytu termination fee payable. Please refer to the *First Generation Loan* discussion within the "*Long-term debt financing*" section.

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, 2021. 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.

	December 31, 2021	September 30, 2021	June 30, 2021	March 31, 2021
Statement of operations data				
Product revenue	\$ 738	\$ 587	\$ 562	\$ 234
Termination Fee	-	-	(50)	(6,204)
Cost of goods sold	393	489	45	191
Research and development	3,309	1,353	928	973
Selling, general & administrative expense	5,234	5,046	6,285	5,287
Finance costs, net	825	925	324	405
Litigation settlement proceeds	-	(2,328)	-	-
Net loss	(9,023)	(4,898)	(7,070)	(12,826)
Basic and diluted net loss per common share	\$ (0.01)	\$ (0.00)	\$ (0.01)	\$ (0.01)
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
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)

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

- As noted in the "Key products and developments" section, we terminated our previous agreement with Aytu on March 31, 2021. Commencing April 1, 2021, we now earn 100% of the gross margin on the sale of Natesto® in the US market. As a result of this change, we are now able to recognize revenue on the basis of monthly sales into our sales channels rather than on periodic bulk shipments to Aytu. Prior quarter fluctuations in product revenue balances are mainly due to the timing of Natesto® inventory shipments to Aytu in the U.S. and declining Estrace® sales due to supply interruptions. Revenues in Q3 2020 reflect a shipment of Natesto® to Aytu, recognition of the potential related top-up revenue, revenue adjustments related to new rebate and trial card programs and an adjustment to previously recognized top-up revenue due to disposal of short-dated product. Revenues in Q3 2019 reflect the temporary shortage of Natesto® in the Canadian and South Korean markets.
- The litigation settlement proceeds recognized in the current quarter were received from Recipharm upon acceptance of their offer to settle our claim as previously reported in the "Litigation" section below.
- In Q1 2021 we recorded a charge against revenue of \$6,204 representing the fair value of the \$7,500 termination fee obligation payable to Aytu. We also paid a fee of \$50 in May 2021 to Carnot Laboratorios to terminate our current agreement.
- Cost of goods sold in the current period includes a charge of \$0.3 million to write off an off-specification production batch of Natesto®. In Q2 2019 we had previously impaired inventory by \$0.3 million and accrued \$0.5 million related to replacing products, discounts and potential returns due to the issue described regarding certain Natesto® lots released in the Canadian and South Korean markets. However, due to the additional delays, we reversed the previous accruals related to discounts and replacement of product and have accrued \$0.7 million for returns in Q3 2019 causing negative net sales and cost of goods values for the quarter. 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.

- Research and development expenses for the current quarter reflects an impairment charge of \$1.7 million for TriVair as explained in the review of annual and quarterly results discussed above as well as an increase over the prior three quarters related to the FDA required Ambulatory Blood Pressure Monitoring trial, which was deferred from 2020. Clinical trial activities have returned to normalized levels since the curtailment of clinical trial activities in Q2 2020 due to CIOVD-19 restrictions. A charge of \$0.2 million was also recognized in March 2021 related to additional costs to achieve the manufacturing transfer related to the sale of Estrace® in 2020.
- Selling, general and administrative expense increases from Q2 2020 through Q4 2021 reflects the completed ramp up of contracted resources deployed under our agreement with Syneos to promote Natesto® in the U.S. Expenses for Q3 2021 include a recovery of \$0.4 million for reimbursement of legal expenses incurred in the Recipharm litigation. The increase in Q2 2021 reflects a noncash loss of \$0.7 million for the loss on the Estrace accrued receivable and \$0.7 million spent on marketing and advertising campaigns for Natesto® in the US market with a new agency.

Financial position

The following table presents a summary of our financial position:

	December 31, 2021	December 31, 2020	Change \$	Change %
Working capital (total current assets less total current liabilities)	\$ (3,424)	\$ 6,931	\$ (10,355)	(149)%
Non-current assets	1,003	2,948	(1,945)	(66)%
Long-term obligations	23,593	6,719	16,874	251 %
Shareholders' (deficit) equity	(26,014)	3,160	(29,174)	(923)%

Working capital

The \$10.4 million decrease in working capital between December 31, 2020 to December 31, 2021 reflects the following:

- \$7.0 million decrease in cash attributable to \$23.5 million of cash used from operations, \$3.3 million used for principal and interest payments, \$0.2 million used for lease payments, offset by \$20.0 million in advances on the subordinated loan facility from First Generation.
- \$2.0 million increase in accounts payable and accrued liabilities maximizing available credit limits.
- \$2.5 million increase in current portion of termination fee payable for obligation accrued in Q1 2021.
- \$0.7 million increase in current portion of long-term debt attributable to SWK loan repayments scheduled for the next twelve months reflecting increased principal repayment pursuant to May 2021 amendment.
- \$0.1 million decrease in accounts receivable.
- \$0.9 million decrease in contract assets due to adjustment attributable to termination of Aytu agreement and the write down of Estrace sale accrued proceeds.

Offset by:

- \$2.3 million increase in inventory reflecting purchases of Natesto® raw materials.
- \$0.3 million increase in prepaids due to timing of annual insurance and FDA fee prepayments.
- \$0.2 million decrease in current portion of lease liability reflecting settlement of termination fee owing upon early lease termination.

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 furniture and manufacturing equipment. Right of use asset relates to the lease of our new head office leased premises in Mississauga, Canada. Intangible assets consist of technology, patents and product rights. At December 31, 2021 manufacturing equipment with a net book value of \$0.4 million was held off-site by a third party (\$0.4 million at December 31, 2020). The \$1.9 million decrease in non-current assets at December 31, 2021 versus December 31, 2020 is attributable to a noncash impairment of \$1.6 million related to our TriVair intangible asset, \$0.6 million of depreciation and amortization expense offset by \$0.3 million addition of the right to use asset.

Long-term obligations

Long-term obligations consist of long-term debt, the subordinated loan facility, the long-term portion of the termination fee, derivative financial instruments and lease liability.

Please refer to the “Long-term debt financing” section above for details on the First Generation Loan, SWK facility and the recent First Generation subordinated loan 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, 2021, we had 1,537,588,081 common shares issued and outstanding, 3,961,218 of outstanding RSUs and 112,728,260 outstanding stock options with a weighted average exercise price of CDN\$0.05.

The \$29.2 million decrease in shareholders' equity at December 31, 2021 versus December 31, 2020 is primarily due to the \$33.9 million net loss offset by a \$1.1 million of share based compensation and by \$3.6 million from the fair value adjustment on the subordinated loan facility, both relieved to contributed surplus.

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 process 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, principal of \$5.95 million with SWK remains outstanding at December 31, 2021. A principal amount of \$20.0 million has been drawn on the First Generation subordinated loan with \$5.0 remaining available as at December 31, 2021. 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 year ended December 31, 2021 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. On February 18, 2022, we announced that we had entered into an amending agreement with First Generation to increase the subordinated loan facility from US\$25 million to US\$30.845 million. This increase was made available to the Company by way of a single advance under a secured grid promissory note with First Generation. The proceeds from the Loan Facility increase were used on February 17, 2022, to settle all obligations under the SWK credit facility. Despite the settlement of the SWK credit facility subsequent to year end, 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, additional capital will be required within the next quarter.

Our ability to accomplish our strategic plans, including funding the contemplated \$6 million up-front fee on the indirect acquisition of Serenity LLC described below in *Subsequent Events*, 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® 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,			Change \$	Change %
	2021	2020			
Operating activities	\$ (23,517)	\$ (22,167)		\$ (1,350)	(6)%
Financing activities	16,539	25,460		(\$8,921)	(35)%
Investing activities	(16)	-		(16)	n/a
Net (decrease) increase in cash	\$ (6,994)	\$ 3,293		\$ (10,286)	(312)%

At December 31, 2021, we had a cash balance of \$2.2 million and \$5.0 million available on the First Generation subordinated loan facility.

The cash outflow from operating activities of \$23.5 million for the year ended December 31, 2021 is a result of a \$33.9 million net loss, an \$1.8 million outflow from working capital, offset by \$12.2 million in non-cash expenses. The cash outflow from operating activities of \$22.2 million for the year ended December 31, 2020 is a result of a \$24.4 million net loss, a \$2.8 million outflow from working capital, offset by \$5.0 million in non-cash expenses.

The cash inflow from financing activities of \$16.5 million for the year ended December 31, 2021 was due to \$20.0 million in advances on the First Generation subordinated loan offset by \$3.3 million in principal and interest payments on the New Facility with SWK and \$0.2 million in capital lease payments. The cash inflow of \$25.5 million from financing activities for the year ended December 31, 2020 was due to the issuance of common shares for proceeds of \$27.8 million offset by a principal repayment of \$0.8 million on the SWK facility, \$0.1 million in principal paid on our lease liability and \$1.4 million in interest and financing costs payments.

Capital expenditures

Capital expenditures net of proceeds from disposition were \$nil million for both the three and twelve months ended December 31, 2021, and \$nil in the comparative periods in 2020.

Contractual obligations and commitments

As of December 31, 2021, 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	\$ 6,523	\$ 575	\$ 300	\$ 50	\$ -	\$ 7,448
Purchase commitments	4,363	2,769	1,375	1,694	19	\$ 10,220
Termination Fee	750	750	1,500	2,250	-	\$ 5,250
Lease liability (principal and interest)	-	7	22	45	143	\$ 217
Long-term debt (principal and interest)	765	748	1,445	4,292	-	\$ 7,250
Subordinated loan facility (principal and interest)	-	-	-	-	26,066	\$ 26,066
As at December 31, 2021	12,401	4,849	4,642	8,331	26,228	\$ 56,451

More significant purchase commitments include \$3.7 million contracted with Syneos Health (discussion under "Natesto® in the U.S." above), \$2.0 million contracted for the US APBM trial and \$1.5 million for the relaunch of Natesto® in Canada.

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 ("TriVair"), 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, 2021 consolidated financial statements) for products submitted for approval by ABI itself.

We may be required to make certain regulatory or sales-based milestone payments as part of many of their in-licensing agreements as described in notes 5(d) and (e) in the consolidated financial statements ended December 31, 2021.

Related party transactions

Key management includes our directors and executive officers. The remuneration of directors and key members of management and professional fees paid for the three and twelve months ended December 31, 2021 and 2020 were as follows:

	For the three months ended December 31,				For the year ended December 31,			
	2021		2020		2021	2020		
	\$	537	\$	343	\$	2,100	\$	1,527
Short-term compensation of key management and directors	\$ 271		219		993		628	
Share-based compensation	298		-		548		212	
Interest expense	\$ 1,106		\$ 562		\$ 3,641		\$ 2,367	

These transactions are in the normal course of operations.

Executive employment agreements allow for total additional payments of approximately \$2.4 million if all are terminated as a result of a change in control, \$2.3 million if all are terminated without cause, and \$nil if all are terminated with cause.

As at December 31, 2021, Acerus had a \$14.0 million receivable (\$10.6 million receivable as at December 31, 2020) from its wholly owned subsidiary ABI. The receivable is non-interest bearing, due on demand and eliminates upon consolidation.

Please refer to the “*Shareholders’ deficiency*” section for details on an equity financing and debt-to-equity conversion by First Generation in February 2020. As a result of these transactions, First Generation’s share ownership increased from 45.1% to 89.5%.

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, 2021, 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.

The long-term debt with SWK and the First Generation subordinate loan are measured at amortized cost. At December 31, 2021, the fair value of the long-term debt with SWK approximates its face value of \$5.95 million. At December 31, 2021, the fair value of the First Generation subordinate loan approximates the current carrying value of \$17.2 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, 2021		
	CDN	EUR	GBP
Cash	\$ 43	\$ -	\$ -
Accounts payable and accrued liabilities	(1,798)	(816)	(18)
Lease liability	(427)	-	-
	\$ (2,182)	\$ (816)	\$ (18)

Based on the above net exposure at December 31, 2021, 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%	\$ 82	\$ (46)	\$ (2)	\$ 34
Depreciate 5%	(91)	46	2	(43)

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 interest 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 interest 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. As at December 31, 2021, 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, 2021. These policies have been consistently applied to all periods presented except as noted below regarding the change in functional currency.

Critical accounting estimates

In preparing our condensed interim 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 condensed interim 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, 2021 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, notwithstanding the subordinated loan funding received from First Generation, and the settlement of the SWK credit facility subsequent to year end, 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 quarter. Our ability to accomplish our strategic plans, including funding the contemplated \$6 million up-front fee on the indirect acquisition of Serenity LLC described below in *Subsequent Events*, 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 in 2022, 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 violating 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

We record Product revenue from sales in North America at the invoiced amount less estimated accruals for gross to net adjustments; namely, early pay discounts, rebates, co-pay, distribution fees, chargebacks and returns. Information about the judgments, estimates and assumptions that have the most significant effect on the recognition and measurement of product revenue are discussed below.

Rebates & Co-Pay

The accrual for rebates and co-pay is a significant and complex estimate used in the recognition of product revenue and represents variable consideration under IFRS 15. Rebates are negotiated with individual PBMs as a percentage off of WAC pursuant to agreements signed with the Company. In return, the PBM agrees to list the Company's drug on its health plan formulary typically in a preferential priority to other drug therapy alternatives. Rebates are invoiced by and paid directly to the PBMs for products subsequently prescribed under the health plans administered by them. Co-Pay represents the Company's cash discount offered to patients directly to cover the remaining out of pocket costs for the Company's products after rebates are applied. The cash rebate is claimed using a Co-Pay card issued to the patient, which is administered by a third party vendor. In our assessment, we estimate accruals for rebates & co-pay based on current contractual terms, historical claims experience and forward looking projected prescription forecasts of shipments from wholesalers that will be dispensed for eligible benefit plan participants. While such experience has allowed for reasonable estimates in the past, historical claims and forward looking forecasts may not always be an accurate indicator of future rebate & co-pay liabilities. We continually monitor the accrual for rebates and co-pay and makes adjustments when we believe that actuals may differ from established accruals. Rebates and co-pay charges are recognized as a reduction of sales revenue in the period in which the underlying sales are recognized.

Returns

The accrual for returns is a significant and complex estimate used in the recognition of product revenue and represents variable consideration under IFRS 15. Our wholesaler agreements provide for an 18-month window for the return of short dated product which commences 6 months before the products expiry date. Accruals for returns are recognized in the period the underlying product revenue is recognized. We estimate accruals for returns based on assumptions of the inventory of its products in the wholesale distribution channel that remain subject to returns, developed using existing return policies with customers, product expiry dates, data from wholesalers and large pharmacy chains of their inventory levels, external prescription data, historical returns experience and projected future returns. During the six months prior to the termination of the Aytu agreement, Aytu experienced higher than previously expected returns of Natesto. History may not always be an accurate indicator of future returns. The key estimates used to calculate the returns accrual include an assumed return rate of 1% and an assumed inventory in the retail channel equal to approximately one months' sales. If the assumed returns rate was to increase or decrease by 100% (i.e. 1% to 2%), the return accrual would increase or decrease by \$50 respectively. We continually monitor accruals for returns and makes adjustments when we believe that actual product returns may differ from established reserves. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future returns.

Impairment of non-financial assets

We have an intangible asset which has a carrying value of \$1,656 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, the Company is 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 the Company 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 reporting period whether there is any indication that this intangible asset may be impaired. If any such indication exists, management is 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 management judgment.

During December 2021, the Company was informed that the application to prosecute a patent for TriVair for the US market was rejected for a second time. This decision culminates several years of effort with the US regulator. Although a Request for Rehearing has been filed to support a third submission, the likelihood of the existing design being patented for the US market without either a significant design modification, or a limitation in therapy application regarding pulmonary and/or nasal delivery, is unlikely. Accordingly, management has determined that an impairment has occurred.

The recoverability of this intangible asset is dependent on successful technology development and subsequent commercialization of related products. Despite successfully prosecuting the TriVair patent in other non-US markets, the absence of success in the US market has impeded any significant commercial success to date. In the absence of a US market patent prosecution, and in the absence of any commercial opportunities to date for the existing technology in non-US markets, the recoverable amount of the intangible asset has been reduced to \$nil at December 31, 2021. Accordingly, a charge of \$1,656 has been recorded in research and development expense.

Derecognition of Estrace product right intangible asset and related accrued receivable

The Company entered into an asset purchase agreement to sell all of its Estrace® assets (excluding accounts receivable and inventory), effective November 30, 2020, to a third party in exchange for consideration in the form of royalties ranging from 10% to 15% on future Estrace product sales made by the third party over a period of approximately five years ending May 31, 2026. However, as the Company was not able to meet certain “launch conditions”, including the transfer of the manufacturing process to the new contract manufacturer by June 30, 2021, the third party is under no obligation to relaunch the product.

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 which required the use of significant judgement by management. In management’s view, based on the facts and circumstances surrounding this transaction, control of the acquired assets was considered to have transferred to the third party on November 30, 2020, notwithstanding the additional performance obligations the Company is required to complete to fulfil the launch conditions specified in the agreement. As a result, the acquired assets were derecognized and a loss of \$1,629 recorded on their disposal in the year ended December 31, 2020, assuming disposal proceeds of \$691 and after providing for \$288 of costs expected to be incurred to complete the transfer of the manufacturing process to the new contract manufacturer as laid out in the proposed manufacturing transfer agreement between the Company, the third party and 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. The Company 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 in the year ended December 31, 2020, which was included in contract assets (note 7). As certain launch conditions were not met by June 30, 2021 (and have still not been met), including the successful transfer of the manufacturing process by the Company to a new contract manufacturer, the third party is under no obligation to relaunch the product. Taking into account the Company’s confidence level in being able to complete the launch conditions, and timing thereof, and the impact this may have on the third party’s decision to relaunch the product, the carrying value has been reduced to \$nil to reflect management’s estimate of the amount highly probable of not being subject to a significant reversal if/when these uncertainties are resolved. No additional costs are considered necessary for expenses associated with delays to date. A launch, assuming launch conditions can be met, is currently indeterminate. A charge of \$150 was recorded in cost of goods sold to reflect the Company’s estimate of the net realizable value of raw materials currently held at the new contract manufacturer.

As noted in the “Key products and developments” section above, further validation delays have been experienced such that we now do not expect to complete the manufacturing transfer until December 31, 2021. Accordingly, we have reassessed the carrying value of the variable consideration recognized at the time of sale. In applying our judgement to a probability weighted assessment, we have concluded to write down the previously recorded accrued receivable to \$nil. Accordingly, a charge for \$691 was previously recorded in selling, general and administrative expenses. No additional costs have been accrued in the current quarter to reflect the current delay. Completion of the manufacturing transfer to the new contract manufacturer is currently indeterminate.

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,			
	2021		2020		2021	2020		
	\$	(9,023)	\$	(7,103)	\$	(33,817)	\$	(24,424)
Net loss								
Adjustments:								
Amortization of intangible assets		38		180		150		717
Depreciation of property and equipment		34		60		513		245
Depreciation of right of use asset		8		13		18		48
Interest expense and other financing costs*		863		362		2,570		1,975
Interest income		(3)		(2)		(8)		(67)
Change in fair value of derivative		(43)		(22)		(84)		(182)
Loss on modification of debt		-		-		64		-
EBITDA	\$	(8,126)	\$	(6,512)	\$	(30,594)	\$	(21,688)
Termination Fees		-		-		6,254		-
Litigation settlement proceeds		-		-		(2,328)		-
Share based compensation		295		230		1,095		654
Foreign exchange (gain) loss		8		(96)		(63)		(112)
Gain on remeasurement of lease liability		-		(75)		-		(75)
Charges related to product recall		-		71		-		-
Impairment loss on intangible asset		1,656		-		1,656		-
Gain from sale of property and equipment		-		-		56		-
Loss on sale of intangible asset		-		1,629		-		1,629
Adjusted EBITDA	\$	(6,167)	\$	(4,753)	\$	(23,924)	\$	(19,592)

* 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, 2021 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, 2021 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, 2021, that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.

Litigation

Schenk Litigation

Valeant Pharmaceuticals International, Inc. and Valeant International Bermuda ("Valeant") are defendants in Ontario Superior Court of Justice Action No. CV-11-438382, which claims a declaration that Valeant is contractually obligated to compensate the plaintiff, Reiner Schenk ("Schenk") pursuant to the terms of a contract between Schenk and Biovail Corporation. The main action was commenced by Notice of Action issued on October 31, 2011 and a Statement of Claim was issued on December 14, 2011. Acerus Pharmaceuticals Corporation was named as one of the defendants in the main action, but the action was discontinued as against Acerus on December 14, 2011. On October 29, 2013, Valeant commenced a third party claim against Acerus (among others) claiming contribution, indemnity and other relief over to the full extent that Valeant may be held liable to Schenk, and damages for breach of fiduciary duty, breach of contract and intentional interference with economic relations in any amount for which Valeant is found liable to Schenk. Acerus has defended the third-party claim, denying any liability to Valeant. The parties have concluded examinations for discovery and attended a pre-trial conference in February 2020. The trial was scheduled to commence in April 2020 and was anticipated to be two weeks long. However, in an effort to reduce the transmission of COVID-19, the Ontario Superior Court suspended all regular operations in March 2020. Accordingly, the trial was adjourned to a later date. The parties attended a further pre-trial conference in December 2021 and the trial is now expected to take place in January 2023. As of December 31, 2021, the Company has not accrued for any potential claims.

Recipharm Litigation

On June 18, 2020, we announced we had commenced litigation against Recipharm in the Commercial Court of London. We alleged that the suspension of Recipharm's manufacturing license in August 2018 was a violation of its contractual obligations and led to a shortage of Etracet® in Canada. On June 15, 2021, we won a preliminary issue trial in which Recipharm argued unsuccessfully that Acerus' claim for damages was barred by the terms of the companies' manufacturing contract. In agreeing with Acerus that its claim for damages was not barred, the Commercial Court of London directed the matter to proceed to a full trial. On July 6, 2021, Recipharm made an offer to settle pursuant to Part 36 of the English Civil Procedure Rules. On August 3, 2021, Recipharm was granted permission to appeal the Commercial Court's decision, with the main proceedings being stayed pending appeal.

In light of permission to appeal being granted and, amongst other things, the delay to the proceedings and to final judgment this will cause, on August 12, 2021, we announced that we had accepted the Part 36 Offer and we receive \$2.3 million (GBP 1.7 million) from Recipharm as a settlement payment on August 24, 2021. In addition, we were entitled to reimbursement of the majority of our legal costs of the litigation and received a further payment of \$0.4 million on October 14, 2021. This latter amount was recognized as a reduction of selling, general and administrative expenses.

Subsequent Events

First Generation advance and settlement of SWL credit facility

On February 18, 2022, we announced that we had entered into an amending agreement with First Generation to increase the subordinated loan facility from US\$25 million to US\$30.845 million. This increase was made available to the Company by way of a single advance under a secured grid promissory note with First Generation. The proceeds from the Loan Facility increase were used on February 17, 2022, to settle all obligations under the SWK credit facility.

Definitive agreement to indirectly acquire Serenity LLC and global rights to Noctiva™

On February 28, 2022, we announced we had entered into a definitive agreement (the "Definitive Agreement") to indirectly acquire Serenity LLC ("Serenity") and the global rights to its Noctiva™ brand in a combined cash and stock transaction. Noctiva™ is prescribed for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. It is the first US Food and Drug Administration approved therapy for nocturia. The transaction closed on March 7, 2022, following approval of the transaction by the Toronto Stock Exchange.

Within 90 days of the effective date of March 7, 2022, the Company will pay a \$6 million up-front fee to Serenity, less certain deductions allowed by the Definitive Agreement. Serenity stockholders will be entitled to receive approximately 804 million common shares (“Common Shares”) of Acerus, payable on the earlier of January 10, 2023, if first commercial sale has occurred before then, or the date of the first commercial sale of Noctiva™ (the “First Commercial Sale Shares”), resulting in Serenity stockholders owning approximately 32.6% of the fully diluted Common Shares as calculated as of closing and without taking into account any future financing or other share issuances.

Two additional one-time equity-based sales milestones valued at \$5 million USD each, will be paid to Serenity stockholders when aggregate Net Sales of Noctiva™ sold in the United States and Canada combined, first reach the respective thresholds of \$100 million and \$150 million USD in annual net sales. These equity milestones will be paid in Common Shares and will be valued at the highest of the then current market price or a pre-determined floor price (the “Sales Milestone Shares”).

Serenity stockholders will also receive tiered low double-digit Contingent Sales Payments, paid in cash, equal to a percentage of Net Sales of Noctiva™ sold in the United States and Canada during each calendar year. Serenity stockholders will also receive Contingent Sales Payments, paid in cash, equal to a percentage of Net Royalty Profits of Noctiva™ sold outside of the United States and Canada during each calendar year.

Additional information

Additional information about Acerus, including the Company’s Annual Information Form dated March 14, 2022, 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.