SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
Pursuant to Rule 13a-16 or 15d-16 under
the Securities Exchange Act of 1934

For the month of: December 2016

Commission File Number: 001-35776

ACASTI PHARMA INC.

(Name of Registrant)

545 Promende du Centropolis
Suite 100
Laval, Québec
Canada H7T 0A3
(Address of Principal Executive Office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ☐ No ☒

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): N/A

This Report on Form 6-K including the exhibits hereto shall be deemed to be incorporated by reference into Acasti Pharma Inc.'s registration statement on Form S-8 (File No. 333-191383) and to be a part thereof from the date on which this report is furnished, to the extent not superseded by documents or reports subsequently filed or furnished.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACASTI PHARMA INC.

Date: December 5, 2016

By: */s/ Jan D'Alvise*
Name: Jan D'Alvise
Title: President and CEO of Acasti Pharma Inc.

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Revised Business Description and Risk Factors relating to the registrant, dated December 5, 2016

VIA EDGAR

December 5, 2016

Acasti Pharma Inc. (the **Corporation**) has updated the business description and risk factors related to the Corporation, as attached hereto. This information updates the business description and risk factors contained in the the Corporation's annual report on Form 20-F for the fiscal year ended February 29, 2016, as filed with the Commission on May 31, 2016.

[signature page follows]

MADE this 5th day of December, 2016.

ACASTI PHARMA INC.

Per: */s/ Jan D'Alvise*
Name: Jan D'Alvise
Title: President and Chief Executive Officer

Exhibit 99.1

BUSINESS DESCRIPTION OF,

AND

RISK FACTORS RELATING TO,

ACASTI PHARMA INC.

Dated as of December 5, 2016

In this document, unless the context otherwise requires, references to “Acasti”, the “Corporation”, “we”, “us”, “it”, “its” or similar terms refer to Acasti Pharma Inc. and references to “Neptune” refer to Acasti’s parent company, Neptune Technologies & Bioressources Inc.

The financial information of the Corporation contained herein are presented in Canadian dollars. All references in this document to “dollars”, “CDN$” and “$” refer to Canadian dollars, and references to “US$” refer to United States dollars. Potential purchasers should be aware that foreign exchange rate fluctuations are likely to occur from time to time and that the Corporation does not make any representation with respect to future currency values. Investors should consult their own advisors with respect to the potential risk of currency fluctuations. On December 2, 2016, the closing exchange rate for the Canadian dollar, expressed in United States dollars, as quoted by the Bank of Canada was CDN$1.00 = US$0.7528.

This document contains company names, product names, trade names, trademarks and service marks of Acasti, Neptune and other organizations, all of which are the property of their respective owners.

Acasti has applied for trademark protection for CaPre®. The trademark CaPre® is now registered in the United States, Canada, Australia, China, Japan and Europe. Acasti is also the owner of the trademark BREAKING DOWN THE WALLS OF CHOLESTEROL™ in Canada and the United States.

Unless otherwise indicated, market data and certain industry data and forecasts included in this document concerning our industry and the markets in which we operate or seek to operate were obtained from internal company surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. Acasti has relied upon industry publications as its primary sources for third-party industry data and forecasts. Industry surveys, publications and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. Acasti has not independently verified any of the data from third-party sources, nor has Acasti ascertained the underlying economic assumptions relied upon therein. Similarly, internal surveys, industry forecasts and market research, which Acasti believes to be reliable based upon management’s knowledge of the industry, have not been independently verified. By their nature, forecasts are particularly subject to change or inaccuracies, especially over long periods of time. In addition, Acasti does not know what assumptions regarding general economic growth were used in preparing the forecasts cited in this document. While Acasti is not aware of any misstatements regarding Acasti’s industry data presented herein, Acasti’s estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under “Forward-Looking Information” and “Risk Factors” in this document. While Acasti believes its internal business research is reliable and market definitions are appropriate, neither such research nor definitions have been verified by any independent source. This document may only be used for the purpose for which it has been published.

All financial information contained in this document is presented in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, other than certain non-IFRS financial measures which are defined under “Non-IFRS operating loss” (net loss before finance costs and income, change in fair value of derivative warrant liabilities, depreciation and amortization, impairment of intangible assets and stock-based compensation), in the Corporation’s management’s discussion and analysis for the fiscal years ended February 29, 2016 and February 28, 2015 and 2014.

FORWARD-LOOKING INFORMATION

This document contains certain information that may constitute “forward-looking information” within the meaning of Canadian securities laws and forward-looking statements within the meaning of U.S. federal securities laws, both of which Acasti refers to as forward-looking information. Forward-looking information can be identified by the use of terms such as “may”, “will”, “should”, “expect”, “plan”, “anticipate”, “believe”, “intend”, “estimate”, “predict”, “potential”, “continue” or other similar expressions concerning

matters that are not statements about the present or historical facts. Forward-looking information in this document includes, but is not limited to, information or statements about:

- Acasti's strategy, future operations, prospects and the plans of management;
- the design, regulatory plan, timeline, costs and results of clinical and nonclinical trials for CaPre;
- the timing and ramp up of patient enrollment;
- the timing of future meetings and discussions with the U.S. Food and Drug Administration (**FDA**);
- planned regulatory filings for CaPre, and the timing thereof;
- Acasti's expectation that its bridging study results will support Acasti's plan to get authorization to use the FDA's 505(b)(2) pathway with new chemical entity (**NCE**) status towards a New Drug Application (**NDA**) approval in the United States;
- the likelihood of Acasti receiving 5-year exclusivity for CaPre as a NCE;
- the timing and results from two competitor outcomes studies in mild to moderate HTG patients;
- additional clinical trials demonstrating safety and efficacy of CaPre;
- anticipated marketing advantages and product differentiation of CaPre and its potential to become the best-in-class omega-3 (**OM3**) compound for the treatment of severe hypertriglyceridemia;
- Acasti's estimates of the size of the potential market for CaPre, unmet medical needs in such market, potential for market expansion, and the rate and degree of market acceptance of CaPre, if reaching commercialization, and Acasti's ability to serve such market;
- the potential to expand CaPre's indication for the treatment of mild to moderate hypertriglyceridemia;
- the degree to which physicians would switch their patients to a product with CaPre's target product profile;
- Acasti's strategy and ability to develop, commercialize and distribute CaPre in the United States and elsewhere;
- Acasti's ability to complete business development, marketing and other pre-commercialization activities before reaching commercial launch of CaPre and the estimated timing thereof;
- the completion of production of clinical trial product and manufacturing scale up of CaPre and the timing thereof;
- the potential benefits and risks of CaPre as compared to other products in the pharmaceutical, medical food and natural health products markets, respectively;
- Acasti's intention and ability to strengthen its patent portfolio and other means of protecting intellectual property rights;
- Acasti's ability to maintain and defend its intellectual property rights;
- the availability and sources of raw materials;
- Acasti's expectation to rely on third parties to manufacture CaPre whose manufacturing processes and facilities are in compliance with current good manufacturing practices (**cGMP**);
- Acasti's sales, distribution and marketing strategy for CaPre;
- Acasti's intention and ability to obtain and maintain regulatory approvals of CaPre, the timing and costs of obtaining same, and the labeling requirements and other post-market regulation that would apply under any approval Acasti may obtain;
- regulatory developments affecting the pharmaceutical market in the United States and elsewhere;
- the success of competing products that are or become available;
- the potential for omega-3s in other CVM indications;
- the attractiveness of CaPre to larger global, regional or specialty pharmaceutical companies and potential for commercial opportunities in different geographies and indications, including co-development and/or marketing partnerships and possible licensing and partnership opportunities, and the benefits to be derived from such commercial opportunities;
- Acasti's intention to pursue development and/or distribution partnerships to support the development and commercialization of CaPre in the United States and in other global markets, and to pursue strategic opportunities to provide development capital, market access and other strategic sources of capital;

- Acasti's projected capital requirements to fund anticipated expenses, including primarily development and general and administrative expenses, as well as capital expenditures until March 31, 2017;
- Acasti's need for additional financing and its estimates regarding future financing and capital requirements; and
- Acasti's expectations regarding its financial performance, including its revenues, profitability, research and development, costs and expenses, gross margins, liquidity, capital resources and capital expenditures.

Although the forward-looking information in this document is based upon what Acasti believes are reasonable assumptions, no person should place undue reliance on such information since actual results may vary materially from the forward-looking information. Certain important assumptions by Acasti in making forward-looking statements include, but are not limited to:

- the assumption that the net proceeds of future financing and existing cash, together with interest thereon, should be sufficient to fund Acasti's operations through December 31, 2017;
- the successful and timely completion of all required clinical and nonclinical trials that may be necessary for regulatory approval of CaPre;
- the successful enrollment of patients in clinical trials as projected;
- that the timeline and costs for Acasti's clinical programs are not incorrectly estimated or affected by unforeseen circumstances;
- the safety and efficacy of CaPre, successful GMP manufacturing and other activities leading up to planned regulatory filings as expected;
- confirmation by the FDA of Acasti's 505(b)(2) regulatory pathway approach with NCE status towards NDA approval in the United States and finalization of the protocol for the Phase 3 trial for CaPre within the anticipated timeframe;
- Acasti's receipt of 5 year market exclusivity for CaPre as a NCE;
- positive outcome study data from two competitors in mild to moderate HTG patients;
- that Acasti obtains and maintains regulatory approval for CaPre on a timely basis;
- Acasti's ability to attract, hire and retain key management and skilled scientific personnel;
- the timely provision of services by third parties;
- Acasti's ability to maintain its supply of raw materials, including krill oil, from its parent company;
- Acasti's ability to secure and maintain a third-party supplier to provide Acasti, as needed, with raw materials to supplement its operations, including raw krill oil (**RKO**), in sufficient quantities and quality and on a timely basis to produce CaPre under cGMP standards;
- Acasti's ability to secure and maintain a third-party to manufacture CaPre whose manufacturing processes and facilities are in compliance with cGMP;
- the Corporation's ability to secure distribution arrangements for CaPre if it reaches commercialization;
- the Corporation's ability to manage future growth effectively;
- the Corporation's ability to gain acceptance of CaPre in its markets and Acasti's ability to serve those markets;
- the Corporation's ability to achieve its publicly announced milestones on time;
- the sufficiency and validity of Acasti's patent portfolio;
- the Corporation's ability to secure and defend its intellectual property rights and to avoid infringing upon the intellectual property rights of third parties;
- Acasti's ability to take advantage of business opportunities in the pharmaceutical industry and the receipt of strategic partner support;
- the assumption that Acasti's projected capital requirements to fund anticipated expenses, including primarily development and general and administrative expenses, as well as capital expenditures until March 31, 2017 will prove to be accurate;
- the Corporation's ability to achieve profitability;
- the Corporation's ability to continue as a going concern;
- Acasti's ability to obtain additional capital and financing as needed on favorable terms;

- the absence of significant increase in competition from other companies in the pharmaceutical, medical food and natural health product industries;
- the assumption that CaPre's concentrated omega-3s from krill oil are absorbed into the body more efficiently than omega-3 fatty acid ethyl esters derived from fish oils;
- the assumption that CaPre would be viewed favorably by payers at launch (Tier 2 or 3 depending on payer plan);
- the absence of material change in omega-3 prescription data as compared to omega-3 prescription data from 2009-2015;
- the assumption that market data and reports reviewed by Acasti are accurate;
- the absence of material deterioration in general business and economic conditions;
- the absence of adverse changes in relevant laws or regulations; and
- that any product liability lawsuits and other proceedings or disputes are satisfactorily resolved.

In addition, forward-looking information in this document is subject to a number of known and unknown risks, uncertainties and other factors, including those described in this document under the heading "Risk Factors" and in the revised annual report on form 20-F of the Corporation for the fiscal year ended February 29, 2016, as filed on SEDAR under Acasti's profile on May 30, 2016 under the heading "Risk Factors", many of which are beyond the Corporation's control, that could cause the Corporation's actual results and developments to differ materially from those that are disclosed in or implied by the forward-looking information, including, without limitation:

- failure to receive regulatory approvals (including stock exchange) or otherwise satisfy the conditions to the completion of financings and the funds thereof not being available to the Corporation;
- risks related to timing and possible difficulties, delays or failures in clinical trials and patient enrollment;
- anticipated pre-clinical and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of CaPre;
- CaPre may not prove to be safe and effective or as potent as currently believed;
- clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results;
- anticipated studies and submissions to the FDA may not occur as currently anticipated, or at all;
- rejection by the FDA of Acasti's 505(b)(2) regulatory pathway approach;
- the failure to receive 5 year market exclusivity for CaPre as a NCE;
- negative outcome study data from two competitors in mild to moderate HTG patients;
- difficulties, delays or failures in obtaining regulatory approvals for the initiation of clinical trials or to market CaPre;
- the need for future clinical trials, the occurrence and success of which cannot be assured;
- the risk of unknown side effects;
- the FDA may refuse to approve CaPre, or place restrictions on its ability to commercialize CaPre;
- uncertainties related to the regulatory approval process and the commercialization of CaPre;
- the risk that CaPre could be subject to extensive post-market obligations and continued regulatory review, which may result in significant additional expense and affect sales, marketing and profitability;
- failure to achieve Acasti's publicly announced milestones on time;
- difficulties in completing the development and commercialization of CaPre;
- risks related to Acasti's dependence on third party relationships to conduct its clinical trials for CaPre;
- difficulties, delays, or failures in obtaining appropriate reimbursement of CaPre;
- recently enacted and future legislation may increase the difficulty and cost for the Corporation to obtain marketing approval of and commercialize CaPre and affect the prices the Corporation may obtain;

- Acasti's business may be materially adversely affected by new legislation, new regulatory requirements, and the continuing efforts of governmental and third party payors to contain or reduce the costs of healthcare through various means;
- uncertainty of the size and existence of a market opportunity for, and insufficient demand and market acceptance of, CaPre;
- the Corporation's reliance on third parties for the manufacture, supply and distribution of CaPre;
- the Corporation's dependence on Neptune and other third party manufacturers and key suppliers for the supply of raw materials, including RKO, in sufficient quantities and quality and to produce CaPre under cGMP standards;
- Neptune currently exercises control over Acasti and has significant influence with respect to all matters submitted to Acasti's shareholders for approval, including the election and removal of Acasti's directors;
- manufacturing risks, the need to manufacture to regulatory standards, uncertainty whether the manufacturing process for CaPre can be further scaled-up successfully or at all and the risk that clinical batches of CaPre may not be able to be produced in a timely manner or at all;
- Acasti's limited sales, marketing and distribution experience;
- difficulties may be experienced in managing Acasti's future growth;
- Acasti's dependence on its exclusive license with Neptune;
- intellectual property risks, including the possibility that patent applications may not result in issued patents, that issued patents may be circumvented or challenged and ultimately struck down, and that Acasti may not be able to protect its trade secrets or other confidential proprietary information;
- risks associated with potential claims of infringement of third party intellectual property and other proprietary rights;
- risks related to potential product liability claims and product recalls;
- intense competition from other companies in the pharmaceutical, medical food and natural health product industries;
- the net proceeds of future financing and existing cash, together with interest thereon, may not be sufficient to fund Acasti's operations through December 31, 2017;
- Acasti's projected capital requirements to fund anticipated expenses, including primarily development and general and administrative expenses, as well as capital expenditures until March 31, 2017 may prove to be inaccurate;
- Acasti has a history of negative operating cash flow and may never become profitable or be able to sustain profitability;
- Acasti will have significant additional future capital needs and may not be able to raise additional financing required to fund further research and development, clinical studies, obtain regulatory approvals, and to meet ongoing capital requirements to continue current operations on commercially acceptable terms or at all;
- the Corporation may be unable to form or enter into commercial opportunities on its anticipated timeline, and may not realize the expected benefits of any such transaction;
- the possibility that Acasti may acquire businesses or products or form strategic alliances in the future and may not realize the benefits of such acquisitions;
- Acasti may be unable to secure development and/or distribution partnerships to support the development and commercialization of CaPre in the United States and in other global markets, and to secure strategic opportunities to provide development capital, market access and other strategic sources of capital;
- Acasti's reliance on key management and skilled scientific personnel; and
- general changes in economic and capital market conditions.

Consequently, all the forward-looking information in this document is qualified by this cautionary statement and there can be no guarantee that the results or developments that the Corporation anticipates will be realized or, even if substantially realized, that they will have the expected consequences or effects on the Corporation's business, financial condition or results of operations. Accordingly, you should not place undue reliance on the forward-looking information. Except as required

by applicable law, Acasti does not undertake to update or amend any forward-looking information, whether as a result of new information, future events or otherwise. All forward-looking information is made as of the date of this document.

BUSINESS DESCRIPTION

Overview

Acasti was incorporated on February 1, 2002 under Part 1A of the *Companies Act* (Québec) under the name "9113-0310 Québec Inc.". On February 14, 2011, the *Business Corporations Act* (Québec) came into effect and replaced the *Companies Act* (Québec). Acasti is now governed by the *Business Corporations Act* (Québec). On August 7, 2008, pursuant to a Certificate of Amendment, the Corporation changed its name to "Acasti Pharma Inc.", its share capital description, the provisions regarding the restriction on securities transfers and the borrowing powers of the Corporation. On November 7, 2008, pursuant to a Certificate of Amendment, the Corporation changed the provisions regarding its borrowing powers. The Corporation became a reporting issuer in the Province of Québec on November 17, 2008.

Acasti's head and registered office is located at 545 Promenade du Centropolis, Suite 100, Laval, Québec H7T 0A3. The Corporation currently employs 12 full-time employees with the majority working out of the Corporation's headquarters in Laval and its laboratory in Sherbrooke. The Corporation's website address is http://www.acastipharma.com.

Intercorporate Relationships

The Corporation has no subsidiaries. As of December 5, 2016, Neptune Technologies and Bioressources Inc. (**Neptune**) owns 5,064,694 Class A shares in the capital of the Corporation (**Common Shares**), representing approximately 47.28% of the issued and outstanding Common Shares.

Summary Description of the Business

Acasti is a biopharmaceutical innovator focused on the research, development and commercialization of prescription drugs using omega-3 fatty acids derived from krill oil. Acasti's lead product candidate is CaPre® (omega-3 phospholipid), which Acasti is developing initially for the treatment of severe hypertriglyceridemia, a condition characterized by abnormally high levels of triglycerides in the bloodstream (over 500 mg/dL) (**severe hypertriglyceridemia** or **severe HTG**). Acasti believes the potential exists to expand CaPre's indication to mild to moderate hypertriglyceridemia (200 – 499 mg/dL) with the likelihood of additional clinical trials being required such as comparative studies and outcome trials, assuming positive outcome study data in the next two years from two competitors. In addition, Acasti may seek to identify new potential indications for CaPre that may be appropriate for future studies and pipeline expansion. See "Risk Factors."

Omega-3 fatty acids have extensive clinical evidence of safety and efficacy in lowering triglycerides in patients with hypertriglyceridemia. Market research commissioned by Acasti[1], suggests there is a significant unmet market need for an effective, safe and well-absorbing omega-3 therapeutic that demonstrates a positive impact on the major blood lipids associated with cardiovascular disease risk. Acasti believes that, if supported by additional clinical trials, CaPre will address this unmet market need.

In four clinical trials conducted to date, Acasti saw the following beneficial effects with CaPre, and is seeking to demonstrate similar safety and efficacy in a Phase 3 clinical study:

- Significant reduction of triglyceride and non-high density lipoprotein cholesterol (**non-HDL-C**) cholesterol levels in the blood of patients with mild to severe hypertriglyceridemia;
- No deleterious effect on low-density lipoprotein cholesterol, or "bad" cholesterol (**LDL-C**), and potential to reduce LDL-C;
- Potential to increase high-density lipoprotein cholesterol, or "good" cholesterol (**HDL-C**);
- Good bioavailability, even under fasting conditions;
- No significant food effect (low fat vs. high fat meal); and

[1] Primary qualitative market research study with Key Opinion Leaders (**KOLs**), High Volume Prescribers (**HVPs**) and Pharmacy commissioned by Acasti in August 2016 by DP Analytics, A Division of Destum Partners, a market research firm (the **Destum Market Research**).

- An overall safety profile similar to that demonstrated by currently marketed OM3s, with added potential for beneficial LDL-C reduction as listed above.

See “Risk Factors”.

About Hypertriglyceridemia (HTG)

According to The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease (2011), triglyceride levels provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low levels of HDL-C, and elevated levels of LDL-C. Hypertriglyceridemia can be caused by both genetic and environmental factors, including obesity, sedentary lifestyle and high-calorie diets. Hypertriglyceridemia is also associated with comorbid conditions such as chronic renal failure, pancreatitis, nephrotic syndrome and diabetes. Multiple genetic studies suggest that patients with elevated triglyceride levels (greater than or equal to 200 mg/dL) have an increased risk of coronary artery disease (**CAD**) and pancreatitis, a life-threatening condition, as compared to those with normal triglyceride levels. Other studies suggest that lowering and managing triglyceride levels may reduce such risks. In addition, the Japan EPA Lipid Intervention Study (JELIS) demonstrated the long term benefit of an omega-3 (EPA) in the prevention of major coronary events in high risk cardiovascular (**CV**) patients.[2]

Predictor	CAD Risk Effect and Interpretations		P-Value
TG	0.36	*Genes regulating TGs and LDL-C are equally strong predictors of CAD*	<<<0.0001
LDL-C	0.38		<<<0.0001
HDL-C	-0.04	HDL-C is a weak CAD predictor	0.35

Table modified from Do R et al. Nature Genetics 2013;45(11):1345-1352 (N=86,995)

About CaPre

CaPre is a krill oil derived mixture containing polyunsaturated fatty acids (**PUFA**s), primarily composed of omega-3 fatty acids, principally eicosapentaenoic acid (**EPA**) and docosahexaenoic acid (**DHA**). EPA and DHA are well known to be beneficial for human health, and may promote healthy heart, brain and visual function[3], and may contribute to reducing inflammation, and blood triglycerides[4]. Krill is a natural source of phospholipids and omega-3 fatty acids. The EPA and DHA contained in CaPre are delivered as free fatty acids or bound to phospholipid esters, allowing these PUFAs to reach the small intestine where they undergo rapid absorption and transformation into complex fat molecules that are required for transport in the bloodstream. Acasti believes that EPA and DHA are more efficiently transported by phospholipids sourced from krill oil than the EPA and DHA contained in fish oil that are transported either by triglycerides (as in dietary supplements) or as ethyl esters in other prescription omega-3 drugs, which must then undergo additional digestion before they are ready for transport in the bloodstream.

CaPre is intended to be used as a therapy in conjunction with positive lifestyle changes including diet, and is to be administered either alone or with other drug treatment regimens such as statins (a class of drug used to reduce cholesterol levels). CaPre is intended to be taken orally once per day in capsule form.

Market for CaPre

[2] Yokoyama et al, Lancet 2007 and Saito et al, Atherosclerosis 2008.
[3] Kwantes and Grundmann, Journal of Dietary Supplements, 2014.
[4] Ulven and Holven, Vascular health and risk management, 2015.

*Except as otherwise indicated, all of the information under this heading has been derived from secondary sources including audited U.S. prescribing data and from a qualitative U.S. commercial and primary market research assessment conducted by DP Analytics, A Division of Destum Partners, Inc. (**Destum**), a market research firm, for Acasti dated August 19, 2016, which is referred to herein as the "Destum Market Research". To conduct this market analysis for CaPre, Destum utilized secondary market data and reports and primary qualitative market research with physicians and third party payers (pharmacy benefit managers (**PBMs**)). One-on-one in-depth phone interviews lasting on average 30-60 minutes were conducted with 22 physicians and 5 PBMs, and key qualitative data was obtained on current clinical practice, unmet medical need, and commercial potential of CaPre. All interviews were conducted by the same individual at Destum and recorded to ensure consistency and collection of key data points. Destum utilized omega-3 prescription data from 2009-2015 for purposes of estimating the size of the market. Based on the discussions with the PBMs, Destum also assumed CaPre would be viewed favorably by payers at launch (e.g. Tier 2 or 3 depending on payer plan, which is comparable to VASCEPA®). Of note, upon completion of the screening questionnaire and upon approval for inclusion in the study, KOLs/HVPs were provided with a study questionnaire and were asked to comment on a target product profile offering a "trifecta" of cardio-metabolic benefits similar to the potential efficacy and safety benefits demonstrated by CaPre in two Phase 1 pharmacokinetic studies and two Phase 2 clinical trials (a **Target Product Profile**). Respondents were told that the unidentified product was being prepared for a Phase 3 study designed to confirm with statistical significance the safety and efficacy in patients with severe hypertriglyceridemia. Such a Target Product Profile was used by Destum strictly for market research analysis purposes and should not be construed as an indication of future performance and should not be read as any form of expectation or guarantee of future performance or results, and will not necessarily be an accurate indication of whether or not such results will be achieved by CaPre in any Phase 3 study.*[5]

According to The American Heart Association, the prevalence of HTG in the United States and globally correlates to the aging of the population and the increasing incidence of obesity and diabetes. Market participants, including The American Heart Association, have estimated that one-third of the adult population in the United States has elevated levels of triglycerides (**TGs**) (of which only 4% are treated), including over 40 million people diagnosed with mild to moderate hypertriglyceridemia, and 3 to 4 million people diagnosed in the United States with severe hypertriglyceridemia[6]. Moreover, according to Ford, Archives of Internal Medicine in a study conducted between 1999 and 2004, 18% of adults in the United States (approximately 40 million[7]) had elevated TG levels equal or greater to 200 mg/dl[8], of which only 3.6% were treated with TG lowering medication[9], providing for a large underserved market opportunity.

In 2015, CaPre's target market in the United States for severe HTG was estimated to be approximately $750 million, with approximately 5 million scripts written annually over the past four years[10]. The total global market is currently estimated to be approximately $2.3 billion[11], with the potential to greatly expand the treatable market to approximately 40 million patients with mild to moderate HTG, assuming favorable outcome studies that are currently ongoing. These outcome trials are expected to report in 2018 and 2019 (REDUCE-IT trial sponsored by Amarin and STRENGTH trial sponsored by Astra Zeneca, designed to evaluate the long-term benefit of lowering triglycerides on cardiovascular risks with prescription drugs containing omega-3 fatty acids). If these trials are successful, it is likely that additional clinical trials would be required for CaPre to expand its label claims to the mild to moderate segment.

The following charts illustrate the estimated global and U.S. markets for HTG in 2015:

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[5] The Corporation has also retained Destum as its exclusive advisor and business development consultant to identify strategic partners for CaPre, pursuant to which Destum may, subject to certain terms and conditions, be entitled to a success fee if a business arrangement or transaction is consummated. Destum's market research and its conclusions were substantially completed, subject to some minor modifications, prior to this agreement having been entered into with Destum.

[6] *Christian et al*., Am. J. Med. 2014.

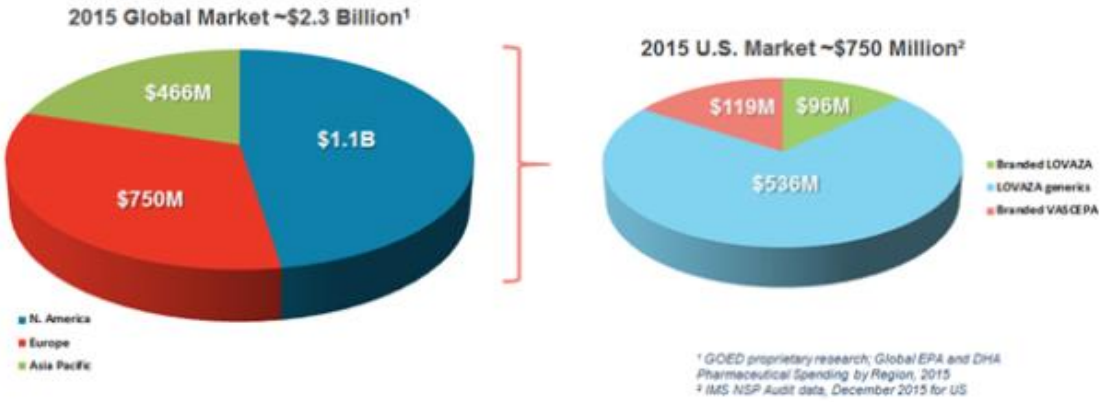
[7] *Kapoor and Miller*, ACC, 2016 (**Kapoor**).

[8] *Ford*, *Archives of Internal Medicine*, 2009; 169(6):572-578 (**Ford**).

[9] Ford. See also: *Christian et al*., Am. J. Cardiology, 2011.

[10] IMS NSP Audit data, December 2015 for US.

[11] GOED Proprietary Research; Global EPA and DHA Pharmaceutical Spending by Region, 2015.



CaPre has two FDA approved and marketed branded competitors (LOVAZA and VASCEPA). In addition, Astra Zeneca has an approved product, EPANOVA®, which has not yet been launched. LOVAZA generics became available on the market[12] in 2013. In spite of generic options, audited prescription data[13] suggests that over 50% of omega-3 prescriptions are written for branded products (LOVAZA or VASCEPA). Consequently, there has been only a 33% decline in total market value in the four years that generic competition has been available in the market, in spite of some generic switching that occurs at the pharmacies. This is in part due to the relatively small differential between branded and generic prices. Based on both primary market research with PBMs and audited prescription reports, the average pricing of generics is about $160/mo., while pricing for branded products average $250 - $300/mo. Amarin has raised prices on VASCEPA annually since launch in late 2013. Pharmacy Benefit Managers (**PBM**s) offer "Preferred Brand" status (Tier 2 or Tier 3), without significant restrictions (i.e. no prior authorization, step edits, or high co-payments).

In light of the following factors, Acasti believes a significant opportunity may exist for omega-3 market expansion:

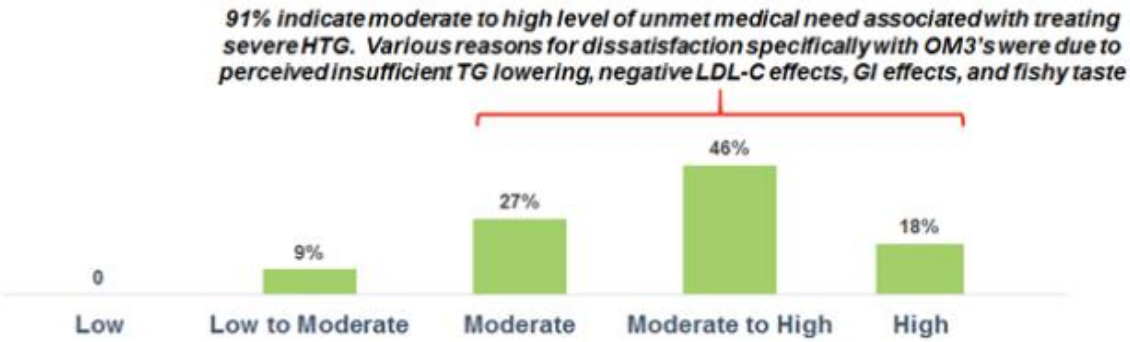
- Cardiovascular diseases (**CVD**) and stroke are the leading causes of morbidity and mortality in the United States. The burden of CVD and stroke in terms of life-years lost, diminished quality of life, and direct and indirect medical costs also remains enormous;
- In addition, evidence suggests potential for omega-3s in other cardiometabolic indications; and
- Assuming two independent cardiovascular outcome trials (REDUCE-IT trial sponsored by Amarin and STRENGTH trial sponsored by Astra Zeneca) (the **CV outcome trials**) are positive, KOLs interviewed by Destum estimated that they would increase their own prescribing of omega-3s by 42% in mild to moderate HTG patients (200 – 499 mg/dL) and by 35% in severe HTG patients.

Given that an estimated one-third of the adult population in the United States has elevated levels of triglycerides (of which only ~4% are treated), including over 40 million people diagnosed with mild to moderate hypertriglyceridemia and 3 to 4 million people diagnosed with severe hypertriglyceridemia[14], Acasti believes there is potential for a 10-fold increase in the total number of patients eligible for treatment if the CV outcome trials are positive.

KOLs/HVPs interviewed by Destum were asked to assess the level of unmet medical need associated with treating patients with severe HTG based on currently available treatment options[15]. As illustrated in the graph below, 91% of physicians interviewed believed that the current unmet need was moderate to high. The various reasons stated for dissatisfaction specifically with currently available OM3s included perceived insufficient TG lowering, negative LDL-C effects, gastrointestinal side effects, and

[12] IMS NSP Audit data, December 2015 for US.
[13] IMS NSP Audit data, December 2015 for US.
[14] Ford; Kapoor; *Christian et al.*, Am. J. Cardiology, 2011.
[15] The Destum Market Research.

fishy taste. Despite the availability of other drug classes to treat severe HTG, physicians would welcome new and improved omega-3 products.



Physicians responded favorably to a product with the CaPre target product profile (a **Target Product**) as evidenced by their weighted prescribing percentages of the Target Product by approximately 35% to 53% (range dependent on the specific profile presented) in the severe HTG patient population within two years of the Target Product approval[16]. About 60% of the respondents liked the "trifecta effect" of the Target Product on LDL-C and HDL-C, and the remaining 40% responded to the Target Product's effective reduction of triglycerides. It should be noted that for purposes of this scenario, physicians were requested to assume the Target Product and all currently available omega-3 products were not subject to any reimbursement/coverage hurdles (e.g. equal playing field for all products).

Acasti plans to continue to conduct additional market research with KOLs, HVPs, primary care physicians and payers in the future to continue to develop and refine its understanding of the marketplace for CaPre.

Clinical Data

CaPre is currently being developed for the treatment of patients with severe hypertriglyceridemia. In two Phase 2 clinical trials (COLT and TRIFECTA), CaPre was found to be safe and well tolerated at all doses tested, with no serious adverse events that were considered treatment related. Among the reported adverse events with an occurrence of greater than 2% of subjects and greater than placebo, only diarrhea had an incidence of 2.2%.

In both studies, CaPre significantly lowered triglycerides in patients with mild to severe hypertriglyceridemia. Importantly, in these studies, CaPre also demonstrated no deleterious effect on LDL-C (unlike LOVAZA, which has been shown to significantly increase LDL-C in patients with severe HTG). Further, the Phase 2 data indicated that CaPre may potentially reduce LDL-C. LDL-C is undesirable because it accumulates in the walls of blood vessels, where it can cause blockages (atherosclerosis). In these studies, CaPre also reduced non-HDL-C, which includes all cholesterol contained in the bloodstream except HDL-C and is considered to be a useful marker of cardiovascular disease. The COLT data showed a mean increase of 7.7% in HDL-C with CaPre at 4 grams a day (p=0.07). Further studies are required to demonstrate statistical significance with HDL-C.

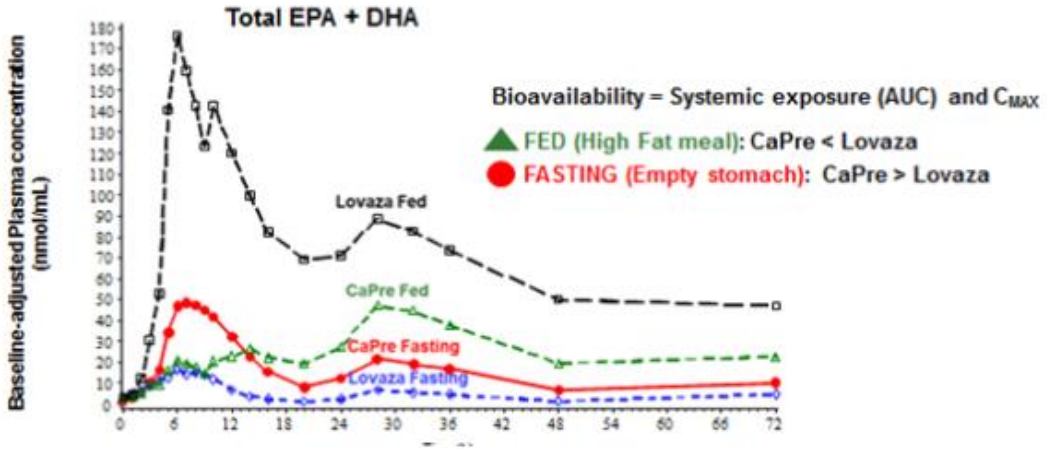
Acasti believes that these multiple potential benefits, if confirmed in a Phase 3 study, could be a significant differentiator for CaPre, as no currently approved omega-3 drug has shown an ability to positively modulate these four major blood lipid categories (e.g. triglycerides, non-HDL-C, LDL-C and HDL-C) in the treatment of hypertriglyceridemia. Acasti also believes that if supported by additional clinical trials, CaPre could potentially become the best-in-class omega-3 compound for the treatment of severe hypertriglyceridemia. See "Risk Factors".

[16] The Destum Market Research.

On September 14, 2016, Acasti announced positive data from its completed comparative bioavailability study (bridging study)[17]. The Bridging study was an open-label, randomized, four-way, cross-over, bioavailability study comparing CaPre given as a single dose of 4 grams in fasting and fed states with the approved hypertriglyceridemia drug LOVAZA (omega-3-acid ethyl esters) in 56 healthy volunteers. The protocol was reviewed and approved by the FDA. The primary objective of the study was based on a comparison of the bioavailability of CaPre as compared to LOVAZA administered as a single 4 gram dose with a high fat meal, which is the condition under which administration of OM3 drugs will yield the highest levels of EPA and DHA in the blood, and therefore the highest potential for toxicity. To allow for reliance on the safety data of LOVAZA to support a 505(b)(2) NDA for CaPre, results had to show that the blood levels of EPA and DHA resulting from a single, 4 gram dose of CaPre are not significantly higher than from a single, 4 gram dose of LOVAZA under fed conditions. The study met its primary objective and demonstrated that the levels of EPA and DHA following administration of CaPre did not exceed the levels following administration of LOVAZA in subjects who were fed a high-fat meal. These results are expected to support the basis for claiming a comparable safety profile of the two products.

Furthermore, among subjects in the fasting state, CaPre demonstrated better bioavailability than LOVAZA, as measured by superior blood levels of EPA and DHA.

The graph below demonstrates that the bridging study achieved all of its objectives:



PK Bridging Study Protocol: 2016-4010: A Single-Dose, Comparative Bioavailability Study of CaPre 1 gram Capsules Compared to LOVAZA 1 g Capsules Under Fasting and Fed Conditions

Absorption of ethyl ester forms of currently available prescription omega-3 drugs derived from fish oil (e.g. LOVAZA and VASCEPA) require the breakdown of fats by pancreatic enzymes (lipases) that are produced in response to the consumption of high fat content meals in order to be optimally absorbed. Consequently, these ethyl ester formulations have demonstrated lower absorption and bioavailability when taken on an empty stomach, whereas absorption of CaPre, which is formulated as omega-3 phospholipids and free fatty acids, is not meaningfully affected by the fat content of a meal consumed prior to drug administration, as shown in the CAP13-101 study[18]. Since a low fat diet is typically a critical component for treatment of patients with severe hypertriglyceridemia, Acasti believes this could give CaPre a significant clinical and marketing advantage over the ethyl ester based OM3s (LOVAZA and VASCEPA).

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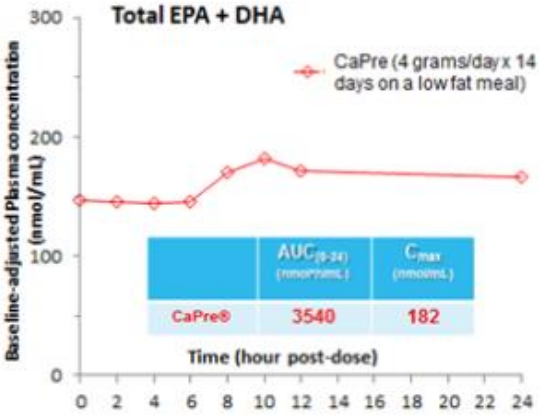
[17] PK Bridging Study Protocol: 2016-4010: A Single-Dose, Comparative Bioavailability Study of CaPre 1 gram Capsules Compared to LOVAZA 1 g Capsules Under Fasting and Fed Conditions.

[18] Evaluation of CaPre Pharmacokinetics Following Single and Multiple Oral Doses in Healthy Volunteers. Protocol Number: CAP13-101. Final Clinical Study Report; January 08, 2015.

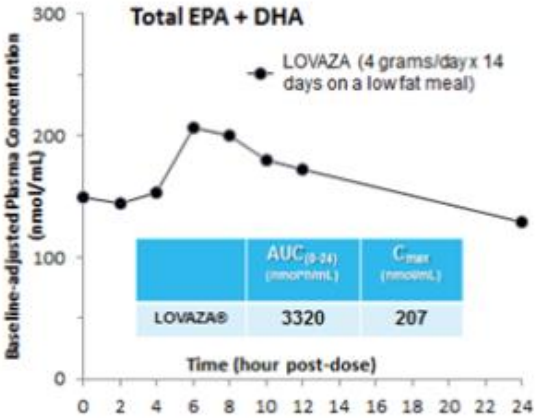
The CAP13-101 study was an open-label, randomized, multiple-dose, single-center, parallel-design study in healthy volunteers. Forty-two (42) subjects were enrolled into 3 groups of 14 subjects who took 1, 2 or 4 grams of CaPre, administered once a day 30 minutes after breakfast. The objectives of the study were to determine the pharmacokinetic profile and safety on Day 1 following a single oral dose and Day 14 following multiple oral doses of CaPre in individuals pursuing a low-fat diet (therapeutic lifestyle changes diet). The effect of a high-fat meal on the bioavailability of CaPre was also evaluated at Day 15. Blood samples were collected for assessment of EPA and DHA total lipids in plasma to derive the pharmacokinetic parameters.

The PK profile of CaPre following multiple 4g doses obtained in the CAP13-101 study (at Day 14) was compared to the results obtained in a similar PK study (Offman 2013 - ECLIPSE 2) where LOVAZA was also administered at 4g a day for 14 days with a low fat diet. Although CaPre contains about 2.5 times less EPA/DHA compared to LOVAZA (approximately 310 mg/1 g capsule for CaPre versus 770 mg/1 g capsule for LOVAZA, CaPre plasma levels of EPA and DHA when administered with a low fat meal appear to be very similar to those of LOVAZA, as indicated by the AUC and Cmax. This study gives Acasti confidence in the dosing and design of the Phase 3 trial.

As demonstrated by the two graphs below, CaPre reaches similar blood and therapeutic levels to LOVAZA after 14 daily doses of CaPre at 4g/day, despite CaPre containing 2.5 times less EPA and DHA compared to LOVAZA:



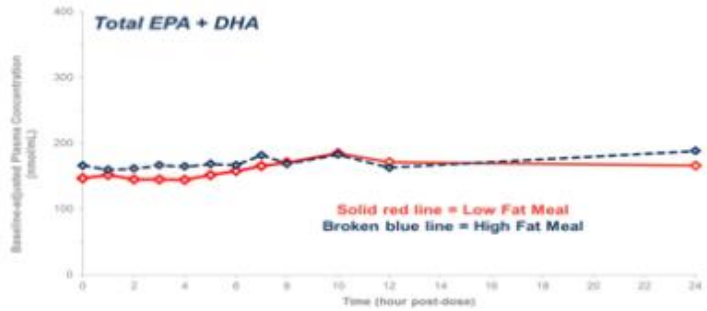
CAP13-101 Final Study Report, January 2015



EPA+DHA levels following LOVAZA were estimated from ECLIPSE II, Offman, VHRM 2013

The graph below illustrates that the bioavailability of CaPre (total EPA+DHA levels in the blood) does not appear to be meaningfully affected by the fat content of a meal after multiple daily doses of CaPre at 4g/day (< 20% difference in AUC). This could represent a significant clinical advantage for CaPre since the administration with a low-fat meal represents a more realistic and attractive regimen for patients with hypertriglyceridemia who must follow a restricted diet.

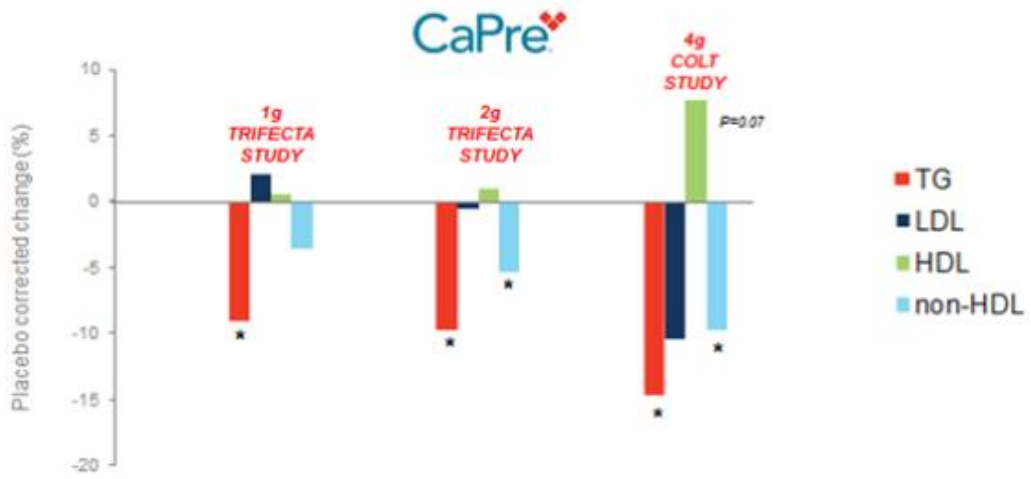
Study CAP13-101 CaPre Pharmacokinetics – Shows No Significant Food Effect



The graph below presents the effects of CaPre on the lipid profile obtained in Acasti's two completed Phase 2 trials, TRIFECTA and COLT. 90% of the patients in these studies had mild to moderate HTG (levels between 200 – 499 mg/dL), and only 10% of patients had severely elevated TG levels between 500 and 877 mg/dL, the latter being the maximum level of TGs permitted per study protocol (Health Canada requirement). Only 30% of the patients were on a background of statins, which is important to note as statins appear to increase the TG lowering effect of OM3s.

This data shows that CaPre significantly reduces TGs, but unlike some other prescription OM3s (EPA/DHA products), it has no deleterious effect on LDL-C and may potentially increase HDL-C (p=0.07) – the "Trifecta Effect". Furthermore a dose response was seen with all of the major lipid markers.

Phase 2 Study Results Show CaPre Dose Response and Potential for "Trifecta" Lipid Effect:

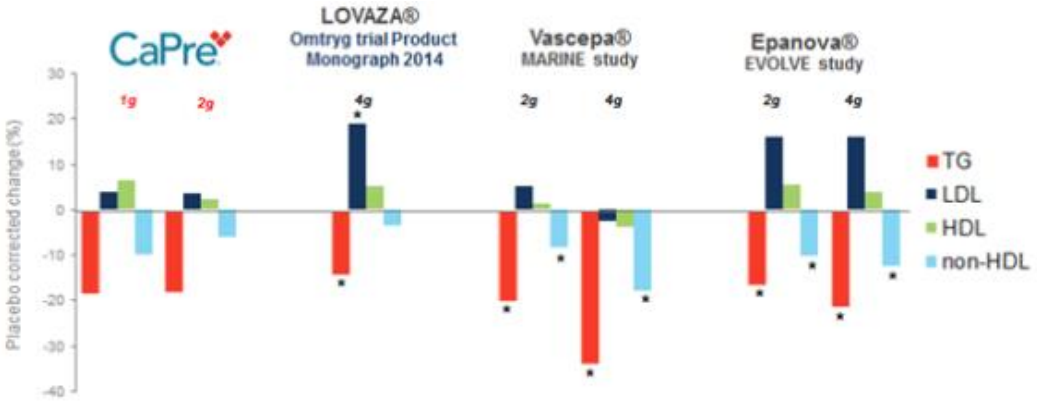


* Indicates results reached statistical significance

COLT and TRIFECTA study data (TG population in mild to moderate is 90%. About 10% were severe. Only 30% of all patients were on statins). TRIFECTA for 1g (N=130) & 2g (N=128) and COLT for 4g (N=62). HDL-C results at 4g from COLT approached statistical significance at P=0.07.

A subgroup analysis including only patients with severe HTG (approximately 10% of patients from the TRIFECTA study) was done to compare the effects of CaPre versus other OM3 drugs in the target population of patients with severe HTG. In spite of being given at a lower dose, the CaPre results compared very well with data from independent studies for the other prescription OM3 drugs approved for the treatment of severe HTG at higher doses of 2 and 4 grams. The results of this subgroup analysis are not statistically significant for CaPre, which may be due to the small sample size, but numerically the results compare well with other OM3 drugs. The results for LDL-C, HDL-C and non-HDL-C are based on descriptive statistics and are directional only (no statistical testing was conducted, and, as such, no "P" values were generated).

Sub-Group Analysis in Patients with Severe HTG: CaPre[19] at 1 & 2 Grams Compares Well with Competition[20] at 2 & 4 Grams:



Only ~1/3 of all patients across all studies were on statins

* Indicates results reached statistical significance

Statins appear to enhance the TG lowering property of OM3 drugs. Accordingly, a subgroup analysis was conducted including only patients who were taking a statin at baseline in the COLT and TRIFECTA studies (approximately 30% of the trial population). The graph below compares the TG lowering effects of CaPre to other OM3s, all on a background of a statin drug, showing that CaPre's TG lowering effects compare well with these other approved OM3 drugs. Also note that the number of patients on statins in the CaPre group was low, with only 39 patients on 2 grams in TRIFECTA and only 22 patients on 4 grams in COLT.

The CaPre 2 gram bar represents the results from patients in the TRIFECTA trial on statins. A statistically significant reduction in TG (-25.7 % placebo corrected) was seen in that statin subgroup. The results for LDL-C, HDL-C and non HDL-C are based on descriptive statistics and are directional only (no statistical testing was conducted and, as such, no "P" values were generated).

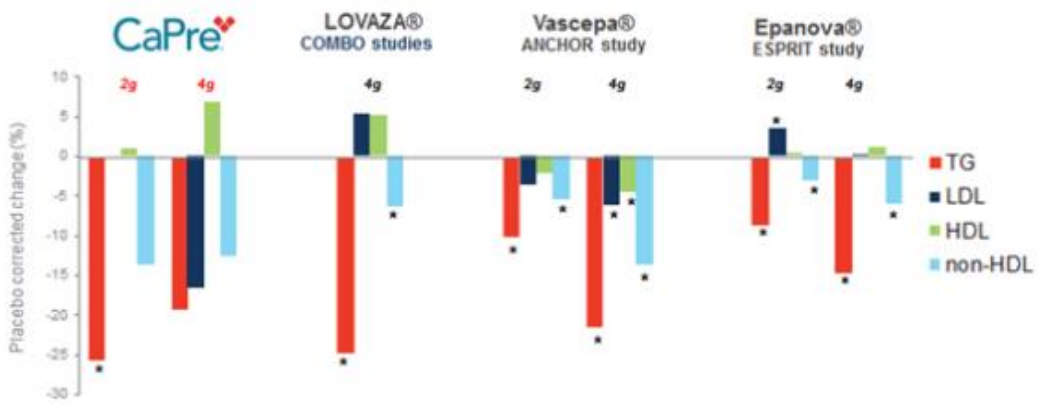
The CaPre 4 gram bar represents patient results only from the COLT trial (there was no 4 gram arm in TRIFECTA). None of the results were statistically significant, which may be explained by the small number of patients (N=22).

As seen in the larger full study analyses, CaPre does not show any deleterious effect on LDL, and shows the potential to increase HDL (p=0.07). This will need to be confirmed in a Phase 3 trial.

[19] Subgroup analysis on CaPre Phase 2 TRIFECTA study data in patients with severe HTG; (N=10 for 1g & N=14 for 2g). Results are not statistically significant for TG which may be explained by the small number of patients in this subgroup analysis. Results for LDL-C, HDL-C and non-HDL-C are based on descriptive statistics only (no statistical testing conducted).

[20] Lovaza 4g (N=103), Vascepa 2g/4g (N=73/76), Epanova 2g/4g (N=100/99).

Sub-Group Analysis in Patients Treated with Statins[21] vs Independent Competitor Data[22]: Potential for CaPre Trifecta Effect



* Indicates results reached statistical significance

In summary, in addition to reducing triglyceride levels in patients with mild to severe hypertriglyceridemia, clinical data collected by Acasti to date has indicated that CaPre may also have beneficial effects on other blood lipids such as HDL-C (good cholesterol) and non-HDL-C. Also, clinical data collected by Acasti to date indicates that CaPre has no deleterious effect on, and may potentially reduce, LDL-C (bad cholesterol) levels. Lastly, the absorption of CaPre is not meaningfully affected by the fat content of a meal consumed prior to drug administration, which Acasti believes could give CaPre a significant clinical and marketing advantage.

CaPre's potential clinical benefits as compared to currently approved competing products are summarized in the table below, suggesting that CaPre may deliver a more complete lipid management solution for patients with severe HTG[23]:

Drug Composition	Products	Therapeutic Effect			
		TG	LDL-C	HDL-C	Non-HDL-C
EPA + DHA Omega-3 Phospholipids/Free Fatty Acids	CaPre	↓	→ / ↓	→ / ↑	↓
EPA + DHA Omega-3 Ethyl Esters	LOVAZA & Generics	↓	↑	→	↓
EPA only Omega-3 Ethyl Esters	VASCEPA	↓	→	→	↓
EPA + DHA Omega-3 Free Fatty Acids	EPANOVA	↓	↑	→	↓

Positive effect Neutral effect Negative effect

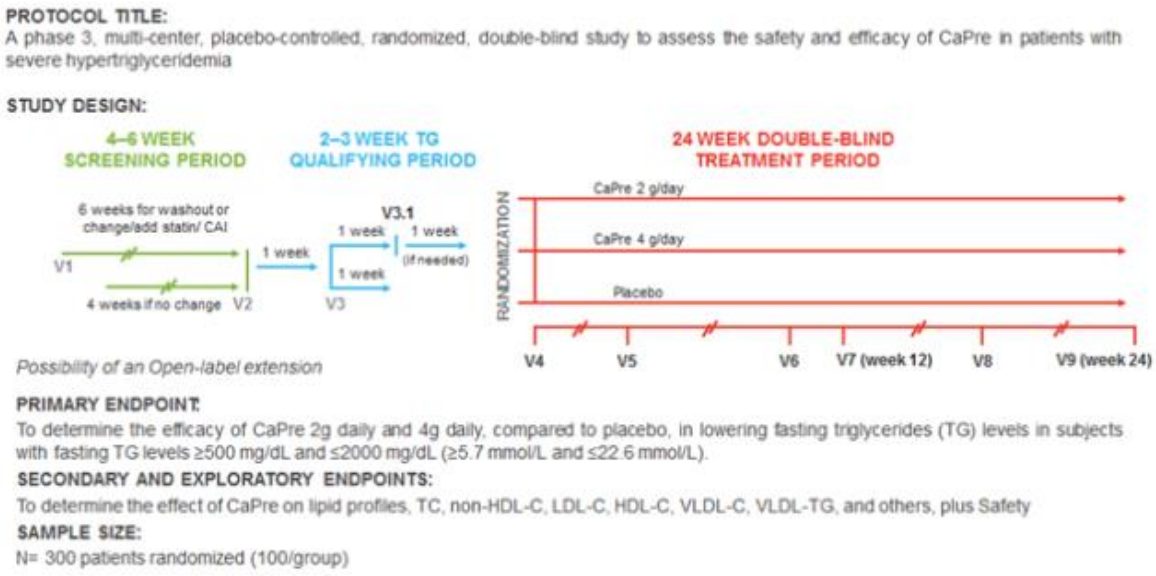
[21] CaPre subgroup analyses on patients treated with statins: TRIFECTA for 2g (N=39) and COLT for 4g (N=22). For CaPre 2g, results for LDL-C, HDL-C, and non-HDL-C are based on descriptive statistics only (no statistical testing was conducted). For CaPre 4g, no results are statistically significant which may be explained by the small number of patients.

[22] All patients on a statin background: Lovaza (N=122 for 4g), Vascepa (N= 234 for 2g, N=227 for 4g), Epanova (N=209 for 2g, N=207 for 4g). Statins have been shown to enhance the efficacy of OM3 products – Vascepa NDA 202057. Statistical review, section 4.2 ''Other special/Subgroup populations', p. 107; and Maki K et al. Clin. Ther. 2013.

[23] In Phase 2 clinical studies, CaPre showed positive effects on TGs, HDL-C and non-HDL-C, and no deleterious (and potentially positive effects) effects were noted on LDL-C. Competitor information from prescription information and SEC company filings.

Planned Phase 3 Clinical Trial Design

The following chart illustrates the planned design and dosing of the Phase 3 clinical trial for CaPre. This plan and design will be submitted to the FDA, and is expected to be reviewed and discussed with the FDA in early 2017:



CaPre Regulatory Strategy

Acasti's strategy is to develop and initially commercialize CaPre for the treatment of severe hypertriglyceridemia. The Corporation is currently aiming to initiate a Phase 3 trial in the second half of 2017, which would be specifically designed to fully evaluate the clinical effect of CaPre on triglycerides, non-HDL-C, LDL-C, and HDL-C levels together with a variety of other interesting cardiometabolic biomarkers in patients with severe hypertriglyceridemia. See "Risk Factors".

In December 2015, Acasti announced that it intended to pursue a 505(b)(2) regulatory pathway towards an NDA approval in the United States. The 505(b)(2) regulatory pathway is defined in the United States *Federal Food Drug and Cosmetics Act* as an NDA containing investigations of safety and effectiveness that are being relied upon for approval and were not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. These applications differ from the typical NDA (described under Section 505(b)(1) of the United States *Federal Food Drug and Cosmetics Act*), in that they allow a sponsor to rely, at least in part, on the FDA's findings of safety and/or effectiveness for a previously approved drug. Acasti intends to pursue this regulatory pathway as a strategy to speed up and streamline the development of CaPre, thereby reducing the associated cost and risk.

In order to qualify for the 505(b)(2) pathway, the FDA supported Acasti's proposal to conduct a bioavailability bridging study that compared CaPre (omega-3 free fatty acid/phospholipid composition) with the already-approved HTG drug LOVAZA (omega-3-acid ethyl esters) in healthy volunteers. These results were discussed above and given that the primary study objective was met, these results are expected to support the basis for claiming a comparable safety profile of CaPre and LOVAZA. This supports Acasti's plan to receive authorization to use the FDA's 505(b)(2) pathway, which would enable the Corporation to rely on the safety data of LOVAZA. The Corporation intends to meet with the FDA in early 2017 to confirm this regulatory approach, and to finalize the protocol for the Phase 3 trial needed for NDA approval. See "Risk Factors".

Acasti is currently preparing for discussions with the FDA about the next steps for the development program of CaPre, including a Phase 3 clinical study in patients with severe hypertriglyceridemia. Such discussions are intended to allow the FDA to provide feedback on Acasti's

regulatory plans and to clarify or answer specific questions that the FDA may have prior to initiating any Phase 3 clinical study. See “Risk Factors”.

The Corporation’s planned key milestones and development timeline are presented below.

CaPre Development Timeline and Key Milestones

Business Strategy

Intellectual Property Strategy

Pursuant to a license agreement entered into with Neptune in August 2008, as amended, Acasti has been granted an exclusive license to Neptune’s intellectual property portfolio related to cardiovascular pharmaceutical applications (the **License Agreement**). The license allows Acasti to develop and commercialize its novel and active pharmaceutical ingredients (**APIs**) for the prescription drug and medical food markets.

As a result of the royalty prepayment transaction entered into between Neptune and Acasti on December 4, 2012, Acasti is no longer required to pay any royalties to Neptune under the License Agreement during its term for the use of the intellectual property under license.

As previously disclosed, Acasti had been marketing ONEMIA®, an omega-3 medical food supplement which has been marketed in the United States since 2011, and was also marketed as a natural health product in Canada since 2012. Acasti’s management decided in late 2015 to find distribution alternatives for ONEMIA to allow Acasti to focus its energy and resources exclusively on the development of CaPre. As a result, Acasti entered into a non-exclusive license agreement with Neptune for the sale and distribution of ONEMIA. Given the resulting low level of sales, Acasti recently decided to discontinue the production of ONEMIA and has notified all customers to that effect. As a result of the discontinuation of ONEMIA, Acasti does not intend to renew its non-exclusive license agreement with Neptune for the distribution of ONEMIA once it expires.

In addition to the license of Neptune’s patents, Acasti continues to expand its own intellectual property (IP) portfolio and patents. Acasti has filed patent applications in 26 jurisdictions including Europe, North America, Asia and Australia for its ‘Concentrated Therapeutic Phospholipid Composition’ to treat hypertriglyceridemia, and currently has 14 issued patents and 20 patents pending in 19 different countries. The last to expire Acasti patent is valid until 2030.

U.S. patents were granted to Acasti protecting a method of reducing serum triglyceride levels comprising administering a composition comprising about 66% phospholipid (PL) (US 8,586,567) and a method of treating HTG comprising administering a composition comprising about 60% PL (US 9,475,830). A U.S. “continuation” patent application was subsequently filed to pursue prosecution of “composition of matter” claims encompassing an extract comprising a PL content between about 60% to about 99%.

Acasti believes these patents increase the potential commercial opportunity for CaPre, including possible licensing and partnership opportunities. Acasti is committed to building a global portfolio of

patents to ensure long-lasting and comprehensive intellectual property protection, while also safeguarding valuable market expansion opportunities.

Acasti's patent No. 600167 in New-Zealand, which is enforceable up until 2030, relating to a concentrated phospholipid composition comprising 60% phospholipid and method of using same for treating cardiovascular diseases has been opposed by BIO-MER Ltd. The corresponding Australian patent No. 2010312238 has been opposed by Enzymotech Ltd. Both oppositions are in early stages and only evidences against the validity of Acasti's New Zealand patent has been submitted as of December 5, 2016, but it is important to note that no new prior art has been presented that was not already considered in other jurisdictions such as in the U.S. and Japan, where the Corporation's patents are in force. See "Risk Factors".

CaPre Manufacturing Process Overview

Acasti is developing CaPre as a NCE and is implementing the Phase 3 clinical program under current good manufacturing practices (**cGMP)**, current good clinical practices (**cGCP**) and current good laboratory practices. All contract manufacturing organizations selected are cGMP compliant (both manufacturing and packaging sites). As batch sizes of 10-12 kg of CaPre have already been successfully produced and tested clinically, Acasti is now scaling up to 100 kg/day to fulfill the planned clinical product requirements for the Phase 3 trial. See "Risk Factors".

Acasti's Business and Commercialization Strategy

Key elements of Acasti's business and commercialization strategy include initially obtaining regulatory approval for CaPre in the United States for severe hypertriglyceridemia, and to pursue development and/or distribution partnerships to support the commercialization of CaPre in the United States and in other global markets. Acasti's preferred strategy is to commercialize through strategic partnerships. A late development-stage and differentiated drug candidate like CaPre could be attractive to various global, regional or specialty pharmaceutical companies. Acasti is taking an opportunistic approach to partnering and licensing in various geographies and indications. See "Risk Factors".

Key goals of the Corporation include:

- Initiate and complete the Phase 3 clinical trial and, assuming the results of the Phase 3 clinical trial are positive, file an NDA to obtain regulatory approval for CaPre in the United States (initially for the treatment of severe hypertriglyceridemia) with the potential to expand the indication thereafter for the treatment of moderate to high hypertriglyceridemia, with the likelihood of additional clinical trials being required such as comparative and outcome trials assuming positive outcome study data from two competitors;
- Continue to strengthen Acasti's patent portfolio and other means of protecting intellectual property rights;
- Acasti may pursue strategic opportunities including licensing or similar transactions, joint ventures, partnerships, strategic alliances or alternative financing transactions to provide development capital, market access and other strategic sources of capital for Acasti. However, we cannot assure when or whether Acasti will pursue any such strategic opportunities. See "Risk Factors".

The Corporation does not currently have in-house sales and marketing capabilities, and currently plans to seek an established marketing partner(s) for the sale and distribution of CaPre in the United States, and development and marketing partners for other major global markets. See "Risk Factors". In addition to completing a Phase 3 clinical trial, Acasti expects that additional time and capital will be required to complete the filing of an NDA to obtain FDA pre-market approval for CaPre in the United

States, and to complete business development, marketing and other pre-commercialization activities before reaching commercial launch of the product, which will initially be for the treatment of severe hypertriglyceridemia.

The Corporation expects to focus initially on lipid specialists, cardiologists and primary care physicians who comprise the top prescribers of lipid-regulating therapies for patients with severe HTG as part of the sales and marketing strategy for CaPre. As part of its strategy, the Corporation intends to pursue various strategic opportunities intended to provide funding support for these development and commercialization activities. See “Risk Factors”.

RISK FACTORS

Investing in the securities of the Corporation involves a high degree of risk. Prospective and current investors should carefully consider the following risks and uncertainties, together with all other information in the Corporation's Annual Report on Form 20-F for the year ended February 29, 2016, as filed with the SEC on May 31, 2016 (the **20-F**), as well as the Corporation's financial statements and related notes and "Management's Discussion and Analysis" (**MD&A**). Any of the risk factors described below could adversely affect Acasti's business, financial condition or results of operations and the market price of Acasti's Common Shares and other securities could decline significantly if one or more of these risks or uncertainties actually occur. Unknown risks or risks that Acasti currently believes to be immaterial may also impair its business, financial condition or results of operations. The Corporation cannot assure you that any of the events discussed in the risk factors will not occur. If any of such events does occur, you may lose all or part of your original investment in the Corporation. Certain statements below are forward-looking information. See "Special Note Regarding Forward-Looking Statements" in the 20-F.

General Risks Related to the Corporation

The Corporation may not be able to maintain its operations and research and development without additional funding.

The Corporation will require substantial additional funds to conduct further research and development, scheduled clinical testing, regulatory approvals and the commercialization of CaPre, including manufacturing and marketing capabilities, and, in the event that the Corporation is unable to secure a strategic partner, establishing a commercial sales force. In addition to completing nonclinical and clinical trials, the Corporations expects that additional time and capital will be required to complete the filing of an NDA to obtain FDA approval for CaPre in the United States and to complete marketing and other pre-commercialization activities. To date, the Corporation has financed its operations through public offering and private placement of Common Shares, proceeds from exercises of warrants, rights and options and research tax credits. The Corporation's cash and short term investments (including its restricted short-term investment) were approximately $10.5 million as of February 29, 2016 and approximately $7.1 million as of October 31, 2016. Depending on the status of regulatory approval or, if approved, commercialization of CaPre, the Corporation will most likely require additional capital to fund its operating needs. To achieve the objectives of its business plan, the Corporation plans to establish strategic alliances and raise the necessary capital. The Corporation may also seek additional funding for these purposes through public or private equity or debt financing, joint venture arrangements, and collaborative arrangements with other pharmaceutical companies, and/or from other sources.

The Corporation has incurred operating losses and negative cash flows from operations since inception. If the Corporation is unable to secure sufficient capital to fund its operations, it may be forced to enter into strategic collaborations that could require the Corporation to share commercial rights to CaPre with third parties in ways that the Corporation currently does not intend or on terms that may not be favorable to the Corporation. There can be no assurance that any additional funding from any other third party will be available on acceptable terms or at all to enable the Corporation to continue and complete the research and development of CaPre. The failure to obtain additional financing on favorable terms, or at all, could have a material adverse effect on Acasti's business, financial condition and results of operations.

We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of CaPre or other research and development initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

The Corporation may never become profitable or be able to sustain profitability.

The Corporation is a clinical-stage biopharmaceutical company with a limited operating history. The likelihood of success of the Corporation's business plan must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which the Corporation operates. Biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. Therefore, the Corporation expects to incur expenses without any meaningful corresponding revenues unless and until it is able to obtain regulatory approval and subsequently sell CaPre in significant quantities. The Corporation has been engaged in developing CaPre since 2008. To date, the Corporation has not generated any revenue from CaPre, and it may never be able to obtain regulatory approval for the marketing of CaPre in any indication. Further, even if the Corporation is able to commercialize CaPre or any other product candidate, there can be no assurance that the Corporation will generate significant revenues or even achieve profitability. The Corporation's net loss for the fiscal year ended February 29, 2016 was approximately $6.3 million and approximately $7.5 million for the eight-month period ended October 31, 2016. As of February 29, 2016, the Corporation had an accumulated deficit of approximately $39.6 million and approximately $47.1 million as of October 31, 2016.

If the Corporation obtains FDA approval, it expects that its expenses will increase as it prepares for the commercial launch of CaPre. The Corporation also expects that its research and development expenses will continue to increase in the event it pursues FDA approval for CaPre for other indications. As a result, the Corporation expects to continue to incur substantial losses for the foreseeable future, and these losses may be increasing. The Corporation is uncertain about when or if it will be able to achieve or sustain profitability. If the Corporation achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair the Corporation's ability to sustain operations and adversely affect the price of the Common Shares and its ability to raise capital.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. If one of our product candidates is approved for sale, and we are unable to secure a strategic partner, we will be required to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other biotechnology and pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

We cannot assure you that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy and stock price may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the securities or industry analysts who publish research about us downgrade our shares or publish inaccurate or unfavorable evaluations of our company or our stock, the price of our shares could decline. If one or more of these analysts cease coverage of our company, our shares may lose visibility in the market, which in turn could cause our shares price to decline.

If the Corporation is not successful in attracting and retaining highly qualified personnel, the Corporation may not be able to successfully implement its business strategy.

The Corporation's ability to compete in the highly competitive pharmaceuticals industry depends in large part upon its ability to attract and retain highly qualified managerial, scientific and medical personnel. Competition for skilled personnel in the Corporation's market is intense and competition for experienced scientists may limit the Corporation's ability to hire and retain highly qualified personnel on acceptable terms. The Corporation is highly dependent on its management, scientific and medical personnel. The Corporation's management team has substantial knowledge in many different aspects of drug development and commercialization. Despite the Corporation's efforts to retain valuable employees, members of its management, scientific and medical teams may terminate their employment with the Corporation on short notice or, potentially, without any notice at all. The loss of the services of any of the Corporation's executive officers or other key employees could potentially harm its business, operating results or financial condition. The Corporation's success may also depend on its ability to attract, retain and motivate highly skilled junior, mid-level, and senior managers and scientific personnel. In addition, we do not maintain "key person" insurance policies on the lives of our executives or those of any of our other employees.

Other pharmaceutical companies with which the Corporation competes for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than the Corporation does. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what the Corporation has to offer. If the Corporation is unable to continue to attract and retain high-quality personnel, the rate and success at which the Corporation can develop and commercialize product candidates would be limited.

Neptune will have significant influence over matters put before shareholders.

Neptune currently owns approximately 47.28% of Acasti's outstanding Common Shares and two members of Neptune's Board of Directors are also members of Acasti's Board of Directors. As a result, Neptune exercises control over Acasti as of the date hereof, and will have significant influence with respect to all matters submitted to the Corporation's shareholders for approval, including without limitation

the election and removal of directors, amendments to the articles of incorporation and by-laws of the Corporation and the approval of certain business combinations. Other holders of Common Shares will have a limited role in the Corporation's affairs. This concentration of holdings may cause the market price of the Common Shares to decline, delay or prevent any acquisition or delay or discourage take-over attempts that shareholders may consider to be favourable, or make it more difficult or impossible for a third party to acquire control of the Corporation or effect a change in the Board of Directors and management. Any delay or prevention of a change of control transaction could deter potential acquirors or prevent the completion of a transaction in which the Corporation's shareholders could receive a substantial premium over the then current market price for their Common Shares.

Neptune's interests may not in all cases be aligned with interests of the other shareholders of the Corporation. Neptune may have an interest in pursuing acquisitions, divestitures and other transactions that, in the judgment of its management, could enhance its equity investment, even though such transactions might involve risks to the other shareholders of the Corporation and may ultimately affect the market price of the Common Shares.

Neptune could lose its control of Acasti.

Neptune currently owns approximately 47.28% of Acasti's outstanding Common Shares and two members of Neptune's Board of Directors are also members of Acasti's Board of Directors. As a result, Neptune exercises control over Acasti as of the date hereof. However, if all outstanding warrants, call options and restricted share units of Acasti were to be exercised, Neptune's ownership interest in Acasti's Common Shares would fall to approximately 36%. If Neptune's ownership of Acasti's Common Shares declines, Neptune may lose its ability to elect members of its Board of Directors to Acasti's Board of Directors and to otherwise exercise control over Acasti. A loss of Neptune's control over Acasti, could, among other things result in:

- investors and analysts placing a different, and possibly lower, value on the Common Shares to reflect a lower degree of exposure by Neptune to Acasti's krill oil-based pharmaceutical business; and
- Acasti making decisions in connection with the development and commercialization of Acasti's products with less or no involvement and approval from Neptune.

Neptune has advised that it does not expect to provide material capital to Acasti in the short term and therefore, its ownership interest in Acasti may continue to decline.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our contract research organizations (**CRO**s) and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Risks Related to Product Development, Regulatory Approval and Commercialization

The Corporation's prospects currently depend entirely on the success of CaPre, which is still in clinical development, and the Corporation may not be able to generate revenues from CaPre.

The Corporation has no prescription drug products that have been approved by the FDA, Health Canada or any similar regulatory authority. The Corporation's only prescription drug candidate is CaPre, for which

the Corporation has not yet filed an NDA, and for which the Corporation must conduct additional clinical trials, undergo further development activities and seek and receive regulatory approval prior to commercial launch, which the Corporation does not anticipate will occur until the calendar year 2022 at the earliest.

The Corporation has invested effort and financial resources in the research and development of CaPre. Further development of CaPre will require substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales, if approved.

The Corporation does not have any other prescription drug candidates in development and, therefore, the Corporation's business prospects currently depend entirely on the successful development, regulatory approval and commercialization of CaPre, which may never occur. Most prescription drug candidates never reach the clinical development stage and even those that do reach clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. If the Corporation is unable to successfully commercialize CaPre for the treatment of severe hypertriglyceridemia, it may never generate meaningful revenues. In addition, if CaPre reaches commercialization and there is low market demand for CaPre or the market for CaPre develops less rapidly than the Corporation anticipates, the Corporation may not have the ability to shift its resources to the development of alternative products.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the number of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for patients and clinical trial sites;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population;
- the risk that disease progression will result in death before the patient can enroll in clinical trials or before the completion of any clinical trials in which the patient is enrolled;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition will reduce the number and types of patients and qualified clinical investigators available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. We may also encounter difficulties finding a clinical trial site at which to conduct our trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates or any future product candidates we may develop.

The Corporation may not be able to obtain required regulatory approvals for CaPre.

No Regulatory Approval

We have very limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and, as a company, we have no experience in obtaining approval of any product candidates.

The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of prescription drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries and those regulations differ from country to country. Acasti is not permitted to market CaPre in the United States until it receives approval of an NDA from the FDA and similar restrictions apply in other countries. In the United States, the FDA generally requires the completion of preclinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. To date, the Corporation has not submitted an NDA for CaPre to the FDA or comparable applications to other regulatory authorities.

If the Corporation's development efforts for CaPre, including its planned additional clinical trials, are not successful for the treatment of severe hypertriglyceridemia, and regulatory approval is not obtained in a timely fashion or at all, the Corporation's business will be materially adversely affected.

Risks Related to Regulatory Approval

The receipt of required regulatory approvals for CaPre is uncertain and subject to a number of risks, including the following:

- the FDA or comparable foreign regulatory authorities or independent institutional review boards (**IRBs**) may disagree with the design or implementation of the Corporation's clinical trials;
- the Corporation may not be able to provide acceptable evidence of the safety and efficacy of CaPre;
- the results of the Corporation's clinical trials may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval;
- the dosing of CaPre in a particular clinical trial may not be at an optimal level;
- patients in the Corporation's clinical trials may suffer adverse effects for reasons that may or may not be related to CaPre;
- the Corporation may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the data collected from the Corporation's clinical trials may not be sufficient to support the submission of an NDA for CaPre or to obtain regulatory approval for CaPre in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may not approve the manufacturing processes or facilities of third party manufacturers with which the Corporation contracts for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering the Corporation's clinical data insufficient for approval.

Moreover, the FDA or other regulatory authorities may respond to these submissions by defining requirements we may not have anticipated. Such responses could lead to significant delays in the development of our product candidates. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the prescription drug candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application.

The FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that the Corporation's data is insufficient for approval and require additional clinical trials, or preclinical or other studies. In addition, varying interpretations of the data obtained from preclinical studies and clinical trials could delay, limit or prevent regulatory approval of CaPre.

If regulatory approval is obtained in one jurisdiction, that does not necessarily mean that CaPre will receive regulatory approval in all jurisdictions in which the Corporation may seek approval. The failure to obtain approval for CaPre in one or more jurisdictions may negatively impact the Corporation's ability to obtain approval in a different jurisdiction. A failure to obtain regulatory marketing approval for CaPre in any indication would prevent the Corporation from commercializing CaPre, and the Corporation's ability to generate revenue would be materially impaired.

Risk Related to Post Regulatory Approval

Moreover, if we obtain regulatory approval for CaPre or any other product candidate, we will only be permitted to market our product for the indication approved by the FDA, and such approval may involve limitations on the indicated uses or promotional claims we may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles. For example, we will not be able to claim that our products have fewer side effects, or improve compliance or efficacy, unless we can demonstrate those attributes to the FDA in comparative clinical trials.

In addition, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for CaPre in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development, marketing or commercialization of CaPre or any other product candidate that we may discover, in-license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for CaPre, we will still need to develop a commercial organization, or collaborate with a third party for the commercialization of CaPre, establish commercially viable pricing and obtain approval for coverage and adequate reimbursement from third parties, including government payors.

Mergers and acquisitions in the cardiovascular industry may result in even more concentration of resources among a smaller number of our competitors.

Mergers and acquisitions in the cardiovascular industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical

trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs. If we fail to compete effectively, our business and operating results would be harmed.

Negative outcome study data from two competitors in mild to moderate HTG patients would have an adverse impact on the potential market for omega-3s.

We are currently anticipating positive outcome study data from two of our competitors in order to benefit from market expansion, including the potential to expand CaPre's indication in the future to the treatment of moderate to high hypertriglyceridemia. In the event of negative outcome study data from one or both of such competitors, or if one or both clinical trials fail to be completed within the anticipated timeline or at all, for any reason, our potential target market for CaPre will be reduced to severe HTG patients and our ability to realize the full market potential of CaPre will be harmed which, in turn, would have a material adverse effect on our business, financial condition and results of operations.

CaPre, if approved, would be subject to competition from products for which no prescription is required.

If approved by applicable regulatory authorities, CaPre will be a prescription-only omega-3. Mixtures of omega-3 fatty acids are naturally occurring substances in various foods, including fatty fish. Omega-3 fatty acids are also marketed by others as dietary supplements or natural health products. Dietary supplements may generally be marketed without a lengthy FDA premarket review and approval process and are not subject to prescription. The Corporation cannot be certain that physicians or consumers will view CaPre as superior or that physicians will be more likely to prescribe CaPre, if approved.

To the extent the price of CaPre is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements or natural health products, physicians may recommend these commercial alternatives instead of CaPre or patients may elect on their own to take commercially available non-prescription omega-3 fatty acids. Either of these outcomes may adversely impact the Corporation's results of operations by limiting how the Corporation prices CaPre and limiting the revenue the Corporation receives from the sale of CaPre.

Recently enacted and future legislation may increase the difficulty and cost for the Corporation to obtain marketing approval of and commercialize CaPre and affect the prices the Corporation may obtain.

In the United States and certain other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for CaPre, restrict or regulate post-approval activities and affect the Corporation's ability to profitably sell CaPre. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. The Corporation does not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of CaPre, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject the Corporation to more stringent product labeling and post-marketing testing and other requirements.

In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. If we fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

United States

In the United States, the Medicare Modernization Act (the **MMA**) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, the Corporation expects that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that the Corporation receives for CaPre and could seriously harm its business. While the MMA applies only to drug benefits for Medicare beneficiaries, private health insurance companies often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private health insurance companies.

The *Patient Protection and Affordable Care Act*, as amended by the *Health Care and Education Affordability Reconciliation Act of 2010* (collectively, the **Health Care Reform Law**) has broadened access to health insurance, reduced or constrained the growth of healthcare spending, enhanced remedies against fraud and abuse, added new transparency requirements for healthcare and health insurance industries, imposed new taxes and fees on the health industry and imposed additional health policy reforms.

Provisions affecting pharmaceutical companies include the following.

- mandatory rebates for drugs sold into the Medicaid program were increased, and the rebate requirement was extended to drugs used in risk-based Medicaid managed care plans;
- the 340B Drug Pricing Program under the *Public Health Services Act* was extended to require mandatory discounts for drug products sold to certain critical access hospitals and other covered entities;
- expansion of eligibility criteria for Medicaid programs;
- expansion of entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the “donut hole”; and
- pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company’s market share of prior year total sales of branded products to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense.

Despite initiatives to invalidate the Health Care Reform Law, the U.S. Supreme Court has upheld certain key aspects of the legislation, including the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the individual mandate. However, due to the results of the recent presidential election, there can be no assurance that the Health Care Reform Law will remain in its current form. There can also be no assurance that any potential amendments to the Health Care Reform Law or its implementing regulations would not have significant negative financial impact on the development or profitability of CaPre. Although there are legal challenges to the Health Care Reform Law in lower courts on other grounds, at this time it appears the implementation of at least certain parts of the Health Care Reform Law will continue. The Corporation will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase the Corporation’s regulatory burdens and operating costs. The Corporation expects that additional federal healthcare reform measures will be adopted in the future, any of which could limit the

amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the value of CaPre and reduce the Corporation's ability to achieve profitability.

Canada

If CaPre is approved in Canada, the Corporation will be restricted in the price it may charge for CaPre. In Canada, the prices of patented drugs are reviewed by the Patented Medicines Pricing Review Board (**PMPRB**). The PMPRB reviews pricing information for patented drug products to ensure that the prices comply with the *Patent Act* (Canada) and does so for the duration of the patent. Following the scientific review, the PMPRB reviews the price of the drug to determine if it is within certain pricing guidelines (**Guidelines**), based on the factors established in the *Patent Act* (Canada).

In Canada, most new patented drug prices are limited so that the cost of therapy is in the range of the cost of therapy for existing drugs sold in Canada used to treat the same disease. As a result:

- prices of moderate and substantial improvement drugs and breakthrough drugs are also restricted by a variety of tests;
- existing patented drug prices cannot increase by more than the Canadian Consumer Price Index; and
- the Canadian prices of patented medicines can never be the highest in the world.

If the PMPRB believes that the price of a patented drug appears to exceed the Guidelines, and where the criteria for commencing an investigation is met, the PMPRB will conduct an investigation to determine the facts. An investigation may result in one of the following:

- the closure of the file, where it is concluded that the price was within the Guidelines;
- a Voluntary Compliance Undertaking by the Corporation to reduce the price and take other measures to comply with the Guidelines; or
- a public hearing to determine if the price is excessive and, if so, the issuance of a remedial order by the PMPRB.

If the Corporation is restricted in the price it can charge for CaPre in Canada (if CaPre is approved in Canada), this will significantly reduce the value of CaPre and have a material adverse effect on the Corporation's ability to generate revenue and achieve profitability.

If the Corporation or its dependent contractors, consultants, manufacturers, collaborators, vendors or service providers fail to comply with healthcare laws and regulations, or if the Corporation violates government price reporting laws, the Corporation may be subject to civil or criminal penalties and affect its ability to develop, market, and sell its product candidates and harm its reputation.

In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. If we fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of federal and state healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of the Corporation's business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging

for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, dispensers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending drugs reimbursable under federal healthcare programs may be subject to scrutiny if they do not qualify for an exemption or safe harbor. The Corporation's practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability.

Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Additional laws and regulations include:

- the U.S. federal *Health Insurance Portability and Accountability Act* (**HIPAA**), which created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud healthcare programs;
- HIPAA, as amended by the *Health Information Technology for Economic and Clinical Health Act* (**HITECH**), which imposes requirements on certain types of people and entities relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information; and
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to report annually to the Centers for Medicare & Medicaid Services (**CMS**) information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, which is published in a searchable form on an annual basis.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribes; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment. Settlements of United States government litigation may include Corporate Integrity Agreements with commitments for monitoring, training, and reporting designed to prevent future violations.

Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our

defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

In addition, if we or any collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others:

- adverse regulatory inspection findings;
- warning letters;
- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on, or prohibitions against, importation or exportation of our products;
- suspension of review or refusal to approve pending applications or supplements to approved applications;
- exclusion from participation in government-funded healthcare programs;
- exclusion from eligibility for the award of government contracts for our products;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

The Corporation relies on third parties to conduct its clinical trials for CaPre.

The Corporation has entered into agreements with a**CRO**s to provide monitors for and to manage data for its ongoing clinical trials. The Corporation relies heavily on these parties for execution of clinical studies for CaPre and controls only certain aspects of their activities. Nevertheless, the Corporation is responsible for ensuring that each of its studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and the Corporation's reliance on CROs would not relieve it of its regulatory responsibilities. The Corporation and its CROs are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, Health Canada and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If the Corporation or its CROs fail to comply with applicable cGCPs, the clinical data generated in the Corporation's clinical trials may be deemed unreliable and the FDA, Health Canada or comparable foreign regulatory authorities may require the Corporation to perform additional clinical trials before approving the Corporation's marketing applications. The Corporation cannot assure you that, upon inspection, the FDA will determine that any of the Corporation's clinical trials comply with cGCPs. In addition, the Corporation's clinical trials must be conducted with products produced under cGMP regulations and require a large number of test subjects. The Corporation's failure or the failure of its CROs to comply with these regulations may require the Corporation to repeat clinical trials, which would delay the regulatory approval process and could also subject the Corporation to enforcement action up to and including civil and criminal penalties.

If any of the Corporation's relationships with these third-party CROs terminate, the Corporation may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to the Corporation's clinical protocols, regulatory requirements or for other reasons, any such clinical trials may

be extended, delayed or terminated, and the Corporation may not be able to obtain regulatory approval for or successfully commercialize CaPre.

Any third parties conducting our preclinical studies and clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf.

The Corporation relies on third parties for the manufacturing, production and supply of CaPre and may be adversely affected if those third parties are unable or unwilling to fulfill their obligations.

The production of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Acasti does not own or operate manufacturing facilities for the production of CaPre, nor does it have plans to develop its own manufacturing operations in the foreseeable future. Accordingly, the Corporation needs to rely on one or more third party manufacturers to produce and supply its required drug product for its nonclinical research and clinical trials for CaPre.

Although we are working to develop a commercially viable manufacturing process, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale up, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials.

Any of these challenges could delay completion of preclinical studies or clinical trials, require bridging studies or trials, or the repetition of one or more studies or trials, increase development costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

The Corporation's reliance on third-parties to produce CaPre exposes Acasti to a number of risks. For example, Acasti may be subject to delays in or suspension of the production of CaPre if a third-party manufacturer:

- becomes unavailable for any reason, including as a result of the failure to comply with current good manufacturing practices, or cGMP regulations;
- experiences manufacturing problems or other operational failures, such as equipment failures or unplanned facility shutdowns required to comply with cGMP or damage from any event, including fire, flood, earthquake, business restructuring or insolvency; or
- fails or refuses to perform its contractual obligations under its agreement with the Corporation, such as failing or refusing to deliver the quantities requested on a timely basis.

If the Corporation's third-party manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, Acasti may be subject to sanctions, including fines, product recalls or seizures, injunctions, total or partial suspension of production, civil penalties, withdrawals of previously granted regulatory approvals, and criminal prosecution. Any of these penalties could delay the initiation of the Corporation's planned Phase 3 clinical trial for CaPre, which could have a material adverse effect on Acasti's business prospects and result of operations.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by ourselves and our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in Canada, the United States and in other jurisdictions governing laboratory procedures and the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers'

procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental, health and safety laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We do not currently have arrangements in place for redundant supply. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

The Corporation is dependent on Neptune, its parent company, for certain essential services. Failure to renew existing shared services agreements with Neptune at all or under mutually favorable terms, could adversely affect our business, financial condition and results of operations.

The Corporation's parent company, Neptune, provides it with, among other things, the ability to source raw krill oil under Neptune's purchasing contracts and access to cost benefits from back office shared services and functions, including corporate affairs, public company reporting, accounting, human resources, payroll, information technology, purchasing, accounts payable, accounts receivable and shared premises at attractive prices. Many of these services and resources are necessary for its operations and the Corporation relies on these services to support its business activities and to help it remain competitive. Any termination of or failure to renew existing agreements for such services could have a material adverse effect on the Corporation's business, financial condition, liquidity and results of operations.

If our supply of raw krill oil, API, or finished product is interrupted, our ability to initiate and/or complete clinical trials, manufacture CaPre or maintain adequate inventory levels could suffer and NDA approval and future revenues could be delayed.

Supply interruptions may occur and, as a result, we may not be able to provide a stable product over a long period of time, and our inventory of finished products may not always be adequate to satisfy demand. Numerous factors could cause interruptions in the supply of our finished products, including failure to have a third party supply chain partner's process validated in a timely manner, shortages or instabilities in raw material, NKPL66 and CaPre and packaging components required by our manufacturers (robust encapsulation process, robust cold supply chain maintenance), changes in our sources for manufacturing or packaging, our failure to timely locate and obtain replacement manufacturers as needed and conditions affecting the cost and availability of raw materials. We are also in the process of scaling-up production of CaPre and, as a result, we cannot guarantee that our product will be comparable when produced in larger quantities (100Kg batches). This may have an adverse effect on our business, financial results and operations.

The Corporation may be subject to the risks of foreign exchange rate fluctuation.

We may be exposed to fluctuations of the Canadian dollar against the U.S. dollar because we publish our financial statements in Canadian dollars, while we intend on entering into an agreement with a CRO based in the United States. The United States exchange rate may fluctuate in relation to the Canadian dollar, and such fluctuation between the Canadian dollar and the U.S. dollar may have a material adverse effect on the Corporation's business, financial position and results of operations.

Negative Operating Cash Flow.

The Corporation has incurred operating losses and negative cash flows from operations since inception. As at August 31, 2016, the Corporation's current liabilities and expected level of expenses in the research and development phase of its drug candidate significantly exceed current assets. The Corporation plans to raise additional funds or find a strategic partner and rely on the continued support of Neptune to pursue its operations in terms of general and administrative shared services. The continuance of this support is outside of the Corporation's control. If the Corporation does not raise additional funds, find a strategic partner or does not receive the continued support from its parent, it may not be able to realize its assets and discharge its liabilities in the normal course of business. As a result, there exists a material uncertainty that casts substantial doubt about the Corporation's ability to continue as a going concern and, therefore, realize its assets and discharge its liabilities in the normal course of business. From November 1, 2016 until March 31, 2017, being the last day of its current financial year (as a result of the recent change in the Corporation's fiscal year end) the Corporation projects that it will require approximately $5.2 million, excluding non-cash stock-based compensation and other non-cash expenses, to fund anticipated expenses, including primarily development and general and administrative expenses, as well as capital expenditures.

The price of the Corporation's Common Shares may fluctuate.

Market prices for securities in general, and that of pharmaceutical companies in particular, tend to fluctuate. Factors such as the announcement to the public or in various scientific or industry forums of technological innovations; new commercial products; patents, exclusive rights obtained by the Corporation or others; disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; the commencement, enrollment or results of future clinical trials we may conduct, or changes in the development status of our product candidates; results or delays of pre-clinical and clinical studies by the Corporation or others; any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings; a change of regulations; additions or departures of key scientific or management personnel; overall performance of the equity markets; general political and economic conditions; publications; failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; research

reports or positive or negative recommendations or withdrawal of research coverage by securities analysts; actual or anticipated variations in quarterly operating results; announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; public concerns over the risks of pharmaceutical products and dietary supplements; unanticipated serious safety concerns related to the use of CaPre; future sales of securities by the Corporation or its shareholders; and many other factors, many of which are beyond our control, could have considerable effects on the price of the Corporation's securities. There can be no assurance that the market price of the Common Shares will not experience significant fluctuations in the future. As a result of any of these factors, the market price of the securities of the Corporation at any given point in time may not accurately reflect the value of the Corporation or its securities.

In addition, the stock market in general, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Common Shares, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Forward-Looking Statements May Prove to be Inaccurate.

Investors should not place undue reliance on forward-looking statements. By their nature, forward-looking statements involve numerous assumptions, known and unknown risks and uncertainties, of both general and specific nature, that could cause actual results to differ materially from those suggested by the forward-looking statements or contribute to the possibility that predictions, forecasts or projections will prove to be materially inaccurate.

Future issuances or actual or potential sales of securities.

In the future, the Corporation may issue additional Common Shares or securities convertible into Common Shares, which may dilute existing shareholders. The Corporation's articles of incorporation permit the issuance of an unlimited number of Common Shares and an unlimited number of preferred shares, issuable in series, and shareholders will have no pre-emptive rights in connection with such further issuances. The directors of the Corporation have the discretion to determine the provisions attaching to any series of preferred shares and the price of issue of further issuances of Common Shares. Also, additional Common Shares may be issued by the Corporation upon the exercise of stock options and upon the exercise of previously issued warrants. The issuance of these additional equity securities may have a similar dilutive effect on then existing holders of Common Shares.

The market price of the Common Shares could decline as a result of future issuances by the Corporation or sales by its existing holders of Common Shares, or the perception that these sales could occur. Sales by shareholders might also make it more difficult for Acasti to sell equity securities at a time and price that Acasti deems appropriate, which could reduce its ability to raise capital and have an adverse effect on its business.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other

operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

The market price of the Common Shares could decline as a result of operating results falling below the expectations of investors or fluctuations in operating results each quarter.

The Corporation's net losses and expenses may fluctuate significantly and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in the price of the Corporation's Common Shares. The Corporation's net losses and expenses have fluctuated in the past and are likely to do so in the future. These fluctuations could cause the market price of the Common Shares to decline. Some of the factors that could cause the Corporation's net losses and expenses to fluctuate include the following:

- results of preclinical studies and clinical trials, or the addition or termination of preclinical studies, clinical trials or funding support;
- the timing of the release of results from any preclinical studies and clinical trials;
- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing of regulatory submissions and approvals;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize the Corporation's products;
- the outcome of any litigation;
- changes in foreign currency fluctuations;
- competition;
- the timing of achievement and the receipt of milestone payments from current or future third parties;
- failure to enter into new or the expiration or termination of current agreements with third parties;
- failure to introduce the Corporation's products to the market in a manner that generates anticipated revenues;
- our execution of any new collaboration, licensing or similar arrangement, and the timing of payments we may make or receive under such existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If the Corporation's quarterly operating results fall below the expectations of investors or securities analysts, the market price of the Common Shares could decline substantially. Furthermore, any quarterly fluctuations in the Corporation's operating results may, in turn, cause the market price of the Common

Shares to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The Corporation does not currently intend to pay any cash dividends on its Common Shares in the foreseeable future.

The Corporation has never paid any cash dividends on its Common Shares. The Corporation does not anticipate paying any cash dividends on its Common Shares in the foreseeable future because, among other reasons, the Corporation currently intends to retain any future earnings to finance its business. The future payment of cash dividends will be dependent on factors such as cash on hand and achieving profitability, the financial requirements to fund growth, the Corporation's general financial condition and other factors the board of directors of the Corporation may consider appropriate in the circumstances. Until the Corporation pays cash dividends, which it may never do, its shareholders will not be able to receive a return on their Common Shares unless they sell them.

The Corporation may be unable to form or enter into commercial opportunities on its anticipated timeline, and may not realize the expected benefits of any such transaction.

The Corporation intends to form or seek co-development and/or marketing partnerships and possible licensing and partnership opportunities with third parties that it believes will complement or augment its development and commercialization efforts with respect to its product candidates and any future product candidates that it may develop. Any of these transactions and relationships may require the Corporation to incur non-recurring and other charges, increase its near and long-term expenditures, issue securities that dilute its existing shareholders or disrupt its management and business. These transactions and relationships also may result in a delay in the development of the Corporation's product candidates if it becomes dependent upon the other party and such other party does not prioritize the development of the Corporation's product candidates relative to its other development activities. In addition, the Corporation faces significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, the Corporation may not be successful in its efforts to establish a strategic partnership or other alternative arrangements for its product candidates on its anticipated timeline, or at all, because its product candidates may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view the Corporation's product candidates as having the requisite potential to demonstrate safety and efficacy. The Corporation cannot be certain that, following a strategic transaction or license, it will achieve the revenue or specific net income that justifies such transaction.

The Corporation may pursue opportunities or transactions that may adversely affect its business and financial condition

Management of Acasti, in the ordinary course of Acasti's business, regularly explores potential strategic opportunities and transactions. These opportunities and transactions may include strategic joint venture relationships, significant debt or equity investments in Acasti by third parties, the acquisition or disposition of material assets, the licensing, acquisition or disposition of material intellectual property, the development of new product lines or new applications for its existing products, significant distribution arrangements, the sale of Common Shares of Acasti and other similar opportunities and transactions. The public announcement of any of these or similar strategic opportunities or transactions might have a significant effect on the price of the Common Shares. Acasti's policy is to not publicly disclose the pursuit of a potential strategic opportunity or transaction unless it is required to do so by applicable law, including applicable securities laws relating to continuous disclosure obligations. There can be no assurance that investors who buy or sell securities are doing so at a time when Acasti is not pursuing a particular strategic opportunity or transaction that, when announced, would have a significant effect on the price of the Common Shares.

In addition, any such future corporate development may be accompanied by certain risks, including exposure to unknown liabilities of the strategic opportunities and transactions, higher than anticipated transaction costs and expenses, the difficulty and expense of integrating operations and personnel of any

acquired companies, disruption of the Corporation's ongoing business, diversion of management's time and attention, and possible dilution to shareholders. The Corporation may not be able to successfully overcome these risks and other problems associated with any future acquisitions and this may adversely affect the Corporation's business and financial condition.

Risk Relating to the Corporation's Intellectual Property Rights

It is difficult and costly to protect Acasti's intellectual property rights, and Acasti cannot ensure the protection of these rights.

The Corporation's activities depend, in part, on its ability to (i) obtain and maintain patents, trade secret protection and operate without infringing the intellectual proprietary rights of third parties, (ii) successfully defend these patents (including patents owned by or licensed to the Corporation) against third-party challenges, and (iii) successfully enforce these patents against third party competitors. There is no assurance that the Corporation will be granted such patents and/or proprietary technology or that such granted patents and/or proprietary technology will not be circumvented through the adoption of a competitive, though non-infringing, process or product. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of the Corporation's intellectual property. Accordingly, the Corporation cannot predict the breadth of claims that may be allowable or enforceable in its patents (including patents owned by or licensed to the Corporation). Failure to protect the Corporation's existing and future intellectual property rights could seriously harm its business and prospects and may result in the loss of its ability to exclude others from using the Corporation's technology or its own right to use the technologies. If the Corporation does not adequately ensure the right to use certain technologies, it may have to pay others for the right to use their intellectual property, pay damages for infringement or misappropriation and/or be enjoined from using such intellectual property. The Corporation's patents do not guarantee the right to use the technologies if other parties own intellectual property rights that are necessary in order to use such technologies. The Corporation's and Neptune's patent position is subject to complex factual and legal issues that may give rise to uncertainty as to the validity, scope and enforceability of a particular patent.

In any case, there can be no assurance that:

- any rights under Canadian, U.S. or foreign patents owned by the Corporation or other patents that Neptune and other third parties license to the Corporation will not be curtailed;
- the Corporation was the first inventor of inventions covered by its issued patents or pending applications or that the Corporation was the first to file patent applications for such inventions;
- the Corporation's pending or future patent applications will be issued with the breadth of claim coverage sought by the Corporation, or be issued at all;
- the Corporation's competitors will not independently develop or patent technologies that are substantially equivalent or superior to the Corporation's technologies;
- any of the Corporation's trade secrets will not be learned independently by its competitors; or
- the steps the Corporation takes to protect its intellectual property will be adequate.

In addition, effective patent, trademark, copyright and trade secret protection may be unavailable, limited or not sought in certain foreign countries.

Further, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed (or 20 years after the filing date of the first non-provisional US patent application to which it claims priority). Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time

between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection.

The degree of future protection for the Corporation's proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect the Corporation's rights, permit it to gain or keep its competitive advantage, or provide it with any competitive advantage at all. The Corporation cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by the Corporation, or that the Corporation or its licensor will not be involved in interference, opposition or invalidity proceedings before U.S., Canadian or foreign patent offices.

The Corporation depends on Neptune to protect a significant portion of its proprietary rights that derive from the Corporation's license agreement with Neptune. Neptune may be primarily or wholly responsible for the maintenance of patents and prosecution of the licensed patent applications relating to important areas of the Corporation's business. If Neptune fails to adequately maintain, prosecute or protect these patents or patent applications, the Corporation may have the right to take further action on its own to protect its technology. However, the Corporation may not be successful or have adequate resources to do so. Any failure by Neptune or by the Corporation to protect its intellectual property rights could significantly harm the Corporation's business and prospects.

The Corporation also seeks to protect its proprietary intellectual property, including intellectual property that may not be patented or patentable, in part by confidentiality agreements and, if applicable, inventors' rights agreements with its strategic partners and employees. There can be no assurance that these agreements will not be breached, that the Corporation will have adequate remedies for any breach or that such persons or institutions will not assert rights to intellectual property arising out of these relationships. The cost of enforcing the Corporation's patent rights or defending rights against infringement charges by other patent holders may be significant and could limit operations.

The Corporation also relies on trade secrets to protect its technology, especially in cases when the Corporation believes patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. If the Corporation cannot maintain the confidentiality of its proprietary and licensed technology and other confidential information, the Corporation's ability and that of its licensor to receive patent protection and its ability to protect valuable information owned or licensed by the Corporation may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of the Corporation's trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, the Corporation's competitors may independently develop equivalent knowledge, methods and know-how. If the Corporation fails to obtain or maintain patent protection or trade secret protection for CaPre or the Corporation's technologies, third parties could use the Corporation's proprietary information, which could impair its ability to compete in the market and adversely affect its ability to generate future revenues and attain profitability.

CaPre is covered by patents that are not owned by the Corporation but are instead licensed to the Corporation by Neptune.

In addition to its proprietary patent applications, the Corporation has an exclusive worldwide license under certain patents and know-how to develop and commercialize CaPre within a specified field of use pursuant to a license agreement with Neptune. The limitation on the Corporation's field of use may prevent it from developing and commercializing CaPre in other fields. Additionally, the Corporation's license is subject to termination for breach of its terms, and therefore its rights may only be available to it for as long as Neptune agrees that the Corporation's development and commercialization activities are sufficient to meet the terms of the license. If this license is terminated for any reason and the Corporation is not able to negotiate another agreement with Neptune for use of its patents and know-how, the Corporation will not be able to manufacture and market CaPre, which would have a material adverse effect on its business and financial condition. See "Business Strategy – Intellectual Property Strategy."

We and our current or future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or technologies at a reasonable cost in a timely fashion or at all. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable.

Disputes may arise between us and regarding intellectual property subject to this license agreement, including with respect to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the rights of Neptune under the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by Neptune and us and our partners.

Any disputes with Neptune over intellectual property that we have licensed from it may prevent or impair our ability to maintain our current licensing arrangement. We depend on these licensed technologies and products to develop CaPre. Termination of our license agreement could result in the loss of significant rights and could materially harm our ability to further develop and commercialize CaPre and any other product candidates.

CaPre may infringe the intellectual property rights of others, which could increase the Corporation's costs and delay or prevent the Corporation's development and commercialization efforts.

The Corporation's success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third party patent rights that may be relevant to the Corporation's proprietary or licensed technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, the Corporation may be unaware of third-party patents that may be infringed by the development and commercialization of CaPre or any other future prescription drug candidate. There may be certain issued patents and patent applications claiming subject matter that the Corporation's licensor or the Corporation may be required to license in order to research, develop or commercialize CaPre, and the Corporation cannot be certain whether such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;

- divert the time and attention of the Corporation's technical personnel and management;
- cause product development or commercialization delays, including delays in clinical trials for CaPre;
- prevent the Corporation from commercializing CaPre until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require the Corporation to cease or modify its use of the technology and/or develop non-infringing technology; or
- require the Corporation to enter into royalty or licensing agreements.

Others may hold proprietary rights that could prevent CaPre from being marketed. Any patent-related legal action against the Corporation claiming damages and seeking to enjoin commercial activities relating to CaPre or the Corporation's processes could subject the Corporation to potential liability for damages potentially including treble damages and attorneys fees if we are found to have wilfully infringed and require the Corporation to obtain a license to continue to manufacture or market CaPre or any other future prescription drug candidates. The Corporation cannot predict whether the Corporation would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. In addition, the Corporation cannot be sure that it could redesign CaPre or any other future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent the Corporation from developing and commercializing CaPre or any other future product candidate, which could harm the Corporation's business, financial condition and operating results.

In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

A number of companies, including several major pharmaceutical companies, have conducted research on pharmaceutical uses of omega-3 fatty acids, which has resulted in the filing of many patent applications related to this research. The Corporation is aware of third-party U.S., Canadian or other foreign patents that contain broad claims related to methods of using these general types of compounds, which may be construed to include potential uses of CaPre or any future product candidates. If the Corporation were to challenge the validity of these or any other issued U.S., Canadian or other foreign patents in court, the Corporation would need to overcome a statutory presumption of validity that attaches to every U.S. and Canadian patent. This means that, in order to prevail, the Corporation would have to present clear and convincing evidence as to the invalidity of the other party's patent's claims. If the Corporation were to challenge the validity of any issued U.S. patent in an administrative trial before the Patent Trial and Appeal Board in the United States Patent and Trademark Office (**USPTO**), the Corporation would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in the Corporation's favor on questions of infringement, validity or enforceability.

If our trademark is not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We have trademarked CaPre. Our trademark may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to this trademark or may be forced to stop using this name, which we need for name recognition by potential

partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademark, we may not be able to compete effectively and our business may be adversely affected.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material adverse impact on our business. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

In addition, in an infringement proceeding, a court may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the *Leahy-Smith America Invents Act* (**AIA**) enacted in 2011 involves significant changes in patent legislation. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Further, the Supreme Court of the United States has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. These changes have led to increasing uncertainty with regard to the scope and value of our issued patents and to our ability to obtain patents in the future.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification derivation and opposition proceedings in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection

which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.