



**ACERUS PHARMACEUTICALS CORPORATION**

**ANNUAL INFORMATION FORM**

**March 20, 2018**

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## EXPLANATORY NOTES

Unless otherwise stated, the information in this Annual Information Form is stated as of December 31, 2017 and all references to Acerus Pharmaceuticals Corporation's (the "**Corporation**") fiscal year are for the year ended December 31, 2017.

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**").

### 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; 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 IMS; 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; and risks relating to securities analyst coverage of the Corporation.

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, and 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, and 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) (the "OBCA") 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" ("CPC") pursuant to Policy 2.4 of the TSX Venture Exchange ("TSX-V") Corporate Finance Manual. On July 14, 2011, J5 (Barbados), Inc. ("J5 Barbados"), 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".

The registered and head office of the Corporation is located at 2486 Dunwin Drive, Mississauga, Ontario, L5L 1J9.

### General Development of the Business

*Recent Developments*2014

On May 28, 2014, the Corporation announced that the United States Food and Drug Administration (“**FDA**”) had approved Natesto® for sale in the United States, the first and only testosterone nasal gel for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

Also on May 28, 2014, the Corporation announced the top-line results of its Phase II clinical trial evaluating the efficacy and safety of Tefina™. The double-blind, placebo-controlled study enrolled 253 pre- and post-menopausal women experiencing acquired female orgasmic disorder (“**FOD**”) in the United States, Canada and Australia. Participants were randomized to one of three dosage strengths (0.6 mg, 1.2 mg, 1.8mg) or a placebo group and treated over the course of 84 days. The primary endpoint of the trial related to the effects of the three dose strengths of Tefina™ nasal testosterone gel to placebo on the occurrence of orgasm. Secondary endpoints included the change from baseline in distress due to orgasmic disorder, change in sexual functioning and sexual event satisfaction. Tefina™ 0.6 mg led to a statistically significant increase in the number of orgasms during the 84-day treatment period.

On July 16, 2014, the Corporation announced that it acquired the Canadian rights for Estrace® (17-beta estradiol) from affiliates of Shire plc. Under the terms of the applicable agreement, the Corporation paid a total of CDN\$44.5 million to acquire the Canadian rights to Estrace®, together with existing inventories of the product. In order to finance the acquisition, the Corporation entered into a senior secured credit and security agreement (the “**MidCap Agreement**”) with MidCap Funding V, LLC (“**MidCap**”), an affiliate of MidCap Financial, LLC, for total facilities of \$25.0 million (\$20.0 million of which was drawn down concurrently with closing of the Estrace® acquisition), as well as a convertible subordinate unsecured term note (the “**First Generation Note**”) in the amount of \$25.0 million in favour of First Generation Capital Inc. (“**First Generation**”), a company affiliated with the chairman of the Board of Directors of the Corporation. This transaction constituted a significant acquisition for purposes of applicable securities laws, and a business acquisition report in respect of the transaction is available on SEDAR at [www.sedar.com](http://www.sedar.com).

On August 22, 2014, First Generation converted a portion of the indebtedness remaining outstanding under the First Generation Note into a total of 8,945,796 common shares of the Corporation in accordance with the terms and conditions of the First Generation Note. Following this conversion (and a partial repayment completed on July 30, 2014), approximately \$4.5 million of the First Generation Note remained outstanding. On December 9, 2014, this remaining amount (together with accrued interest) was repaid in full and no amounts remain outstanding under the First Generation Note as at the date hereof.

On November 24, 2014, the Corporation announced that Acerus Biopharma had entered into an agreement (the “**Endo Agreement**”) with Endo Bermuda Ventures Limited (“**Endo**”), an affiliate of Endo International plc, providing Endo with the exclusive rights to market Natesto® in the United States and Mexico. Under the terms of the agreement, Acerus Biopharma was eligible to receive payments of up to \$165.0 million based on certain regulatory and sales milestones in addition to an upfront fee of \$25.0 million and a prepaid inventory deposit of \$5.0 million paid upon closing of the transaction in December 2014. Additionally, Acerus Biopharma remained responsible for the manufacture of Natesto® and received a tiered supply price for the product. This transaction formally closed on December 9, 2014, and Natesto® was commercially launched in the United States in the first quarter of 2015.

## 2015

In January 2015, the Corporation filed a New Drug Submission (“NDS”) with Health Canada for Natesto®.

On September 8, 2015, the Corporation formally changed its name to “Acerus Pharmaceuticals Corporation”. Shortly thereafter, the Acerus Common Shares commenced trading under the symbol “ASP” on the TSX.

On November 5, 2015, the Corporation announced that Endo had informed it of its intention to conduct a portfolio optimization process to realize their U.S. branded resources. This process was expected to lead to the deprioritization of select brands including Natesto®. On December 30, 2015, Endo provided Acerus with its formal notice to terminate the agreement with Acerus relating to the commercialization of Natesto® in the United States and Mexico with an effective date of June 30, 2016.

On November 20, 2015, the Corporation announced that a third party generic version of Estrace® was approved by Health Canada.

On December 11, 2015, the Corporation announced that it had entered into an amendment to the MidCap Agreement, pursuant to which it immediately retired \$17.0 million of the \$25.0 million principal amount that was previously outstanding. The remainder of the existing principal amount had a final maturity date in early 2017.

On December 21, 2015, the Corporation announced that it had entered into an agreement with West Face Long Term Opportunities Global Master Fund L.P. and K2 Principal Fund L.P., two of its largest shareholders, providing for, among other things, certain changes to its Board of Directors.

## 2016

In January 2016, the Corporation received a Notice of Compliance approving Natesto® for 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® was officially launched in Canada in September 2016. For the launch, the Corporation prioritized key physicians and other healthcare professionals prescribing testosterone replacement therapy (“TRT”) and deployed a sales force across major Canadian provinces.

On April 18, 2016, the Corporation entered into a license and supply agreement with Medinova AG, a Swiss pharmaceutical company, granting the Corporation the exclusive rights to commercialize Gynoflor™ in Canada. Gynoflor™ is an ultra-low dose estrogen (estriol) and probiotic (*Lactobacillus acidophilus*) combination vaginal tablet used for the treatment of symptoms of vaginal atrophy, for the restoration of vaginal flora following the use of anti-infectives and for the treatment of certain vaginal infections.

On April 22, 2016, the Corporation entered into a license and supply agreement with Aytu Biosciences Inc. (“Aytu”) pursuant to which Aytu began commercializing Natesto® in the United States in July 2016 (the “Aytu Agreement”). Under the terms of the Aytu Agreement, the Corporation was entitled to upfront payments equaling \$8.0 million, all of which have been received as of the date hereof. Additionally, the Corporation is entitled to sales-based milestones that could potentially equal \$37.5 million. Finally, the Corporation is responsible for the manufacturing of the product and receives a tiered supply price that varies during the term of the agreement. As of the date hereof, the tiered supply price under the Aytu Agreement is equal to the greater of (i) 115% of the Corporation’s

cost of goods for the product or (ii) 16% of the net sales of the product in the U.S. Commencing in July 2018 and thereafter, the tiered supply price under the Aytu Agreement will be equal to the greater of (i) 115% of the Corporation's cost of goods for the product or (ii) 25% of the net sales of the Product in the U.S.

On April 27, 2016, the Corporation completed a private placement with Aytu, pursuant to which Aytu purchased 12,245,411 common shares of Acerus for gross cash proceeds of \$2.0 million.

Concurrently with the two Aytu transactions described above, the Corporation used \$3.0 million to retire a portion of the outstanding principal amount owed to MidCap pursuant to the MidCap Agreement. In connection with such repayment, an amendment to the MidCap Agreement was entered into pursuant to which certain adjustments were made to the Corporation's minimum cash covenants. At the end of December 31, 2016, the outstanding principal owed to MidCap under the MidCap Agreement was \$2.7 million and a \$0.4 million exit fee.

On June 30, 2016, the Corporation entered into a transition Agreement with Endo. Pursuant to the transition agreement, both parties have also entered into an agreement related to the customer deposit (pre-paid inventory) owed to Endo following the termination of the Endo Agreement. A \$0.5 million cash payment was paid to Endo on July 5<sup>th</sup>, 2016 and the remaining \$3.8 million principal amount was subject to a promissory note with a maturity date of June 30, 2020 (as amended on March 15, 2018 (as further described below)), the "**Endo Note**"). As of December 31, 2016, the remaining principal amount under the Endo Note was \$2.4 million. For further information please see filings available on SEDAR at [www.sedar.com](http://www.sedar.com).

In July 2016, a third party generic version of Estrace® obtained public reimbursement across major provinces. As expected, Estrace® sales decreased in 2016 due to the generic launch. Estrace® sales for the twelve months ending December 31, 2016 were CDN\$9.0 million compared to CDN\$10.1 million in the same prior year period, representing a 10% decrease. Estrace® sales for the twelve months ending December 31, 2017 were CDN\$5.7 million compared to CDN\$9.0 million in the same prior year period, representing a 37% decrease. We are closely monitoring the situation and have implemented initiatives which can potentially minimize further erosion of sales going forward. As of the date hereof, the sales of Estrace® appear to have stabilized in the last four quarters. For further information, please see the Corporation's MD&A dated as of the date hereof and available on SEDAR at [www.sedar.com](http://www.sedar.com).

On December 15, 2016, the Corporation entered into a license, development and supply agreement with Hyundai Pharm Co., LTD. ("**Hyundai**"), a South Korean pharmaceutical company, whereby it granted Hyundai the exclusive rights to market Natesto® in South Korea (the "**Hyundai Agreement**"). Pursuant to the agreement with Hyundai, the Corporation received a non-refundable upfront fee in January 2017 and is eligible to receive another milestone payment upon regulatory approval of the product in South Korea, as well as a transfer price for supplying the product.

#### 2017

On January 6, 2017, the Corporation completed the full repayment of all amounts due under the MidCap Agreement as well as the corresponding release of all collateral pledged as security.

On February 28, 2017, the Corporation submitted a NDS to Health Canada to obtain marketing approval for Gynoflor™ in Canada. At the time of this filing, there were no approved products in Canada containing estriol, or the unique combination of estrogen and lactobacillus.

On April 5, 2017, Hyundai filed for the marketing approval of Natesto® with the Ministry of Food and Drug Safety (MFDS) in South Korea.

The Corporation has entered into the following license, development and supply agreements with regards to Natesto® on the dates set forth below:

| Date              | Company  | Territory  | Terms  |
|-------------------|--|--|--|
| June 5, 2017      | Therios Healthcare ("Therios")                               | Saudi Arabia, United Arab Emirates, and Egypt  | <ul style="list-style-type: none"> <li>• Fixed supply price per unit</li> </ul>  |
| June 14, 2017     | medac Gesellschaft für Klinische Spezialpraxis mbH ("medac") | 15 European countries (Germany, United Kingdom, France, Italy, Czech Republic, Slovakia, Spain, Sweden, Finland, Denmark, Norway, Poland, Austria, Netherland and Belgium) | <ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payments upon marketing approval in certain countries as well as milestone payments based on sales targets</li> <li>• Tiered supply price per unit</li> </ul> |
| October 17, 2017  | Eu Hwa Pte LTD. ("EU")                                       | Thailand, Malaysia/Brunei, Singapore, Vietnam, Philippines, Hong Kong/Macau and one other small South East Asian country   | <ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment upon submission of certain regulatory data and on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>                              |
| November 23, 2017 | Apsen Farmacêutica ("Apsen")                                 | Brazil   | <ul style="list-style-type: none"> <li>• Non-refundable upfront fee</li> <li>• Milestone payment on regulatory approval</li> <li>• Tiered supply price per unit</li> </ul>   |

On December 6, 2017, the Corporation entered into a senior secured term credit facility with Quantius Inc. ("Quantius") for gross proceeds of up to CDN\$5.0 million, of which CDN\$3.0 million was disbursed at closing, with the remaining CDN\$2.0 million becoming available upon satisfaction of certain future conditions, including (i) Aytu achieving a pre-determined number of prescriptions per month for Natesto® in the U.S., and (ii) maintaining Estrace® sales at a pre-determined minimum level. The credit facility bears interest at a rate equivalent to the Bank of Canada prime rate plus 11.05% and matures on December 1, 2019. The credit facility is repayable in monthly instalments of 1/48 of the balance owing commencing December 1, 2018 with the remaining balance due at maturity. As part of the transaction, Quantius received an underwriting fee representing low single digit percentage of the maximum facility amount and will receive a royalty fee representing low single digit percentage on the Corporation's revenues over the term of the facility, capped at a high single digit percentage of the borrowed amount. Under terms of the agreement, the Corporation will have the option to prepay the loan with the payment of low single digit prepayment penalties. The prepayment penalties will be fully offset against the royalty fee payable at the time of termination. The terms of the agreement also contain customary financial covenants.

On December 20, 2017, the Corporation entered into a license, development and supply agreement with Viramal Limited ("Viramal"), a London-based specialty pharmaceutical company, granting the Corporation exclusive rights to commercialize the Elegant™ franchise in Canada. The Elegant™

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

On December 24, 2017 the Corporation received a Notice of Deficiency (“NOD”) on its Gynoflor™ submission. In its notice, Health Canada requested additional technical information on Gynoflor™ in order to complete its assessment of the product, which the Corporation believes will cause a delay in the review process.

On January 8, 2018 the Corporation entered into an exclusive distributor and license agreement with Innovus Pharmaceuticals, Inc. (“**Innovus**”), granting the Corporation the exclusive rights to commercialize UriVarx® in Canada. UriVarx® is a Natural Health Product (NHP) that helps reduce symptoms of hyperactive bladder such as daytime urinary frequency, urgency and nocturia. The product was recently approved by Health Canada and will be offered over-the-counter to Canadians dealing with such symptoms. Under the terms of the exclusive distributor and license agreement, the Corporation paid an upfront payment at signing and will pay milestone payments based on the Corporation achieving certain sales targets. Innovus will oversee the manufacturing of UriVarx® and will receive a supply price for the product.

On February 1, 2018, following a positive recommendation from Quebec’s National Institute for Excellence in Health and Social Services (“**INESSS**”) to the Health Minister, Natesto® was included on the list of medications of the Régie de l’assurance maladie du Québec.

On March 15, 2018, the Endo Note was amended such that principal repayments under the Endo Note would now be made annually on December 31, 2018 of each year instead of quarterly. Payments of interest will continue to be made quarterly.

### **Intercorporate Relationships**

The Corporation is the parent corporation to two wholly-owned subsidiaries. The Corporation owns a 100% interest in Acerus Labs Inc. (“**Acerus Labs**”), which was incorporated under the laws of the Province of Ontario on June 19, 2017, and Acerus Biopharma Inc. (“**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.

The Corporation is the principal operating entity of the business of the Corporation relating to Gynoflor™, UriVarx® and Viramal™, and is the owner or licensee, as applicable, of the intellectual property required for the conduct of such businesses.

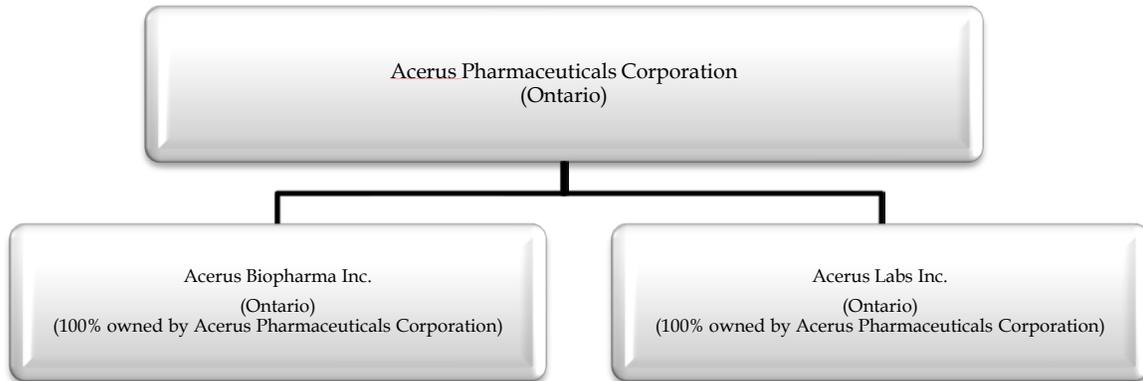
Acerus Biopharma is the principal operating entity of the business of the Corporation relating to Natesto®, Tefina™ and TriVair™ and is the owner or licensee, as applicable, of the intellectual property required for the conduct of such businesses.

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.

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 Canadian-based specialty pharmaceutical company focused on the development, manufacture, marketing and distribution of branded products that improve patient experience, with a primary focus in the field of men's and women's health. The Corporation commercializes its products via its own salesforce in Canada, and through a global network of licensed distributors in the U.S. and other territories.

The Corporation currently has three marketed products:

- (1) Estrace®, a product for the symptomatic relief of menopausal symptoms, is commercialized in Canada;
- (2) 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 for distribution in 29 additional countries worldwide. Marketing approvals for Natesto® in jurisdictions outside of North America are expected to take place over the course of the coming years; and
- (3) UriVarx®, a Natural Health Product that helps reduce symptoms of hyperactive bladder such as daytime urinary frequency, urgency and nocturia. UriVarx® was recently approved by Health Canada and will be offered over-the-counter to Canadians dealing with such symptoms.

The Corporation's pipeline of products includes four innovative products:

- (1) Elegant™ Vaginal Moisturizer, which provides comfort to women suffering from vaginal dryness;
- (2) Elegant™ pH, which is a pH balanced vaginal product;

(3) Gynoflor™, an ultra-low dose vaginal estrogen combined with a probiotic, for which a NDS has been filed in Canada for the treatment of vaginal atrophy, restoration of vaginal flora and treatment of certain vaginal infections; and

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

In addition, 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 stage of development.

## **Products**

### *The Corporation's Development Technology*

#### Natesto® and Tefina™ Technology

Pursuant to the intellectual property rights and development agreement (the “**IP Agreement**”) with M&P Patent AG (since renamed Mattern Pharma AG)(“**Mattern Pharma**”) (see “*Material Contracts*” below), the Corporation has licensed 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 Pharma, the Corporation has developed a multi-dose nasal dispenser (the “**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.

#### 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 a third party, 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 relates to the delivering of 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, is currently working on setting up a series of pharmacokinetic clinical trials, and is actively looking at potential partnering transactions for these initiatives.

## *The Corporation's Product Portfolio*

### Natesto® - Male Hypogonadism

The Corporation's first 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 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. When comparing Natesto® versus currently marketed topical testosterone gel preparations, the Corporation believes that in addition to the avoidance of skin transference risks, enhanced patient compliance may be derived from the ease of application and the convenient dosing via the novel multi-dose nasal dispenser.

Natesto® was approved for sale in the United States by the FDA in May 2014, as described under "*Recent Developments*" above. 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. As described under "*Recent Developments*" above, 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.

The Corporation markets Natesto® through a dedicated sales force to Primary Care physicians, Urologists and Endocrinologists. Natesto® is principally sold through independent wholesale distributors.

In September 2016, the Corporation initiated an open-label study in approximately 120 hypogonadal males in 11 Canadian centers. The study assessed a modified titration methodology, which is simplified and more in line with Canadian Men's Health Foundation Multidisciplinary Guidelines as endorsed by both the Canadian Urological Association and the Canadian Society of Endocrinology and Metabolism. The study also captured information on the change in symptoms from baseline and patient preference relative to their study medication, for patients having prior experience on TRT therapy. The study was closed in November 2017. The Corporation has completed the key data analysis, the study report is currently being finalized and the Corporation is aiming to submit the study for publication in 2018.

Additionally, the Corporation is pursuing a global expansion of the Natesto® platform via implementation of additional commercial partnerships in other jurisdictions, as further described under "*Recent Developments*" above.

### Estrace® - Menopausal Symptoms

The Corporation acquired the Canadian rights to Estrace® from affiliates of Shire plc in July 2014.

Estrace® provides symptomatic relief of menopausal symptoms and may also contribute to the prevention of osteoporosis in naturally occurring or surgically induced estrogen-deficiency. Estrace® is an oral tablet that is available in three dosage strengths (0.5 mg, 1.0 mg and 2.0 mg). Other than as described under “*Recent Developments*” above with respect to the launch of a third party generic version of Estrace® in 2016, Estrace® is still the only oral 17-beta estradiol currently available in Canada.

Estrace® has been available on the Canadian market for approximately 40 years and generated net sales of CDN\$5.7 million in 2017.

### UriVarx® - hyperactive bladder

As described under “*Recent Developments*” above, the Corporation licensed the exclusive right to commercialize UriVarx® in Canada from Innovus on January 8, 2018.

UriVarx® is a Natural Health Product (NHP) that helps reduce symptoms of hyperactive bladder such as daytime urinary frequency, urgency and nocturia. The product was recently approved by Health Canada and will be offered over-the-counter to Canadians dealing with such symptoms.

Nearly 1 in 5 Canadians over the age of 35 experiences overactive bladder symptoms. Men and women’s lives are directly impacted by an overactive bladder, and the current treatment options may come with systemic side effects.

### Gynoflor™ Product Pipeline

Gynoflor™ is an ultra-low dose estrogen (estriol) and probiotic (*Lactobacillus acidophilus*) combination vaginal tablet used for the treatment of symptoms of vaginal atrophy, for the restoration of vaginal flora following the use of anti-infectives and for the treatment of certain vaginal infections.

Gynoflor™ has been approved in 41 countries across Europe, Asia-Pacific, the Middle East, Africa and South America, and it is estimated that up to 32.7 million women worldwide have been treated with the product to date.

On February 28, 2017, the Corporation submitted a NDS to Health Canada to obtain marketing approval for the product in Canada. Currently, there are no approved estriol + lactobacillus products on the Canadian market.

As described under “*Recent Developments*” above, on December 24, 2017 the Corporation received a NOD. In its notice, Health Canada requested additional technical information on Gynoflor™ in order to complete its assessment of the product, which the Corporation believes will cause a delay in the review process. The Corporation is currently working on responding to the NOD and currently intends to focus on the vaginal atrophy indication in its response to Health Canada. If Health Canada approves the Corporation’s revised submissions in response to the NOD, the Corporation would expect to receive approval for Gynoflor™ in the first half of 2019. The Corporation may revisit with Health Canada at a later date the indications for restoration of vaginal flora following the use of anti-infectives and for the treatment of certain vaginal infections.

### Elegant™ Product Pipeline

As described under “Recent Developments” above, the Corporation licensed the exclusive right to commercialize the Elegant™ franchise in Canada from Viramal on December 20, 2017.

The Elegant™ franchise comprises Elegant™ Vaginal Moisturizer, which provides comfort to women suffering from vaginal dryness, and Elegant™ pH, which is a pH balanced vaginal product. Vaginal dryness is most common in post-menopausal women and those suffering from vaginal atrophy. Vaginal dryness has been estimated to occur in 21% of women within one year of menopause and 47% by the third year of the menopausal transition. Elegant™ Vaginal Moisturizer and Elegant™ pH are over-the-counter products designed to be a more user-friendly alternative over Replens™ and RepHresh™ (both of which are trademarks of Church & Dwight Co. Inc.), which are market leaders in Canada.

### 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.

Study analysis concluded that of the 56 pre-menopausal women that participated in the study during the VTS treatment phase and were included in the endpoint analysis (45 of which having been administered Tefina™), four women who were administered Tefina™ self-reported an orgasm during VTS treatment, while an additional eight patients treated with Tefina™ reported sensations indicative of an actual orgasm as part of the post-treatment exit interview. Of the patients in the placebo arm (n=11), two patients self-reported an orgasm during the VTS treatment, however one of these two patients is believed to have experienced an orgasm during the screening portion of the study, and should have been excluded from proceeding into the treatment phase. Patients treated with Tefina™ demonstrated a statistically significant improvement in vaginal pulse amplitude (a physiological measurement of blood flow in the vagina corresponding with engorgement of female genitalia) versus placebo, and elevation of sexual arousal, as well as positive trends in terms of elevating sensuality, sexual desire and pleasurable genital sensation.

In May 2014, the Corporation announced the results of its second Phase 2 trial commenced in May 2012. The double-blind, placebo-controlled study enrolled 253 pre- and post-menopausal women experiencing acquired FOD in the United States, Canada and Australia. Participants were randomized to one of three dosage strengths (0.6 mg, 1.2 mg, 1.8 mg) or a placebo group and treated over the course of 84 days. The primary endpoint of the study related to the effects of the three dose strengths of Tefina™ nasal testosterone gel to placebo on the occurrence of orgasm. Secondary endpoints included the change from baseline in distress due to orgasmic disorder, change in sexual functioning and sexual event satisfaction (although the trial was not powered to demonstrate

statistical significance for the secondary endpoints). Safety and tolerability were also assessed. The trial demonstrated statistically significant results for certain primary and secondary endpoints (at the 0.6 mg dose of Tefina™) and certain other encouraging findings.

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. Per FDA guidance, questionnaires such as the FSDS-DAO, which are intended for use in future Phase 3 trials, must be validated in the patient population. 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 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 approval of Addyi™ (flibanserin) in August 2015, signalled a clear pathway to approval in the indication of Hyposexual Desire Disorder (HSDD), the most prevalent category of FSD and was a key event that led the Corporation to redirect attention to this indication for future development of Tefina™.

#### TriVair™ Product Pipeline

On October 13, 2015, Acerus Biopharma entered into an intellectual property rights and development agreement with a third party pursuant to which the applicable third party 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 Bioharma is entitled to certain milestone and royalty payments upon the achievement of certain regulatory, clinical and commercial events.

### **Markets, Applications and Competition**

#### *Male Hypogonadism*

##### U.S. Market

Male hypogonadism – commonly known as “Low T” – 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 2017, the total United States TRT market saw over 6.8 million prescriptions reported, an increase of approximately 7% over the previous 12-month period. Sales of total TRT products for 2017 were US\$1.8 billion with a decline of 0.8% from 2016, mostly driven by the availability of generics. In terms of market share, topical products represent more than 83% of the total sales, with injectables making up most of the remainder.

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 previous 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 as well as a buccal patch. Additionally, at least one potential oral treatment is in the later stages of development, but has not yet been approved in the United States and has encountered some regulatory hurdles (see next section below).

### U.S. Competitive Landscape

AndroGel® (Abbvie) is the leading brand in the TRT market. A generic version of AndroGel® 1.62% could be approved for sale at any time based on an undisclosed settlement agreement. Further generic forms of other topical gels may also potentially become available at some point. Axiron® (Lilly) was discontinued in 2017.

All marketed topical gel testosterone products, including AndroGel®, became subject to a 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.

As at the date of this Annual Information Form the Corporation is aware of certain late stage development programs that could enter the competitive landscape in the next few years. In particular, the Corporation understands that Lipocine Inc. had submitted a New Drug Application (“NDA”) for its oral testosterone replacement drug candidate, which the FDA rejected in June 2016, but that Lipocine conducted further clinical trials to satisfy the FDA. In January 2018, Lipocine announced that the Reproductive and Urologic Drugs Advisory Committee (“BRUDAC”) of the U.S. FDA voted six in favor and thirteen against the benefit/risk profile of Tlando™, Lipocine's oral testosterone product candidate for testosterone replacement therapy in adult males suffering from hypogonadism. In addition, BRUDAC was also considering a testosterone replacement therapy product called Jatenzo™, owned by Clarus Therapeutics, Inc., and voted 10–9 against approval of Jatenzo™ on January 9, 2018. Although the FDA will consider the recommendation of BRUDAC, the final decision regarding the approval of Tlando™ and Jatenzo™ will be made by the FDA, and the recommendations by BRUDAC are non-binding.

### Canadian Market

In Canada, there were over 593,000 TRT prescriptions dispensed in 2017, a growth of 3.8% over the previous year.

Topical treatments represent 49.4%, oral treatments represent 18.6%, and injectable treatments represent 32.0% of the total prescription TRT market in 2017. The 2017 prescription growth over the prior year for each of these categories saw an increase of 2.0% for topical treatments, a decrease of 5.2% for oral treatments and an increase of 13.0% 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 2016 and 2017. The increase in prescriptions seen in 2017 for the TRT market was the second consecutive year of growth.

In Canada, sales of total TRT products for 2016 were CDN\$66.7 million with an increase of 3.6% from 2015. Topical products made up 78% of all dollar sales in the TRT market. In Canada, sales of total TRT products for six months ending June 2017 were CDN\$33.4 million with a growth of 3.0% from the first six months in 2016.

#### Canada Competitive Landscape

AndroGel® (BGP Pharma ULC, a division of Mylan) is 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.

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.

#### *Female Sexual Dysfunction*

#### U.S. Market

Female sexual dysfunction consists of three recognized disorders in the Diagnostic and Statistical Manual of Mental Disorders (5<sup>th</sup> 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.

At present, 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 (Rekynda™ (Palatin)), an injectable formulation for on-demand treatment of HSDD in pre-menopausal women, has completed two Phase 3 trials. The anticipated filing date in the U.S. for a NDA for Rekynda™ is in early 2018, with an anticipated approval and launch by early 2019, if approved. 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 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 (Rekynda™ (Palatin)), an injectable formulation for on-demand treatment HSDD in pre-menopausal women, has an anticipated filing date in the U.S. for a NDA for Rekynda of early 2018, with an anticipated approval and launch by early 2019. In February 2017, AMAG Pharmaceuticals completed a licensing deal with Palatin for exclusive North American commercial rights.

### Canadian Market

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

#### *Female Menopausal Symptoms*

### Canadian Market

Estrogen-only hormone replacement therapy (HRT) was first approved in 1942 by the FDA for the treatment of menopausal symptoms, such as hot flashes, sleep disturbances and vaginal/vulvar atrophy. In the mid-1970s, several studies heightened the relationship between HRT and increased risk of endometrial cancer, leading to concerns and confusion about the safety of HRT. As a result, HRT use declined through the 1980s and into the 1990s. Later in the decade, new evidence on the benefits and risks of HRT emerged; some showing reductions in hip fractures and coronary heart disease, while others linked HRT to an increased risk of breast cancer. This led to conflicting usage and prescribing patterns, particularly following publication of the Women's Health Initiative (WHI) study in 2002. This study concluded that overall health risks exceeded benefits from the use of combination estrogen and progestin, or estrogen-only HRT for chronic disease prevention among healthy, post-menopausal women, and that practice guidelines should instead focus on the therapeutic use of HRT. As such, HRT safety and prescribing recommendations have since been addressed and updated as recently as 2014 by the American Congress of Obstetricians and Gynecologists (ACOG), the North American Menopause Society (NAMS) and the Society of Obstetricians and Gynaecologists of Canada (SOGC). The current menopause guidelines now endorse the primary indication for HRT to be for the management of moderate to severe menopausal symptoms, and suggest that it be prescribed at the lowest effective dose and for the appropriate duration to achieve the treatment goals, considering the potential risks and benefits of each patient.

There are a variety of estrogen-only HRT products available in Canada, including both conjugated equine estrogens and natural (plant) source estrogen oral tablets, as well as newer routes of administration/formulations introduced within the last ten years, such as transdermal patches and gels, and vaginal rings and suppositories.

It is estimated that approximately 3.9 million women in Canada are between the ages of 45-59, and could benefit from hormone replacement therapy. For the 12 months ending December 2016, the total Canadian estrogen only HRT market reported sales in excess of CDN\$111 million, having grown 4.3% over the previous 12-month period. For the six months ending June 2017, the total Canadian estrogen only HRT market reported sales in excess of CDN\$54.8 million, with growth of 4.5% over the previous six month period in 2016.

### Canadian Competitive Landscape

As at December 31, 2017, Estrace® (Acerus) remains one of the highest prescribed HRT brand on the Canadian market. The top brands (by dollar sales) are Vagifem® (Novo Nordisk), an estradiol vaginal tablet, Premarin® (Pfizer), a conjugated equine estrogens oral tablet, Estrogel® (Merck), a 17-beta estradiol (a natural source estrogen) transdermal gel, and Estrace® (Acerus), a 17-beta estradiol (natural source) oral tablet. There are significant differentiating factors between the leading brands, from a medical perspective relating to (i) the estrogen source, (ii) patient convenience and (iii) compliance factors with respect to the method of delivery, and from a market access standpoint with (a) varying prices between the brands and (b) availability of private/public coverage across the provinces. At present, Estrace® represents the lowest-cost branded therapy option available for Canadian women seeking to use estrogen-based HRT therapies, with comprehensive private coverage and full public reimbursement available in all provinces of Canada other than Ontario.

In November 2015, Health Canada granted a Notice of Compliance (NOC) for a third party generic version of Estrace®, which obtained public reimbursement across major provinces as of July 2016 and is commercially available in Canada. As expected, Estrace® sales have decreased in 2017 due to the generic presence in the market. The Corporation is closely monitoring the situation and has implemented initiatives which can potentially minimize the further decline of sales going forward.

*Vaginal Atrophy, Restoration of Vaginal Flora and Vaginal Infections*

Market

Gynoflor™, if approved by Health Canada, may be used in multiple therapeutic areas; including both the vaginal atrophy and the vaginal infection markets, although in responding to the NOD, the Corporation will be focusing first on the vaginal atrophy indication.

Up to 55% of peri-menopausal and post-menopausal women suffer from vaginal atrophy (in excess of 2 million Canadian women). The vaginal atrophy market in 2016 totalled CDN\$57.7 million, with a growth of 8.3% over the prior year. The vaginal atrophy market for the first six months in 2017 totalled just over CDN\$29.3 million with a decline of 2% over the previous six month period.

In 2017 there were in excess of 1,000,000 prescriptions written in the vaginal atrophy market. Vagifem 10® (Novo Nordisk) is the most prescribed product in this market with 56% market share.

With respect to the treatment of restitution of vaginal flora, approximately 75 per cent of women will experience at least one episode of vulvovaginal candidiasis (the most common type of vaginal infection) during their lifetime, and five to ten per cent will have more than one episode. As well, it is estimated by Health Canada that 10-30% of pregnant women and 10% of family practice patients will have an episode of a vaginal infection.

The vulvovaginal candidiasis market was estimated at CDN\$37.9 million in 2016. This represents both RX and OTC products. The vulvovaginal candidiaseis market for the first six months in 2017 is estimated at CDN\$16 million. Diflucan® (Pfizer) and CanesOral® (Bayer) are the market leaders.

Competitive landscape

For the indication of vaginal atrophy due to menopause, Gynoflor™, if approved, will primarily compete against Vagifem® (Novo Nordisk), an estradiol vaginal tablet also indicated for vaginal atrophy due to menopause.

In the treatment of vaginal infections, Gynoflor™, if approved, may compete with products used to treat mild vaginal infections as well as products for pH maintenance. Products for vaginal infections include both RX and OTC products and may include metronidazole (Flagyl®), clindamycin (Dalacin®) as well as RepHresh® and Vagisil pH®.

In the restoration of vaginal flora, Gynoflor™, if approved, would compete with various standalone OTC products aimed at restoring the vaginal flora.

*Overactive Bladder*

Market

UriVarx®, approved by Health Canada as a Natural Health Product, may be used to help reduce symptoms of overactive bladder such as daytime urinary frequency, urgency and nocturia.

In Canada, it is estimated that 18.1% of men and women aged 35 years and older suffer from overactive bladder, with the prevalence being lower in men (14.8%) than in women (21.2%). The overactive bladder and nocturia market in 2016 totalled CDN\$119 million for prescription products, with a decline of 21% from the previous year. The decline in sales for 2016 was due in part to loss of patent on Detrol LA® (Pfizer) and Vesicare® (Astellas). There are also numerous natural health products available for overactive bladder, but estimating the market size is challenging.

### Competitive Landscape

For the indication of overactive bladder and nocturia, UriVarx®, will primarily compete against both Rx and OTC Products. Rx products that are used to treat overactive bladder are Toviaz® (Pfizer), Enablex® (Merus Labs) and Myrtbetriq® (Astellas) as well as Detrol LA® (Pfizer) and Vesicare® (Astellas) that have now both lost patent protection. OTC products that will compete with UriVarx® include Overactive Bladder® (Jamieson) and other natural health products that have been approved for overactive bladder.

Vaginal Dryness (*Vulvovaginal Atrophy*) and pH

### Market

Elegant™ Vaginal Moisturizer, if approved by Health Canada, may be used to provide comfort to women suffering from Vaginal Dryness (vulvovaginal atrophy).

In North America, it is estimated that vulvovaginal atrophy may affect up to 40% (2.3M) of midlife and older women. Approximately 25% of these women seek treatment and it is estimated that over 300,000 patients are being treated annually. The market is dominated by OTC products, and includes Replens™ (Church & Dwight Co) as the #1 market leader.

Elegant™ pH, which is a pH balanced vaginal product may, if approved by Health Canada, be used by women suffering from mild vaginal infections or seeking to maintain a healthy vaginal pH.

With respect to vaginal infections and vaginal pH, it is estimated by Health Canada that 10-30% of pregnant women and 10% of family practice patients will have an episode of a vaginal infection. Vaginal pH of a healthy vagina is 3.5 to 4.5, which is acidic. When feminine pH is unbalanced, odour-causing microorganisms can flourish and women may be more susceptible to developing a vaginal infection. There are several OTC products available to help maintain vaginal pH.

### Competitive Landscape

In the vulvovaginal atrophy market, Elegant™ Vaginal Moisturizer will primarily compete against OTC products, such as Replens™ (Church & Dwight Co), RepaGyn® (BioSyvent), Gynatrof® (Tyros) and Zestica Moisture® (Bescot Pharma).

In the vaginal infections and pH maintenance market, Elegant™ pH, if approved by Health Canada, may compete with products used to treat mild vaginal infections as well as products for pH maintenance. Products for vaginal infections include both Rx and OTC products and may include metronidazole (Flagyl®), clindamycin (Dalacin®) as well as RepHresh® (Church & Dwight) and Vagisil pH® (Combe Incorporated).

### **Employees**

As at the date of this Annual Information Form, the Corporation and its subsidiaries collectively have 23 full time employees, of which seven work in clinical/manufacturing and R&D, twelve work in commercialization and business development, and the remainder are part of the Corporation's administration or management. In Q4 2017, the Corporation transitioned from using a contract sales force to directly employing its own full-time sales representatives. As of the date of this Annual Information Form, the Corporation had eight representatives detailing Natesto® and Estrace® to urologist, endocrinologists, gynecologist and high prescribing general practitioners. The Corporation anticipates strategically building its direct salesforce to take advantage of market opportunities, expand its territorial coverage and in preparation for new product launches.

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. If issued, these patents applications may provide protection for Natesto® until 2032, but may provide protection up to 2034 in the U.S.

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

#### 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 and Barbados.

*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*

A number of patent applications have been prepared and filed with respect to the Corporation's Cannabinoids Initiative, 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, 2017 the Corporation had positive working capital of \$2.8 million and during the three years ended December 31, 2017, the Corporation has incurred total net losses of \$8.7 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*

The Corporation has only begun to market and generate revenues from the commercialization of its products relatively recently. With the exception of Natesto®, Estrace®, Gynoflor™, the Elegant™ franchise and UriVarx®, the Corporation's product candidates are not expected to be commercially available for several years, if at all. Tefina™, for instance, will require additional clinical testing and/or investment prior to commercialization. A commitment of substantial resources by the Corporation to conduct time-consuming research and clinical trials would be required if it is to complete the development of Tefina™. There can be no assurance that Tefina™ or 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 the Corporation's partner for Natesto® in the United States and in the rest of the world are not able to successfully commercialize the product, 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 and 2017), 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;
- 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, including, without limitation, as a result of the commercial availability of third party generic version of Estrace®; 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.

### *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 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 under "*Recent Developments*" above, a notice of compliance was issued by Health Canada for a third party version of Estrace®, which is 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.

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 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 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, 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. 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 candidate 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 FDA announced that it was undertaking an investigation of the risk of stroke, heart attack and death in men taking 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 FDA considered this issue. The FDA presented its own conclusions that it was unable to establish any conclusive link between testosterone replacement therapy and cardiovascular risks as reported in this 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 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 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 is in negotiations with other pharmaceutical companies to form a consortium to conduct the clinical trial. As a consortium member, the Corporation will be responsible for funding its proportion of the study costs, which are estimated to be \$2.0 M over the life of the study, based on current study cost projections (additional information on the study will be forthcoming on [clinicaltrials.gov](http://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.

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 has retired the MidCap Agreement, issued a note in favour of Endo and entered into a senior secured credit facility with Quantius. The terms of the Quantius loan facility include certain restrictions requiring the Corporation to dedicate a portion of its cash to payments on a monthly basis (which the Corporation's operational cash flows may not fully support) and maintain a minimum cash balance, thereby reducing the availability of cash to fund working capital, capital expenditures and other general corporate purposes. Additionally, the Quantius loan facility includes certain restrictions on the ability of the Corporation's ability to borrow additional funds, even where necessary to maintain adequate liquidity. The ability of the Corporation to repay its indebtedness under the Quantius loan facility will be contingent upon the Corporation receiving sufficient revenues or other cash proceeds to be able to make the necessary payments.

Additionally, all of the assets of the Corporation and its subsidiaries are subject to a senior secured interest in favour of Quantius in support of the Corporation's obligations under the Quantius loan facility. Consequently, a default under the Quantius loan facility would have a material adverse effect on the Corporation.

Additionally, the Corporation has certain early repayments obligations under the Endo Note that may limit its ability to use all of the proceeds from certain transactions for general purposes. Finally, a default under the outstanding debts would accelerate repayment and may have a material adverse effect on the Corporation.

For further information please see filings available on SEDAR at [www.sedar.com](http://www.sedar.com).

#### ***Marketing and Distribution Risk***

Except for the various partnership for Natesto® described more fully under "Recent Developments" above, the Corporation currently does not have arrangements with commercial partners to market, sell or distribute its products. 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.

### ***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. This could result in production delays, substantial lost revenue opportunity, clinical trial delays or contract liability to third parties. 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.

### ***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. 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 the Corporation.

### ***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. 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 the Corporation.

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.

#### *Reliance on Data Obtained from IMS*

The Corporation relies on operational data obtained from IMS, an industry accepted data source. IMS data may not accurately reflect actual prescriptions. If IMS 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.

#### *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 these 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 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. 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 results or delays in any clinical or non-clinical trials;
- announcements of 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.

***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 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.

### *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 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 is or 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 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 that vest over time, 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 Common Shares. Dilution may similarly be experienced by the grant of additional stock options pursuant to the 2015 stock option plan of the Corporation (the "**Stock Option Plan**").

#### *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.

#### ***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 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.

#### ***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.

#### ***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.

### ***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 than 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, efficient or convenient in the treatment of hypogonadism, or if the medical industry determined that another pre-existing product was more effective, 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 three products (Estrace®, Natesto® and UriVarx®) and revenues from these products, as well as revenues from the sales of Gynoflor™ and the Elegant™ franchise 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, the business, financial condition and operating results of the Corporation would be adversely impacted.

At present, Natesto® revenues are received almost entirely from (i) Aytu in accordance with the Aytu Agreement and (ii) a small number of Canadian pharmaceutical wholesalers. Estrace® revenues are earned from a small number of Canadian pharmaceutical wholesalers. 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. 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.

#### ***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.

### **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, 213,118,645 Acerus Common Shares are issued and outstanding.

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.

#### **Stock Options**

The Stock Option 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 Stock Option Plan.

The Stock Option 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 Stock Option 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 number of Acerus Common Shares reserved for issuance to any one person shall not exceed 5% of the issued and outstanding Acerus Common Shares.

The Stock Option 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 the applicable option.

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

- (a) the maximum number of Acerus Common Shares reserved for issuance under the Stock Option Plan;
- (b) a reduction in the exercise price for options held by insiders (as defined in the *Securities Act* (Ontario) and here "**Insiders**");
- (c) an extension to the term of any option held by Insiders;
- (d) an increase in any limit on grants of options to Insiders; and
- (e) any amendment that is not necessary to ensure continuing compliance with applicable laws or of a "housekeeping" nature.

As of the date hereof, there are outstanding: (a) options to purchase 17,316,200 Acerus Common Shares with a weighted average exercise price of CDN\$0.23 and a weighted average contractual life of 3.3 years.

A complete summary of the Stock Option Plan is available in the management information circular of the Corporation dated May 5, 2015 which is available on SEDAR at [www.sedar.com](http://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 MidCap Agreement, MidCap was issued warrants exercisable for an aggregate of 3,034,814 Acerus Common Shares. The warrants are exercisable for seven years at an exercise price of CDN\$0.7095.

## **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 2017 were as follows:

|             | Share Price (\$)<br>(in Canadian Dollars) |       | Average Daily<br>Trading Volume of<br>Shares |
|-------------|---|-------|--|
|             | High                                      | Low   |  |
| <b>2017</b> |   |       |  |
| January     | 0.150                                     | 0.130 | 231,276                                      |
| February    | 0.145                                     | 0.125 | 201,844                                      |
| March       | 0.135                                     | 0.100 | 369,020                                      |
| April       | 0.135                                     | 0.105 | 193,432                                      |
| May         | 0.135                                     | 0.110 | 120,297                                      |
| June        | 0.140                                     | 0.100 | 185,070                                      |
| July        | 0.130                                     | 0.110 | 44,958                                       |
| August      | 0.125                                     | 0.100 | 86,547                                       |
| September   | 0.115                                     | 0.095 | 214,342                                      |
| October     | 0.135                                     | 0.100 | 179,476                                      |
| November    | 0.520                                     | 0.115 | 1,319,678                                    |
| December    | 0.380                                     | 0.260 | 548,332                                      |

### Prior Sales

During 2017, the Corporation issued the following securities:

| Security                | Date of<br>Issue/Grant | Price Per Security | Number of<br>Securities |
|-------------------------|------------------------|--------------------|-------------------------|
| Acerus Stock<br>Options | March 10, 2017         | CDN\$0.12          | 4,810,000               |
|                         | May 18, 2017           | CDN\$0.13          | 900,000                 |
|                         | June 1, 2017           | CDN\$0.11          | 500,000                 |
|                         | Jun 12, 2017           | CDN\$0.11          | 50,000                  |
|                         | Sep 17, 2017           | CDN\$0.11          | 425,000                 |
|                         | Nov 9, 2017            | CDN\$0.12          | 3,235,000               |
|                         | Nov 22, 2017           | CDN\$0.17          | 20,000                  |
|                         | Dec 6, 2017            | CDN\$0.36          | 200,000                 |
|                         | Dec 11, 2017           | CDN\$0.35          | 35,000                  |

## 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 six.

Five of the six current directors are independent of the management of the Corporation. Mr. Mainville is currently Interim Chief Executive Officer of the Corporation. Accordingly, Mainville is non-independent for purposes of applicable securities laws.

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   |
|---|-------------------|---|---|
| Norma Beauchamp<br>Director<br>Ontario, Canada                | June 26, 2015     | <ol style="list-style-type: none"> <li>1. Audit Committee</li> <li>2. Corporate Governance &amp; Nominating Committee (Chair)</li> </ol>                                  | <p>Director and Chair of the Corporate Governance and Compensation Committee, MedReleaf Corp. (June 2017 – present)</p> <p>President and Chief Executive Officer, Cystic Fibrosis Canada (November 2014 – November 2017)</p> <p>Head, MS Patient-Centered Care, Sanofi Canada (July 2013 – August 2014)</p> <p>President, Healthcare Consulting (February 2009 – July 2013)</p> |
| Borys Chabursky<br>Director<br>Ontario, Canada                | December 20, 2015 | <ol style="list-style-type: none"> <li>1. Corporate Governance &amp; Nominating Committee</li> <li>2. Compensation Committee</li> </ol>                                   | <p>Founder and Chairman, Shift Health (February 2011 – Present)</p> <p>Chairman, SHI Capital (February 2011 – Present)</p> <p>President, SHI Ventures (February 2011 – Present)</p>   |
| Stephen Gregory,<br>Director<br>Quebec, Canada                | July 14, 2011     | <ol style="list-style-type: none"> <li>1. Corporate Governance and Nominating Committee</li> <li>2. Compensation Committee (Chair)</li> <li>3. Audit Committee</li> </ol> | <p>President, IsaiX Technologies Inc. (March 1989 to present)</p>   |
| Ian O. Ihnatowycz<br>Chairman of the Board<br>Ontario, Canada | September 9, 2013 | None  | <p>President and Chief Executive Officer, First Generation Capital Inc. (April 2011 to present)</p> <p>Chairman, President and Chief Executive Officer, Acuity Investment Management Inc. and Acuity Funds Ltd. (1990 to February 2011)</p>   |
| J. Mark Lievonen,<br>Director<br>Ontario, Canada              | December 6, 2018  | <ol style="list-style-type: none"> <li>1. Audit Committee (Chair)</li> <li>2. Compensation Committee</li> </ol>   | <p>Director, Oncolytics Biotech Inc. (April 2004 to present)</p> <p>Director, Quest Pharmatech Inc. (July 2017 to present)</p> <p>President, Sanofi Pasteur Limited (March 1999 to December 2016)</p>   |

| Name, Province or State and Country, Position Held | Director Since | Standing Board Committee Memberships | Principal Occupation During the Previous Five Years  |
|--|----------------|--------------------------------------|--|
| Luc Mainville,<br>Director<br>Quebec, Canada       | July 21, 2016  | None                                 | Interim CEO of Acerus Pharmaceuticals Corporation (October 2, 2017 to present)<br>Chairman of the board of directors, Zucara Therapeutics Inc. (August 2017 to present)<br>President, LUMA Life and Luma Capital (December 2011 to present)<br>Executive Vice President, Cardiome Pharma Corp. (January 2016 to December 2016)<br>President & CEO, Neopharm Labs Inc. (July 2012 to July 2015)<br>Vice-Chairman, BIOTECanada (November 2010 to May 2012)<br>Board Member, Enobia Pharma (August 2007 to February 2012) |

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  |
|--|---------------------------------|--|
| Luc Mainville<br>Quebec, Canada                  | Interim Chief Executive Officer | Interim CEO of Acerus Pharmaceuticals Corporation (October 2, 2017 to present)<br>Chairman of the board of directors, Zucara Therapeutics Inc. (August 2017 to present)<br>President, LUMA Life and Luma Capital (December 2011 to present)<br>Executive Vice President, Cardiome Pharma Corp. (January 2016 to December 2016)<br>President & CEO, Neopharm Labs Inc. (July 2012 to July 2015)<br>Vice-Chairman, BIOTECanada (November 2010 to May 2012)<br>Board Member, Enobia Pharma (August 2007 to February 2012) |

| Name, Province or State and Country of Residence | Officer's Title   | Principal Occupation During the Previous Five Years  |
|--|---|--|
| Patricia Symmes<br>Ontario, Canada               | Chief Operating Officer                                 | Chief Operating Officer, Acerus Pharmaceuticals Corporation (November 2016 - present)<br>General Manager, Alcon Canada (June 2015 - August 2016)<br>Country Business Head Pharmaceutical, Alcon Canada (May 2014 - June 2015)<br>Business Unit Head Ophthalmology Retina Therapeutics, Alcon Canada (July 2013 - May 2014)<br>Vice President Respiratory, Immunology, Transplant Business Franchise, Novartis Canada (April 2012 - April 2013)<br>Vice President Sales Primary Care, Novartis Canada (August 2011 - August 2012) |
| Ken (Kae-Won) Yoon<br>Ontario, Canada            | Chief Financial Officer                                 | Chief Financial Officer, Acerus Pharmaceuticals Corporation (June 2017 - present)<br>CFO & Executive VP of Corporate Development, Vive Crop Protection Inc. (May 2007 - May 2017)  |
| Nathan Bryson<br>Ontario, Canada                 | Chief Scientific Officer                                | Chief Scientific Officer (formerly Vice President, Scientific Affairs), Acerus Pharmaceuticals Corporation (February 2014 - present)<br>Chief Scientific Officer, Cynapsus Therapeutics Inc. (May 2009 - January 2014)   |
| Philippe Savard<br>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)<br>Director & Counsel, DRI Capital Inc. (September 2013 - June 2016)<br>Corporate Counsel, Iovate Health Sciences (March 2013 - September 2013)<br>Associate, Paul, Weiss, Rifkind, Wharton & Garrison LLP (July 2011 - February 2013)  |

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 2018. 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 108,147,184 Acerus Common Shares representing approximately 50.7% of the issued and outstanding Acerus Common Shares.

#### **Corporate Cease Trade Orders or Bankruptcies**

Other than as disclosed below, 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. Mr. Luc Mainville was the Chairman of Powertech Corporation Inc. when it was cease traded on September 2, 2010 for not meeting filing requirements.

Other than as disclosed below, to the knowledge of the Corporation, 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. Luc Mainville was CEO and a Director of LAB Research Inc. from August 2006 to February 2011 and Lab Research Inc. filed for bankruptcy in April 2011.

### **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 three Directors (the “**Audit Committee**”). The Audit Committee is chaired by J. Mark Lievonen and the other committee members are Steve Gregory and Norma Beauchamp. 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. A copy of the Audit Committee charter is included as Appendix “A” attached hereto.

## Relevant Education and Experience

*Norma Beauchamp* - Ms. Beauchamp was until recently the President and Chief Executive Officer of Cystic Fibrosis Canada. An accomplished business and non-profit leader, Ms. Beauchamp has three decades of senior leadership positions in Canada and Germany, including executive positions at Genzyme, Bayer, Sanofi and the Canadian Foundation for Women's Health. Ms. Beauchamp is a seasoned senior fundraising volunteer, having served on the boards of the St. Joseph's Health Centre Foundation, Providence Healthcare Foundation and the Breast Cancer Society of Canada. Ms. Beauchamp has been a passionate patient advocate in recent years and has worked with patient and healthcare organizations to enhance access to care. Ms. Beauchamp completed the University of Toronto's Rotman School of Management Director's Education Program (ICD.D) in 2009 and graduated from Bishop's University with a Bachelor of Business Administration in Marketing.

*Steve Gregory* - Mr. Gregory is President, Chairman and the controlling shareholder of IsaiX Technologies, a privately held company headquartered in Montreal, with offices in the United States and England. 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 clients human development programs, medical writing and physician scheduling platform services. Mr. Gregory is the President of the Quebec Chapter of the Canada Company and is a member of its Executive Committee. 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.

*J. Mark Lievonen* - Mark Lievonen has over 30 years of experience in the pharmaceutical industry, more recently as the President of Sanofi Pasteur Limited, the Canadian vaccine division of Sanofi, a global pharmaceutical company. He is a Director of Oncolytics Biotech Inc., Quest PharmaTech Inc., and the Gairdner Foundation. Mr. Lievonen has served on a number of industry and not-for-profit boards including as Chair of Rx&D (now Innovative Medicines Canada), BIOTECCanada, the Ontario Genomics Institute, and Vice-Chair of the Ontario Institute for Cancer Research. He was appointed to the Order of Canada in 2015, named a Chevalier de l'Ordre National de Mérite by the government of France in 2007, and was inducted into the Canadian Healthcare Marketing Hall of Fame in 2013. Mr. Lievonen holds a BBA in accounting and a MBA in finance and marketing from the Schulich School of Business, York University. In 2015, he received an Honorary Doctor of Laws degree from York University. Mr. Lievonen is a Chartered Professional Accountant and received his designation while working with PricewaterhouseCoopers prior to joining Sanofi Pasteur. He was elected as a Fellow of the Institute of Chartered Accountants of Ontario in 2007.

## 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, 2017 is set out below:

| <u>Fiscal Year</u> | <u>Audit Fees</u>        | <u>Audit Related Fees</u> | <u>Tax Fees<sup>(1)</sup></u> | <u>All Other Fees</u> | <u>Total</u> |
|--------------------|--------------------------|---------------------------|-------------------------------|-----------------------|--------------|
| 2017               | \$114,500                | \$nil                     | \$147,958                     | \$0                   | \$262,458    |
| 2016               | \$111,337 <sup>(2)</sup> | \$ nil <sup>(2)</sup>     | \$42,382                      | \$nil                 | \$153,719    |

- (1) The amounts shown are comprised of the fees charged by the Corporation's external auditors in connection with certain tax compliance and consulting services.
- (2) \$15,097 of fees related to work on quarterly unaudited financial statements were re-classified to Audit Fees for fiscal 2016.

### **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.

#### Shenk 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 almost concluded examinations for discovery. It is expected that a date for trial will be set in the next few weeks.

### Melnyk Litigation

In April 2016, the Corporation was served with a statement of claim filed in the Ontario Superior Court of Justice by Mr. Eugene Melnyk against the Corporation, as well as its Chairman and President & Chief Executive Officer. The Corporation firmly believes that the entirety of the allegations are without merit from a factual or legal basis, and maintains its position regarding the appropriate conduct of the business and management. In particular, the Corporation believes that the claims relating to alleged improper related party and non-arm's length transactions are entirely baseless and without support. The Corporation, together with the other named co-defendants, brought a motion to strike the action as disclosing no reasonable cause of action, which was scheduled to be heard on July 27, 2016. In response to this motion the plaintiff advised of his intention to bring a motion to convert the proceeding into a derivative action and to pursue a new action in his personal capacity seeking, among other things, damages in the amount of CDN\$100 million for negligent and/or reckless and/or fraudulent misrepresentation (the "**Personal Action**"). As a result, the hearing date was vacated, and the Court scheduled Mr. Melnyk's motion to convert the action into a derivative action, seeking, among other things, CDN\$150 million in damages, for December 21, 2016. No further steps have occurred or have been scheduled with respect to the Personal Action. On December 21, 2016, the Honourable Mr. Justice Wilton-Siegel of the Ontario Superior Court of Justice heard the motion brought by Mr. Eugene Melnyk for leave to commence a derivative action in the name of the Corporation and Justice Wilton-Siegel dismissed the motion with written reasons to follow. On February 22, 2017, Justice Wilton-Siegel issued his written reasons dismissing Mr. Melnyk's claim with costs. On April 6, 2017, Mr. Eugene Melnyk served a Notice of Appeal to appeal the decision of Justice Wilton-Siegel to the Divisional Court of the Ontario Superior Court of Justice. The appeal was heard by the Divisional Court on February 26, 2018 and was dismissed in a decision released on March 1, 2018. On March 14, 2018, Mr. Melnyk delivered a notice of motion for leave to appeal the dismissal of the motion to convert the action to a derivative action to the Court of Appeal for Ontario.

## 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 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.

First Generation Capital Inc., a private holding company under the control and direction of Mr. Ian Ihnatowycz, the Chairman of the Board of Directors, acquired: (a) 9,203,797 Acerus Common Shares as part of the private placement completed on February 21, 2014; and (b) 8,945,796 Acerus Common Shares upon conversion of the First Generation Note on August 22, 2014. Additionally, First Generation Capital Inc. was party to the First Generation Note and was repaid a total of approximately \$20.16 million in principal and interest payments thereunder (see "*General Development of the Business – Recent Developments*" above).

## 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

Except for contracts made in the ordinary course of business, unless such a contract is (i) a contract to which directors, officers, or promoters are parties other than a contract of employment; (ii) a continuing contract to sell the majority of the reporting issuer's products or services or to purchase the majority of the reporting issuer's requirements of goods, services, or raw materials; (iii) a franchise or licence or other agreement to use a patent, formula, trade secret, process or trade name; (iv) a financing or credit agreement with terms that have a direct correlation with anticipated cash distributions; (v) an external management or external administration agreement; or (vi) a contract on which the reporting issuer's business is substantially dependent, the following are the only material contracts entered into by the Corporation or its affiliates within two years prior to the date hereof, which are currently in effect and considered to be currently material:

- (a) the Aytu Agreement;
- (b) the Endo Note;
- (c) the Quantius loan facility; and
- (d) the IP Agreement.

### **Aytu Agreement**

As described under "*Recent Developments*" above, on April 22, 2016, the Corporation entered into a license and supply agreement with Aytu pursuant to which Aytu began commercializing Natesto® in the United States in the third quarter of 2016. Under the terms of the Aytu Agreement, the Corporation was entitled to upfront payments equaling \$8.0 million, all of which have been received as of the date hereof. Additionally, the Corporation is entitled to sales-based milestones that could potentially equal \$37.5 million. Finally, the Corporation is responsible for the manufacturing of the product and receives a tiered supply price that varies during the term of the agreement. As of the

date hereof, the tiered supply price under the Aytu Agreement is equal to the greater of (i) 115% of the Corporation's cost of goods for the product or (ii) 16% of the net sales of the product in the U.S. Commencing in July 2018 and thereafter, the tiered supply price under the Aytu Agreement will be equal to the greater of (i) 115% of the Corporation's cost of goods for the product or (ii) 25% of the net sales of the Product in the U.S.

### **Endo Note**

As described under "*Recent Developments*" above, on June 30, 2016, the Corporation entered into a transition Agreement with Endo. Pursuant to the transition agreement, both parties have also entered into an agreement related to the customer deposit owed to Endo following the termination of the Natesto® agreement. A \$0.5 million cash payment was paid to Endo on July 5<sup>th</sup>, 2016 and the remaining \$3.8 million principal amount is subject to a promissory note with a maturity date of June 30, 2020. Under the Endo Note, the Corporation may have obligations to prepay all or a portion of the Endo Note if it receives cash as a result of certain types of transactions. On March 15, 2018, the Endo Note was amended such that principal repayments under the Endo Note would now be made annually on the last business day of the month of December of each year instead of quarterly. Payments of interest will continue to be made quarterly. As of December 31, 2017, the remaining principal amount under the Endo Note is \$2.4 million.

### **Quantius Debt**

As described under "*Recent Developments*" above, on December 6, 2017, the Corporation entered into a senior secured term credit facility with Quantius for gross proceeds of up to CDN\$5.0 million, of which CDN\$3.0 million was disbursed at closing, with the remaining CDN\$2.0 million becoming available upon satisfaction of certain future conditions, including (i) Aytu achieving a pre-determined number of prescriptions per month for Natesto® in the U.S., and (ii) maintaining Estrace® sales at a pre-determined minimum level. The credit facility bears interest at a rate equivalent to the Bank of Canada prime rate plus 11.05% and matures on December 1, 2019. The credit facility is repayable in monthly instalments of 1/48 of the balance owing commencing December 1, 2018 with the remaining balance due at maturity. As part of the transaction, Quantius received an underwriting fee representing low single digit percentage of the maximum facility amount and will receive a royalty fee representing low single digit percentage on the Corporation's revenues over the term of the facility, capped at a high single digit percentage of the borrowed amount. Under terms of the agreement, the Corporation will have the option to prepay the loan with the payment of low single digit prepayment penalties. The prepayment penalties will be fully offset against the royalty fee payable at the time of termination. The terms of the agreement also contain customary financial covenants.

### **IP Agreement**

On May 22, 2009, Acerus Biopharma entered into an intellectual property rights and product development agreement with Mattern Pharma. Pursuant to this agreement, Acerus Biopharma had acquired worldwide rights (except in Brazil and Russia) to develop, manufacture and market certain technology related to certain specific product candidates using the nasal bio-adhesive gel platform. Pursuant to the terms and conditions of this agreement, Acerus Biopharma is collaborating with Mattern Pharma AG on the development of product candidates utilizing this technology in exchange for milestone, royalty and other payments. On October 20, 2010 and June 6, 2011 the parties entered into amendments to this agreement to clarify certain points arising in the original agreement.

A further amendment to this agreement was entered into in December 2013. In connection with this amendment, all outstanding matters previously under dispute between Acerus Biopharma and

Mattern Pharma with respect to Natesto® and Tefina™ were resolved and all previously pending arbitration proceedings were terminated in consideration of a payment of \$4.25 million by Acerus Biopharma to Mattern Pharma, representing a portion of the approximately \$5.0 million milestone payments that were the subject of existing arbitration proceedings. In addition, Acerus Biopharma was granted non-exclusive commercialization rights to Brazil and Russia for Natesto® (previously Acerus Biopharma had no rights to these markets) and granted to Mattern Pharma limited, non-exclusive rights to commercialize alternative male products in certain jurisdictions around the world subject to certain terms and conditions. Acerus Biopharma and Mattern Pharma also agreed on a revised model intended to best facilitate the prosecution of intellectual property related to Natesto® and Tefina™. Finally, under this amendment Acerus Biopharma abandoned any right to rely on Mattern Pharma's technology in connection with any dopamine-based products. Additionally, a minor amendment to this agreement was entered into in December 2014.

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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](http://www.sedar.com) or upon request from the Corporation at 2486 Dunwin Drive, Mississauga, Ontario, L5L 1J9.

#### 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, 2017 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](http://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.
- The Committee will ensure that Acerus establish 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.