ACERUS PHARMACEUTICALS CORPORATION

ANNUAL INFORMATION FORM

March 14, 2022

TABLE OF CONTENTS

EXPLANATORY NOTES

Unless otherwise stated, the information in this Annual Information Form is stated as of December 31, 2021 and all references to Acerus Pharmaceuticals Corporation's (the "**Corporation**") fiscal year are for the year ended December 31, 2021.

In this Annual Information Form, the Corporation and its subsidiaries are collectively referred to as "Acerus", the "Corporation" or the "Business".

Any reference in this document to intellectual property rights held by the Corporation and related commercialization efforts are for convenience purposes only and in no way change or limit the rights held by Acerus Biopharma Inc. (formerly known as Acerus Pharmaceuticals SRL) ("**Acerus Biopharma**"), Acerus Labs Inc. ("**Acerus Labs**") and Serenity Pharmaceuticals LLC ("**Serenity**").

Currency

All dollar amounts set forth in this Annual Information Form are in United States (US) dollars, except where otherwise indicated.

FORWARD-LOOKING STATEMENTS

Certain statements contained in this Annual Information Form, or incorporated herein by reference, constitute forward-looking information within the meaning of applicable securities laws ("**forward-looking statements**"). Statements concerning the Corporation's objectives, goals, strategies, intentions, plans, beliefs, expectations and estimates, and the business, operations, financial performance and condition of the Corporation and its subsidiaries are forward-looking statements. The words "believe", "expect", "anticipate", "estimate", "intend", "may", "will", "would" and similar expressions and the negative of such expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are subject to important assumptions and the Corporation has also made certain macroeconomic and general industry assumptions in the preparation of such forward-looking statements. While the Corporation 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 Corporation'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 Corporation to continue as a going concern; the Corporation's limited operating history; the Corporation's ability to meet future capital requirements; the fluctuating operating results of the Corporation; First Generation's significant influence over matters put before shareholders; the degree of market acceptance of the Corporation's products; risks relating to generic competition for the Corporation'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 Corporation's products; risks related to reliance on data obtained from IQVIA or similar providers; intellectual property risks, including the uncertainty of intellectual property protection, risks associated with licensed patent rights and the risk of third party claims of infringement; risks related to disputes regarding ownership or inventorship of products and technologies; risks associated with trade secrets; risks related to the performance of services by third parties; risks associated with the public market and volatility associated with the Corporation's shares; risk of potential third-party liability; risks relating to clinical testing conducted by the Corporation; 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 Corporation 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 Corporation's ability to generate ancillary additional revenue; risks relating to securities analyst coverage of the Corporation; 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 Corporation's acquisition of Serenity including: the Corporation'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 related to 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.

Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Forward-looking statements are based on management's current plans, estimates, projections, beliefs and opinions and are made as of the date of this Annual Information Form. The Corporation does not undertake any obligation to update forward-looking statements should assumptions related to these plans, estimates, projections, beliefs and opinions change except as required by applicable securities laws.

All of the forward-looking statements made in this Annual Information Form are qualified by these cautionary statements and other cautionary statements or factors contained herein. There can be no assurance that the actual results or developments will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, the Corporation.

BACKGROUND AND STRUCTURE

Name, Address and Formation

Acerus was incorporated under the *Business Corporations Act* (Ontario) on July 15, 2009 as J5 Acquisition Corp. ("**J5**"). From incorporation until July 11, 2011, when J5 amended its articles of incorporation to change its name to "Trimel Pharmaceuticals Corporation", the Corporation operated as a "capital pool company" pursuant to Policy 2.4 of the TSX Venture Exchange ("**TSX-V**") Corporate Finance Manual. On July 14, 2011, J5 (Barbados), Inc., a wholly-owned subsidiary of J5 incorporated under Barbados law, amalgamated with Trimel BioPharma Holdings Inc. ("**Trimel Holdings**") under the name "Trimel BioPharma Holdings Inc." Upon completion of the amalgamation, the Corporation completed its qualifying transaction (the "**Qualifying Transaction**") by way of a reverse takeover transaction through an exchange of shares, resulting in the former shareholders of Trimel Holdings obtaining control of the Corporation and acquiring 100% of the common shares of the Corporation (the "**Acerus Common Shares**"). On September 8, 2015, the name of the Corporation was formally changed from "Trimel Pharmaceuticals Corporation" to "Acerus Pharmaceuticals Corporation".

On July 19, 2011, the Corporation's common shares were delisted from the TSX-V and graduated and listed for trading on the Toronto Stock Exchange (the "**TSX**") under the symbol "TRL". Concurrent with the change of corporate name in September 2015, the trading symbol of the Acerus Common Shares on the TSX was changed to "ASP". In May 2019, the Corporation's shares were approved to be quoted on the OTCQB Venture Market under the symbol "ASPCF".

The registered and head office of the Corporation is located at 7025 Langer Drive, Suite 205, Mississauga, ON, L5N 0E8.

General Development of the Business

Recent Developments

2019

On January 11, 2019, the Corporation reported on anticipated shortage of certain doses of Estrace® on the Drug Shortages Canada website in relation to supply issues arising from the Corporation's contract manufacturer. The Corporation was notified by its contract manufacturer of a partial manufacturing license suspension at the facility where Estrace® is produced as a result of an audit by U.K. health authorities. The Corporation had been notified that the manufacturing license reinstatement had not yet occurred and that, as such, the Corporation's next expected shipment of Estrace® would be delayed. The Corporation determined that this could lead to potential shortage of the 0.5 mg and 1.0 mg doses of Estrace® within the next six months as forecasted demand may exceed in-stock inventory. As of January 11, 2019, the Corporation did not foresee a shortfall of the 2.0 mg dose in the next six months based on existing inventory in stock. As of the date hereof, manufacturing of Estrace® has not resumed. The Corporation is working to transfer Estrace® manufacturing to a new contract manufacturer and, as further described below, sold its rights in Estrace® pursuant to the APA (as defined below).

On January 25, 2019, the Corporation announced that it had received a Notice of Deficiency-Withdrawal Letter from Health Canada for its Gynoflor™ NDS. The Corporation has decided not to file a Request for Reconsideration of the Notice of Deficiency-Withdrawal Letter and has informed Medinova AG ("**Medinova**"), the Swiss pharmaceutical company, that granted the Corporation the exclusive rights to commercialize Gynoflor™ in Canada, that further studies will be needed in order for Gynoflor™ to be approvable by Health Canada. Under the agreement with Medinova, neither the Corporation nor Medinova was obligated to conduct such further studies. On June 20 2019, the Corporation and Medinova terminated their agreement regarding the commercialization of Gynoflor™.

On February 27, 2019, the Corporation announced the publication of two new scientific reports in the online version of the Canadian Urological Association Journal in connection with the Study (as defined below): Part 1 entitled "*MY-T study: Symptom-based titration decisions when using testosterone nasal gel, Natesto®*"; and Part 2 entitled "*My-T study: Patient satisfaction and preference comparing topical and nasal testosterone therapies*." The Study found that titration based on symptoms was successful in achieving normal levels of total testosterone in 77% of patients with statistically significant improvements in symptoms. The symptoms predictive of success were erectile function, libido and energy/endurance. Patients switched from topical therapy to Natesto® also reported significant improvements in clinical symptoms of hypogonadism ($p<0.0001$; +15%), increased treatment effectiveness (+20%), convenience (+30%) and global satisfaction (+3%) compared to their previous topical testosterone replacement therapy ("**TRT**"). The Study clearly showed that patients perceived Natesto's® fast, easy nasal dosing schedule as a convenience when compared to once-daily topical products spread by hand over the shoulders and thighs. Overall, 67.2% of patients agreed or strongly agreed that they preferred testosterone nasal gel over topical TRT, citing ease of use, convenience, effectiveness and travel friendliness as advantages of the nasal therapy.

On February 27, 2019, the Corporation announced that Hyundai Pharm Co., LTD. ("**Hyundai**") confirmed receipt of its first purchase order of Natesto® destined for the South Korean market and placed a second purchase order for delivery in Q2-2019. Hyundai also informed the Corporation that it intended to launch Natesto® at the end of Q1 or beginning of Q2 of 2019.

On March 4, 2019, the Corporation announced that it submitted an NDS to Health Canada to obtain marketing approval for avanafil in Canada. See the heading "*Avanafil Product Pipeline*" for a discussion of the status of the avanafil NDS.

On March 29, 2019, the Corporation announced that it closed a non-brokered private placement of 23,230,772 common shares of the Corporation to directors and management of the Corporation at a price of $0.195 per common share for aggregate proceeds of approximately $4.53 million ("**March 2019 Private Placement**"). The Corporation used the net proceeds from the March 2019 Private Placement to fund the

Corporation's working capital requirements, including (i) to support its current payment on a royalty buyout for intellectual property related to the Corporation's nasal gel technology for Natesto®, (ii) for purposes of deposits to build its inventory in advance of receiving European approval of Natesto® and (iii) ongoing selling, general and administrative expenses and research and development requirements.

On April 29, 2019, the Corporation announced that it engaged Paradigm Capital Inc. ("**Paradigm**") as its financial advisor to leverage its proprietary nasal delivery technology in cannabinoid applications through licensing, partnership agreements or other transactions with interested parties.

On May 8, 2019, the Corporation announced that its shares were approved to be quoted on the OTCQB Venture Market and would trade under the symbol "ASPCF". The listing on the OTCQB Venture Market was part of a long-term strategy to introduce the Corporation to a broader audience.

On May 30, 2019, the Corporation announced that it signed a patent license agreement with the University of Texas at Austin for technology related to the nasal administration of testosterone. The newly patented, aqueous-based, nasal delivery technology ("**Aqueous Nasal Delivery Technology**") was developed by Robert Josephs, a UT Austin Professor of Clinical and Social Psychology, and Craig Herman, a Doctor of Pharmacy at MedCara Pharmaceuticals in Conrad, Iowa. Under the agreement, Acerus has licensed worldwide exclusive rights to this technology in all applicable fields.

As a result of a strategic review of the Corporation's portfolio, a decision was made to focus the Corporation's resources and effort on the prescription products business. Therefore, on June 6, 2019, the Corporation announced that it reached a mutual agreement with Innovus Pharmaceuticals Inc. to terminate the exclusive distributor and license agreement that granted the Corporation the rights to commercialize UriVarx® in Canada.

On June 27, 2019, the Corporation announced that Health Canada had completed the initial screening process for the NDS for avanafil. The dossier is now in active review by Health Canada and the Corporation expects review completion and, if approved, NOC issuance to be in early Q2 of 2020. See the heading "*Avanafil Product Pipeline*" for a discussion of the status of the avanafil NDS.

On June 28, 2019, the Corporation announced that it entered into an amended agreement relating to its a senior secured term loan credit facility with SWK Funding LLC ("**SWK**") for up to US$11 million (the "**New Facility**"). The New Facility was entered into on October 12, 2018 and an initial tranche of US$9 million under the New Facility was available at closing, with the remaining US$2 million of the New Facility becoming available on or before March 31, 2019, upon satisfaction of certain future conditions. The New Facility replaced a CDN$5 million senior secure credit with Quantius Inc. entered into on December 6, 2017 ("**Quantius Facility**"). The New Facility bore interest at a rate per annum equal to the greater of (a) the three-month London Inter-Bank Offered Rate ("**LIBOR**"), or (b) 1.50%, with such base rate being capped at no greater than 4.25%, plus an applicable margin of 10.50%. Under the terms of the agreement, the Corporation had the option prepay the loan prior to the maturity date subject to the payment of certain prepayment fees. The terms of the agreement also contained customary financial covenants. The proceeds from the New Facility were used primarily to (i) repay the amount outstanding under the Quantius Facility, including a prepayment penalty and royalty retirement fee; (ii) retire a promissory note with Endo Bermuda Ventures Limited with a payment in the amount of approximately US$860,000; and (iii) for ongoing general working capital. As part of the transaction, SWK received an origination fee representing a low single digit percentage of the maximum facility amount and received a final payment representing a single digit percentage of the principal amount actually advanced under the facility. The Corporation also issued 5,331,563 common share purchase warrants (the "**SWK Warrants**") to SWK as partial consideration for the New Facility. Each SWK Warrant entitled SWK to purchase one common share of the Corporation at an exercise price of CDN$0.40 per common share were initially set to expire on October 11, 2023. The SWK Warrants were repriced and extended on September 30, 2019 and repriced again on February 21, 2020 as further described below. Further, as discussed in the "*2022*" subheading below, on February 18, 2022, the New Facility was retired. For further information please see filings available on SEDAR at www.sedar.com.

The nature of the June 28, 2019 amendment to the New Facility was to set the minimum threshold for

Consolidated Unencumbered Liquid Assets required to be maintained by the Corporation. This amount was defined in the agreement as cash adjusted for a certain portion of accounts receivable and payable. This level was set at US$1 million at all times up until July 31, 2019 and either: (i) US$2 million at all times thereafter unless the Corporation can demonstrate that it has raised a minimum of US$5 million in gross equity or subordinated debt (or any combination thereof) between June 25, 2019 and July 31, 2019 (the "**Subsequent Raise**"); or (ii) US$1 million at all times thereafter if the Subsequent Raise is completed. All other terms and conditions in the SWK loan agreement remained unchanged. For further information please see filings available on SEDAR at www.sedar.com.

On July 8, 2019, the Corporation announced the acceptance of a new manuscript to the Journal of the Endocrine Society, describing how Natesto® achieves similar symptom improvement, regardless of the degree of a patient's baseline testosterone deficiency. This scientific report describes a post-hoc analysis of data from the pivotal Phase 3 study of Natesto®, which enrolled 306 patients from 52 sites in the United States, who were treated with Natesto®, for up to 1 year. Patient data from the phase 3 study was classified based on the degree of testosterone deficiency demonstrated by patients at study entry. Each dose of Natesto® resulted in a short-term return of testosterone to the upper normal range (800 ng/dL; 28 nmol/L) irrespective of how low the patient's baseline testosterone was prior to the study. In the patient group with the lowest baseline testosterone level, a mean average serum testosterone level of 295 ng/dL (10.2 ng/dL) was achieved with Natesto® exposure. As well, statistically significant improvements in symptom relief (erectile function, mood and lean body mass) were observed in these patients. In between Natesto® doses, all patients in the phase 3 study maintained their natural testosterone at the same levels they had prior to entry into the study, indicating that Natesto® does not suppress natural testosterone production. Based on the data, Acerus believes that the mechanism of action of Natesto® is unique whereby the peaks in testosterone generated by Natesto® dosing provide efficacy and improvement of symptoms, while the time between doses (4-8 hours) allows for the maintenance of testicular testosterone production and sperm production.

On July 10, 2019, the Corporation announced that Hyundai officially launched the commercialization of Natesto® in South Korea at the Korean Symposium on Sexual Medicine and Andrology (KSSMA). This was the first commercial launch of Natesto® outside North America.

On July 19, 2019, the Corporation announced that it entered into a US$5 million subordinated term loan facility with First Generation Capital Inc. ("**First Generation**"), a company affiliated with the Chairman of the Board of Directors of the Corporation (the "**First Generation Loan**"). The First Generation Loan was subordinated to the New Facility and bore interest at a rate per annum equal to the three-month LIBOR rate, plus an applicable margin of 10.50%. Subject to the terms of the subordination and intercreditor agreement between First Generation and SWK, the First Generation Loan was initially 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 the Corporation's market capitalization and aggregate annual revenue, and could have been be prepaid in full or in part without penalty following repayment in full of indebtedness owing to SWK. The proceeds from the First Generation Loan were used for ongoing general working capital. A copy of the promissory note covering the loan was filed under the Corporation's profile on SEDAR at www.sedar.com. The First Generation Loan was amended and restated on December 18, 2019 and then retired on February 12, 2020 as discussed below. In addition, the Corporation entered 2021 FGC Loan as further discussed below.

On July 24, 2019, the Corporation announced that Natesto® is now on formulary and covered nationwide by a leading national pharmacy benefit manager (PBM) in the United States. This PBM contract provides for unrestricted patient access to Natesto® across the PBM's national open formularies and plans that service government clients. According to Aytu, over six million U.S. lives are covered by these prescription plans.

On July 30, 2019, the Corporation announced that it would be taking an expanded role in the commercialization of Natesto® in the U.S. The Corporation has entered into an amended and restated licensing agreement with Aytu (the "**Revised Aytu Agreement**"), which, upon closing, moved the partnership from an out-license model to a co-promotion arrangement. Under the terms of the Revised Aytu Agreement, Aytu returned the NDA for Natesto® in the U.S. back to the Corporation on December 18, 2019. Going forward the Corporation assumed all regulatory and clinical responsibilities and costs for the product in the U.S. The Corporation took on a more expansive role in matters such as U.S. marketing,

reimbursement and medical strategy as part of the companies' joint commercialization committee, and launched a specialist sales force focused on urologists and endocrinologists (Acerus Sales Channel). Aytu retained its primary care sales force (Aytu Sales Channel) and continued to book all product net revenue while serving as the exclusive U.S. supplier of Natesto® to wholesalers, pharmacies and other customers that receive a direct shipment. Financial payments were based upon a tiered level of net revenue, post cost of goods sold (COGS), based on annual sales performance in the respective Acerus and Aytu Sales Channels. The Corporation engaged Syneos Health ("**Syneos**"), a leading integrated biopharmaceutical solutions organization including the industry's largest Contract Commercial Organization (CCO), to be its commercialization partner. Syneos has extensive experience in Men's Health and with Natesto®, and offers an end-to-end model that enabled Acerus to rapidly stand up a U.S. commercial team; to scale across all aspects of commercialization, including medical and regulatory affairs, managed markets, marketing and sales; and provided greater flexibility and effectiveness in resource deployment.

As part of the amended and restated partnership agreement, the Corporation did not pay Aytu to regain the marketing authorization for Natesto® in the U.S. The royalty structure currently in place was replaced with a pay-for-performance incentive structure intended to drive Natesto® revenue growth in both Sales Channels. The revised agreement extended the partnership to the later of 2027, the launch of an FDA approved, AB-rated generic equivalent to Natesto®, or the expiration or invalidation of the last to expire Natesto® patent. Aytu paid the Corporation a variable rate commission for sales made in the Acerus Channel as per the following schedule: up to the current status quo of Natesto® net sales ($0 – 5.5M), the Corporation received a commission equivalent to 25% of net revenue generated; for the next $4.5M in net revenue ($5.5M – 10M), the Corporation received a commission equivalent to 50% of net revenue generated; and above $10M in net revenue, the Corporation received a commission equivalent to the combination of 90% of urologists and endocrinologists related net revenues and 10% of Aytu's sales channel net revenue generated.

Closing was conditioned upon the Corporation raising capital, whether by way of equity or debt, of at least USD $10 million on or before January 29, 2020. This condition was mutually waived by both parties on December 1, 2019. On April 1, 2021, the Revised Aytu Agreement was superseded by Aytu Buyback Agreement as discussed in the "*2021*" subheading below.

On August 1, 2019, the Corporation made an announcement regarding its clinical trial on the effects of Natesto® on reproductive hormones and semen parameters. The study was conducted at the University of Miami's Department of Urology and is a single-center, prospective study evaluating testosterone levels, gonadotropin levels, and semen parameters in 40 hypogonadal men between 18 and 55 years of age, receiving treatment with Natesto® testosterone nasal gel over six months ("**Spermatogenesis Study**"). The results of the Spermatogenesis Study were accepted for presentation as a "Late-Breaking Abstract" by the American Society for Reproductive Medicine (ASRM). The study results were also presented at the 75th ASRM Scientific Congress & Expo in Philadelphia, PA October 12-16, 2019. The Natesto® Spermatogenesis Study was one of only six abstracts accepted for presentation by ASRM. Abstracts are accepted for presentation based on the impact of the study findings. Interim results presented at the time of the announcement demonstrated that almost all subjects completing the six-month treatment period had serum testosterone levels return to the normal range, and all measures of semen parameters including sperm concentration, sperm motility, and total motile sperm count (TMSC) remained unchanged through three months and six months of therapy.

On August 2, 2019, the Corporation announced that it had identified four commercial lots of Natesto® released in the Canadian and South Korean markets that were found to be non-conforming during long-term stability studies, even though such lots were fully in-specification at the time of release. This post-release non-conformity is not harmful to the patient, but may result in difficulties in dispensing. At that time, the temporary shortage of the product in the Canadian and South Korean markets was expected to continue until the end of October 2019. The Corporation noted this shortage on the Drug Shortages Canada website and continued to dialogue with Health Canada to identify solutions to try to minimize the disruption to patients in the affected markets.

On September 30, 2019, the Corporation announced that it entered into an amended agreement related to the New Facility and that it received a waiver letter from SWK related to certain financial covenants for Q3

2019. The nature of the amendment was to set the minimum threshold for Consolidated Unencumbered Liquid Assets required to be maintained by the Corporation. This amount is defined in the agreement as cash adjusted for a certain portion of accounts receivable and payable. This level was set at (i) US$1 million at September 30, 2019, (ii) US$5 million at December 15, 2019, (iii) US$4 million at December 31, 2019, (iv) US$2 million at January 31, 2020, and (v) $1 million at all times after January 31, 2020. In connection with the amendment, the Corporation agreed to reprice the 5,331,563 SWK Warrants that were issued with the signing of the New Facility in 2018. The SWK Warrants were repriced from CDN$0.40 to CDN$0.11. In addition, the SWK Warrants' expiry date was extended from October 11, 2023 to September 30, 2024. The SWK Warrants were repriced again on February 21, 2020 as further described below. The volume-weighted average trading price of the Corporation's common shares on the TSX for the five-trading-day period ending September 30, 2019 was CDN$0.11. The repricing and the extension of the expiry date of the SWK Warrants became effective on October 15, 2019.

The Corporation also issued 1,361,544 common share purchase warrants (the "**New Warrants**") to SWK in connection with the amendment. Each New Warrant entitled SWK to purchase one common share of the Corporation at an exercise price of CDN$0.11 per common share and will expire on September 30, 2024. The terms of the New Warrants were otherwise be identical to those of the Original Warrants. As such, in certain circumstances, the Corporation may cause SWK to exercise the New Warrants prior to their expiry date if the closing price of the Corporation's common shares on the TSX exceeds CDN$0.80 per share for a period of at least 21 consecutive trading days.

Finally, SWK issued a waiver letter to the Corporation waiving the Adjusted EBITDA and Aggregate Revenue covenants for Q3 2019 contained in the credit agreement. All other terms and conditions in the SWK loan agreement remained unchanged.

On October 17, 2019, the Corporation announced the presentation of data from the Natesto® Spermatogenesis Study as part of the "Late Breaking" Abstract Session at the 75th Annual ASRM Scientific Conference. Findings from the study demonstrated that 95% of men treated with Natesto® for hypogonadism for three and six months, maintained their semen parameters within the normal range while increasing serum testosterone levels to normal and improving hypogonadal symptoms. This is the first such study to demonstrate conclusively that a TRT can maintain key fertility parameters in hypogonadal men. Researchers attributed these findings to Natesto®'s fast absorption and unique dosing schedule designed to produce fluctuations of testosterone levels in the bloodstream. In total, 55 men were eligible and enrolled in the trial. Of the 55 who enrolled, 33 patients have completed the six-month treatment period. Nearly all subjects completing the six-month treatment period had their testosterone levels return to the normal range. Mean (SD) serum testosterone levels increased from 230 (62) ng/dL at baseline to 605 (278) ng/dL at six months (p=0.005). In addition, mean baseline levels of Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH) (3.9 IU/mL and 4.0 IU/mL, respectively) were preserved within the normal range over this time (2.6 IU/mL and 3.0 IU/mL, respectively).

Most importantly, mean semen parameters remained unchanged (P > 0.05):

Semen Parameter	**Baseline (SD)**	**3 Months, n= 44 (SD)**	**6 Months, n=33**
Sperm Concentration (million/cc)	31.9 (21.8)	26.2 (19.6)	24.5 (15.8)
Sperm Motility (%)	52.6% (12.0)	50.2% (19.2)	51.6% (15.2)
Total Motile Sperm Count (million)	47.1 (46.1)	42.4 (61.4)	34.1 (24.1)

Additionally, there was improvement across all domains of erectile function including libido and overall sexual satisfaction, as well as improvement in overall energy, which are common hypogonadal symptoms.

No serious adverse events (AEs) were reported in the study. The most commons AEs were nasal irritation (five cases, 13.1%), oligospermia (three cases, 7.9%) and azoospermia (one case, 2.6%). All of these men recovered spermatogenesis after discontinuation.

On November 1, 2019, the Corporation provided an update on the temporary unavailability of Natesto® in Canada and South Korea, following the previous announcement of the voluntary recall of certain Natesto® lots released on the Canadian and South Korean markets.

The Corporation initially made minor modifications to the manufacturing process that appeared to have resolved the previously identified issues and has produced a batch of Natesto® (the "**Revised Batch**"). While Acerus believed the changes would have been classified by Health Canada as level III, thereby requiring only an annual notification update to Health Canada and allowing for product to be released in Q4-2019, Health Canada, after much deliberation, classified the modifications as level I, requiring the submission of a Supplemental New Drug Submission ("**SNDS**") prior to the release of the Revised Batch in the Canadian market. Ultimately, the issue was resolved by the Corporation providing an internal corrective action plan in February 2021. The Corporation notified Health Canada of its intention to reactivate the DIN for Natesto® in July 2021.

On December 2, 2019, Acerus announced that the Revised Aytu Agreement closed and was fully effective as of December 1, 2019. Both parties mutually waived the closing conditions on the Revised Aytu Agreement, including the requirement that Acerus complete a raise of a minimum of USD 10 million on or before the end of January 2020, enabling Acerus to launch a U.S.-based specialty sales force, which will promote Natesto® to urologists and endocrinologists. Aytu will continue to book all Natesto® in the United States and they will promote Natesto® to all other specialties including internal medicine and family practice.

To accelerate the launch of Acerus' U.S. commercial team, Aytu agreed to transfer 5 current sales personnel to Acerus as of December 2, 2019. Throughout 2020, Acerus built out a complete US-based specialty care sales force and other commercial functions, through Syneos, significantly increasing the number of employees working directly on Natesto® in the United States.

This co-promotion increased sales force coverage of an additional 2,700 targeted U.S. specialty prescribers, putting a higher promotional focus on urologists and endocrinologists, while enabling Aytu to focus its promotional efforts in primary care and other specialties. On December 18, 2019, the NDA for Natesto® was transferred back to Acerus. As discussed in the "*2021*" subheading below, on April 1, 2021, the Revised Aytu Agreement was superseded by the Aytu Buyback Agreement.

On December 16, 2019, Acerus announced that it entered into an amendment agreement related to its existing credit facility with SWK and that it received a waiver letter related to certain financial covenants for Q4 2019, namely the December 15, 2019 Unencumbered Liquid Asset covenant as well as the December 31, 2019 Adjusted EBITDA and Aggregate Revenue covenants contained in the credit agreement (the "**SWK Waiver**"). The nature of the amendment was to set the minimum threshold for Consolidated Unencumbered Liquid Assets required to be maintained by the Corporation. This amount is defined in the agreement as cash adjusted for a certain portion of accounts receivable and payable. The only change contemplated by the amendment was to set this level at US$2.0 million up from US$1.0 million at all times after January 31, 2020.

The SWK Waiver of the covenants was contingent on Acerus raising an additional US$6.5 million prior to December 23, 2019. In connection therewith, Acerus obtained a commitment letter from First Generation, a company affiliated with the Chairman of the Board of Directors of Acerus, to amend and restate the US$5.0 million subordinated secured term loan facility previously entered into on July 19, 2019 between Acerus and First Generation to (i) increase the borrowed amount to US$11.5 million, thereby providing the capital required to meet the condition of the SWK Waiver, (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 FGC Loan (including interest paid from the closing of the original US$5.0 million subordinated secured term loan facility) to an amount equal to 9.99% of the market capitalization of Acerus at the time of closing ("**the A&R FGC Loan**"). The transaction was approved by all of the independent directors of the board of directors of Acerus. The other terms of the A&R FGC Loan remained unchanged from the original facility.

On December 18, 2019, Acerus announced that it had closed the A&R FGC Loan with a cap on the total amount of interest payable to First Generation under the A&R FGC Loan (including interest paid from the

closing of the original US$5.0 million subordinated secured term loan facility) to an amount equal to Cdn.$1,696,266.44. The proceeds from the A&R FGC Loan were used for ongoing general working capital. A copy of the amended and restated promissory note covering the A&R FGC Loan was filed, following the closing of the transaction, under the Corporation's profile on SEDAR at www.sedar.com.

Closing the A&R FGC Loan also fully satisfied the conditions of the previously mentioned waiver letter from SWK related to certain financial covenants for Q4 2019, namely the December 15, 2019 Unencumbered Liquid Asset covenant as well as the December 31, 2019 Adjusted EBITDA and Aggregate Revenue covenants contained in the credit agreement.

2020

On January 10, 2020, Acerus announced that the dossier filed as a Decentralized Procedure in 19 European countries for the approval of Natesto® was voluntarily withdrawn in order to satisfy several non-clinical questions related to the product that were raised by the Reference Member State (RMS), Sweden. The regulatory dossier was filed by our European licensee - medac Gesellschaft fur klinische Spezialpraparate mbH ("**medac**").

The MPA (Swedish Health Authority), the Reference Member State (RMS) for the procedure, 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 mutually agreed to withdraw the application to allow for the completion of the studies, with the goal of subsequently re-submitting the dossier.

On January 28, 2020, the Corporation announced the acceptance of a scientific abstract reporting the results of the Natesto® Spermatogenesis Study by the Endocrine Society for presentation at their Annual Meeting. The clinical study results were presented during a poster session at ENDO 2020, which held in San Francisco, California from March 28-31, 2020.

On February 5, 2020, the Corporation announced the acceptance of two Natesto® clinical studies for presentation at the American Urological Association's AUA2020 Scientific Program. The AUA2020 meeting was held May 15–18 in Washington, DC. Additionally, the results of a Natesto® retrospective analysis were accepted for a Moderated Poster Session. Selection of the abstracts for publication in the press program does not imply endorsement of Natesto® by AUA.

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

The Refinancing Transactions consisted of:

- a private placement to First Generation of 449,148,891 Acerus Common Shares at an offering price of C$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 Corporation of US$18 million (the "**FGC Private Placement**");
- the conversion of the Corporation's outstanding US$11.5 million (plus accrued interest of US$526,021) owing to First Generation under the A&R FGC Loan into approximately 300,081,885 Acerus Common Shares at a conversion price of C$0.053269 per Acerus Common Share (the "**Debt Conversion**"); and
- an amendment to the New Facility (the "**February 2020 SWK Amendment**") which would, among other things, (i) set the minimum threshold for consolidated unencumbered liquid assets required to be maintained by the Corporation at US$1,500,000, (ii) reset the revenue and EBITDA covenants to better reflect the nature of the Corporation's business at this time compared to the time the New

Facility was entered into, (iii) delay the date on which the Corporation must begin repaying principal from Q1-2021 to Q2-2021; (iv) require pre-payment of US$750,000 of principal in three instalments during 2020 and a commensurate reduction in the amount used to calculate exits fees; and (v) provide flexibility to the Corporation 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, the Corporation paid SWK an amendment fee of US$80,000 and amended the exercise price of the 6,693,107 outstanding SWK Warrants and New Warrants, which expire on September 30, 2024, from C$0.11 to C$0.053269.

On February 21, 2020, the Corporation announced the closing of the Refinancing Transactions. Acerus received US$18,000,000 in gross proceeds from the private placement of 449,148,891 Acerus Common Shares to First Generation and converted US$11.5 million (plus accrued interest of US$526,021) owing to First Generation under the A&R FGC Loan into 300,081,885 Acerus Common Shares. In addition, the February 2020 SWK Amendment became effective. As consideration for and in connection with the SWK Amendment, the Corporation paid SWK an amendment fee of US$80,000 and amended the exercise price of the SWK Warrants and New Warrants, which expire on September 30, 2024, from C$0.11 to C$0.053269. The Corporation also made a prepayment of US$250,000 of principal to SWK. This prepayment was the first of the three installments previously announced on February 12, 2020. Two further US$250,000 prepayments of principle were made on October 15, 2020 and December 14, 2020.

In addition, the Debt Conversion resulted in a change of control for Canadian income tax purposes. A change of control triggers a tax year end, requires adjustments, if any, to the tax carrying value of tangible and intangible assets to the lesser of fair value and disallows the carry forward of unused capital losses. It also provides that any adjustments to reduce tax assets to the lesser of fair value may be added to the Company's net operating loss carry forwards. The Company has net operating loss carry forwards (expressed in thousands) of $147,932 that will expire by 2041 ($3,553 in 2035, $25,551 in 2036, $18,843 in 2037, $23,132 in 2038, $21,840 in 2039, $25,510 in 2040 and $29,503 in 2041). The net operating loss carry forward of $21,840 expiring in 2039 includes $18.5 million for fair value adjustments described above.

On April 2, 2020, the Corporation provided a business update related to the impact of COVID-19. The Corporation announced that all Acerus staff were working from home to abide by social distancing and stay at home guidelines from various governments in both Canada and the United States. As of the date hereof, the Corporation's employees all continue to work from home. Because of these guidelines, the ability of sales staff to visit physicians is severely limited.

The Corporation's supply chains and contract manufacturers are still active and are supporting the Corporation's efforts to expand its business. New batches of Natesto® have been manufactured and shipped to the United States, Taiwan and South Korea, with supply to Canada expected to resume in 2021. The Corporation is also continuing its efforts in supporting the return of Estrace® to the Canadian market.

On April 20, 2020, the Corporation received a Notice of Deficiency ("**NOD**") from Health Canada regarding avanafil. 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. Until this information was provided to Health Canada, the avanafil review process was halted. The Corporation had 90 calendar days to respond fully to the NOD. The Corporation requested an extension of time, which was granted, and a submission was made before the end of the extended deadline. On December 11, 2020, Health Canada accepted the submission into review. In October, 2021, the Company received another NOD. 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. On January 24, 2022, Petros Pharmaceuticals announced that it had partnered with a new contract manufacturing organization for the production of avanfil. 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 2023.

On April 21, 2020, the Corporation announced publication of results for the Natesto® Spermatogenesis Study in the Journal of Urology. The study concluded that Natesto® was found to be both effective in restoring hypogonadal men to normal testosterone levels, while also simultaneously improving both erectile function and quality of life. Importantly, gonadotropin hormones remained within normal ranges and semen parameters were preserved through 6 months of treatment in 95% of men.

The study authors estimate that up to 16% of men being prescribed testosterone therapy (TTh) are under 39 years old. The most commonly prescribed testosterone therapies, injections and topical gels, can impair semen parameters and can cause azoospermia (absence of sperm in the semen) in up to 2/3^{rds} of men. Therapies such as clomiphene citrate, a selective estrogen receptor modulator (SERM), are widely used off-label to preserve spermatogenesis while simultaneously increasing testosterone. Many of these off-label products can have several adverse reactions; therefore, identifying alternatives to increase testosterone in men without impacting gonadotropin levels and sperm parameters is paramount.

The Phase IV clinical trial investigating the impact of nasally administered Natesto® on restoration of testosterone and preservation of fertility parameters evaluated 44 subjects through 3 months, and 33 subjects through 6 months of treatment. Mean testosterone increased from 231 ng/dL to 652 ng/dL after 6 months of Natesto® treatment. There was improvement across all domains of erectile function (based in IIEF-15), with particularly significant improvements in sexual desire and overall satisfaction. Additionally, sperm concentration, sperm motility, and total motile sperm count were maintained through 6 months of Natesto® treatment. Key data are summarized in the following table:

	Mean Values (SD)			
	Baseline	**3 Months**	**6 months**	**P value**
Testosterone (ng / dL)	231 (61)	616 (267)	652 (305)	< 0.001
	Semen Parameters			
Sperm Concentration (Mill. / cc)	29.9 (18.7)	25.9 (19.5)	24.2 (15.7)	> 0.05
Sperm Motility (%)	52.1 (12.3)	49.1 (20.4)	51.6 (15.2)	> 0.05
Total Motile Sperm Count (Mill.)	45.9 (45.5)	40.8 (60.5)	33.9 (24.3)	> 0.05
	Symptom Improvement			
IIEF - Sexual Desire	5.8 (2.2)	7.6 (1.3)	7.3 (1.6)	< 0.001
IIEF - Overall Satisfaction	6.0 (2.8)	7.8 (2.0)	7.8 (2.1)	0.001

On May 4, 2020, the Corporation appointed Dr. Geoff Cotton to its Board of Directors.

On May 6, 2020, the Corporation announced the resignation of Norma Beauchamp as director of the Corporation.

On June 3, 2020, the Corporation announced that, as of July 1, 2020, Express Scripts, Inc., one of the leading pharmacy benefit managers (PBMs) in the United States, elected to make Natesto® (testosterone nasal gel) a preferred brand on its National Preferred Drug List. Express Scripts serves more than 3,000 clients covering 70 million lives, including approximately 9 million lives managed by Cigna HealthCare. Drugs listed on formulary as preferred brands have been evaluated by the pharmacy benefit manager from a therapeutic and value perspective. Preferred brand drugs may be available to patients at a lower co-pay or co-insurance than non-preferred brand drugs.

On June 18, 2020, the Corporation announced that it has commenced litigation against Recipharm Limited ("**Recipharm**"), a wholly-owned subsidiary of Recipharm AB, in the Commercial Court of London. The Corporation alleges that the suspension of Recipharm's manufacturing license in August 2018, in

contravention of its contractual obligations to the Corporation, led to a shortage of Estrace® in Canada. In 2018, Estrace® generated sales revenues of USD$4.2M. However, due to the shortage, Estrace® revenues and the Corporation's market share have decreased substantially each year since the shortage began. Consequently, the Corporation has sued Recipharm for, among other things, its loss of profits and loss of market share caused by the shortage. This litigation was settled as further described below.

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

On July 20, 2020, the Corporation announced the launch of a dedicated specialty sales team to promote the Corporation's key product, Natesto® (testosterone nasal gel), to urologists and endocrinologists across the United States. The 22 specialty sales representatives targeted 2,700 high-prescribing (decile 6-10) medical practitioners who currently treat men with hypogonadism. The Corporation, in partnership with Syneos Health, has equipped its U.S. team with a suite of digital technologies that allow sales reps to conduct virtual meetings and customer engagements, given varying state rules regarding COVID-19 restrictions. In addition, as per the terms of the revised partnership agreement between the Corporation and Aytu, Aytu focused their own U.S. sales team (as of the date of the announcement comprised of some 33 representatives) on the promotion of Natesto® to high-prescribing primary care physicians who treat men with hypogonadism. In the first full quarter of promotion, prescriptions of Natesto among Target specialists grew by 30%, and number of prescribers of Natesto grew by 20% respectively (Q4 2020 compared to Q2 2020) signaling specialists favorable reaction to the clinical profile of Natesto.

On July 21, 2020, the Corporation announced that Dr. Christopher Sorli, MD, PhD, FACE would join the Company as Chief Medical Officer, effective August 3, 2020, and become a member of the Corporation's Senior Leadership Team.

On July 28, 2020, the Corporation announced that production of new batches of Natesto® (testosterone nasal gel) was underway and that shipments were already in transit to several key markets in North America and Asia (the United States, Taiwan and South Korea). The first country resupplied with Natesto® was the United States, ensuring that product is available to meet anticipated demand in support of the Acerus Specialty Sales Force. In addition, Eu HWA, a subsidiary of Orient EuroPharma ("**OEP**") – The Corporation's licensee across South Asia – officially introduced Natesto® to Taiwan at the Taiwanese Urology Association's annual meeting on August 22-23, 2020 representing the second commercial launch of Natesto® outside North America. OEP is also preparing entry strategies for nearby markets including Hong Kong, the Philippines, Singapore, Malaysia & Vietnam. Supply of Natesto® in Canada is expected to resume in 2021.

On September 14, 2020, the Corporation announced that Kevin Hickey joined the Corporation as Senior Vice President, US Commercial. Mr. Hickey also became a member of the Corporation's Senior Leadership Team.

On September 29, 2020 the Corporation announced that it received a waiver letter from SWK related to the required revenue covenant for the third quarter of fiscal 2020 in its existing credit facility.

On October 20, 2020 the Corporation announced that it would be offering rights (the "**Rights Offering**") to holders of the Acerus Common Shares of record at the close of business on October 27, 2020 (the "**Record Date**"). Pursuant to the Rights Offering, each holder of Acerus Common Shares received one transferable right (a "**Right**") for each Acerus Common Share held. Every 1.91984064 Rights entitled a holder to purchase one Acerus Common Share at a price of $0.025 per common share (the "**Subscription Price**"). The Rights Offering raised gross proceeds of approximately $13,165,000.

The Subscription Price was equal to approximately an 37.97% discount to the volume weighted average trading price of the Acerus Common Shares on the TSX for the 5 day period ending on October 19, 2020. Based on the 1,010,988,081 Acerus Common Shares outstanding as of the date of October 20, 2020, a

maximum of 526,600,000 Acerus Common Shares could be issued pursuant to the Rights Offering, representing 52.09% of the then currently issued and outstanding Acerus Common Shares. The Rights Offering was conducted in Canada, and in those jurisdictions where the Corporation may lawfully offer the Rights.

The Rights Offering included an additional subscription privilege under which holders of Rights who fully exercised their basic subscription privilege was entitled to subscribe *pro rata* for additional Common Shares, if available, that were not otherwise subscribed for in the Rights Offering.

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

On November 25, 2020, the Corporation announced the completion of the Rights Offering. The Rights Offering was over-subscribed and resulted in the issuance of 526,600,000 Acerus Common Shares at a price of $0.025 per share for gross proceeds of approximately $13,165,000. Although the Corporation had a standby commitment in place with First Generation, no funding was required under the standby commitment.

On November 27, 2020 the Corporation further announced with respect to the completion of the Rights Offering, the Corporation issued 526,600,000 Acerus Common Shares under the Rights Offering at a price of $0.025 per share for gross proceeds of approximately $13,165,000.

The Rights Offering was over-subscribed by $483,402 or 19,336,079 Common Shares due to demand for the Common Shares. Total subscriptions, including those exercised pursuant to the additional subscription privilege, represented $13,648,402, or more than 104% of the Common Shares available under the Rights Offering. Although the Corporation had a standby commitment in place with First Generation, no funding was required under the standby commitment.

A total of 468,494,434 Common Shares were issued pursuant to the basic subscription privilege of the Rights Offering. Of these, 458,643,154 Common Shares were issued to insiders of the Corporation and 9,851,280 Common Shares were issued to all other persons. A total of 58,105,566 Common Shares were issued pursuant to the additional subscription privilege of the Rights Offering. Of these, 57,698,702 Common Shares were issued to insiders of the Corporation and 406,864 Common Shares were issued to all other persons. Following completion of the Rights Offering, the Corporation has 1,537,588,081 Common Shares issued and outstanding.

To the knowledge of the Corporation, after reasonable inquiry, no persons became an insider of the Corporation from the distribution under the Rights Offering. The Corporation did not pay any fees or commissions in connection with the distribution of securities in the Rights Offering.

The estimated net proceeds of the Rights Offering were used to make repayments of principal and interest under its existing senior secured term loan credit facility with SWK; for research and development expenditures related to clinical and non-clinical trials for Natesto®, the Corporation's testosterone nasal gel for androgen replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone; and for working capital expenditures.

Pursuant to the Rights Offering, First Generation acquired an aggregate of 451,669,872 Common Shares through the exercise of the basic subscription privilege of the Rights Offering, for an aggregate purchase price of $11,291,746.80 and an aggregate of 57,698,702 Common Shares through the exercise of the additional subscription privilege of the Rights Offering, for an aggregate purchase price of $1,442,467.55.

Immediately after the completion of the Rights Offering, First Generation beneficially owned or controlled 1,377,127,750 Common Shares, including shares that were issuable upon exercise of 625,000 options that had vested, representing 89.5% of the issued and outstanding Common Shares. The foregoing represented an increase to First Generation's holding of Common Shares by approximately 3.7%.

On November 30, 2020, the Corporation entered into an Asset Purchase Agreement ("**APA**") with a third party in respect of its Estrace® asset. Under the APA, the Corporation has agreed to sell its interest in Estrace® in exchange for royalty payments based on gross sales of Estrace® for up to 5 years. However, the third party is not required to commence commercial sales of Estrace® unless certain conditions are satisfied by June 30, 2021. The conditions have not yet been met, but the Corporation continues to work collaboratively with a third party to complete the technology transfer.

On December 24, 2020 the Corporation announced that it received a waiver letter from SWK related to the required revenue covenant for the fourth quarter of fiscal 2020 in its existing credit facility.

2021

On March 26, 2021, the Corporation announced that it entered into an amended agreement related to its existing credit facility with SWK. The nature of the amendments were to: i) set principal repayment at US$1.1 million for May 15, 2021 followed by quarterly principal repayments of US$600,000 effective August 15, 2021 and thereafter; ii) adjust the minimum threshold for Consolidated Unencumbered Liquid Assets (as defined in the credit facility as cash adjusted for certain portions of accounts receivable and accounts payable) required to be maintained by the Company at US$2.0 million effective May 15, 2021; iii) remove all revenue and Adjusted EBITDA covenants for the balance of 2021; and iv) adjust revenue and Adjusted EBITDA covenants for 2022 and onward. All other terms and conditions in the SWK credit facility remained unchanged.

On March 30, 2021, the Corporation announced the signing of an agreement granting Maylen Farma ("**Maylen**") the exclusive rights to market Natesto® in 20 countries across Europe, Central Asia, and the Middle East. Maylen is a privately-owned pharmaceutical company based in Lugano, Switzerland that specializes in bringing innovative pharmaceutical products and healthcare services to patients in emerging markets. Nations covered by the agreement with the Corporation include Belarus, Georgia, and Ukraine; Azerbaijan, Uzbekistan, Tajikistan, Kazakhstan, and Kyrgyzstan; Albania, Kosovo, North Macedonia, Serbia, and Bosnia and Herzegovina; the United Arab Emirates, Kingdom of Saudi Arabia, Kuwait, Qatar, Bahrain, Jordan, and Lebanon.

On April 1, 2021, the Corporation announced the signing of an agreement with Aytu, whereby the Corporation bought back all remaining rights to Natesto® in the U.S. that were not already returned to the Corporation as part of the 2019 Amended and Restated Agreement with Aytu ("**Aytu Buyback Agreement**"). Acerus launched promotional efforts to key Urology and Endocrinology specialists in August of 2020. Following early growth in the specialty segment, assuming full ownership of Natesto® fulfills the Corporation's mission to build and leverage a robust commercial business unit in the U.S.

The Corporation agreed to purchase these rights from Aytu for $7.5 million USD, paid evenly over 30 monthly installments and assumed all product responsibilities following the effective date. The Corporation expects these payments to be funded from net revenues generated by Natesto®. In addition to the Corporation detailing to Specialty HCPs, the Corporation gained full distribution rights and full reporting of net revenues. To ensure a smooth transition, Aytu agreed to assist the Corporation throughout a 120-day Transition period from the effective date. During the transition period, Aytu continued to provide distribution of Natesto® under the terms of the Revised Aytu Agreement.

On April 30, 2021, the Corporation announced that it entered into a US$15 million subordinated secured loan facility (the "**2021 FGC Loan Facility**"), which was made available to the Company by way of one or more advances under a secured grid promissory note with First Generation.

The 2021 Loan Facility was subordinated to the existing facility with SWK and bore interest at a rate of eight percent (8%) per annum. Subject to the terms of the subordination and intercreditor agreement between First Generation and SWK, the 2021 FGC Loan Facility was repayable in full on December 31, 2024, with cash payments of interest and/or principal subject to certain exceptions related to the Company's market capitalization and the outstanding principal amount of the senior facility with SWK; the 2021 FGC Loan Facility can be prepaid in full or in part without penalty. The proceeds from the 2021 FGC Loan Facility was used for ongoing general working capital. A copy of the secured grid promissory note covering

the 2021 FGC Loan Facility was filed under the Corporation's profile on SEDAR at www.sedar.com.

On May 10, 2021, the Corporation announced that it entered into a three-year agreement with Amneal Pharmaceuticals Inc. ("**Amneal**") to co-promote Natesto® in the U.S. Endocrinology segment, leveraging the company's extensive relationships with Endocrinology healthcare providers. Amneal will promote Natesto® through its 50+ sales representatives in a P2 position.

Under the terms of the agreement, Amneal will sell Natesto® to the company's existing Endocrinology targets through June 30, 2024. In compensation for its marketing efforts, Amneal will receive a commission for most of the net profits attributed to Endocrinology targets in the three active promotional years, with the Corporation retaining a low double-digit percentage of such net profits during the active promotion period. Amneal will also receive a three-year trailing royalty following the active promotion period, with compensation to Amneal decreasing from a majority of the net profits to a minority of the net profits.

On June 29, 2021, the Corporation announced effective July 1, 2021, an additional leading pharmacy benefit manager (PBM) in the United States elected to make Natesto® (testosterone nasal gel) a "Preferred Brand" on its National Preferred Drug List. Drugs listed on formulary as preferred brands have been evaluated by the PBM from a therapeutic and value perspective. Preferred branded drugs may be available to patients at a lower co-pay or co-insurance than non-preferred brand drugs.

On July 12, 2021, the Corporation announced that, on June 15, 2021, it prevailed at a preliminary issue trial in which Recipharm alleged that the Corporation's claim for damages was barred by the terms of the companies' manufacturing contract. In agreeing with the Corporation that its claim for damages was not barred, the Commercial Court of London directed the matter to proceed to a full trial. Recipharm asked for permission to appeal the court's decision.

On August 12, 2021, the Corporation announced that it had accepted a Part 36 settlement offer made by Recipharm. In light of permission to appeal being granted regarding the preliminary issue decision and, amongst other things, the delay to the proceedings and to final judgment this would have caused, the Corporation accepted the Part 36 Offer and received from Recipharm in settlement a payment of GBP 1.7 million. In addition, the Corporation was entitled to payment of the majority of its costs of the litigation.

On August 23, 2021, the Corporation announced that it would participate in the H.C. Wainwright 23rd Annual Global Investment Conference held on September 13-15 in New York. Management hosted a general presentation, viewable online, and was available for virtual meetings with institutional investors throughout the course of the conference.

On December 13, 2021, the Corporation announced that it entered into an amending agreement with First Generation to increase the 2021 FGC Loan Facility from US$15 million to US$25 million. This increase was made available to the Corporation by way of one or more advances under a secured grid promissory note with First Generation provided that any such advance was made before February 1, 2022.

The 2021 Loan Facility was subordinated to the senior facility with SWK and bears interest at a rate of eight percent (8%) per annum. Subject to the terms of the subordination and intercreditor agreement between First Generation and SWK, the 2021 Loan Facility is repayable in full on December 31, 2024 and can be prepaid in full or in part without penalty. The proceeds from the 2021 Loan Facility were used for ongoing general working capital.

In addition to the increase in the 2021 Loan Facility, SWK has consented to temporarily amend their facility to reduce the minimum Consolidated Unencumbered Liquid Asset (generally defined as cash adjusted for certain accounts receivable and payable) covenant from US$2 million to US$250,000 until February 1, 2022.

2022

On January 10, 2022, the Corporation announced the signing of an agreement with Verity Pharmaceuticals ("**Verity Pharma**") for the exclusive rights to promote Natesto® in Puerto Rico. Verity Pharma will begin promoting Natesto® to health care professionals throughout Puerto Rico in Q1, 2022. Verity Pharma is a

privately-owned pharmaceutical company with offices in Canada, the United States, and Ireland that specializes in providing innovative, market-leading pharmaceutical products to patients across North America. Under the terms of the agreement, Verity Pharma will promote Natesto® across the island of Puerto Rico, leveraging its existing commercial footprint and health care network. The Corporation will maintain control of distribution, market access, and regulatory activities on the island of Puerto Rico.

On February 18, 2022, the Corporation announced that it entered into an amending agreement with First Generation, a company affiliated with the Chairman of the Board of Directors of Acerus, to increase the 2021 FGC 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 the increase were used on February 17, 2022 to settle all obligations under the New Facility.

On February 28, 2022, the Corporation announced hat it has entered into a definitive agreement (the "**Serenity Definitive Agreement**") to indirectly acquire Serenity and the global rights to its Noctiva™ brand in a combined cash and stock transaction. Serenity, based in Miami, FL, is a specialty pharmaceutical company, focused on developing therapies for diseases associated with voiding disorders, and had previously been granted approval by the U.S. Food and Drug Administration (FDA) for its Noctiva™ (desmopressin acetate) nasal spray. Noctiva™ is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void.1 It is the first FDA-approved therapy for nocturia.

Within 90 days of the effectiveness of the acquisition (the "**Acquisition**"), Acerus will pay a $6 million USD up-front fee to Serenity, less certain deductions allowed by the Serenity Definitive Agreement. Serenity stockholders will be entitled to receive approximately 804 million Acerus 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 Acerus 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 Acerus 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.

The combined company will continue to be led by Edward Gudaitis, President and Chief Executive Officer of Acerus and will be headquartered in Mississauga, Ontario. The board of the combined company will consist of six members designated by Acerus and one member designated by Serenity, including Serenity Chief Executive Officer and Director Dr. Samuel Herschkowitz (who will assume the role of Vice-Chair) and Serenity Chief Medical Officer and Director Dr. Seymour Fein (who will assume a Board Observer role).

Completion of the Acquisition could result in the issuance of up to 1,533,642,008 Acerus Common Shares assuming the First Commercial Sale Shares and each tranche of the Sales Milestone Shares become issuable to the Serenity stockholders in accordance with the terms of the Definitive Agreement (and the Sales Milestone Shares are issued at the floor price) representing approximately 99.74% of Acerus' currently issued and outstanding Common Shares.

As of the date hereof, Acerus has 1,537,588,081 Acerus Common Shares issued and outstanding on a non-diluted basis. Serenity has two key securityholders, Dr. Samuel Herschkowitz and Rev5 Family Trust, who Acerus expects will receive approximately 33.35% and 25.94%, respectively, of the Acerus Common Shares issuable to Serenity securityholders in connection with the Acquisition. Assuming the full number of

Acerus Common Shares issuable under the Definitive Agreement become issuable (which includes issuance of the Sales Milestone Shares at the floor price) and there are no other changes to Acerus' issued and outstanding Common Shares as of the date hereof, Dr. Herschkowitz and Rev5 Family Trust would own approximately 16.65% and 12.95% respectively of Acerus' issued and outstanding Common Shares at such time. Based on the same assumptions, First Generation Capital Inc., Acerus' current controlling shareholder, would continue to own approximately 44.8% of Acerus' issued and outstanding Common Shares at such time. All of the Serenity securityholders are arm's-length to Acerus and none of Acerus' directors or officers are insiders of Serenity.

On March 7, 2022, the Corporation announced the closing of the Acqusition. In addition to the above discussion, details of the Acqusition can be found in the Company's filings in the US at https://www.sec.gov/edgar.shtml and in Canada at www.sedar.com.

Intercorporate Relationships

The Corporation is the parent corporation to three wholly-owned subsidiaries. The Corporation owns a 100% interest in Acerus Labs, which was incorporated under the laws of the Province of Ontario on June 19, 2017, and Acerus Biopharma, which was continued under the laws of the Province of Ontario on November 8, 2017 (formerly Acerus Pharmaceuticals SRL incorporated under the laws of Barbados). In addition, the Corporation used to own a 100% interest in Acerus Pharmaceuticals (Barbados) Inc. ("**Acerus Barbados**"), which was incorporated under the laws of Barbados on September 9, 2008 as the former corporate parent. On March 7, 2022 the Serenity, a Delaware limited liability company, became a wholly-owned subsidiary of the Corporation in connection with the Acquisition.

The Corporation is the principal operating entity of the business of the Corporation relating to Lidbree™ (as defined below) and avanafil and is the owner or licensee, as applicable, of the intellectual property required for the conduct of such businesses.

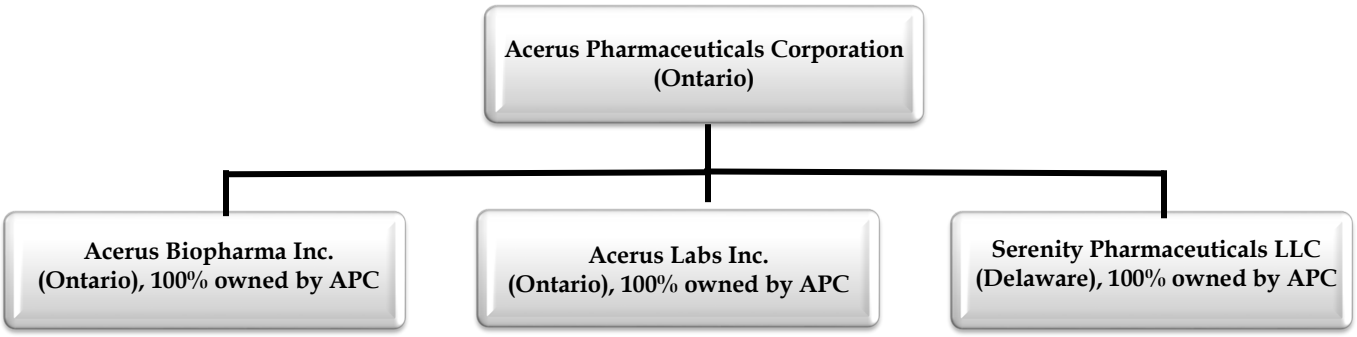
Acerus Biopharma is the principal operating entity of the business of the Corporation relating to Natesto®, Tefina™ and TriVair™ and is the owner or licensee, as applicable, of the intellectual property required for the conduct of such businesses.

Acerus Labs is the principal operating entity of the business of the Corporation relating to certain early stage research and developments projects, including research projects related to the intranasal delivery of various botanical and synthetic cannabinoids formulations, and is the owner of the intellectual property required for the conduct of such businesses.

Serenity owns the intellectual property for the Noctiva™ desmopressin acetate product.

Acerus Barbados was a shell company, which was officially dissolved on February 26, 2018.

The following table illustrates the relationship between the Corporation and its subsidiary entities:



DESCRIPTION OF THE BUSINESS

Overview

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

(1) Natesto®, the first and only testosterone nasal gel for testosterone replacement therapy in adult males diagnosed with hypogonadism, is commercialized in Canada and the U.S. In addition, Natesto® has been licensed to partners in numerous countries and is currently approved in South Korea and Taiwan.

(2) Noctiva™, is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

The Corporation's pipeline of innovative products includes the following:

(1) Lidbree™, a short acting lidocaine formulation delivered through a proprietary device into the vaginal mucosal tissue.

(2) Avanafil is a PDE5 inhibitor for the treatment of erectile dysfunction. Avanafil was approved by the United States Food and Drug Administration ("**U.S. FDA**") under the trade name of Stendra™ and the EMA under the trade name of Spedra®.

(3) Tefina™, a clinical stage product aimed at addressing a significant unmet need for women with female sexual dysfunction.

(4) Two additional combination formulation concepts based upon Noctiva™. These combinations products would comprise of a formulation of Noctiva™ plus a product for benign prostatic hypertrophy (BPH) or Noctiva™ plus a product for overactive bladder (OAB). These two combination products concepts are in the pre-clinical development stage.

(5) An additional Noctiva™ reformulation concept that could be utilized to treat pediatric nocturnal enuresis (PNE, night-time bed wetting). This concept is in the pre-clinical development stage.

The Corporation has investigated the utility of the nasal gel technology in delivering cannabinoids (whether synthetic or naturally derived cannabinoids) intranasally to patients, which may have multiple possible therapeutic applications (the "**Cannabinoids Initiative**"). The Corporation has filed patent applications on the Cannabinoids Initiative and achieved first positive results from dosing of subjects in a Phase I clinical trial test a proprietary intranasal formulation of nasal tetrahydrocannabinol THC–rich cannabis oil in healthy volunteers.

Moreover, the Corporation owns or has a license to numerous patents relating to proprietary delivery systems as well as novel formulations of products currently in the early stages of development.

Products

The Corporation's Development Technology

Natesto® and Tefina™ Technology

Pursuant to the IP Agreement with Mattern (formerly M&P Patent AG) (see "*Material Contracts*" below), the Corporation has licensed certain rights to a drug delivery technology platform in relation to certain specific product development programs including: (a) male testosterone replacement therapy (i.e., Natesto®), (b) female sexual dysfunction therapy (i.e., Tefina™), and (c) certain anti-anxiety molecules. This

technology, when combined with testosterone, results in a proprietary bioadhesive drug/gel combination designed to adhere to the lateral wall of the nasal cavity. The gel allows for the release of testosterone through the nasal mucosa. The nasal mucosa offers an easily accessible, high permeability route of administration, resulting in rapid absorption into the peripheral circulatory system.

Alongside the technology licensed from Mattern, the Corporation has developed, with its supplier Aptar France SAS ("**Aptar**"), a multi-dose nasal dispenser, which the Corporation is currently using for Natesto®. The multi-dose dispenser provides a convenient, consistent and precise delivery of each dose. The sealed construction of the dispenser prevents air from coming in contact with the drug, thereby preventing contamination.

M&P Buyout

On May 17, 2018, the Corporation entered into an agreement with Mattern Pharma AG ("**Mattern**") to buy out all of its obligations (the "**M&P Buyout**") under the Amended and Restated Intellectual Property Rights and Product Development Agreement, dated December 21, 2013 (as amended) ("**IP Agreement**"), including all its future royalty payment obligations. Pursuant to the M&P Buyout, with the payment of U.S. $7.5 million, all of the Corporation material obligations owed to Mattern were suspended, but Mattern's obligations to the Corporation remain in force. Under the M&P Buyout, among other rights, the Corporation received a perpetual, fully-paid, irrevocable license to all of Mattern's patents and know-how for the products covered by the IP Agreement. All of the payments due to Mattern under the IP Agreement were completed as of April 16, 2020. The M&P Buyout also included a covenant not to sue and a waiver from Mattern, which became irrevocable upon payment of the last installment to Mattern. The M&P Buyout will remain in full force and effect as long as the IP Agreement is in force.

TriVair™ Pulmonary Delivery Technology

In November 2009, Acerus Biopharma acquired assets of Keldmann Healthcare A/S which have subsequently been rebranded as TriVair™. TriVair™ is a disposable single unit dose dry powder inhalation drug delivery technology platform with applications for both nasal and pulmonary dosing. TriVair™'s patented drug delivery technology may provide significant benefits to patients suffering from certain major respiratory and other disorders. The TriVair™ technology is currently licensed to IP Med Inc. ("**IP Med**"), who has the primary responsibility for developing this technology.

Early R&D Projects

The Corporation is working on expanding its product portfolio by leveraging its technology and expertise. As such, the Corporation has a number of ongoing early stage R&D projects. One of these projects is the Cannabinoids Initiative. On December 11, 2018, the Corporation announced positive results of a Phase 1 clinical trial test a proprietary intranasal formulation of a tetrahydrocannabinol. See *"Recent Developments"* for further information. In addition, the Corporation has filed patent applications on the Cannabinoids Initiative and is actively looking at potential partnering transactions for these initiatives.

The Corporation's Product Portfolio

Natesto® - Male Hypogonadism

The Corporation's first U.S. FDA and Health Canada approved development product, Natesto®, is a bioadhesive nasal gel formulation of testosterone. Natesto® is designed with a view to providing hypogonadal patients with superior safety and enhanced convenience over currently available treatment options. Natesto® is designed to be applied to the lateral wall of the nasal cavity. There is virtually no smell or taste associated with the gel. As a result of the "no touch" targeted delivery to the nasal mucosa, Natesto® minimizes skin-to-skin transference to third parties, resulting in Natesto® being approved by the U.S. FDA without the "black box" warning for secondary transference included in the product labels of all other topical testosterone gel preparations available on the market today. Patients on Natesto® can safely restore

their T levels and relieve symptoms while allowing their hypothalamic-pituitary-gonadal (HPG) axis to remain active. This makes it an effective treatment not associated with some of the safety concerns sometimes linked to T therapy, providing patients a treatment option with a low risk of polycythemia and clinical evidence for the maintenance of spermatogenesis.

Natesto® was approved for sale in the United States by the U.S. FDA in May 2014. In December 2014, the Corporation completed a transaction with Endo pursuant to which Endo was provided the exclusive right to commercialize the product in the United States and Mexico and the product was subsequently made commercially available in the United States in the first quarter of 2015. Endo continued commercial sales of the product until June 30, 2016, after which Aytu began its commercialization of Natesto® in the United States.

In January 2016, Natesto® was approved by Health Canada for commercial sale in Canada with a convenient twice-daily starting dose. In addition, Natesto® demonstrated significant improvements in erectile function, intercourse satisfaction, orgasmic function, sexual desire, overall satisfaction and positive mood versus baseline. Natesto® became commercially available in Canada in September 2016. Importantly, Natesto®'s product monograph does not include the black box warning related to secondary transference which is required for all other topical gel testosterone products.

In September 2016, the Corporation initiated an open-label study in 117 hypogonadal males (75% of whom were on a topical TRT prior to study initiation) in 11 Canadian centers (the "**Study**"). The Study assessed a titration methodology based on improvement in patient symptoms, a key treatment outcome according to Canadian Men's Health Foundation Multidisciplinary Guidelines and as endorsed by both the Canadian Urological Association and the Canadian Society of Endocrinology and Metabolism. Titration outcomes were confirmed by analysis of serum total testosterone levels. The Study captured information on symptoms and patient treatment satisfaction prior to, as well as after, Natesto® treatment in order to glean information on Natesto® relative to their prior topical medication

On February 1, 2018, the Corporation announced that it received notice from Quebec's National Institute for Excellence in Health and Social Services (INESSS) of a positive recommendation to the Health Minister for the inclusion of Natesto® on the list of medications of the Régie de l'assurance maladie du Québec. This recommendation took effect on February 1st, 2018.

In June 2018, South Korea's Ministry of Food and Drug Safety approved Natesto® for the treatment of hypogonadism.

In April 2018, the Corporation entered into an agreement granting Producto Cientificos, S.A. de C.V ("**Carnot Laboratorios**") the exclusive right to market Natesto® in Mexico, Argentina, Colombia, Peru, Chile, Ecuador, Guatemala, El Salvador, Nicaragua, Honduras, Panama, Costa Rica, Cuba, Dominican Republic, Venezuela, Bolivia, Uruguay, Paraguay and Haiti. In April 2021, Carnot Laboratorios and the Corporation terminated the agreement, effective as of March 8, 2021.

In October 2018, the Corporation signed an amendment to its existing licensing and supply agreement with medac, expanding the German pharmaceutical company's exclusive right to market Natesto® in the totality of the 28 current EU member countries (including the United Kingdom) as well as Norway, Liechtenstein, Iceland, Turkey (including Turkish Cyprus), Australia, New Zealand, Israel and South Africa. In addition, the Corporation announced that medac had submitted a dossier for Natesto® in the first 21 European Member States under the Decentralised Procedure.

On May 6, 2019, the Corporation entered into a Master Commercial Services Agreement with Syneos ("**Syneos MSA**") to be the Corporation's commercialization partner in the United States. Syneos is a leading integrated biopharmaceutical solutions organization including the industry's largest Contract Commercial Organization (CCO). Syneos has extensive experience in Men's Health and with Natesto®, and offers an end-to-end model that enabled Acerus to rapidly stand up a U.S. commercial team; to scale across all aspects of commercialization, including medical and regulatory affairs, managed markets, marketing and sales; and provides greater flexibility and effectiveness in resource deployment. The Syneos MSA provides the main terms and conditions under which Syneos provide us with services to commercialize Natesto® in the United States. Each of those services has been described in specific project agreements. Since signing

the MSA, we have entered into project agreements, including project agreements that relate to:

a) the provision of a specialty sales force;
b) medical science liaison personnel;
c) national account managers;
d) public relations services;
e) advertising services;
f) medical affairs services;
g) market access services;
h) commercial integration services; and
i) message testing.

The Syneos MSA contains customary representations and warranties, indemnification, confidentiality, intellectual property and termination provisions. The Syneos MSA is scheduled to expire on May 6, 2022, unless earlier terminated or extended. The Syneos MSA is expected to be extended or renewed, to ensure continuity of our specialty sales force, national account managers and medical affairs teams. Ongoing Statements of Work with Syneos will vary in order to meet the needs of our evolving business.

On April 1, 2021, the Corporation announced the signing of an agreement with Aytu, whereby the Corporation bought back all remaining rights to Natesto® in the U.S. that were not already returned to the Corporation as part of the 2019 Amended and Restated Agreement with Aytu. Acerus launched promotional efforts to key Urology and Endocrinology specialists in August of 2020. Following early growth in the specialty segment, assuming full ownership of Natesto® fulfills the Corporation's mission to build and leverage a robust commercial business unit in the U.S.

The Corporation agreed to purchase these rights from Aytu for $7.5 million USD, paid evenly over 30 monthly installments and will assume all product responsibilities following the effective date. The Corporation expects these payments to be funded from net revenues generated by Natesto®. In addition to the Corporation detailing to Specialty HCPs, the Corporation gained full distribution rights and full reporting of net revenues. To ensure a smooth transition, Aytu agreed to assist the Corporation throughout a 120-day Transition period from the effective date. During the transition period, Aytu continued to provide distribution of Natesto® under the terms of the existing License and Supply Agreement.

On May 10, 2021, the Corporation announced that it entered into a three-year agreement with Amneal to co-promote Natesto® in the U.S. Endocrinology segment, leveraging the company's extensive relationships with Endocrinology healthcare providers. Amneal will promote Natesto® through its 50+ sales representatives in a P2 position.

Under the terms of the agreement, Amneal will sell Natesto® to the company's existing Endocrinology targets through June 30, 2024. In compensation for its marketing efforts, Amneal will receive a commission for most of the net profits attributed to Endocrinology targets in the three active promotional years, with the Corporation retaining a low double-digit percentage of such net profits during the active promotion period. Amneal will also receive a three-year trailing royalty following the active promotion period, with compensation to Amneal decreasing from a majority of the net profits to a minority of the net profits.

Until March 2021, product revenues received related to the Natesto® business were primarily generated by sales of inventory to various partners and a commission based on subsequent sales, other than in Canada where the Corporation was booking sales directly. These revenues in, 2019 and 2020 respectively were: USD$2.108M, USD$0.86M. In 2021, product revenues for Natesto® were USD$2.121M.

See the *2019* and *2020 "Recent Developments"* for more recent developments, including those related to clinical studies, manufacturing, launching in South Korea, the Revised Aytu Agreement, the SNDS and the Revised Batch. See the *2021 "Recent Developments"* heading for recent developments regarding the Aytu Buyback Agreement.

Noctiva™ (desmopressin acetate) - Nocturia

The Corporation acquired Serenity on March 7, 2022, pursuant to which it now owns the rights to Noctiva™ (desmopressin acetate).

Noctiva™ is the first FDA approved product for the treatment of nocturia, the condition of waking two or more times per night to void, due to nocturnal polyuria (overproduction of urine during the night). Noctiva™ is an emulsified low-dose vasopressin analog administered through a preservative-free nasal spray 30 minutes before bedtime. Noctiva™ has two dosage strengths, 0.83 mcg/0.1 mL and 1.66 mcg/0.1 mL. Each spray delivers 0.1 mL of Noctiva™. The Corporation believes that nocturia affects approximately 40 million Americans and that nocturnal polyuria is present in approximately 88 percent of those.[1] Of the 40 million Americans affected by nocturia, over 10 million actively seek treatment for their condition. Noctiva™ is designed to decrease the number of nighttime voids in men and women suffering from nocturia, and uses a patented spray technology to maximize drug delivery while minimizing the risk for Hyponatremia.

Noctiva™ will be manufactured pursuant to a manufacturing agreement between the Corporation and a third party contract manufacturing organization. The Corporation anticipated that Noctiva™ will be manufactured in a sterile one-of-a-kind manufacturing facility located in the United States that is in compliance with cGMP guidance and directives applicable to the manufacture of Noctiva™. This manufacturing facility will be built specifically for the manufacture of Noctiva™, and allows for the product to be the only preservative free nasal spray for this prescription.

Avanafil Product Pipeline

On March 28, 2018, the Corporation announced that it had entered into an exclusive distributor and license agreement with Metuchen Pharmaceuticals LLC ("**Metuchen**"), a privately-held specialty pharmaceutical company, granting the Corporation the exclusive right to commercialize avanafil (brand named Stendra™ in the U.S.) in Canada. Avanafil is a new chemical entity targeting the large and growing erectile dysfunction market. If approved by Health Canada, avanafil will be the only branded PDE5 Inhibitor in Canada (all others already being genericized). According to the Canadian study of Erectile Dysfunction, approximately 49% of men over 40 suffer from erectile dysfunction, a condition affecting their physical and psychosocial well-being and quality of life.[1] Contemporary treatment focuses on highly-effective, minimally invasive therapies, the most common of which is the PDE5 Inhibitors. Under the terms of the sublicense agreement, Metuchen will receive regulatory milestone payment upon the Corporation filing a New Drug Submission ("**NDS**") with Health Canada and upon the Corporation receiving marketing approval in Canada. Metuchen will also receive milestone payments based on the Corporation achieving certain sales targets. Metuchen will oversee the manufacturing of avanafil and will receive a supply price for the product comprised of a transfer price and royalties on net sales of the product. Avanafil is approved by the U.S. FDA for the treatment of erectile dysfunction. Metuchen has exclusive marketing rights to avanafil in the U.S. (which it sells in the U.S. under the trade name Stendra®), Canada, South America, and India. Spedra®, the trade name for avanafil in the EU, is approved by the European Medicines Agency ("**EMA**") for the treatment of erectile dysfunction in the EU. Vivus, Inc. has granted an exclusive license to the Menarini Group through its subsidiary Berlin- Chemie AG to commercialize and promote Spedra® for the treatment of erectile dysfunction in over 40 European countries plus Australia and New Zealand.

On March 4, 2019, the Corporation announced that it submitted an NDS to Health Canada to obtain marketing approval for avanafil in Canada.

On April 20, 2020, the Corporation received a NOD from Health Canada regarding avanafil. 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. Until this information was provided to Health Canada, the avanafil review process was halted. The Corporation had 90 calendar days to respond fully to the NOD. The Corporation requested an

[1] Leslie SW, Sajjad H, Singh S. Nocturia. [Updated 2021 Aug 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK518987/

extension of time, which was granted, and a submission was made before the end of the extended deadline. On December 11, 2020, Health Canada accepted the submission into review. In October, 2021, the Company received another NOD. 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. On January 24, 2022, Petros Pharmaceuticals announced that it had partnered with a new contract manufacturing organization for the production of avanfil. 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 2023.

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

Lidbree™ - Product Pipeline

In May 2018, the Corporation entered into an exclusive agreement to commercialize Palette Life Sciences AB formerly known as Pharmanest AB, Short Acting Lidocaine Product ("**Lidbree™**") a novel pain relief drug device combination in Canada. Lidbree™ is a novel technology that provides pain relief on vaginal mucosal tissue. In a Phase 2 clinical study conducted in Sweden, Lidbree™ treatment was associated with significant reduction of pain and discomfort in women undergoing gynaecological interventions without causing bothersome side effects.

Tefina™ Product Pipeline

The Corporation's product candidate Tefina™ is a nasal, low-dose gel formulation of testosterone. Tefina™ is being developed to potentially offer women experiencing one or more symptoms of female sexual dysfunction ("**FSD**") a "use as required" treatment option.

In a Phase I study conducted in 2010, the administration of Tefina™ resulted in an increase in plasma testosterone levels without exceeding the "upper limit of normal" testosterone plasma levels in women. Tefina™ was also shown to induce physiological and subjective sexual arousal within 30 minutes post-administration. To the knowledge of the Corporation, this is the first known study involving testosterone to ever show an increase in genital responsiveness within 30 minutes post-drug (testosterone) administration, and this is likely due to its unique nasal delivery technology.

Results of a Tefina™ Phase II trial were released in February 2012. This Phase II trial in 56 pre-menopausal women experiencing FOD, a subset of female sexual dysfunction, was studied in a hospital setting by employing the established Vibrotactile Stimulation ("**VTS**") FOD research model. Women suffering primary or secondary FOD were treated with a single dose of Tefina™ or a placebo and then challenged with a VTS device designed to induce orgasm at different time points post dose. In May 2014, the Corporation announced the results of its second Phase 2 trial commenced in May 2012.

In May 2015, the Corporation initiated a Psychometric Evaluation of the Female Sexual Distress Scale, including domains for desire arousal orgasm (FSDS-DAO) Questionnaire in pre-menopausal women with FOD. This U.S.-based, multi-site observational study included 60 pre-menopausal women without FOD, using hormonal and non-hormonal contraception methods, as well as relevant data from patients in the Phase II study completed in May 2014, to evaluate questionnaire reliability and validity. Results from this study indicated that the FSDS-DAO has acceptable reliability and validity among FOD subjects, particularly in the pre-menopausal patient population.

Following several interactions with the U.S. FDA since the completion of Phase II trials to clarify the

regulatory and clinical pathway for Tefina™ in FOD, the Corporation began a re-evaluation of the most appropriate clinical indication for the development of Tefina™ to treat types of FSD. The Corporation is continuing to evaluate the appropriate pathway for the clinical development of Tefina™.

TriVair™ Product Pipeline

On October 13, 2015, Acerus Biopharma entered into an intellectual property rights and development agreement with IP Med pursuant to which it is responsible for undertaking certain development work in connection with the TriVair™ platform and potential drug candidates for use in connection therewith. Under such agreement, Acerus Biopharma is entitled to a double-digit percentage of certain milestone and royalty payments upon the achievement of certain regulatory, clinical and commercial events. Among other things, IP Med has made enhancements to the device and filed new patents. Some of these enhancements include: (i) a custom one-way valve to ensure medication is delivered into the nasal cavity; (ii) a cone-shaped design to help create optimal dispersion of medication; and (iii) a nose piece to improve the patient experience.

Markets, Applications and Competition

Male Hypogonadism

U.S. Market

Male hypogonadism refers to the reduction of circulating endogenous testosterone. Symptoms of hypogonadism include diminished libido, fatigue and irritability. Hypogonadism is often misdiagnosed as a host of other maladies, including depression and erectile dysfunction. It is conservatively estimated that hypogonadism affects 13 million American men, up to 90% of whom go undiagnosed or untreated. Current treatment guidelines focus on the restoration of normal physiological testosterone level through the use of exogenous testosterone preparations.

For the 12 months ending December 2021, the total United States TRT market saw over 7.981 million prescriptions reported, an increase of approximately 2.9% over the previous 12-month period. 2021 saw lower than average yearly market growth due to the pandemic.

Certain events, including an increase in class action lawsuits filed against certain testosterone product manufacturers in the United States and claims of a purported link between cardiovascular risk and testosterone replacement therapy (see "*Risk Factors – Extensive Government Regulation*" below), are believed to be in part responsible for the decline observed in earlier years. The current United States competitive landscape for testosterone preparations offers topical products, in both gel and patch presentations, short-acting and long-acting injectables delivered intramuscularly or subcutaneously.

U.S. Competitive Landscape

The U.S. market landscape continues to evolve and get more competitive. Most recently, Antares Pharma launched a weekly auto-injector testosterone enanthate, Xyosted®, in December 2018 and is the leading brand in the TRT market in terms of total prescriptions at 196,105 in 2021. Clarus Therapeutics launched a daily oral testosterone udecanoate, Jatenzo®, in February 2020 and had 21,431 prescriptions in 2021. Branded testosterone products supported by promotional sales teams in 2021 included Xyosted®, Jatenzo® and Natesto®. TLANDO®, a second oral testosterone product, is expected to gain FDA approval sometime in the first half of 2022 and will be marketed by Antares.

Approximately 76% of all testosterone prescriptions written in the U.S. are paid for by commercial insurers. Natesto® currently has 74% commercial formulary coverage, which represents best in class access among promoted brands.

All marketed topical gel testosterone products, including AndroGel®, became subject to a U.S. FDA black-box warning as of May 2009 after the agency received reports of adverse effects in children who were inadvertently exposed to testosterone through contact with another person being treated with these products (secondary exposure or transference). Unlike other topical gel testosterone products, the label for

Natesto® is not required to include the black-box warning.

Canadian Market

In Canada, between January and October of 2019, there were 524,753 TRT prescriptions, a growth of 4% over the same time period in 2018.

Topical treatments represent 47.4%, oral treatments represent 18.2%, and injectable treatments represent 34.4% of the total prescription TRT market between January and October of 2019. The prescription growth between January and October 2019 over the same time period in 2018 for each of these categories saw a decrease of 0.9% for topical treatments, a decrease of 7.5% for oral treatments and an increase of 13.4% for injectable treatments. The issuance of updated Canadian TRT Guidelines (diagnosis and management of testosterone deficiency syndrome in men: clinical practice guideline) at the end of 2015 have re-established confidence in the safety of this class of medicines and helped to increase total prescription growth in the TRT market in 2017, 2018 and the first 10 months 2019 compared to the same time period in 2018. The increase in prescriptions seen in 2018 for the TRT market was the fourth consecutive year of growth.

In Canada, sales of total TRT products for 2018 were CDN$64.6 million with an increase of 3.47% from 2017. Topical products made up 73% of all dollar sales in the TRT market. In Canada, sales of total TRT products for six months ending June 2019 were CDN$33.1million with an increase of 5.4% from the first six months in 2018.

The information in this section is based on prescription data available up to October 2019.

Canada Competitive Landscape

As of October 2019, when the Corporation last purchased data for the Canadian market, AndroGel® (BGP Pharma ULC, a division of Mylan) was the most prescribed TRT product in Canada followed by injectables and orals.

At present, there is only one third party generic topical TRT products available in Canada. The generic version of AndroGel®, Taro-Testosterone (Taro Pharmaceuticals Inc.) became available in November 2017.

Axiron® (Lilly) was discontinued for sales in Canada as of December 2017. Both Xyosted® and Jatenzo® have not been approved or available for sale in Canada at this time.

Health Canada has also added black box warnings to all marketed topical gel testosterone products with regards to secondary exposure to testosterone. Natesto®'s product monograph does not include the black box warning related to secondary transference, which is required for all other topical gel testosterone products.

As discussed in "*Recent Developments*", the Corporation was unable to release the Revised Batch to the Canadian market until the submission of an SNDS. Ultimately, the issue was resolved by the Corporation providing an internal corrective action plan in February 2021. The Corporation notified Health Canada of its intention to reactivate the DIN for Natesto® in July 2021. As of the date hereof, Natesto® has not returned to the Canadian market.

Nocturia

US Market

The Corporation believes that nocturia affects approximately 40 million Americans and that nocturnal polyuria is present in approximately 88 percent of those.[2] Only ~30% of patients seeking treatment for nocturia receive pharmacotherapy with the other 70% opting for behavioral modification, or not addressing

[2] Leslie SW, Sajjad H, Singh S. Nocturia. [Updated 2021 Aug 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK518987/

the condition.[3] The diagnosis and treatment rates for nocturia are expected to increase, driven by an increasing awareness of nocturia as a condition independent of its perceived causes and population growth.

There is an estimated approximately $1.5B direct disease burden associated with nocturia stemming from an increase in night-time falls resulting from waking to void and increased mortality; there is an additional estimated approximately $60B in indirect disease burden from lost productivity from sleep deprivation, and diminished overall health

US Competitive Landscape

At present, the only branded product approved and marketed for the treatment of nocturia is Nocdurna® (Antares), a sublingual tablet. Nocdurna® currently achieves approximately 650 prescriptions per month The Corporation also anticipates that it will compete with products that have been historically used off-label to treat nocturia, primarily medications indicated for overactive bladder and benign prostatic hyperplasia, and other forms of demopressin.

Erectile Dysfunction

Market

Avanafil, if approved by Health Canada, will be indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

According to the Canadian study of Erectile Dysfunction, approximately 49% of men over 40 suffer from erectile dysfunction, a condition affecting their physical and psychosocial well-being and quality of life. The erectile dysfunction market in 2018 totalled CDN$198 million for prescription products, with a growth of 3.5% from the previous year. Erectile dysfunction market is comprised of both maintenance and acute products, of which acute has 99.2% of yearly sales in 2018. In Canada, sales of total erectile dysfunction products for six months ending June 2019 were CDN$91.1 million with a decline of 4.5% from the first six months in 2018.

The information in this section is based on prescription data available up to October 2019.

Competitive Landscape

For the indication of erectile dysfunction, avanafil will primarily compete against prescription products. The main prescription products that are currently used to treat erectile dysfunction are Viagra® (Pfizer), Cialis® (Lilly) and Levitra® (Bayer), along with all generic forms thereof as all no longer benefit from patent protection or regulatory exclusivity.

On March 4, 2019, the Corporation announced that it submitted an NDS to Health Canada to obtain marketing approval for avanafil in Canada.

On April 20, 2020, the Corporation received a NOD from Health Canada regarding avanafil. 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. Until this information was provided to Health Canada, the avanafil review process was halted. The Corporation had 90 calendar days to respond fully to the NOD. The Corporation requested an extension of time, which was granted, and a submission was made before the end of the extended deadline. On December 11, 2020, Health Canada accepted the submission into review. The NDS review process may take up to 360 days to complete. In October, 2021, the Company received another NOD. 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

[3] Int Neurourol J. 2016 Dec;20(4):304-310. doi: 10.5213/inj.1632558.279. Epub 2016 Dec 26

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. On January 24, 2022, Petros Pharmaceuticals announced that it had partnered with a new contract manufacturing organization for the production of avanfil. 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 2023.

Vaginal Pain

Market

Lidbree™, if approved by Health Canada, may be used as a topical anaesthesia for cervical and intrauterine procedures, such as placement of intrauterine contraception, hysteroscopy, cervical and endometrial biopsies, in adults and adolescents.

In Canada it was estimated that in 2018 there were more than 262,000 IUDs purchased, with a growth of 13.4%. In Canada, it is estimated for the six months ending June 2019 there were more than 138,000 IUDs purchased insertions, with a growth of 6.4% from the first six months in 2018.

The information in this section is based on data available up to October 2019.

Competitive Landscape

For the indication of topical anaesthesia for cervical and intrauterine procedures, there are currently no competitive products.

Female Sexual Dysfunction

U.S. Market

Female sexual dysfunction consists of three recognized disorders in the Diagnostic and Statistical Manual of Mental Disorders (5th Edition): (a) female sexual interest/arousal disorder, a combination of sexual desire and arousal disorders, such as HSDD, (b) genito-pelvic pain/penetration disorder (painful sexual intercourse) and (c) FOD. In a survey of over 1,700 women aged 18 to 59 published in 1999, 43% acknowledged some form of sexual dysfunction. The data further suggested that 32% of the women lacked interest in sex and 26% could not experience orgasm.

Two products have been approved for HSDD. Flibanserin (Addyi™ (Valeant)), as a chronic daily administration, is the only approved product for the treatment of HSDD in pre-menopausal women in the United States. Bremelanotide (Vyleesi™ (Palatin)), an injectable formulation for on-demand treatment of HSDD in pre-menopausal women, was approved on June 21, 2019. Other off-label treatments have been used, including compounded testosterone preparations, psychotropic medications and phosphodiesterase- 5 inhibitors.

U.S. Competitive Landscape

In August 2015, the U.S. FDA approved Addyi™ (flibanserin), a product developed by Sprout Pharmaceuticals for use in generalized HSDD in premenopausal women. The product is now available for sale in the United States.

Bremelanotide (Vyleesi™ (Palatin)) is an injectable formulation for on-demand treatment HSDD in pre-menopausal women. On June 4, 2018, Palatin announced that the U.S. FDA accepted the bremelanotide NDA for filing. The Prescription Drug User Fee Act goal date for completion of the U.S. FDA review of the bremelanotide NDA is March 23, 2019. In February 2017, AMAG Pharmaceuticals completed a licensing deal with Palatin for exclusive North American commercial rights. On June 21, 2019, the U.S. FDA approved Vyleesi™ (bremelanotide), an injectable formulation for treatment of HSDD in pre-menopausal women.

Canadian Market

As of February 27, 2018, Health Canada issued a Notice of Compliance for Addyi™ (flibanserin).

As of November 13, 2018, Addyi® (Sprout Pharmaceuticals Inc) received marketed status from Health Canada and had recognized sales of $25,000 as of June 2019.

Employees

As at the date of this Annual Information Form, the Corporation and its subsidiaries collectively have 14 full-time employees, including senior management, in Canada and 2 members of senior management who reside in the United States. In addition, as described in Recent Developments above, the Corporation continues to partner with Syneos to maintain scale across many aspects of commercialization, including medical, managed markets, and sales. As of the date hereof, the Corporation utilizes 30 Syneos employees based in the United States, to conduct a substantial majority of the Corporation's commercial operations in the United States. See the heading "*Natesto® - Male Hypogonadism*" above for a discussion of the services that Syneos has provided to the Corporation.

None of the Corporation or its subsidiaries is subject to a collective bargaining agreement.

Intellectual Property

The Corporation's success depends in part on its and its licensors' ability to obtain patents, protect trade secrets and know-how, as well as to operate without infringing on the proprietary rights of others. The Corporation seeks to protect its products by filing patents in all countries of the world where such patents are important to the development and continuation of its business.

Natesto® and Tefina™

Patents

A number of patent applications have been prepared and filed, and/or patents issued, with respect to the Corporation's Natesto® and Tefina™ products in a number of jurisdictions worldwide including, without limitation, Argentina, Australia, Brazil, Canada, China, Europe, India, Indonesia, Iran, Japan, Korea, Malaysia, Mexico, Norway, Poland, Russia, Saudi Arabia, Singapore, South Africa, Thailand, Taiwan, the United Arab Emirates and the United States. In certain jurisdictions, including Canada and certain countries in the EU, patents have issued on Natesto® that extend patent protection to 2032. In the USA, the Corporation has extended patent protection to 2034. If issued in other jurisdictions and with respect to other patent application families that may issue, patent protection may be extended for Natesto® until 2037.

Pursuant to the intellectual property rights and product development agreement between Acerus Biopharma and Mattern, Acerus Biopharma has been granted certain rights with respect to certain patents registered in the name of Mattern in connection with the Corporation's rights to develop, manufacture and market Natesto® and Tefina™. In particular, Mattern has been issued four "Orange Book" listed patents in the United States with respect to Natesto®. The four Mattern "Orange Book" listed patents in the U.S. for Natesto® are set to expire in 2024. In addition, the Corporation has secured a patent, listed in the Orange Book, set to expire in 2034.

Trademarks

Acerus Biopharma has applied for and/or registered a variety of trademarks in respect of Natesto® and Tefina™. Such trademarks have been applied for or received in several jurisdictions including Australia, the European Community, New Zealand, China, Hong Kong, Japan, the United States, Canada, Philippines, Vietnam, Singapore and Barbados.

In addition, the Corporation has applied for trademark protection in respect of the mark "TESTOSTEROWN™" in Canada, the United Kingdom and the United States. The trademark was granted in the United States and United Kingdom, and the trademark application in Canada is pending.

Noctiva™

Patents

The Corporation owns patents covering Noctiva™ that are expected to expire beginning in 2023 and ending in 2030. Patents extending to 2030 have been granted in the following countries: Australia, Austria, Belgium, Canada, Denmark, France, Germany, Hong Kong, Ireland, Italy, Japan, South Korea, Mexico, Netherlands, Poland, Russia, Spain, Sweden, the United Kingdom and the United States.

Trademarks

The Corporation owns a number of trademarks for potential use in marketing its desmopressin acetate product. The Corporation currently owns the trademark to the *Noctiva* name in the United Kingdom, Canada and the EU.

TriVair™ Deposition System

Patents

A number of patent applications have been prepared and filed, and/or patents issued, with respect to the TriVair™ platform in a number of jurisdictions worldwide including Australia, Brazil, Canada, China, Denmark, France, Germany, Greece, India, Italy, Japan, Mexico, New Zealand, Norway, Poland, Russia, South Korea, Spain, Sweden, Switzerland, Thailand, Turkey, the United Kingdom, the United States and Vietnam.

Trademarks

Acerus Biopharma has applied for and/or registered a variety of trademarks in respect of its TriVair™ platform. Such trademarks have been applied for or received in several jurisdictions including the United States, Canada, Australia, the European Community, New Zealand, China, Hong Kong and Japan.

Cannabinoids Initiative and other early stage projects

A number of patent applications have been prepared and filed with respect to the Corporation's early stage projects, including the Cannabinoids Initiative and the Aqueous Nasal Delivery Technology all of which are in the early stages of patent prosecution.

RISK FACTORS

Investment in the Corporation involves a high degree of risk and should be regarded as speculative due to the nature of its business. The Corporation has incurred losses and expects to incur further losses in the near term. In addition to the other information contained in this Annual Information Form, the following factors should be considered carefully by investors when evaluating an investment in our securities.

Going Concern Risk

The ability of the Corporation to continue as a going concern is dependent upon the Corporation successfully commercializing its existing products, bringing new products and technologies to market and achieving future profitable operations. As of December 31, 2021, the Corporation had positive working capital of $3.3 million and during the three years ended December 31, 2021, the Corporation has incurred total net losses of $32.1 million. The ability of the Corporation to continue as a going concern for the foreseeable future and continue the development and commercialization of its products is dependent on the Corporation receiving additional funding, either from growth in commercial sales of its existing products, commercial transactions or investors. There can be no assurances that the Corporation will be able to receive the necessary financing (whether from its commercial operations or otherwise) in the future. Factors within and outside the Corporation's control could have a significant bearing on the ability of the Corporation to receive the necessary additional funds.

Limited Operating History and Sales Generally

The Corporation has only begun to market and generate revenues from the commercialization of its products relatively recently. The Corporation's products are either not expected to be profitable in the near future due to launch expenses or are not expected to be commercially available for several years, if at all. There can be no assurance that any of the Corporation's future product candidates will meet applicable regulatory standards, obtain required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs or be successfully marketed. Additionally, in the event that Natesto® in the United States and in the rest of the world cannot be successfully commercialized, it could have a material adverse effect on the financial position of the Corporation.

Ability to Meet Future Capital Requirements

The development of the business of the Corporation will depend upon, among other things, ongoing sales revenues (and/or milestones or other payments) and the amount of additional financing available. Failure to receive sufficient sales revenues (and/or milestones or other payments) or obtain sufficient financing may result in delaying, scaling back, eliminating or indefinitely postponing the development of existing or future products and the business of the Corporation's current or future operations, or may result in the Corporation being required to relinquish rights to or sell certain of its products that it would otherwise not relinquish or sell. There can be no assurance that additional capital or other types of financing will be available, if needed, or that, if available, the terms of such financing will be acceptable. Loans have been obtained by the Corporation (in 2012, 2014, 2016, 2017, 2018, 2019 and 2021), and further loans may be required to be obtained from financial institutions or the public debt markets. There is no assurance that the business of the Corporation will generate sufficient cash flow from operations in the future to service any debt or other obligations and to make necessary capital expenditures, in which case the Corporation may seek additional financing, dispose of certain assets or seek to refinance some or all of its debt.

Future capital requirements will depend on many factors including, without limitation:

- the financial performance of the Corporation's products being sold;
- the cost of possible acquisitions of drug delivery technologies, compounds, product rights or companies;
- progress in the application of delivery and formulation technologies, which may require further refinement;
- the number and complexity of product development programs pursued and the pace at which each such program is pursued;
- the scope, rate of progress, results and costs of pre-clinical and clinical trials;
- the time and costs associated with seeking regulatory approvals;
- the ability to establish collaborative arrangements with others and the terms of any such arrangements;
- the ability to meet milestones and other obligations under any collaborative arrangements;
- the time and expense required to prosecute, enforce, defend and/or challenge patent and other intellectual property rights;
- the development of necessary manufacturing infrastructure and ongoing working capital requirements to support manufacturing and commercial operations;
- competing technological and market developments;

- costs for recruiting and retaining employees and consultants;
- legal, accounting and other costs and liabilities related to the business of the Corporation; and
- capital and debt market conditions.

Fluctuating Operating Results

The nature of the Corporation's business involves numerous variable factors. The Corporation expects its operating results to be subject to quarterly fluctuations, subject to numerous factors including (without limitation):

- variations in the level of expenses incurred by the Corporation with respect to its products and development activities;
- regulatory developments affecting the Corporation's products or activities, including regulatory requirements relating to the release of the Revised Batch of Natesto® in Canada;
- the Corporation's execution of any partnership or similar agreements, and the timing of payments which the Corporation may make or receive under such arrangements;
- the level of underlying demand for the Corporation's products; and
- the continued market acceptance of the Corporation's products.

If the Corporation's quarterly operating results fall below the expectations of investors or securities analysts, the price of the Acerus Common Shares could decline substantially.

As a consequence of the temporary shortage of Natesto® in Canada, the Corporation has implemented cost cutting measures, including a reduction of the number of employees of the Corporation covering the Canadian Territory, that could cause a reduction in future revenues.

First Generation will have Significant Influence over Matters put Before Shareholders

First Generation, which is controlled by Ian Ihnatowycz (a director and chairman of our board of directors) currently owns approximately 89.5% of the Acerus Common Shares. As a result, First Generation exercises control over the Corporation as of the date hereof, and will have significant influence with respect to all matters submitted to the Corporation's shareholders for approval, including without limitation the election and removal of directors, amendments to the articles of incorporation and bylaws of the Corporation and the approval of certain business combinations. Other holders of Acerus Common Shares will have a limited role in the Corporation's affairs. This concentration of holdings may cause the market price of the Acerus Common Shares to decline, delay or prevent any acquisition or delay or discourage take-over attempts that shareholders may consider to be favourable, or make it more difficult or impossible for a third party to acquire control of the Corporation or effect a change in the board of directors and management. Any delay or prevention of a change of control transaction could deter potential acquirors or prevent the completion of a transaction in which the Corporation's shareholders could receive a substantial premium over the then current market price for their Acerus Common Shares.

First Generation's interests may not in all cases be aligned with interests of the other shareholders of the Corporation. First Generation may have an interest in pursuing acquisitions, divestitures and other transactions that, in the judgment of its management, could enhance its equity investment, even though such transactions might involve risks to the other shareholders of the Corporation and may ultimately affect the market price of the Acerus Common Shares. First Generation may also have an interest in pursuing other transactions or activities that will enable the Corporation to pay down the 2021 FGC Loan Facility and such transactions or activities may not in all cases be aligned with the interests of other shareholders.

In addition, as discussed above, Serenity stockholders will be entitled to receive approximately 1,533,642,008

Acerus Common Shares 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™, 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. Assuming the full number of Acerus Common Shares issuable under the Definitive Agreement become issuable (which includes issuance of the Sales Milestone Shares at the floor price) and there are no other changes to Acerus' issued and outstanding Common Shares as of the date hereof, two key securityholders of Serenity, Dr. Samuel Herschkowitz and Rev5 Family Trust, would own approximately 16.65% and 12.95% respectively of Acerus' issued and outstanding Acerus Common Shares at such time. Based on the same assumptions, First Generation, Acerus' current controlling shareholder, would continue to own approximately 44.8% of Acerus' issued and outstanding Acerus Common Shares at such time.

Market Acceptance

The degree of market acceptance of the Corporation's products will depend on a number of factors, including those set out in further detail below. Even if any of the Corporation's products are initially accepted by the market, sales may thereafter decline for a number of reasons, including the introduction of a competing product (including, without limitation, a generic version of any of the Corporation's products), change in market dynamics, regulatory changes, performance of any third parties engaged by the Corporation in connection with the sale, distribution and marketing of the products, pricing and reimbursement developments and other factors. The Corporation and its partners may need to demonstrate a significant advantage over competing products in order to support product pricing and/or payor reimbursement.

In order to successfully commercialize the Corporation's products, it will be necessary to demonstrate to healthcare professionals, payors, and patients that such products afford benefits to patients that are cost-effective as compared to the benefits of alternative therapies, many of which may be more established than those of the Corporation. The degree of market acceptance of the Corporation's product, and product candidates, if commercialized, will depend on a number of factors including, without limitation:

- the receipt of regulatory clearance of labeling claims for the uses being developed;
- the establishment and demonstration in the medical community of the safety and efficacy of the Corporation's products and product candidates and their potential advantages over existing products;
- the timing of market entry relative to competitive treatments;
- the relative cost, convenience, product dependability and ease of administration;
- the prevalence and severity of any adverse side effects in clinical trials or commercial use;
- the adequacy and effectiveness of the Corporation's production, distribution and marketing capabilities and those of any commercial partner;
- the sufficiency of coverage and reimbursement of product candidates by governmental and other third party payors; and
- product labeling or insert restrictions required by the U.S. FDA, Health Canada or regulatory authorities in other countries including, without limitation, with respect to Natesto® as a result of the initiatives described under "*Extensive Government Regulation*" below.

Generic Entrant Risk

As described above, a notice of compliance was issued by Health Canada for a third-party version of Estrace®, which was responsible for a material portion of the Corporation's revenue. This third party generic molecule is commercially available in Canada and reimbursed on the major provincial formularies since July 2016. Its availability in the market has had an adverse impact on the Corporation and may have

a material adverse impact on the Corporation in the future particularly because of the anticipated stock shortage for Estrace®.

The launch and commercialization of a generic alternative to any of the Corporation's present and future products may have a material adverse impact on the business, financial condition and operating results of the Corporation. Generic manufacturers taking advantage of the Abbreviated New Drug Application procedure of the U.S. FDA or Abbreviated New Drug Submissions in Canada (and similar processes in other jurisdictions) are not required to conduct the same degree of costly and time-consuming clinical trials to establish the safety and efficacy of their products, and are instead permitted to rely on the innovator's data in this regard. Accordingly, generic manufacturers are often able to sell their products at prices that are much lower than those charged by innovators.

Strong performance of any of the Corporation's products may make it more likely for a competitor to develop a generic formulation that competes directly with the products of the Corporation. In addition, the launch of a generic competitor for any of the Corporation's products may have certain material adverse impacts under third party agreements of the Corporation and its Affiliates, including the Aytu Buyback Agreement.

Extensive Government Regulation

Government regulation is a significant factor in the production and marketing of the Corporation's products. Research and development, testing, manufacture, marketing and sales of pharmaceutical products or related products are subject to extensive regulatory oversight, often in multiple jurisdictions, which may cause significant additional costs and/or delays in bringing products to market, and in turn, may cause significant losses to investors. The regulations applicable to the Corporation's products and product candidates may change. Even if granted, regulatory approvals may include significant limitations on the uses for which products can be marketed or may be conditioned on the conduct of post-marketing surveillance studies. Failure to comply with applicable regulatory requirements and laws can, among other things, result in warning letters, the imposition of civil penalties or other monetary payments, delay in approving or refusal to approve a product candidate, suspension or withdrawal of regulatory approval, product recall or seizure, operating restrictions, interruptions of clinical trials or manufacturing, injunctions or criminal prosecution. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of the Corporation's product candidates and may require that the labelling claims of approved products be changed.

Requirements for regulatory approval vary widely from country to country. Whether or not approved in the United States or Canada, regulatory authorities in other countries must approve a product prior to the commencement of marketing the product in those countries. The time required to obtain any such approval may be longer or shorter than in the United States or Canada. Approved drugs, as well as their manufacturers, are subject to continuing and ongoing review, and discovery of problems with these products or the failure to adhere to manufacturing or quality control requirements may result in regulatory restrictions being imposed.

In particular, testosterone, the active ingredient in both the Corporation's product candidates Natesto® for treatment of male hypogonadism and Tefina™ for the treatment of FSD, is a controlled substance subject to regulatory controls. The Corporation may be unable to obtain, or maintain, regulatory approvals for its products or may be required to expend additional resources or there may be significant delays to secure, or maintain, such approvals on favourable terms. Additionally, any such approvals may impose considerable restrictions and conditions on the Corporation with respect to the manufacturing, distribution and production of its applicable products, which may result in additional expenses being required to be incurred.

In January 2014, the U.S. FDA announced that it was undertaking an investigation of the risk of stroke, heart attack and death in men taking U.S. FDA-approved testosterone products as a result of a retrospective meta-analysis of published scientific literature and two reviews based on health record database searches of patients having received testosterone replacement therapy. In September 2014, an advisory committee convened by the U.S. FDA considered this issue. The U.S. FDA presented its own conclusions that it was

unable to establish any conclusive link between testosterone replacement therapy and cardiovascular risks as reported in these articles. The advisory committee did, however, express concerns that prescription rates of testosterone replacement were higher than the incidence of primary or classical hypogonadism (the originally intended indication, where low testosterone levels result from an associated underlying medical condition (congenital deficiency or the result of severe testicular damage)) and that testosterone replacement therapy may be being used in "aging males" with naturally declining testosterone levels (but without an underlying medical condition) for whom clinical efficacy has not been established. The committee proposed changes to the drug class label and recommended that additional clinical studies may be warranted to support efficacy and safety in the aging male population. On March 3, 2015, the U.S. FDA announced that it would be requiring that manufacturers of all prescription testosterone products change their labelling to clarify the approved uses, and to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. Finally, pursuant to a requirement by the U.S. FDA that manufacturers of certain approved testosterone products conduct a prospective clinical trial to evaluate the effect of testosterone replacement therapy on the incidence of major cardiovascular events in men, the Corporation formed a consortium with other pharmaceutical companies to conduct the clinical trial. As a consortium member, the Corporation will be responsible for funding its proportion of the study costs, which were $442,000 in 2020, $285,000 in 2021 and $220,000 anticipated for 2022 (additional information on the study is available on clinicaltrials.gov). In the event that the current study cost estimates change or that the terms under which the Corporation expects to enter into an agreement with other manufactures differ from the Corporation's current expectations it may have a material adverse effect on the business, results of operations or financial condition of the Corporation. Should the Corporation not be able to fund its portion of the applicable clinical trial costs, this may limit or restrict its ability to commercialize Natesto® in the United States or otherwise expose the Corporation to penalty or sanction. Furthermore, the results of any such clinical trial, if unfavourable (and any regulatory requirements resulting from such trial's findings), could adversely impact the commercial viability of Natesto® in the future.

A similar process has occurred in each of the European Union and Canada. In the EU, testosterone replacement therapy is only recommended when an abnormally low level of the hormone has been confirmed by signs and symptoms and appropriate laboratory tests, and restoration of age-related decline in testosterone levels in healthy older men is not an authorised use of the medicine. In 2014, a pharmacovigilance risk assessment committee of the European Medicines Agency considered that the risks of effects on the heart and circulation should continue to be monitored. In Canada, label changes implemented by Health Canada for any approved products should provide that testosterone replacement therapy should only be initiated if deficiency is clearly demonstrated by clinical features and confirmed by biochemical assays. Health Canada concluded that evidence suggested a possibility of a link between testosterone replacement therapy and cardiovascular risk and that patients should also be closely monitored for possible serious cardiovascular events while on testosterone therapy.

As a consequence of closer scrutiny of cardiovascular safety with TRT products generally since 2014, and as a result of observed changes in heart rate and blood pressure resulting from treatment with oral testosterone undecanoate preparations in 2018, the U.S. FDA requested that all current NDA holders propose a design and timetable for conduct and completion of a well-designed, adequately sized, and appropriately controlled study to monitor blood pressure and heart rate in an ambulatory setting. The responsibility for the conduct of this study remained with Aytu until the NDA was transferred back to the Corporation in connection with the Revised Aytu Agreement. As of the date hereof, the Corporation anticipates total spending $5.4M in connection with this study, of which $2.2M has been incurred through December 31, 2021. If the results of the study cause the U.S. government to impose restrictions or conditions which impact the ability of the Corporation to sell Natesto®, this could cause a material adverse impact on the Corporation.

Any restrictions or limitations on testosterone replacement therapy usage, or post-approval clinical trials or other requirements, that may follow from these or other investigations or reviews may have a significant impact on the commercial success of Natesto® as well as the entire class of testosterone replacement therapies.

Risks Associated with Debt Financing

As described under "*Recent Developments*" above, the Corporation entered into the 2021 FGC Loan.

All of the assets of the Corporation and its subsidiaries are subject to a secured interest in favour of First Generation in support of the Corporation's obligations under the 2021 FGC Loan. Consequently, a default under the 2021 FGC Loan would have a material adverse impact on the Corporation.

The ability of the Corporation to repay its indebtedness under the 2021 FGC Loan will be contingent upon the Corporation receiving sufficient revenues or other cash proceeds to be able to make the necessary payments. The payments due under the 2021 FGC Loan may be affected by changes in the 3 month LIBOR rate. If the 3 month LIBOR rate is increased, the interest expense for our outstanding debt would be increased and the Corporation's ability to make such increased payments may be materially adversely affected. A default under the 2021 FGC Loan would accelerate repayment and may have a material adverse effect on the Corporation.

In addition, please see the *Recent Developments* on February 12, 2020 and February 21, 2020 regarding the Refinancing Transactions.

For further information please see the Corporation's filings available on SEDAR at www.sedar.com.

Marketing and Distribution Risk

As described more fully under "*Recent Developments*" above, the Corporation relies heavily on arrangements with commercial partners to market, sell or distribute its products. Although the Corporation has taken on an increasing role in the commercialization of Natesto® in the United States, it is still dependent on Syneos for commercialization. Except with respect to those products that the Corporation intends to commercialize itself, the Corporation intends to collaborate with third parties that have direct sales forces and established distribution systems, either to augment, or in lieu of, its own sales force and distribution systems. For any collaboration to be successful, the Corporation must identify partners whose competencies complement those of the Corporation; however, it is not certain that any sales, fees or royalties payable to the Corporation under any commercial arrangement will allow the Corporation to fully recoup its investment made on its products or product candidates. To the extent that the Corporation enters into co-promotion or other commercial arrangements, its share of product revenue is likely to be lower than if the Corporation directly marketed or sold its products. In addition, any revenue received will depend in whole or in part upon the efforts and decisions of such third parties, which may not be successful and will generally not be within the Corporation's direct control. Furthermore, any commercial agreements may be subject to termination by a partner of the Corporation, and any such termination may make it difficult for the Corporation to attract new partners or adversely affect how the Corporation is perceived in the business and financial communities.

If the Corporation is not successful in commercializing its existing products and future product candidates, either on its own or through collaborations with one or more parties, future product revenue will suffer and the Corporation may incur significant losses.

Manufacturing-Related Risks

The Corporation has relied and will continue to rely on third party contractors engaged by the Corporation or its licensors to support its current and near-term manufacturing needs. If the Corporation or its licensors are not able to secure suitable third party manufacturing contractors to meet the product quantities required for commercial manufacturing or to support large clinical trials in a timely manner or at a reasonable cost, the Corporation may risk delaying its clinical trials or regulatory approvals, reduction in levels of saleable inventory of the Corporation's products and potentially breaching its obligations under current or future out-licensing agreements or other commercialization arrangements, including the agreements described under "*Recent Developments*" above, for so long as it remains in effect. Such consequences could have a material adverse impact on the financial position of the Corporation. Similarly, should systems fail, or a disaster strike, the ability to produce products would be negatively affected, which in turn, would also adversely affect the Corporation's business.

While the Corporation has manufacturing capacity for its testosterone products with third party manufacturers (certain of which are single source in nature), were such facilities to become unavailable for any reason, finding substitute facilities that are properly qualified to handle controlled substances or otherwise capable of serving as a backup supplier may prove difficult and/or result in a significant delay in manufacturing product. Similarly, finding initial backup facilities that are appropriately qualified for its other products may also be problematic. Additionally, any contractual rights that the Corporation may be entitled to in connection with its third party relationships may not be adequate and sufficient to ensure that the Corporation's access to materials is protected and that appropriate manufacturing standards are adhered to. Pharmaceutical manufacturing involves risks and uncertainties related to the demonstration of adequate stability, sufficient purification of drug products, the identification and elimination of impurities, optimal formulations, process validation and challenges in controlling for all of these factors. Finally, to the extent that the manufacturing costs charged by third party contractors increase and such costs are not able to be fully passed on to the Corporation's customers, the profit margins of the Corporation on its products may be adversely impacted.

With respect to Natesto®, as discussed in "*Recent Developments*", Health Canada required the submission of a SNDS prior to the release of the Revised Batch in the Canadian market. Ultimately, the issue was resolved by the Corporation providing an internal corrective action plan in February 2021. The Corporation notified Health Canada of its intention to reactivate the DIN for Natesto® in July 2021. As of the date hereof, Natesto® has not returned to the Canadian market.

Supplier Risks

The Corporation may face limited supplies of products, critical materials or manufacturing components that may only be obtained from a single or limited number of suppliers, two examples of which being the dispenser for Natesto® being sourced from Aptar and the limited number of suppliers through which large quantities of active pharmaceutical ingredient can be obtained. This could result in production delays, substantial lost revenue opportunity, clinical trial delays or contract liability to third parties. For example, the active pharmaceutical ingredient used to manufacture Natesto® was on back order following the voluntary recall of Natesto® in Canada, which delayed the resumption of production. Any interruption in the supply of single source components could cause the Corporation to seek alternative sources of supply or to manufacture such components internally, which may impose considerable costs and/or delays on the production of the Corporation's products and product candidates. If the supply of necessary components is interrupted, components from alternative suppliers may not be available in sufficient volumes or at acceptable quality levels within required timeframes, if at all, to meet the needs of the Corporation. Additionally, if the costs of key supplies of materials or manufacturing components increases, the profit margins of the Corporation may be adversely impacted.

As discussed in *Recent Developments*, on June 2020, the Corporation commenced litigation against Recipharm, alleging that the suspension of Recipharm's manufacturing license in August 2018, in contravention of its contractual obligations to the Corporation, led to a shortage of Estrace® in Canada. This litigation was subsequently settled as discussed in the 2021 section of *Recent Developments*.

In addition, see the heading "Additional Risks Related to Serenity Acquisition" below for a discussion of supplier risks related to the production of Noctiva™

Raw Material Exposure

The Corporation utilizes a number of raw materials which are subject to price fluctuations beyond its control. Market price fluctuations of these raw materials could have a material adverse effect on the Corporation's financial condition and results of operations. There can be no assurance that the price of the Corporation's raw materials will not increase in the future and, if such increase occurs, that the Corporation will be able to effectively pass the costs associated with such an increase on to its customers.

Publication of Clinical Trial Results

From time to time, studies or clinical trials on various aspects of pharmaceutical products, including a product's active ingredient, are conducted by academic researchers, government agencies or other third parties, sometimes of their own accord and sometimes in collaboration with the Corporation. The results of these studies or trials, when published, may have a significant effect on the market for the pharmaceutical product or products that are the subject of the study or trial. The publication of negative results or studies or clinical trials related to the Corporation's products, an active ingredient in the Corporation's products or the therapeutic areas in which the Corporation's products compete (or are anticipated to compete) could have an adverse impact on the Corporation's current or future sales, prescribing trends for the Corporation's products or the reputation of the Corporation and its products. Such an impact could have a material adverse effect on the financial position of theCorporation.

Risks Related to Unexpected Product Safety or Efficacy Concerns

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, as well as potential product liability, consumer fraud or other claims. Any of such occurrences could have a material adverse effect on the Corporation's business, financial condition and results of operations.

Risks Relating to Promotional Activities

The Corporation will from time to time engage in direct promotional activities with respect to its products or engage third parties to act on its behalf in this regard. The marketing and promotional activities of pharmaceutical companies, as well as the manner in which companies or third party sales forces interact with purchasers, prescribers and patients (as applicable), are subject to extensive regulation. A breach of any applicable regulations could result in the imposition of civil and/or criminal penalties, injunctions and/or limitations on marketing practices for the Corporation's products. In addition, allegations of any breach of applicable regulations could result in a diversion of management's attention and damage to the reputation of the Corporation.

Cost of Products and Reimbursement Availability

In Canada and certain other jurisdictions, the pricing of prescription drugs may be subject to governmental control in certain circumstances. The prices of patented medicines in Canada are regulated by the Patented Medicine Prices Review Board ("**PMPRB**"). On August 9, 2019 the Government of Canada announced certain amendments to the *Patented Medicines Regulations* that would change how the PMPRB sets prices for patented medicines. The amendments may lower the price of patented medicines in Canada, including Natesto® and avanafil, and the Corporation's future product candidates. This may result in reduced revenues. The amendments to the *Patented Medicines Regulations* were scheduled to come into force on July 1, 2021 and then delayed to July 1, 2022. However, on February 18, 2022, the Quebec Court of Appeal held that the proposed amendments were partially invalid. It is not clear how the Canadian government will respond to this decision and what changes if any will be implemented by July 1, 2022. If the pricing mandated by the applicable rules and regulations is unsatisfactory, this may have a material adverse effect on the business, results of operations and financial condition of theCorporation.

The Corporation's ability to successfully market its products and product candidates, if regulatory approval is obtained, depends, in part, on whether appropriate reimbursement levels for the cost of the products and related treatments are obtained from payors such as government authorities, private health insurers and other organizations such as Health Maintenance Organizations and Managed Care Organizations. Payors increasingly challenge the pricing and cost effectiveness of pharmaceutical products and such challenges could affect the Corporation's ability, or the Corporation's commercial partners' ability, to sell its products and may have a material adverse effect on its business, results of operations and financial condition. The Corporation's products and product candidates may not be reimbursable by third party payors, or may not be considered cost-effective and not adequately reimbursed at price levels to maintain profitability.

Uncertainty exists about the reimbursement status of newly approved pharmaceutical products. Reimbursement or co-pay levels in the United States and other countries may not be available for some of

the Corporation's products. Any reimbursement granted may not be maintained or limits on reimbursement available from third party payors may reduce demand for, or negatively affect the price of, those products. These issues could have a material adverse effect on the Corporation's business, results of operations and financial condition. The Corporation is unable to predict if additional legislation or regulation impacting the healthcare industry or third party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on the Corporation's business.

In addition, the Corporation may experience pricing pressure on its products due to social or political pressure to lower the cost of drugs, which would reduce revenues.

Reliance on Data Obtained from Symphony or Similar Providers

The Corporation relies on operational data obtained from Symphony and other similar data providers ("**Data**"). The Data may not accurately reflect actual prescriptions. If the Data does turn out to be inaccurate or unreliable and the Corporation's controls are not effective, there could be an adverse effect on the Corporation's ability to properly manage inventory and its financial performance.

In the 2021 fiscal year, the Corporation purchased Data for the U.S. market, but did not purchase Data for Canada. The Corporation anticipates that it may buy Data for the Canadian market in 2022, but if it does not, this may negatively affect the Corporation's ability to generate strategies for commercializing its products in Canada and to track the effectiveness of those strategies.

Intellectual Property Rights

The Corporation's commercial success depends, in part, on obtaining and maintaining patent protection, trade secret protection and regulatory protection of its proprietary technology, products, and information in various jurisdictions around the world and operating without infringing on the proprietary rights of others. The Corporation is able to protect its proprietary technology, products and information from use by third parties only to the extent that valid and enforceable patents, trade secrets or regulatory protection cover them and the Corporation has exclusive rights to utilize them within its territories. The ability of the Corporation's licensors, collaborators and suppliers to maintain their patent rights against third party challenges to their validity, scope or enforceability will also play an important role in determining the Corporation's future.

If the Corporation is required to defend itself in any lawsuit related to its intellectual property rights, this could result in it incurring substantial costs and a diversion of management's attention, regardless of the merit of any such action. In addition, if the Corporation determines that litigation is necessary to enforce any of its proprietary rights against others, this could result in substantial expense and diversion of management attention, regardless of the outcome, and may not be resolved in the Corporation's favour. Furthermore, the inability of the Corporation to maintain effective patent protection may, in addition to the direct consequences associated therewith, result in adverse consequences arising under agreements between the Corporation or its Affiliates and third parties including, without limitation, the potential reduction of amounts payable to the Corporation or its Affiliates in respect of the applicable product(s).

Uncertainty of Intellectual Property Protection

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions that include unresolved principles and issues. Patent applications owned or licensed by the Corporation may not be approved or approved as desired. Inconsistent policies regarding the breadth of claims allowed in certain pharmaceutical companies' patents have emerged to date in Canada and the United States, and the patent situation outside Canada and the United States is even more uncertain. As a result, the Corporation's scope of intellectual property rights may not successfully prevent third parties from developing similar or competitive products. Changes in either intellectual property laws or in interpretations of intellectual property laws in Canada, the United States or other countries may diminish the value of the Corporation's intellectual property rights. Therefore, the Corporation cannot predict with any certainty the scope of its intellectual property rights, including its patent claims that may be allowed or enforceable in its patents or in-licensed patents.

Licensed Patent Rights

The Corporation has obtained patent licences and plans to obtain licenses to products, technologies, and other patents. The Corporation may be required to pay license fees or royalties or both to obtain such licenses which may have an adverse impact on the Corporation's revenues, and there is no guarantee that such licenses will be available on acceptable terms, if at all. Even if the Corporation is able to successfully obtain a license, the rights may be non-exclusive, which may give access to the Corporation's competitors to the same intellectual property it may have rights to, which could prevent the Corporation from commercializing a product. If licenses are terminated, the Corporation would lose the right to use licensed technologies with the result that the Corporation may have to stop developing product candidates or stop selling products. Any such restriction on development or sales may have an adverse financial impact on the Corporation

Reliance on Licensor(s) to Maintain Patent Rights

The Corporation's commercial success also depends, in part, on maintaining and defending patent rights related to products either currently markets or that the Corporation may market in the future. Since the Corporation may not fully control the patent prosecution of any licensed patent applications it is possible that the licensors will not devote the same resources or attention to the prosecution of the licensed patent applications as the Corporation would if it controlled the prosecution of the applications. The licensors may also not pursue and successfully prosecute, enforce or defend any potential patent infringement or invalidity claim, may fail to maintain their issued patents or prosecute or maintain their patent applications, or may pursue any litigation less aggressively than the Corporation would. Consequently, the resulting patent protection, if any, may not be as strong or comprehensive, which could have a material adverse effect on the Corporation.

Risk of Third Party Claims for Infringement

The Corporation is not aware that any of its products or products in development infringe the know-how or granted patents of any third parties. However, third parties may have filed patent applications, or hold issued patents, relating to products competitive with those the Corporation is currently developing. There can be no assurance that third parties will not claim infringement with respect to current or future products or processes. If any of the Corporation's products or future product candidates are found to infringe a valid claim of a third-party patent, the Corporation would need either to obtain a license under such patent or obtain a court judgment that such patent claims are invalid. The defence of intellectual property rights, including patent rights, through lawsuits would be costly and could divert technical and management personnel from their normal responsibilities, and the Corporation may not have sufficient financial resources to conduct such defence. Settlement of such a dispute may require the Corporation to stop developing product candidates, stop selling products or enter into royalty or licensing agreements, which may or may not be available on terms acceptable to the Corporation, if at all. The failure to do any of the foregoing may have a material adverse effect on the Corporation.

Disputes Regarding Ownership or Inventorship of Products and Technologies

From time to time the Corporation may become involved in disputes relating to the ownership or inventorship of its existing and future products and technologies. If the Corporation is unsuccessful in obtaining such assignments of patents or is otherwise unable to establish its ownership of the invention covered by the patents, the Corporation may face additional expense in perfecting its title to these patents and its business may be adversely affected.

Reliance on Trade Secrets

The Corporation will rely on trade secrets to protect its technology, especially where the Corporation does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While the Corporation seeks to protect confidential information, in part, through confidentiality agreements with employees, consultants, contractors, or scientific and other advisors and other parties, they may unintentionally or wilfully disclose the Corporation's confidential information to competitors. Additionally, the Corporation cannot guarantee that any such agreements will provide meaningful

protection, that these agreements will not be breached, or that the Corporation will have an adequate remedy for any such breach. Enforcing a claim against a third party related to the illegal acquisition and use of trade secrets can be expensive and time consuming, and the outcome is often unpredictable. Others may independently develop substantially equivalent proprietary information without violating the Corporation's rights. If the Corporation is not able to maintain patent or trade secret protection on its technologies and products or product candidates, then the Corporation may not be able to exclude competitors from developing or marketing competing products, which may have a material adverse effect on the Corporation.

Risks Related to Third Party Services

The Corporation relies on certain third parties to provide distribution, logistics, invoicing, compliance and sales services in connection with certain of its products. If the third parties cease to be in a position to provide such services or fail to provide such services in a professional manner in accordance with the terms and conditions of the applicable agreements, the business, financial condition and operating results of the Corporation may be adversely impacted. Additionally, the ability of the Corporation to successfully integrate new products into its business may be adversely impacted.

Public Market; Possible Volatility of Share Price

No assurance can be given regarding the liquidity of any public market for Acerus Common Shares or that the Corporation will continue to meet the listing requirements of the TSX or the OTCQB. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies have historically been highly volatile. The market price of Acerus Common Shares can be subject to wide fluctuations in response to, among other things, variations in operating results, the Corporation's ability to execute its business plan, competition and other events or factors. Trading prices of the Acerus Common Shares may be influenced by many factors, including, without limitation:

- investor perception of the Corporation;
- expectations regarding any potential future acquisitions or sales of Acerus Common Shares by one or more shareholders;
- market conditions relating to the Corporation's segment of the pharmaceutical industry or the securities markets in general;
- research analyst recommendations and the Corporation's ability to meet or exceed performance expectations of analysts or investors;
- failure of any of the Corporation's third-party collaborators to successfully market and successfully commercialize any of the Corporation's product or product candidates;
- adverse events affecting the Corporation's manufacturers, including with respect to recent announcements regarding Estrace®;
- adverse results or delays in any clinical or non-clinical trials;
- announcements of U.S. FDA, Health Canada or other governmental authority approval or non-approval of products in the Corporation's product pipeline or adverse announcements related to approved products;
- the results of pre-clinical testing and clinical studies or trials by competitors to the Corporation;
- changes in government regulations, regulatory decisions or patent decisions; and
- general market conditions.

In February 2020, the Corporation underwent remedial delisting review with the TSX. Although the Corporation remained in compliance with all continued listing requirements of the TSX, no assurance can be provided as to the continued qualification for listing on the TSX.

Potential Liability

Pharmaceutical companies may be exposed to potential clinical trial liability, environmental liability, product liability and other risks that are inherent in the testing, manufacturing and marketing of their products. These liabilities, if realized, could have a material adverse effect on the Corporation's business, results of operations and financial condition.

The Corporation carries product liability insurance in respect of its approved products in such amounts as is believed to be sufficient for its business. However, it cannot be assured that any of the insurance coverage in place will be sufficient to satisfy any liabilities as they arise, and the Corporation's financial position may be materially adversely affected by a product liability claim. Furthermore, a product liability claim could also significantly harm the Corporation's reputation and delay market acceptance of its products or product candidates.

Additionally, product recalls may be issued at the direction of the U.S. FDA, other government agencies or other companies having regulatory control for pharmaceutical sales. The Corporation cannot be assured that product recalls will not occur in the future or that, if such recalls occur, such recall will not adversely affect its business, financial condition or reputation. As discussed in *Recent Developments*, on August 2, 2019, the Corporation announced that it had identified four commercial lots of Natesto® released in the Canadian and South Korean markets that were found to be non-conforming during long-term stability studies, even though such lots were fully in-specification at the time of release. The post-release non-conformity was not harmful to the patient, but may have resulted in difficulties in dispensing.

With regard to the U.S. market in particular, the Corporation depends heavily upon Syneos to ensure that Natesto®'s commercial presence in the U.S. is compliant with all applicable laws and regulations. In the event that Syneos fails to comply with applicable laws and regulations, the Corporation may be subjected to civil and/or criminal claims, injunctions and/or limitations on marketing practices.

Clinical Testing

The clinical development and testing of drug candidates is a long, expensive and uncertain process. The Corporation has incurred substantial expense for, and devoted a significant amount of time to, pre-clinical testing and clinical trials, and currently expects to continue to do so. The commencement and rate of completion of clinical trials may be delayed by many factors including, without limitation:

- the nature of the applicable trial design and protocol, including eligibility criteria;
- adequate funding to support the capital needs of the development programs;
- delays in identifying and reaching agreement on acceptable terms with prospective investigators and trial sites;
- delay or failure to obtain sufficient supplies of the applicable product or product candidate for use during the trial;
- inability to recruit and retain acceptable clinical trial participants at the expected rate;
- failure of clinical trials to demonstrate a product candidate's safety or efficacy or provide data sufficient to achieve the purpose of the clinical trials (including, without limitation, reaching the next phase of clinical development);
- requests by regulatory authorities for additional analyses, reports, data, non-clinical studies or other information;

- unforeseen safety issues;
- inability to manufacture or obtain sufficient quantities of materials used for clinical trials; and
- unforeseen governmental or regulatory delays.

Results of clinical trials of the Corporation's current and potential products may not be viewed favourably by the Corporation or third parties, including regulatory authorities, investors, analysts and potential commercial partners, even if the applicable endpoints of the trials in question have been met. The quality and robustness of the results and data of any clinical trial the Corporation conducts will depend upon the selection of a patient population for clinical testing. If the selected population is not of a sufficient size or representative of the intended population, further clinical testing of product candidates or termination of research and development activities related to the selected product may be required. Additionally, success in preclinical or earlier clinical trials does not ensure that later clinical trials will be successful. The Corporation's ability to commence clinical testing or the choice of clinical development path could compromise business prospects and may have a material adverse effect on the Corporation.

The Corporation depends on independent clinical investigators, contract research organizations and other third-party service providers to conduct clinical trials for its products and product candidates. Though the Corporation relies heavily on such parties for the successful execution of clinical trials and is ultimately responsible for their activities, many aspects of such activities are beyond the control of the Corporation. Third parties may not complete activities on schedule or may not conduct clinical trials in accordance with regulatory requirements or stated protocols, which may delay or otherwise have an adverse effect on the applicable clinical trials. Additionally, the Corporation has no control over the financial health of the third-party service providers retained by the Corporation to conduct clinical trials. Should one or more of such third-party service providers become insolvent or otherwise not able to continue to provide services to us, the clinical trial(s) in respect of which such service provider participates could become delayed and the Corporation may be adversely affected.

Regulatory Approval Process

The Corporation must receive regulatory approval of any product candidate before such candidate can be commercialized. The development required to take a technology from its earliest stages to its incorporation in a product that is sold commercially can take many years and cost a substantial amount of money. The Corporation's technologies can be quite complex, with many different components. Any particular technology may not perform in the same manner when used with different therapeutic agents and, therefore, these technologies may not prove to be as useful or valuable as originally thought, resulting in additional development work. Delays or unanticipated increases in costs of development at any stage, or failure to solve a technical challenge, could adversely affect the Corporation's operating results.

The development and manufacturing of any product candidate developed independently or in collaboration with third parties, as well as the distribution, marketing and record keeping of such product candidate, are regulated by numerous federal, state, provincial and local governmental authorities, principally the U.S. FDA in the United States and Health Canada in Canada, and other similar agencies in other countries. The procedures for obtaining marketing approval of a new product candidate vary among countries. These procedures vary depending on such factors as the novelty of the drug and its intended use. The development and regulatory approval process in each jurisdiction takes many years, requires the expenditure of substantial resources, is uncertain and subject to delays. In addition, approval by a regulatory authority of one country does not ensure the approval by regulatory authorities of other countries.

Many factors could delay the Corporation's receipt of revenues from the commercialization of its product candidates. Failure to obtain regulatory approval, any delay or setback in obtaining regulatory approval or limitation on drug use required as a condition of approval could adversely affect the Corporation's ability to market any drugs developed independently or with partners; affect the Corporation's ability to negotiate partnership and other agreements; impose additional costs and diminish any competitive advantages that

the Corporation may attain; or adversely affect the Corporation's ability to generate new product sales and/or royalties based on these sales.

Minimum Payment Obligations

The Corporation may become subject to certain contractual arrangements that may require the payment of certain annual minimum fees to the applicable counterparties (e.g. technology partners), regardless of the sales or quantities of applicable products required. Payment of such amounts, without a corresponding revenue inflow, may have an adverse effect on the financial position of the Corporation. Additionally, certain arrangements may require the Corporation to purchase more quantities of raw materials than are necessary to sustain annual production requirements. If such materials are not used prior to their expiry, this could have an adverse effect on the financial position of the Corporation.

Dependence on Key Personnel

As a technology-driven company, intellectual input from key management and personnel is critical to achieve the Corporation's business objectives. Consequently, the Corporation's ability to retain these individuals and attract other qualified individuals is critical to the Corporation's success. The loss of the services of key individuals may significantly delay or prevent achievement of the Corporation's business objectives. In addition, because of a relative scarcity of individuals with the high degree of education, commercial experience and scientific achievement required for the Corporation's business, competition among life sciences companies, which increasingly includes cannabis companies in Canada, for qualified employees is intense and, as a result, the Corporation may not be able to attract and retain such individuals on acceptable terms, or at all.

The Corporation also has relationships with scientific collaborators at academic and other institutions, some of whom conduct research at its request or assist the Corporation in formulating its research and development strategies. These scientific collaborators are not the Corporation's employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to the Corporation. In addition, even though its collaborators are required to sign confidentiality agreements prior to working with the Corporation, they may have arrangements with other companies to assist such other companies in developing technologies that may prove competitive to the Corporation.

Incentive provisions for the Corporation's key executives include the granting of stock options, restricted stock units and performance stock units that vest over time, which designed to encourage such individuals to stay with the Corporation. However, a low share price, whether as a result of disappointing progress in the Corporation's sales or development programs or as a result of market conditions generally, could render such agreements of little value to the Corporation's key executives. In such event, the Corporation's key executives could be susceptible to being hired away by its competitors who could offer a better compensation package. If the Corporation is unable to attract and retain key personnel, its business, financial conditions and results of operations may be adversely affected.

Dilution of Holders of Acerus Common Shares

Subject to the availability of alternative financing or revenue sources, the Corporation may be required to issue additional equity securities to raise funds, thus reducing the ownership share of existing holders of Acerus Common Shares. Dilution may similarly be experienced by the grant of additional stock options pursuant to the 2020 Omnibus Incentive Plan of the Corporation (the "**Omnibus Incentive Plan**").

On February 21, 2020, the Corporation announced the closing of the Refinancing Transactions, which increased the total number of Acerus Common Shares outstanding from 261,225,290 to 1,010,456,066. For further details, please see the Corporation's announcements on February 12, 2020 and February 21, 2020 in the *Recent Developments* section.

On November 25, 2020, the Corporation announced that it had completed the Rights Offering, which resulted in the issuance of an additional 526,600,000 Acerus Common Shares. See the *2020* heading of

"*Recent Developments*" above for further details regarding the Rights Offering.

On February 28, 2022, the Corporation announced the Acquisition. Completion of the Acquisition could result in the issuance of up to 1,533,642,008 Acerus Common Shares assuming the First Commercial Sale Shares and each tranche of the Sales Milestone Shares become issuable to the Serenity stockholders in accordance with the terms of the Definitive Agreement (and the Sales Milestone Shares are issued at the floor price) representing approximately 99.74% of Acerus' currently issued and outstanding Common Shares.

As of the date hereof, Acerus has 1,537,588,081 Acerus Common Shares issued and outstanding on a non-diluted basis. Serenity has two key securityholders, Dr. Samuel Herschkowitz and Rev5 Family Trust, who Acerus expects will receive approximately 33.35% and 25.94%, respectively, of the Acerus Common Shares issuable to Serenity securityholders in connection with the Acquisition. Assuming the full number of Acerus Common Shares issuable under the Definitive Agreement become issuable (which includes issuance of the Sales Milestone Shares at the floor price) and there are no other changes to Acerus' issued and outstanding Common Shares as of the date hereof, Dr. Samuel Herschkowitz and Rev5 Family Trust would own approximately 16.65% and 12.95% of Acerus' issued and outstanding Acerus Common Shares at such time. Based on the same assumptions, First Generation, Acerus' current controlling shareholder, would continue to own approximately 44.8% of Acerus' issued and outstanding Acerus Common Shares at such time.

Risks Relating to Future Acquisitions

The Corporation intends to grow by, in part, acquiring new products at a reasonable price to allow it to earn a desirable rate of return on its investment. The Corporation expects to compete to identify and acquire products with other potential purchasers, including pharmaceutical companies and other third parties that may have greater resources than the Corporation. If the Corporation is not able to acquire or license additional products at reasonable prices, its ability to grow its business operations may be adversely impacted.

In the course of any proposed acquisition, the Corporation will undertake business, legal and financial due diligence with the goal of identifying and evaluating any material risks. Despite any such efforts, the Corporation may not be successful in identifying and evaluating all such risks and may not realize the anticipated advantages of any given investment. Any such failure could adversely affect the Corporation's business, results of operations or financial condition. Acquisitions or licensing transactions in connection with new products can be complex, time-consuming and expensive. The Corporation may fail to consummate a transaction in connection with a given product despite considerable investment of time and resources. If a transaction is not completed, the Corporation may be subject to several risks including that: (a) the market price of the Acerus Common Shares may reflect an assumption that one or more transactions may be undertaken, and a failure to consummate such transactions could result in a negative market perception and associated decline in share price; and (b) many costs related to the pursuit of a given opportunity may be payable by the Corporation whether or not such transaction is completed.

The integration of any newly acquired or licensed business or product may be complex and time-consuming. If such business or product is not successfully integrated, the Corporation may not be able to achieve the anticipated benefits, cost savings or growth opportunities.

Any given acquisition or licensing transaction may not further the Corporation's strategy as anticipated, and may expose the corporation to increased risks, liabilities and competition. Any one of such challenges or risks could impact the Corporation's ability to realize any benefit from a given transaction and this could have a material adverse effect on the Corporation's business, results of operations or financial condition.

As discussed under *Recent* Developments, on February 28, 2022, the Corporation announced the Acquisition. Our internal analyses may have overestimated the market opportunity in the United States for the drug desmopressin acetate, which we intend to market under the brand name "Noctiva™". If one or more of the assumptions underlying our internal analyses are incorrect, the benefits we anticipate from the Acquisition may not be realized or may be smaller than expected. We may also fail to effectively exploit the market opportunity for Noctiva™, and such failure could have a material adverse effect on our

business, financial condition, operating results and liquidity.

Risks Related to Expiry of Inventory

The Corporation values its inventory of finished products for sale at the lower of cost determined on a first-in, first out basis, and net realizable value. The Corporation may establish accounting reserves for inventory from time to time to reflect situations in which the costs of the inventory is not expected to be recovered. The reserve for inventory is expected to be equal to all or a portion of the inventory which has reached its expiration or is close to expiration and not expected to be sold, based on specific facts and circumstances. Any write-down of inventory may have a material adverse effect on the business, results of operations or financial condition of the Corporation. During the year, $nil million was charged against earnings for expired inventory. The Corporation also reviews its inventory of raw materials for expired or obsolete stock. During the year, the Company also charged $0.3 million against earnings for obsolete raw material.

Value of Intangible Assets

The Corporation is obligated to review the carrying value of its intangible assets for impairment periodically or when there is an indication of impairment. Events that may impact the projected future results relating to a particular intangible may result in the Corporation impairing the value of the particular asset, which will be charged to income during the period in which the impairment is determined. Any such impairment may have a material adverse effect on the business, results of operation or financial condition of the Corporation.

On January 11, 2019, the Corporation reported an anticipated shortage of certain doses of Estrace® on the Drug Shortages Canada website in relation to supply issues arising from the Corporation's contract manufacturer. As such, the Corporation determined that the intangible asset related to Estrace® had been impaired by $2,641,000. The intangible asset was written down to its recoverable amount using a value-in-use discounted cash flow model. Key assumptions included a pre-tax discount rate of 16.9%, estimated cash flows and projected declines in revenue on the assumption that the contract manufacturer's license would be reinstated by June 2019 and that the Corporation received its next shipment of Estrace® by September 2019. The Corporation was subsequently informed of further delays in lifting the license suspension and as a result, the asset was impaired by a further $2.5 million at March 31, 2019.

On November 30, 2020, the Corporation entered into the APA with a third party to sell its Canadian rights to Estrace®. The Corporation recorded the disposal of its Estrace® assets and derecognized this intangible asset along with related plant and equipment. The Corporation also accrued $0.3 million for costs it agreed to pay related to completing the manufacturing transfer of the product to a new contract manufacturer resulting in a loss on sale of $1.6 million.

Risks Regarding Returns, Allowances and Chargebacks

The Corporation will from time to time establish reserves based on the best estimate of the impact of returns, allowances and chargebacks may have on the financial results of the Corporation. The Corporation cannot ensure that such reserves will be adequate or that the Corporation's estimates will be matched by actual observed amounts. Any difference in this regard could have a material adverse impact on the business, results of operations or financial condition of the Corporation.

Ability to Expand Operations

The Corporation plans to expand its business by exploring opportunities for growth both domestically and internationally, developing, acquiring or licensing new products and expanding its manufacturing capabilities and/or those of the third parties it engages to manufacture its products. This expansion will place substantial demands on the Corporation's managerial, operational, technological and other resources. If the Corporation fails to manage the growth of its business effectively and efficiently, there may be material and adverse effects on its operations and its ability to capitalize on new business opportunities, either of which could materially and adversely affect its operating results.

In particular, on February 28, 2022 the Corporation acquired Serenity and its Noctvia™ product. Successfully incorporating Noctiva™ will involve substantial risks and the investment of management time. See the subheadings "*Additional Risks Related to the U.S. Natesto® and* Noctiva™ *Business*" and "*Additional Risks Related to the Serenity Acquisition*" below.

Competition

The pharmaceutical industry is intensely competitive in all phases and the Corporation competes with other companies that have greater research and development, manufacturing, marketing, sales, distribution, financial and managerial resources than the Corporation and many of such companies may have products and product candidates that are on the market or in a more advanced stage of development that the Corporation's product candidates. Competition could adversely affect the Corporation's results of operations, business and prospects.

For example, and without limitation to the foregoing, if a new drug or drug delivery platform was developed that was more effective, safe, efficient or convenient in the treatment of hypogonadism, or if the medical industry determined that another pre-existing product was more effective, safe, efficient or convenient in the treatment of hypogonadism, this could significantly affect the potential profitability of Natesto®, and could have a material adverse effect on the business, operations, financial condition and anticipated cash flows of the Corporation.

Rapid Technological Change; New Products and Standards

The pharmaceutical industry is characterized by rapid technological change, frequent new product and services introductions embodying new technologies and emergence of new industry standards and practices that could render the Corporation's existing products and system obsolete. The Corporation's products and services embody complex technology and may not always be compatible with current and evolving technical standards and products developed by others. Failure or delays by the Corporation to meet or comply with the requisite and evolving industry or user standards could have a material adverse effect on its business, results of operations and financial condition.

Foreign Exchange Risk

Currency exchange rate fluctuations can affect the Corporation's results of operations to the extent that the revenues and expenses of the Corporation may be in differing currencies. While the financial results of the Corporation are presented in United States dollars, certain expenses of the Corporation are paid using Euros, Canadian dollars and/or British Pounds, and certain revenues of the Corporation are received in Canadian dollars. Accordingly, a change in the relative exchange rates of these currencies could have an impact on the results of operations and financial condition of the Corporation.

Concentration Risk

At present, the Corporation derives all of its revenues from one product (Natesto®) and revenues from these products, as well as revenues from the sales of avanafil, Lidbree™ if approved by Health Canada, are expected to continue to account for 100% of the Corporation's revenues for the near term unless the Corporation acquires, in-licenses, or develops new products. Accordingly, if demand for any of these products declines for any reason, including, without limitation, due to a shortage of Natesto®, the business, financial condition and operating results of the Corporation would be adversely impacted.

At present, Natesto® revenues are received almost entirely from the sale of Natesto® subject to the Aytu Buyback Agreement. Estrace® revenues were earned from a small number of Canadian pharmaceutical wholesalers until the Corporation's sale of Estrace®. Future revenues related to Estrace® are uncertain and may come in the form of royalties pursuant to the APA. Any significant reduction or loss of business, or difficulties in obtaining payment, from any of these limited number of customers could have a material adverse effect on the Corporation.

Indemnity Agreements and Indemnity Arrangements

All directors and/or officers of the Corporation, and each of its various subsidiary entities, are indemnified by the Corporation for various items including, but not limited to, all costs to settle lawsuits or actions due to their association with the Corporation, subject to certain restrictions. The Corporation has purchased directors' and officers' liability insurance to mitigate the cost of any potential future lawsuits or actions. The term of the indemnification is not explicitly defined, but is limited to events for the period during which the indemnified party served as a director or officer of the applicable Corporation entity. The maximum amount of any potential future payment cannot be reasonably estimated but could have a material adverse effect on the Corporation.

In the normal course of business, the Corporation has entered or may enter into agreements that include indemnities in favour of third parties, such as purchase and sale agreements, confidentiality agreements, engagement letters with advisors and consultants, leasing contracts, license agreements, information technology agreements and various product and service agreements. These indemnification arrangements may require the applicable Acerus entity to compensate counterparties for losses incurred by the counterparties as a result of breaches in representations, covenants and warranties provided by the particular Acerus entity or as a result of litigation or other third party claims or statutory sanctions that may be suffered by the counterparties as a consequence of the relevant transaction. In some instances, the terms of these indemnities are not explicitly defined. The applicable Acerus entity, whenever possible, tries to limit this potential liability within the particular agreement or contract, but due to the unpredictability of future events the maximum amount of any potential reimbursement by the Corporation or its subsidiary entities cannot be reasonably estimated, but could have a material adverse effect on the Corporation.

Tax-Related Risks

The Corporation and its subsidiaries have operations in more than one country that have differing tax laws and rates. The Corporation's and its subsidiaries' income tax reporting is subject to audit by domestic and foreign authorities. On November 6, 2017, Acerus Biopharma was continued into the Province of Ontario, which effectively changed its jurisdiction of incorporation, corporate law residence, and tax residence from Barbados to Ontario. In the future, the Corporation's effective tax rate may change from year to year based on changes in the mix of activities and income allocated or earned among the jurisdictions in which it operates; changes in tax laws in these jurisdictions; changes in the tax treaties entered into by the countries in which it operates; changes in eligibility for benefits under those tax treaties; and changes in the estimated values of deferred tax assets and liabilities. Such changes may result in an increase in the effective tax rate on all or a portion of the income of the Corporation and/or any of the Corporation's subsidiaries to a rate possibly exceeding the statutory income tax rate of Canada.

The amount of income tax required to be paid by the Corporation and/or its subsidiaries will be affected by the amount of net income earned in the relevant operating jurisdictions, the structure of its operations, the availability of benefits under tax treaties, and the rates of taxes payable in respect of that income. The Corporation must make estimates and judgments as well as take tax filing position, based on its knowledge and understanding of applicable tax laws and tax treaties, and the application of those tax laws and tax treaties to its business, in determining its consolidated tax provisions. The Corporation's judgments in this regard will be particularly important in the U.S. as it is conducting an increasing amount of activities in the US. For example, certain countries may seek to tax a greater share of income than has been determined and provided for. Provisions for uncertain tax positions are recorded based on the Corporation's estimate of the most likely outcome. The final outcome of any audits by taxation authorities may differ from the estimates and assumptions used in determining the tax treatment by the Corporation and/or its subsidiaries as well as the consolidated tax provisions and accruals. This may result in a material adverse effect on the consolidated income tax provision, financial condition and the net income for the period in which such determinations are made.

In addition, Serenity undertook certain reorganizations prior to the closing of the Acquisition. The Corporation is indemnified against claims related to those reorganizations. However, the Corporation may not be able to realize on that indemnity and may be forced to defend itself.

Ability to Generate Additional Ancillary Revenue

The Corporation continues to pursue ancillary revenue generation opportunities. The Corporation's ability to achieve its business objectives may depend in part on its success in increasing these revenue streams. The Corporation cannot guarantee that it will be able to effectively generate additional ancillary revenue and the Corporation's inability to do so could have an adverse effect on its business and results of operations.

Securities Analyst Coverage

The trading market for Acerus Common Shares may be influenced in part by research and reports published by securities analysts that cover the Corporation. The Corporation does not have control over such analysts. There is no guarantee that securities analysts will cover the Corporation or initiate coverage in the future. If securities analysts do not cover the Corporation, the lack of research coverage may adversely affect the market price of the Acerus Common Shares. If the Corporation is covered by securities analysts, and any of such analysts publish an unfavourable report, the price of the Acerus Common Shares may decline.

As of the date hereof, the Corporation is not covered by any securities analysts.

Our business may be adversely affected by the effects of the COVID-19 pandemic.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. It has since spread to multiple other countries; and, in March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. This pandemic has adversely affected or has the potential to adversely affect, among other things, the economic and financial markets and labor resources of the countries in which we operate, our manufacturing and supply chain operations, research and development efforts, commercial operations and sales force, administrative personnel, third-party service providers, business partners and customers, and the demand for some of our marketed products.

The COVID-19 pandemic has resulted in travel and other restrictions to reduce the spread of the disease, including governmental orders across the globe, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, maintain social distancing, and order cessation of non-essential travel. As a result of these recent developments, the Corporation has implemented work-from-home policies for its employees. The effects of shelter-in-place and social distancing orders, government-imposed quarantines, and work-from-home policies may negatively impact productivity, disrupt the Corporation's business, and delay business timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Corporation's ability to conduct business in the ordinary course. Such restrictions and limitations may also negatively impact the Corporation's access to regulatory authorities (which may be affected, among other things, by travel restrictions and may be delayed in responding to inquiries, reviewing filings, and conducting inspections). The COVID-19 pandemic may also result in the loss of some of key personnel, either temporarily or permanently. In addition, the Corporation's sales and marketing efforts may be impacted by postponement or restrictions on face-to-face meetings and restrictions on access by non-essential personnel to medical centres and offices, all of which could slow adoption and implementation of the Corporation's marketed products, resulting in lower net product sales. Demand for some or all of the Corporation's marketed products may continue to be reduced while the shelter-in-place or social distancing orders are in effect and, as a result, some of our inventory may become obsolete and may need to be written off, impacting operating results. These and similar, and perhaps more severe, disruptions in the Corporation's operations may materially adversely impact our business, operating results, and financial condition. Quarantines, shelter-in-place, social distancing, and similar government orders (or the perception that such orders, shutdowns, or other restrictions on the conduct of business operations could occur) related to COVID-19 or other infectious diseases may be impacting personnel at the Corporation's manufacturing facilities, suppliers, and other third parties on which we rely, and may impact the availability or cost of materials produced by or purchased from such parties, which could result in a disruption in the Corporation's supply chain. In addition, infections and deaths related to COVID-

19 may disrupt healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay, FDA review and potential approval of the Corporation's marketed products. It is unknown how long these disruptions could continue. Further, while we are focused on therapies to address the COVID-19 pandemic, the Corporation's other product candidates may need to be deprioritized. Any elongation or de-prioritization of the Corporation's other products could materially affect our business. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for the Corporation to access capital if needed. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect the Corporation's business and the value of the Acerus Common Shares. The global COVID-19 pandemic continues to rapidly evolve. The ultimate impact of this pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on the Corporation's business, healthcare systems, or the global economy as a whole. These effects could have a material adverse impact on the Corporation's operations.

Additional Risks Related to the U.S. Natesto® and Noctiva™ Business

The Corporation has limited experience in the U.S market and is heavily dependent on Syneos Health to develop and execute its commercial strategy in the U.S.

The Corporation has engaged Syneos to be its commercialization partner for Natesto® in the U.S. The Corporation is reliant upon Syneos to operate a U.S. commercial team and scale across all aspects of commercialization required for the sale of Natesto® and the Aytu Buyback Agreement, including medical and regulatory affairs, managed markets and marketing and sales. If Syneos fails to do so effectively, a substantial portion of the Corporation's projected future business will be jeopardized. The Corporation also has limited operating experience in the U.S. market and relies upon Syneos to assist it with developing a commercialization strategy for Natesto® and Noctiva™ that is effective and compliant with applicable laws and regulations. If any aspect of that strategy is ineffective or incorrect, the Corporation's ability to commercialize Natesto® in the U.S. will be jeopardized.

The Corporation's business may be negatively affected by the actions of its commercial partners

Conflicts may arise between the Corporation and Aytu or the Corporation and Syneos due to one or more of the following:

- disputes or breaches with respect to payments that we believe are due under the applicable agreements;
- disputes on strategy as to what development or commercialization activities should be pursued;
- disputes as to the responsibility for conducting development and commercialization activities pursuant to the applicable collaboration, including the payment of costs related thereto;
- disagreements with respect to ownership of intellectual property rights;
- unwillingness on the part of a commercial partner to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of those activities;
- legal disputes that may arise between us and our partners and/or with third parties and regulators in connection with the actions of our partners;
- delays or reductions of commercialization efforts; and
- termination or non-renewal of our agreements with Syneos.

Conflicts arising with our commercial partners could impair the progress of our product candidates, harm our reputation, result in a loss of revenues, reduce our cash position, and cause a decline in our stock price.

We expect to incur significant costs to comply with U.S. laws and regulations

Prior to the Corporation entering into the Revised Aytu Agreement, the Corporation did not have a physical commercial presence in the United States. In addition, the New Drug Application for Natesto®, previously held by Aytu, is now held by the Corporation as part of the Revised Aytu Agreement and the Aytu Buyback Agreement. Accordingly, the Corporation will need to comply with additional federal and state U.S. laws. The Corporation has limited compliance experience in the U.S. market and will need to rely heavily upon its consultants, legal advisors and commercial partners to ensure compliance with applicable laws and regulations. The Corporation will likely incur significant compliance costs as a result. These risks will be further compounded by the acquisition of Noctiva™, as even further resources and attention will need to be devoted to compliance for this additional product.

The marketing of Natesto® and Noctiva™ within the United States is also subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce or reward, the referral of business, including the purchase or prescription of a particular drug that is subject to government reimbursement. Due to the breadth of the statutory provisions, it is possible that we might be challenged under anti-kickback or similar laws. Sanctions under these laws include civil monetary penalties, exclusion from U.S. federal and state healthcare programs (i.e., those programs will not provide reimbursement or payment coverage for Noctiva™ or Natesto®), and criminal penalties, including imprisonment; further, an alleged violation of the anti-kickback statute would be used as a basis for a False Claims Act challenge. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to certain third-party payors (including Medicare and Medicaid) claims for reimbursement for drugs or services that are false or fraudulent. Generally, claims for drugs prescribed for off-label uses may be considered to be "false claims". Sanctions under false claims laws include significant civil monetary penalties. In addition, there is ability for private individuals to bring similar actions.

In addition, several states require that companies implement compliance programs or comply with industry ethics codes, adopt marketing spending limits, and report to state governments any gifts, compensation, and other remuneration provided to certain healthcare professionals. Regulations implementing certain provisions of federal health care legislation require record-keeping and disclosure to the federal government of certain transfers of value to U.S.-licensed physicians and certain teaching hospitals, otherwise known as the "Sunshine Act". Any activities relating to the sale and marketing of Noctiva™ or Natesto® may be subject to scrutiny under these laws. The Corporation relies heavily upon third party contractors to file these reports. Failure to make the required reports or comply with these laws can result in civil monetary penalties and/or other sanctions. If the government were to allege or convict us of violating these laws, our business could be harmed.

Natesto® contains, and future other product candidates may contain, controlled substances, the manufacture, use, sale importation, exportation, prescribing and distribution of which are subject to regulation by the US. Drug Enforcement Administration

Natesto®, which is approved by the FDA, is regulated by the U.S. Drug Enforcement Administration ("DEA") as a Schedule III controlled substance. Before any commercialization of any product candidate that contains a controlled substance, the DEA will need to determine the controlled substance schedule, taking into account the recommendation of the FDA. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible. Natesto is, and our other product candidates may, if approved, be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or CSA, and the implementing regulations

of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our third-party manufacturers and to distributors, prescribers and dispensers of our product candidates. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the U.S. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

U.S. third-party payer actions may impact access to and sales of Noctiva™ and Natesto®

Third-party payers, including private third-party payers, governmental authorities and other managed care entities, such as pharmacy benefit managers, continue to take action to manage the utilization of drugs and control the cost of drugs. Consolidation among Managed Care Organizations ("MCOs") has increased the negotiating power of MCOs and other private third-party payers. Private third-party payers, as well as governments (including U.S. Medicare and Medicaid), increasingly employ formularies to control costs by taking into account discounts in connection with decisions about formulary inclusion or favorable formulary placement. Failure to obtain or maintain timely adequate pricing or favorable formulary placement for Noctiva™ or Natesto®, or failure to obtain such formulary placement at all or at favorable pricing, will likely adversely impact revenue. Private third-party payers, including self-insured employers, often implement formularies with copayment tiers to encourage utilization of certain drugs and have also been raising co-payments required from beneficiaries, particularly for branded pharmaceutical products. Our ability to market and sell Noctiva™ and Natesto® will likely be negatively impacted if patients have an unacceptably high co-pay amount. Private third-party payers are also implementing new initiatives like so-called "copay accumulators" (policies that provide that the value of copay assistance does not count as out-of-pocket costs that are applied toward deductibles) that can shift more of the cost burden to manufacturers and patients. This cost shifting has increased consumer interest and input in medication choices, as they pay for a larger portion of their prescription costs and may cause consumers to favor lower cost generic alternatives to branded pharmaceuticals. Private third-party payers also use additional measures such as new-to-market blocks, exclusion lists, indication-based pricing, and value-based pricing/contracting to improve their cost containment efforts. Private third-party payers also are increasingly imposing utilization management tools, such as clinical protocols, requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. As the U.S. payer market consolidates further and as more drugs become available in generic form, pharmaceutical companies may face greater pricing pressure from private third-party payers, who will continue to drive more of their patients to use lower cost generic alternatives. Third-party payers may also decrease the level of reimbursement of a product or cease such reimbursement and the occurrence of any of these events could materially adversely affect the sales of Noctiva™ and Natesto® and in turn may have a material adverse effect of the health of the Corporation.

U.S. Federal coverage and reimbursement policies and healthcare reforms may impact access to and sales of Noctiva™ and Natesto®

Our business may be impacted by legislative actions changing U.S. federal reimbursement policy or that cause other U.S. healthcare reforms. The Corporation has limited U.S. experience and will likely rely upon its consultants and advisors to keep appraised of relevant reimbursement policies and practices. Accordingly, if a substantial portion of the Corporation's U.S. business relies upon reimbursement from U.S. federal government healthcare programs or commercial insurance plans regulated by U.S. federal and state governments, a substantial portion of the Corporation's revenues could be impacted by healthcare reforms.

If the Corporation is unable to effectively train and equip the U.S. sales force, its ability to commercialize Noctiva™ and Natesto® will be harmed

The Corporation uses sales representatives hired by Syneos to promote Natesto® and Noctiva™ in the U.S. Some of these sales representatives have had no prior experience promoting Natesto® and none have had prior experience promoting Noctiva™. As a result, the Corporation has had to expend significant time and resources to train the Syneos sales force to be credible, persuasive, and compliant with applicable laws in marketing Noctiva™ and Natesto®. In addition, the Corporation must ensure that consistent and appropriate messages about Noctiva™ and Natesto® are being delivered to potential customers by the sales force. If the Corporation is unable to effectively train its sales force and equip them with effective materials, including

medical and sales literature to help them inform and educate potential customers about the benefits of Noctiva™ and Natesto® and its proper administration, the Corporation's efforts to successfully commercialize Noctiva™ and Natesto® in the U.S. could be put injeopardy.

Evolving trade policy between the United States and other countries, including those in the EU, may have an adverse effect on our business and results of operations.

The Corporation uses third party suppliers and manufacturers outside the U.S. to manufacture Natesto®. There is currently significant uncertainty about the future relationship between the U.S. and various other countries, with respect to trade policies, treaties, government regulations and tariffs. The U.S. government has called for substantial changes to, U.S. foreign trade policy, including the possibility of imposing greater restrictions on international trade and significant increases in tariffs on goods imported into the U.S. These tariffs could potentially disrupt existing supply chains and impose additional costs on the Corporation's business, including costs with respect to raw materials upon which the business depends. The Corporation currently manufactures Natesto® in the EU. Furthermore, if tariffs, trade restrictions or trade barriers are placed on products such as the Corporation's by foreign governments, it could cause us to raise prices for the Corporation's products, which may result in the loss of customers and the Corporation's business, financial condition and results of operations may be harmed. If the Corporation is unable to pass along increased costs to the Corporation's customers, the Corporation's margins could be adversely affected. Additionally, the Corporation's business may be adversely impacted by retaliatory trade measures taken by other countries, causing us to raise prices or make changes to the products, which could materially harm the business, financial condition and results of operations. Further, the continued threats of tariffs, trade restrictions and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact the Corporation's sales.

Additional Risks Relating to the Serenity Acquisition

The Corporation has no prior experience marketing products for the treatment of nocturia

The Corporation has no prior experience commercializing products for the treatment of nocturia. Our ability to establish effective marketing and advertising campaigns for Noctiva™ will be key to our success in commercializing the drug. If we are unable to increase awareness of nocturia (i.e., adult night-time non-incontinent urination, which Noctiva™ is intended to reduce), the establishment of nocturnal polyuria as the critical etiology that must be treated despite any other co-morbidities and the potential benefits of Noctiva™, our effort to build a substantial customer base for the drug may not be successful. In addition, our overall marketing activities or pricing strategies may not be successful in promoting or selling Noctiva™. If our marketing and advertising programs are not adequate to support future growth of Noctiva™ sales, its expected results may experience a material adverse effect on our business, financial condition and results of operations.

The Corporation may have overestimated the market opportunity for Noctiva™ or we may not effectively exploit such market opportunity.

Our internal analyses may have overestimated the market opportunity for Noctiva™. If one or more of the assumptions underlying our internal analyses are incorrect, the benefits we anticipate from the acquisition may not be realized or may be smaller than expected. We may also fail to effectively exploit the market opportunity for Noctiva™, and such failure could have a material adverse effect on our business, financial condition, operating results and liquidity.

Our cost to commercialize Noctiva™ could exceed our estimates or such costs may not provide the intended results.

Our past and future internal budgets, plans and projections may underestimate the costs it will incur to develop and commercialize Noctiva™, including transaction and integration costs and the costs of other financial, business and strategic initiatives related to the Acquisition. Even if we adequately control and effectively manage such costs, our expenditures in developing and commercializing Noctiva™ may not

produce the sales revenues expected by the Corporation. Further, we may incur higher than expected operating costs, and we may encounter general economic and business conditions that adversely affect it relating to the Acquisition.

The Corporation does not currently have an agreement in place to manufacture Noctiva™ and anticipates that it will rely on a single third-party supplier

The Corporation does not currently have an agreement in place to manufacture the Noctiva™ product. The Corporation anticipates that it will depend on a single contract manufacturing organization for the manufacturing and supply of Noctiva™. If the supplies of Noctiva™ are interrupted for any reason, or if the Corporation is unable to quickly secure a contract manufacturing organization, our manufacturing and marketing of Noctiva™ could be delayed. These delays could be extensive and expensive, especially in situations where a substitute is not readily available, where additional regulatory approval is required, or if patients switch to a competing product. Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations. The risks associated with depending upon a single third-party supplier previously materialized with respect to the Corporation's Estrace® business, see the 2020 and 2021 sections of *Recent Developments* and the *Legal Proceedings and Regulatory Actions* heading below for further details.

The development and commercialization of Noctiva™ will likely require significant management attention, which could disrupt our business and adversely affect our financial results.

The development and commercialization of Noctiva™ will likely require significant management attention, which could disrupt our business and adversely affect our financial results. By diverting management's attention away from our other products, particularly Natesto® which is the Corporation's only other currently marketed product, our ongoing operations could suffer, which could have a material adverse effect on our business, financial condition, results of operations or prospects.

DESCRIPTION OF CAPITAL STRUCTURE

Acerus Common Shares

The authorized capital of the Corporation consists of an unlimited number of Acerus Common Shares without par value. As of the date hereof, 1,537,588,081 Acerus Common Shares are issued and outstanding. However, as many as 1,533,642,008 additional Acerus Common Shares may be issued in connection with the Serenity Acquisition. Such an issuance would represent approximately 99.74% of Acerus' currently issued and outstanding Common Shares. For further details about the Acquisition, see the "*2022*" subheading in the *Recent Events* section and the Corporation's filings in the US at https://www.sec.gov/edgar.shtml and in Canada at www.sedar.com. Each Acerus Common Share entitles the holder thereof to receive notice of and exercise one vote at all meetings of shareholders. The holders of Acerus Common Shares are entitled to such dividends as the Corporation's board of directors may declare from time to time, which dividends are payable in money or property or by issuing fully paid Acerus Common Shares or options or rights to acquire fully paid Acerus Common Shares.

In the event of the liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary, or any other distribution of assets of the Corporation among its shareholders for the purpose of winding-up its affairs, the holders of Acerus Common Shares are entitled to share equally the remaining property and assets of the Corporation.

There are no pre-emptive, redemption, purchase or conversion rights attached to Acerus Common Shares.

Share-Based Compensation

On June 23, 2020, the Shareholders of the Corporation approved the Omnibus Incentive Plan, replacing the 2018 Amended and Restated Stock Option Plan. No further grants or awards will be made under the 2018 Amended and Restated Stock Option Plan. However, the Amended and Restated Stock Option Plan will continue in effect after approval of the Omnibus Incentive Plan for so long as and solely to the extent necessary

to administer previously-granted awards that remain outstanding under such plan.

The Omnibus Incentive Plan is administered by the Corporation's board of directors, which may, from time to time, delegate to a committee of the board of directors or to the chief executive officer of the Corporation, all or any of the powers conferred to the board under the Omnibus Incentive Plan.

The evolution of the employment marketplace has contributed to the continuing development of innovative compensation practices involving several alternative forms of equity-based incentives. In view of these developments, the Board recommended the adoption and approval of a new long-term incentive plan permitting the grant of stock options and restricted share units ("**RSUs**") and performance share units ("**PSUs**" and together with RSUs, "**Share Units**") settled in Shares (or, at the election of Acerus, their cash equivalent) that would provide Acerus with a flexible and dynamic long-term incentive compensation structure that: (i) allows for the implementation of potential performance vesting conditions; and (ii) removes the link between stock option awards and short-term performance. In addition, under the proposed plan, Acerus would be able to grant deferred share units ("**DSUs**") to directors.

The Omnibus Incentive Plan provides that the board of directors of the Corporation may from time to time, at its discretion, grant to directors, officers, employees, consultants and any other person or entity engaged to provide ongoing services to the Corporation non-transferable options to purchase Acerus Common Shares, provided that the number of Acerus Common Shares reserved for issuance under the Omnibus Incentive Plan shall not exceed 10% of the total issued and outstanding Acerus Common Shares from time to time. The exercise price of options may not be below the market price of Acerus Common Shares at the time of grant (as determined in accordance with the rules of the TSX). In addition, the grant of Awards under the Plan is subject to the following additional limitations:

> (a) no more than 10% of the Company's outstanding issue may be issued under the Plan or pursuant to any other security-based compensation arrangements of the Company in any one (1) year period;
>
> (b) no more than 5% of the Company's outstanding issue may be issued under the Plan or pursuant to any other security-based compensation arrangements of the Company to any one Person;
>
> (c) the number of Shares issuable to insiders at any time pursuant to all of the Company's security-based compensation arrangements shall not exceed 10% of the outstanding Shares on a non-diluted basis and the number of Shares to be issued to insiders, within any one year period, pursuant to all of the Company's security-based compensation arrangements shall not exceed 10% of the outstanding Shares on a non-diluted basis; and
>
> (d) the aggregate number of Shares reserved for issue to any one service provider of the Company shall not exceed 2% of the total number of Shares then outstanding, excluding Shares issued to such service provider upon the exercise of Options over the preceding 12-month period.

The Omnibus Incentive Plan also provides that:

1. upon the surrender, termination or expiry of any options granted under the Stock Option Plan, without such options being exercised, or upon the exercise of any options, Acerus Common Shares subject to such options shall become available under the Stock Option Plan to satisfy future grants of new options under the Stock Option Plan; and

2. a holder of an option may, rather than exercise such option, elect a cashless exercise of such option payable in Acerus Common Shares equaling the amount by which the value of an underlying share at that time exceeds the exercise price of an option or warrant to acquire such shares.

The board of directors of the Corporation may amend the Omnibus Incentive Plan from time to time without the Corporation shareholders' approval except for amendments relating to:

> (i) any increase in the maximum number of Shares that may be issuable from treasury pursuant to Awards granted under the Plan;

(ii) any reduction in the Exercise Price of an Option benefitting an insider of the Company;

(iii) any extension of the Expiry Date of an Award benefitting an insider of the Company, except in the case of an extension due to a Blackout Period;

(iv) any increase in the maximum number of Awards that may be issuable to insiders and associates of such insiders at any time; and

(v) any amendment to Section 7(10)(c) (Amendments not requiring not requiring shareholder approval) or Section 7(10)(d) (Amendments requiring shareholder approval) of the Plan.

As of the date hereof, there are outstanding: (a) options to purchase 112,728,260 Acerus Common Shares with a weighted average exercise price of CDN$0.06 and a weighted average contractual life of 3.7 years; and (b) 3,961,217 RSUs, which have vested and are anticipated to be settled in the near future.

A complete summary of the Omnibus Incentive Plan is available in the management information circular of the Corporation dated May 28, 2020, which is available on SEDAR at www.sedar.com.

Warrants

On July 18, 2012, in connection with a previous loan transaction, certain brokers were issued warrants exercisable for an aggregate of 51,639 Acerus Common Shares. The warrants were exercisable for five years at an exercise price of $1.4524. The warrants expired July 18, 2017.

In June 2014, in connection with the senior secured credit and security agreement between MidCap Funding V, LLP ("**MidCap**") and the Corporation, MidCap was issued warrants exercisable for an aggregate of 3,034,814 Acerus Common Shares. The warrants were exercisable for seven years at an exercise price of CDN$0.7095. These warrants were classified as a derivative financial instrument on the financial statements and expired unexercised on July 16, 2021.

On June 6, 2018, the Corporation entered into an agreement with Mackie Research Capital Corporation (the "**Underwriter**"), whereby the Underwriter agreed to purchase, on a bought-deal basis, 16,667,000 units (each individually a "**Unit**") of the Corporation at a price of CDN$0.30 per Unit. Each Unit was comprised of one common share of the Corporation and one common share purchase warrant (each whole warrant, a "**Warrant**") of the Corporation (the "**Offering**"). Each Warrant entitled the holder thereof to purchase one additional common share of the Corporation at an exercise price of CDN$0.40 at any time up to 24 months following closing of the Offering. In connection with the Offering, the Corporation granted the Underwriter an over-allotment option to purchase up to an additional 15% of the total number of Units to be issued under the Offering, at any time up to 30 days after closing of the Offering. The Units were offered by way of short form prospectus to be filed in those provinces of Canada, other than Quebec, as the Underwriter may have designated pursuant to the National Instrument 44-101 – Short Form Prospectus Distributions. The Units were not offered in the United States. The Warrants expired on June 28, 2020.

On June 7, 2018, the Corporation entered into a revised agreement with the Underwriter, to increase the size of the Offering to $5,750,010 of Units of the Corporation, at a price of CDN$0.30 per Unit.

On June 28, 2018, the Corporation closed the Offering, pursuant to which 22,041,705 Units (including the full exercise of the over-allotment option granted to the Underwriter of the Offering) were issued at a price of CDN$0.30 per unit. Each Unit was comprised of one common share of the Corporation and one Warrant of the Corporation. Each Warrant entitled the holder thereof to purchase one additional common share of the Corporation at an exercise price of CDN$0.40 at any time up to 24 months following the closing of the Offering. The Warrants traded on the TSX on closing of the Offering under the ticker symbol "ASP-WT", but are now expired. On closing, the Underwriter received a cash commission equal to 7% of the gross proceeds from the sale of Units and compensation options entitling it to purchase 1,542,919 common shares of the Corporation at a price of CDN$0.30 within 24 months of the closing of the Offering.

On October 12, 2018, the Corporation entered into a senior secured term loan credit facility with SWK for up to $11,000,000. As part of the transaction, SWK received the SWK Warrants which have been classified as a derivative financial instrument on the financial statements. Each SWK Warrant entitles SWK to purchase one common share of the Corporation at an exercise price of CDN$0.40 per common share, expires on October 11, 2023 and has a cashless exercise feature. Following the second anniversary of the issuance of the SWK Warrants, the Corporation can cause SWK to exercise the SWK Warrants prior to their expiry date if the closing price of the Corporation's common shares on the TSX is at or above CDN$0.80 per common share for a period of at least 21 consecutive trading days.

On September 30, 2019, the Corporation agreed to reprice the 5,331,563 SWK Warrants that were issued with the signing of the New Facility in 2018. The SWK Warrants were repriced from CDN$0.40 to CDN$0.11. In addition, the SWK Warrants' expiry date was extended from October 11, 2023 to September 30, 2024. No other changes were made to the term of the SWK Warrants. The volume-weighted average trading price of the Corporation's common shares on the TSX for the five-trading-day period ending September 30, 2019 was CDN$0.11. The repricing and the extension of the expiry date of the SWK Warrants became effective on October 15, 2019.

The Corporation also issued 1,361,544 New Warrants to SWK in connection with the amendment. Each New Warrant will entitle SWK to purchase one common share of the Corporation at an exercise price of CDN$0.11 per common share and will expire on September 30, 2024. The terms of the New Warrants will otherwise be identical to those of the SWK Warrants. As such, in certain circumstances, the Corporation may cause SWK to exercise the New Warrants prior to their expiry date if the closing price of the Corporation's common shares on the TSX exceeds CDN$0.80 per share for a period of at least 21 consecutive trading days.

As described above, as consideration for and in connection with the February 2020 SWK Amendment, the Corporation paid SWK an amendment fee of US$80,000, a prepayment fee of US$250,000 and amended 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. Two further principal payments of US$250,000 were made on September 15, 2020 and December 15, 2020, respectively.

DIVIDENDS AND DISTRIBUTIONS

Dividend Policy

The declaration and payment of dividends on the Acerus Common Shares is at the discretion of the Corporation's board of directors. It is the board of directors' present policy to retain its earnings to finance growth, fund future development projects and expand its operations. As such, it does not anticipate paying any dividends in the foreseeable future.

Any declaration and payment of dividends by the Corporation will be dependent upon the Corporation's consolidated results, financial position, cash requirements, future prospects, profits available for distribution and other factors regarded by the directors on the board of directors as relevant at the time.

The Corporation has not paid any dividends on the Acerus Common Shares since the Qualifying Transaction to the date hereof.

MARKET FOR SECURITIES

Trading Price and Volume

The Acerus Common Shares are listed for trading on the TSX under the symbol "ASP". The monthly price ranges and total monthly trading volumes for the Acerus Common Shares during 2021 were as follows:

	Share Price ($) (in Canadian Dollars)		Average Daily Trading Volume of Shares
	High	**Low**	
2021			
January	0.05	0.035	148,034
February	0.065	0.04	426,538
March	0.06	.045	115,787
April	0.06	0.05	63,272
May	0.055	0.04	54,407
June	0.055	0.04	95,607
July	0.05	0.04	44,747
August	0.045	0.035	55,366
September	0.045	0.035	43,620
October	0.045	0.035	48,325
November	0.04	0.025	134,482
December	0.04	0.03	116,193

The Acerus Common Shares are also listed for trading on the OTCQB under the symbol "ASPCF". The monthly price ranges and total monthly trading volumes for the Acerus Common Shares during 2021 were as follows:

	Share Price ($) (in US Dollars)		Average Daily Trading Volume of Shares
	High	**Low**	
2021			
January	0.05	0.021	119,157
February	0.0678	0.0315	44,619
March	0.055	0.03472	25,980
April	0.0562	0.03526	35,991
May	0.06	0.032	20,416
June	0.0449	0.028	15,144
July	0.0408	0.0344	10,531
August	0.0388	0.0266	6,792
September	0.0397	0.0263	7,831
October	0.03454	0.0261	10,292
November	0.0366	0.023	9,298
December	0.0239	0.0189	3,878

Prior Sales

During 2021, the Corporation issued the following securities:

Security	Date of Issue/Grant	Price Per Security	Number of Securities
Acerus Common Shares	None	N/A	N/A
Acerus Stock Options	June 29, 2021 June 29, 2021	$0.0479 $0.0479	1,170,609 40,820,109
Acerus Warrants	None	N/A	N/A
RSU's	None	N/A	N/A

DIRECTORS AND OFFICERS OF THE CORPORATION

Name, Occupation and Security Holding

The Corporation may have between a minimum of three and a maximum of eleven directors. The directors are responsible for supervising the activities and managing the affairs of the Corporation. The number of directors is currently set at seven.

Four of the seven current directors are independent of the management of the Corporation. Mr. Edward Gudaitis is currently the President and Chief Executive Officer of the Corporation. Accordingly, Mr. Gudaitis is non-independent for purposes of applicable securities laws. Dr. Herschkowitz has been retained by the Corporation as a consultant in connection with the Acquisition and is therefore also non-independent.

The following table and notes thereto set out the name, province/state and country of residence of each director, their current position and office with the Corporation, the date on which they were first elected or appointed as a director and the members of each committee of the board of directors:

Name, Province or State and Country, Position Held	Director Since	Standing Board Committee Memberships	Principal Occupation During the Previous Five Years
Borys Chabursky Director Ontario, Canada	December 20, 2015	1. Audit Commitee 2. Compensation Committee 3. Corporate Governance and Nominating Committee	Founder and Chairman, Shift Health (February 2011 – Present) Chairman, SHI Capital (February 2011 – Present) President, SHI Ventures (February 2011 – Present)
Geoffrey David Cotton, Director, California, USA	May 4, 2020	1. Audit Committee 2. Compensation Committee 3. Corporate Governance and Nominating Committee (Chair)	CEO, Evvia Therapeutics (March 2021 – Present) Entrepreneur in Residence, Mission Bay Capital (January 2020 to March 2021) Vice President, Commercial Planning, Gilead Sciences Inc. (September 2016 – April 2018)

Stephen Gregory, Director Quebec, Canada	July 14, 2011	1. Audit Committee 2. Compensation Committee (Chair) 3. Corporate Governance and Nominating Committee	President, IsaiX Technologies Inc. (March 1989 to present)
Edward Gudaitis, Director and Chief Executive Officer Ontario, Canada	May 1, 2018	None	President and Chief Executive Officer, Acerus Pharmaceuticals Corporation (May 2018 to present) Vice President and Country Manager, Canada, Allergan Inc. (October 2016 – April 2018)
Dr. Sam Herschkowitz, Vice Chair, New York, USA	March 7, 2022	None	Vice Chairman of the Board of Directors and Consultant, Acerus Pharmaceuticals Corporation (March 2022 to present) Chief Executive Officer and Founder, Serenity Pharmaceuticals LLC (2007 – March 2022)
Ian O. Ihnatowycz Chairman of the Board Ontario, Canada	September 9, 2013	None	President and Chief Executive Officer, First Generation Capital Inc. (April 2011 to present)
Scott Leckie, Director Ontario, Canada	June 23, 2020	1. Audit Committee (Chair) 2. Compensation Committee 3. Corporate Governance and Nominating Commitee	7th Merchant Corporation, Principal and Chairman (December 2021 – Present) Chairman and CEO, Takota Asset Management Inc. (2012- December 2021)

The following table and notes thereto set out the name, province/state and country of residence of each officer of the Corporation, their current position and office with the Corporation:

Name, Province or State and Country of Residence	Officer's Title	Principal Occupation During the Previous Five Years
Edward Gudaitis Ontario, Canada	President and Chief Executive Officer	President and Chief Executive Officer, Acerus Pharmaceuticals Corporation (May 2018 to present) Vice President and Country Manager, Canada, Allergan Inc. (October 2016 – April 2018)

Gavin Damstra, Ontario Canada	Senior Vice President, International Commercial	Senior Vice President, International Commercial, Acerus Pharmaceuticals Corporation (May 2019 – Present) Executive Director Women's Health & GI, Allergan (June 2017 – December 2018)
Kevin Hickey, Pennsylvania, USA	Senior Vice President, US Commercial	Senior Vice President, US Commercial (September 2020 – Present) Senior Director, Marketing - SUNOSI®, Jazz Pharmaceuticals (February 2018 – September 2020) Vice President / General Manager Commercial Operations, Syneos Health (August 2014 – February 2018)
Robert M. Motz Ontario, Canada	Chief Financial Officer	Chief Financial Officer, Acerus Pharmaceuticals Corporation (October 2018 – present) Chief Financial Officer & Corporate Secretary, Hydrogenics Corporation (November 2012 – May 2018)
Philippe Savard Ontario, Canada	Vice President, General Counsel and Corporate Secretary	Vice President, General Counsel and Corporate Secretary (formerly Vice President, Legal Affairs and Corporate Secretary), Acerus Pharmaceuticals Corporation (July 2016 – present)
Dr. Christopher Sorli, MD, PhD, FACE Montana, USA	Chief Medical Officer	Chief Medical Officer, Acerus Pharmaceuticals Corporation (August 2020 – Present) Sanofi, Vice President US Medical Affairs, Head of Cardio Metabolic Disease Primary Care Business Unit (November 2019 – July 2020) Sanofi, Vice President Medical Affairs, Head of Diabetes US Primary Care Busines Unit (November 2018 – November 2019) Sanofi, Global Medical Lead for New Products (December 2016 – November 2018)

Generally, directors will be elected at each annual meeting of the Corporation's shareholders to hold office for a term expiring at the close of the next annual meeting presently anticipated to be held in June 2022. The term of the office for each officer expires at the direction of the board of directors of the Corporation.

As at the date of this Annual Information Form, the directors and executive officers of the Corporation as a group beneficially own, directly or indirectly, or exercise control or discretion over 1,405,000,924 Acerus Common Shares representing approximately 91.377% of the issued and outstanding Acerus Common Shares. However, it is anticipated that the number of Acerus Common Shares, as well as the total percentage of issued and outstanding Acerus Common Shares, owned by directors and executive officers of the Corporation may change in connection with the Serenity Acquisition. For further details about the Acquisition, see the "*2022*" subheading in the *Recent Events* section and the Corporation's filings in the US at https://www.sec.gov/edgar.shtml and in Canada at www.sedar.com.

Corporate Cease Trade Orders or Bankruptcies

To the knowledge of the Corporation, no directors or executive officers of the Corporation are, as at the date hereof, or have been, within the 10 years before the date of this Annual Information Form, a director, chief executive officer or chief financial officer of any company (including the Corporation) that, (i) was

subject to a cease trade order, an order similar to a cease trade order or an order that denied the relevant company access to any exemption under securities legislation that was in effect for a period of more than 30 consecutive days (an "**Order**") that was issued while the person was acting in the capacity as director, chief executive officer or chief financial officer; or (ii) was subject to an Order that was issued after the person ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

To the knowledge of the Corporation, other than as described below, no Directors or executive officers of the Corporation or a shareholder holding a sufficient number of securities of the Corporation to affect materially the control of the Corporation (a) are, as at the date of this Annual Information Form, or have been within 10 years before the date of this Annual Information Form, a director or executive officer of any company (including the Corporation) that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets, or (b) have, within the 10 years before the date of this Annual Information Form, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of that person.

Mr. Scott Leckie was a director of Groupe Bikini Village Inc. until July 2014, when he resigned, and Groupe Bikini Village Inc. filed a notice of intention to make a proposal under the Bankruptcy and Insolvency Act on February 17, 2015.

Penalties and Sanctions

To the knowledge of the Corporation, other than as described below, none of directors nor any personal holding company owned or controlled by any of them: (a) has been subject to any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or (b) has been subject to any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

On June 30, 2005, Mr. Scott Leckie agreed to pay a fine of $100,000 under a settlement agreement with Market Regulation Services Inc. with regard to certain trading activities.

Conflicts of Interest

To the knowledge of the Corporation, no director or senior officer of the Corporation has any existing or potential material conflict of interest with the Corporation or any of its subsidiaries.

PROMOTERS

No person or company has been a promoter of the Corporation or of a subsidiary of the Corporation within the two most recently completed financial years.

AUDIT COMMITTEE

The Directors have established an audit committee comprised of four Directors (the "**Audit Committee**"). The Audit Committee is chaired by Scott Leckie and the other committee members are Geoff Cotton, Borys Chabursky and Steve Gregory. All of the Audit Committee members are independent of management of the Corporation as required by National Instrument 52-110 – *Audit Committees* and each member is financially literate in that each has the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Corporation's financial statements.

The mandate of the Audit Committee is set out in the written Charter of the Audit Committee. The Audit Committee charter was updated on May 10, 2019 and is included as Appendix "A" attached hereto.

Relevant Education and Experience

Borys Chabursky - Mr. Borys Chabursky specializes in strategic planning, fundraising, financial management and business development for biotechnology, medical device, imaging and oncology companies and science and technology incubators in both the public and private sector. As the founder and Chairman of Shift Health, he has overseen the successful completion of over 500 life sciences assignments for more than 300 clients in North America, Europe and the Middle East; the development of compelling business cases and implementation plans that have helped leverage over $1B in financing from private and public sector resources; and the creation and facilitation of more than 50 public-private partnerships in biomedical research, infrastructure development and global health. Mr. Chabursky has worked closely with industry thought leaders, large pharmaceutical companies, government agencies, hospital boards and healthcare networks. He has also provided interim management for seven start-up companies and angel financing for ten new start-up ventures. With his experience spearheading large-scale, multi-stakeholder, global initiatives, Mr. Chabursky often serves as an advisor to influencers and developers of government policy.

Dr. Geoff Cotton - Dr. Cotton is a healthcare executive, venture capital adviser, and angel investor with 20 years experience in the pharmaceutical industry. He spent over 17 years with Gilead Sciences Inc. in Medical Affairs and Commercial roles of increasing responsibility culminating in leadership of the Global Commercial Strategy group, and leadership of the U.S. HIV business unit, with responsibility for over $8B in revenue and $100M of expenses annually. Dr. Cotton has extensive experience in U.S. pharmaceutical product launch and promotion, Key Opinion Leader development, sales leadership and execution, product lifecycle development, U.S. and EU pricing and reimbursement, portfolio strategy, M&A assessment, clinical development, and medical affairs. His therapeutic experience includes anti-virals and anti-infectives, immunology, oncology, cardiovascular, respiratory, and renal disease. Dr. Cotton has worked in the U.S., EU, Global and country level roles. Under Dr. Cotton's business unit leadership, Gilead launched Genvoya®, Odefsey®, and Descovy® for the treatment of chronic HIV infection, with Genvoya® achieving the fastest launch of any HIV product at that time. Dr. Cotton also launched Truavada® for post exposure prophylaxis, a novel HIV preventative achieving over $1B in revenue in the U.S.

Dr. Cotton graduated in Medicine with a BSc and MB BS from the University of London and practiced internal medicine in the UK prior to joining the pharmaceutical Industry. He has an MBA from Golden State University.

Steve Gregory - Mr. Gregory has served as a Director since July 2011. Mr. Gregory is President, Chairman and the controlling shareholder of IsaiX Technologies, a privately held company headquartered in Montreal. IsaiX Technologies works extensively across a wide variety of industry segments and has ongoing business relationships with more than 100 companies in the pharmaceutical, finance, banking and insurance sectors. IsaiX Technologies provides and implements for its client's human development programs, medical writing and physician scheduling platform services. Mr. Gregory also spearheads charitable endeavours for the children of Canadian soldiers serving overseas. Mr. Gregory has also completed the Institute of Corporate Directors Education Program offered jointly by the Institute of Corporate Directors and the Rotman School of Business of the University of Toronto.

Dr. Samuel Herschkowitz, M.D. - Since 1982, Dr. Samuel Herschkowitz has been a known leader in the area of biotechnology, healthcare devices and pharmaceutical development. Until its merger with Acerus Pharmaceuticals, Dr. Herschkowitz served as the Chairman and Chief Executive Officer as well as a founder of Serenity. During his career, which spans four decades, has was as Strategic Advisor for Amarantus BioSciences, Inc., Dov Pharmaceuticals, Perceptive Systems, Theragenics Corporation, T-Cell Sciences, Oncogene Sciences, Crossover Ventures, and Mira Dx. Between 1998 and 2006 he was a founder and Chief Technical Officer and Chairman of Delcath Systems, Inc. He then served as Interim Chief Operating Officer of Delcath Systems, Inc. from January 4, 2007 to July 1, 2007 before moving on to a fulltime position at Serenity Pharmaceuticals. Earlier in his career, he co-founded Venkol Ventures, a venture capital firm specializing in

medical technology investments (1987-2002). Prior to that in 1982, Dr. Herschkowitz was a founder and general partner of Banipal Ventures that specialized in investing in start-up healthcare technology and pharmaceuticals. Prior to founding Banipal, Dr. Herschkowitz was a founder of Medtech Associates. Medtech was a consulting company specializing in due diligence investigations on behalf of health care investors. In 1988, he founded Receptor Technologies, Inc. that subsequently was purchased by Senetek, PLC in 1995. From 1995 until 1998 he was a director of Senetek, PLC, a health care company on the London exchange. Dr. Herschkowitz is a Clinical Professor at PANY, an affiliate of New York University Medical Center. He is Board Certified in Psychiatry and Neurology. He received his Medical degree with honors from Downstate Medical Center College of Medicine in 1976.

Scott Leckie - Mr. Leckie is Principal and Chairman of 7th Merchant Corporation. 7th Merchant is a private merchant bank. Mr. Leckie was previously a founding partner, director, and senior officer at Aquilon Capital, an investment firm started in 1990 and sold to National Bank Financial in 2008. While at Aquilon Capital Mr. Leckie's portfolio management efforts produced a successful capital allocation track record of approximately 20% per annum over the 18 years of the firm's existence. Mr. Leckie has founded seven different private companies at which he held senior management and Board of Director responsibilities. In addition, Mr. Leckie's activities as an investor have resulted in his taking Board seats on certain public companies in the past. Currently Mr. Leckie serves on the Board of the public company Abaxx Technologies Inc., and the private company Sterling Maple Corp. Mr. Leckie is a Chartered Financial Analyst, having earned that designation in 1992 and is currently completing his ICD.D designation with ICD-Rotman.

Reliance on Certain Exemptions

At no time since the commencement of the Corporation's most recently completed financial year has the Corporation relied on the exemptions in Section 2.4 of National Instrument 52-110 (*De Minimis Non-audit Services*), Section 3.2 of National Instrument 52-110 (*Initial Public Offerings*), Section 3.4 of National Instrument 52-110 (*Events Outside of Control of Member*), Section 3.5 of National Instrument 52-110 (*Death, Disability or Resignation of Audit Committee Member*), or an exemption from National Instrument 52-110, in whole or in part, granted under Part 8 of National Instrument 52-110.

Additionally, at no time since the commencement of the Corporation's most recently completed financial year has the Corporation relied on the exemptions in subsection 3.3(2) of National Instrument 52-110 (*Controlled Companies*), Section 3.6 of National Instrument 52-110 (*Temporary Exemption for Limited and Exceptional Circumstances*) or Section 3.8 of National Instrument 52-110 (*Acquisition of Financial Literacy*).

Audit Committee Oversight

At no time since the commencement of the Corporation's most recently completed financial year was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the board of directors of the Corporation.

Pre-Approval Policies and Procedures

The Audit Committee is authorized by the Corporation's board of directors to review the performance of the Corporation's external auditors and approve in advance the provision of services by them other than auditing and to consider the independence of the external auditors, including reviewing the range of services provided. The Audit Committee may delegate to any independent member of the Audit Committee the authority to pre-approve any non-audit services.

External Auditor Service Fees

A summary of the external auditor service fees and billings paid or payable to the Corporation's external auditors in respect of the last two fiscal years ended December 31, 2021 is set out below:

Fiscal Year	Audit Fees	Audit Related Fees	Tax Fees[1]	All Other Fees[2]	Total
2021	**$139,678**	**$70,842**	**$63,545**	**$2,968**	**$277,033**
2020	**$132,058**	**$49,276**	**($26,725)**	**$23,961**	**$178,570**

(1) The amounts shown are comprised of the fees charged by the Corporation's external auditors in connection with certain tax compliance services.
(2) The amounts shown are comprised of the fees charged by the Corporation's external auditors in connection with consulting services.

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

Other than as disclosed herein, to the knowledge of the Corporation there are no material legal proceedings or regulatory actions known or known to be contemplated against the Corporation or to which any of its property is or may be subject. No penalties or sanctions have been imposed against the Corporation by a court relating to securities legislation or by a securities regulatory authority and no settlement agreements have been entered into by the Corporation before a court relating to securities legislation or with a securities regulatory authority.

Jones Day Litigation

On December 11, 2019, Jones Day commenced an action in the New York State Supreme Court against Serenity, and certain members of its senior management, for alleged unpaid legal bills. On September 21, 2020, Serenity filed an answer with counterclaims against Jones Day. Serenity's counterclaim alleges breach of contract in connection with Jones Day's representation of Serenity in a prior lawsuit, fraud in respect of certain billing issues and malpractice. Also on September 21, 2020, the senior management members filed a motion to dismiss Jones Day's complaint as against them. Jones Day also brought a motion to dismiss Serenity's counterclaims. On May 12, 2020, a decision was rendered in both motions. Serenity's motion was dismissed and Jones Day's motion was granted with respect to the counterclaims in fraud and malpractice, but dismissed in respect of the breach of contract claim. The parties are now proceeding through discovery, which is anticipated to be complete by March 15, 2022.

Recipharm Litigation

Due to the delays in Recipharm getting its license reinstated in the U.K., resulting in further delays in Estrace® delivery, Acerus filed a claim against Recipharm on June 18, 2020 in the Commercial Court of London. The claim alleges that the suspension of Recipharm's manufacturing license in August 2018, in contravention of its contractual obligations to Acerus, led to a shortage of Estrace® in Canada. Acerus sought to be compensated for, among other things, its loss of profits and loss of market share caused by the shortage. On August 12, 2021, the Corporation announced that it had accepted a settlement offer made by Recipharm. The Corporation received a settlement payment of GBP 1.7 million and payment of the majority of its costs of the 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.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Other than as disclosed herein, to the knowledge of the Corporation, none of (i) the directors, officers; or (ii) persons that beneficially owns, or controls or directs, directly or indirectly, more than 10% of the outstanding securities of the Corporation; or (ii) any associate or affiliate of the persons referred to in (i), has or has had any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year that has materially affected or will materially affect the Corporation or any of its subsidiaries.

TRANSFER AGENT AND REGISTRAR

The Corporation's transfer agent and registrar for the Acerus Common Shares is TMX Equity Transfer Services at its principal office in Toronto, Ontario.

MATERIAL CONTRACTS

The following are the material contracts of the Corporation that are in effect other than certain agreements entered into in the ordinary course of business. Summaries of each of the material contracts can be found in the section entitled *"Recent Developments"*. The summaries are subject to, and qualified in their entirety by reference to the material contract, copies of which have been filed with the Canadian securities regulatory authorities and are available on SEDAR at www.sedar.com under the Corporation's profile. Investors are encouraged to read the full text of such material agreements.

(a) the IP Agreement;

(b) M&P Buyout;

(c) Serenity Definitive Agreement;

(d) 2021 FGC Loan Facility;

(e) the Aytu Buyback Agreement; and

(f) the Syneos MSA.

Copies of all the Corporation's material contracts, past and present, including those described above, are available on the Corporation's profile on SEDAR at www.sedar.com or upon request from the Corporation at 7025 Langer Drive, Suite 205, Mississauga, ON, Canada, L5N 0E8.

INTERESTS OF EXPERTS

Since the completion of the Qualifying Transaction in July 2011, the Corporation has retained PricewaterhouseCoopers LLP as its external auditor. PricewaterhouseCoopers LLP is independent with respect to the Corporation in accordance with the Rules of Professional Conduct of the Chartered Professional Accountants of Ontario.

No director, officer or employee of PricewaterhouseCoopers LLP, is or is expected to be elected, appointed or employed as a director, officer or employee of the Corporation or any associate or affiliate of the Corporation.

ADDITIONAL INFORMATION

Additional information, including Directors' and officers' remuneration and indebtedness, the executive compensation for named executive officers of the Corporation, principal holders of the Corporation's securities, and interests of insiders in material transactions, as applicable, is contained in the Corporation's management information circular for its most recent annual meeting of shareholders. Additional financial information is provided in the financial statements and MD&A for the year ended December 31, 2021 of the Corporation. A copy of the management information circular, financial statements and MD&A may be obtained upon request from the Corporation and those documents and other information in respect of the Corporation are also available on SEDAR at www.sedar.com.

APPENDIX "A"

ACERUS PHARMACEUTICALS CORPORATION
("Acerus")

AUDIT COMMITTEE CHARTER

Organization

This Charter governs the operations of the Audit Committee of Acerus (the "Committee"). The board of directors will appoint a Committee of at least three members and will designate one member as chair or delegate the authority to designate a chair to the Committee. All of the members will be directors who are "independent", as defined by National Instrument 52-110 – *Audit Committees*.

Each member of the Committee will be financially literate, or become financially literate within a reasonable period of time.

The Committee will meet at least quarterly. The Committee will meet separately and periodically with management, internal audit and with the independent auditors. The Committee will report regularly to the board with respect to its activities.

Purpose

The purpose of the Committee will be to provide assistance to the board in fulfilling its oversight responsibility to the shareholders, potential shareholders, the investment community, and others relating to: (i) the integrity of Acerus' financial statements; (ii) Acerus' compliance with legal and regulatory requirements; and (iii) the independent auditors' qualifications and independence.

The Committee may retain (and set and pay the compensation) of such outside legal, accounting or other advisors as it considers necessary to carry out its duties.

In fulfilling its purpose, it is the responsibility of the Committee to maintain free and open communication between the Committee, independent auditors and management, and to determine that all parties are aware of their responsibilities.

Duties and Responsibilities

The Committee has the responsibilities and powers set forth in this Charter. Management is responsible for the preparation, presentation, and integrity of Acerus' financial statements, for the appropriateness of the accounting principles and reporting policies that are used and for implementing and maintaining internal control over financial reporting. The independent auditors are responsible for auditing Acerus' annual financial statements and for reviewing Acerus' unaudited interim financial statements.

The following will be the principal duties and responsibilities of the Committee. These are set forth as a guide with the understanding that the Committee may supplement them as appropriate.

- The Committee will be responsible to advise the board, for the board's recommendation to shareholders, in respect of the appointment, compensation and retention of the independent auditors.

- The Committee will be directly responsible for the oversight of the work of the independent auditors (including resolution of disagreements between management and the auditors regarding financial reporting) for the purpose of preparing or issuing an audit report or performing other audit, review, or attest services for Acerus, and the independent auditors report directly to the Committee.

- Annually, the Committee will obtain and review a report by the independent auditors describing: (i) the firm's internal quality control processes; (ii) all relationships between the independent auditors and Acerus (to assess the auditors' independence); and (iii) such other matters as are required by law or regulation.

- The Committee will determine that the independent audit firm has a process in place to address the rotation of the lead audit partner and other audit partners serving the account as required under Canadian independence standards.

- The Committee will pre-approve all audit and non-audit services provided by the independent auditors and will only engage the independent auditors to perform non-audit services permitted by law or regulation. The Committee may delegate pre-approval authority to a member of the Audit Committee. The decisions of any Committee member to whom pre-approval authority is delegated must be presented to the full Committee at its next scheduled meeting.

- The Committee will discuss with the independent auditors the overall scope and plans for their audits.

- The Committee will review with the independent auditors any audit problems or difficulties encountered during the course of the audit work, including any restrictions on the scope of the independent auditors' activities or access to requested information, and management's response. The Committee will review any accounting adjustments that were noted or proposed by the auditors but were not recorded (as immaterial or otherwise) and any "management" or "internal control" letter issued, or proposed to be issued, by the audit firm.

- The Committee will review and recommend approval of the quarterly and annual audited financial statements to the board, including Management's Discussion and Analysis, with management and the independent auditors prior to the issuance and/or filing of same. (References in this paragraph to the external auditors apply to the annual financial statements only.) The Committee's review of the financial statements will include: (i) major issues regarding accounting principles and financial statement presentation, including any significant changes in Acerus' selection or application of accounting principles, and major issues as to the adequacy of Acerus' internal controls and any specific remedial actions adopted in light of material control deficiencies; (ii) discussions with management and the independent auditors regarding significant financial reporting issues and judgments made in connection with the preparation of the financial statements and the reasonableness of those judgments; (iii) consideration of the judgment of both management and the independent auditors about the quality of accounting principles; and (iv) the clarity of the disclosures in the financial statements. Also, the Committee will discuss the results of the annual audit and any other matters required to be communicated to the Committee by the independent auditors under professional standards.

- The Committee will review and approve all related party transactions not in the ordinary course of business in the absence of a special committee of the board designated for such function.

- The Committee will review earnings press releases for recommendation to the board.

- The Committee will discuss with management and the independent auditors the adequacy and effectiveness of internal control over financial reporting, including any significant deficiencies or material weaknesses identified by management in respect of Canadian securities laws requirements.

- The Committee will review with management Acerus' compliance systems with respect to legal and regulatory requirements.

- As requested by the board, discuss with management and, where appropriate, the external auditors of Acerus, Acerus' major risk exposures (whether financial, operational or otherwise) and the steps management has taken to monitor and control such exposures.

- The Committee will ensure that Acerus establishes appropriate policies and procedures for the receipt, retention, and treatment of complaints received by Acerus regarding accounting, internal accounting controls, or auditing matters, and the confidential, anonymous submission by employees of Acerus of concerns regarding questionable accounting or auditing matters.

- The Committee will ensure that Acerus has in effect clear hiring policies for employees or former employees of the independent auditors that meet Canadian independence standards and applicable stock exchange listing standards.

- The Committee will perform an evaluation of its performance at least annually to determine whether it is functioning effectively.

- The Committee will review and reassess this Charter at least annually.