



**ANNUAL INFORMATION FORM**

**Fiscal Year Ended February 28, 2014**

**May 29, 2014**

## TABLE OF CONTENTS

Basis of Presentation .....	1
Cautionary Note Regarding Forward-Looking Information.....	1
Corporate Structure .....	3
Company Overview .....	3
Intercorporate Relationships .....	3
Acasti’s Business.....	3
Business Strategy .....	4
Treatments for Cardiometabolic Disorders – Acasti’s Market .....	5
Acasti’s Products .....	7
ONEMIA® .....	8
Clinical and Nonclinical Research.....	9
Sales and Marketing.....	12
Competition .....	13
Intellectual Property.....	14
Raw Materials, Manufacturing and Facility.....	16
Employees, Specialized Skills and Knowledge .....	17
Litigation.....	17
Government Regulation.....	20
History and Development of the Corporation .....	24
Three-Year History .....	24
Recent Developments .....	27
Risk Factors.....	28
Dividends .....	46
Description of Capital Structure.....	46
Common Shares.....	46
Preferred Shares.....	47
Market for Securities.....	50
Trading Prices and Volumes for Acasti .....	50
Escrowed Securities and Securities subject to Restriction on Transfer.....	51
Directors and Officers .....	51
Name, Occupation and Security Holding of Directors and Executive Officers.....	51
Cease Trade Orders, Bankruptcies, Penalties or Sanctions .....	53
Legal Proceedings and Regulatory Actions.....	54
Interest of Management and Others in Material Transactions.....	54
Transfer Agents and Registrars .....	54
Material Contracts .....	54
Interest of Experts .....	54
Report on Audit Committee .....	55
Audit Committee’s Charter.....	55
Composition of the Audit Committee.....	55
External Auditor Fees .....	56
Additional Information.....	56
Schedule “A”.....	1

## **BASIS OF PRESENTATION**

As used in this annual information form (“**AIF**”), unless the context otherwise requires, references to “Acasti”, “Acasti Pharma”, “Corporation”, “it”, “its” or similar terms refer to Acasti Pharma Inc., references to “Neptune” refer to Acasti’s parent company, Neptune Technologies & Bioresources Inc., and references to “NeuroBioPharm” refer to Acasti’s sister company, NeuroBioPharm Inc.

Market data and certain industry data and forecasts included in this AIF 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. Forecasts are particularly likely to be inaccurate, 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 AIF. 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 “Risk Factors” in this AIF. 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 AIF may only be used for the purpose for which it has been published.

Unless otherwise noted, in this AIF, all information is presented as of February 28, 2014. All references in this AIF to “dollars”, “CDN\$” and “\$” refer to Canadian dollars, and references to “US\$” refer to United States dollars, unless otherwise expressly stated.

## **CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION**

This AIF 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 in this AIF 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 AIF includes, but is not limited to, information or statements about:

- Acasti’s ability to conduct its current Phase II, PK and future additional clinical trials for CaPre<sup>®</sup>, including the timing and results of those clinical trials;
- Acasti’s ability to commercialize and distribute CaPre<sup>®</sup> and ONEMIA<sup>®</sup> in the United States and elsewhere;
- Acasti’s estimates of the size of the potential markets for CaPre<sup>®</sup> and ONEMIA<sup>®</sup> and the rate and degree of market acceptance of CaPre<sup>®</sup> and ONEMIA<sup>®</sup>;
- the benefits of CaPre<sup>®</sup> and ONEMIA<sup>®</sup> as compared to other products in the pharmaceutical and medical food markets, respectively;
- Acasti’s ability to maintain and defend its intellectual property rights;
- Acasti’s ability to maintain its supply of raw materials, including krill oil, from its parent company;
- Acasti’s ability to secure a third-party supplier to provide Acasti, as needed, with raw materials to supplement its operations, including krill oil, used to manufacture CaPre<sup>®</sup> and ONEMIA<sup>®</sup>;

- Acasti's ability to secure and maintain a third-party to manufacture CaPre® whose manufacturing processes and facilities are in compliance with current good manufacturing practices ("cGMP");
- Acasti's ability to obtain and maintain regulatory approval of CaPre®, and the labeling requirements that would apply under any approval Acasti may obtain;
- regulatory developments affecting the pharmaceutical and medical food markets in the United States and elsewhere;
- the size and growth of the potential markets for CaPre® and ONEMIA® and Acasti's ability to serve those markets;
- the rate and degree of market acceptance of CaPre®, if it reaches commercialization;
- the success of competing products that are or become available; and
- Acasti's expectations regarding its financial performance, including its revenues, research and development, expenses, gross margins, liquidity, capital resources and capital expenditures.

Although the forward-looking information in this AIF 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.

In addition, the forward-looking information in this AIF is subject to a number of known and unknown risks, uncertainties and other factors, including those described in this AIF 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:

- whether the current and future clinical trials by the Corporation will be successful;
- whether CaPre® and ONEMIA® can be successfully commercialized;
- the Corporation's reliance on third parties for the manufacture, supply and distribution of its products and for the supply of raw materials, including the ability to find a third party to supply krill oil in sufficient quantities and quality and to produce CaPre® under cGMP standards;
- the Corporation's reliance on a limited number of distributors for ONEMIA® and its 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 achieve profitability;
- the Corporation's ability to secure future financing from Neptune or other third party sources on favorable terms or at all;
- the Corporation's ability to gain acceptance of its products in its markets;
- the Corporation's ability to attract, hire and retain key management and scientific personnel;
- the Corporation's ability to achieve its publicly announced milestones on time;
- the Corporation's ability to successfully defend any product liability lawsuits that may be brought against it;
- intense competition from other companies in the pharmaceutical and medical food industries; and

- the Corporation's ability to secure and defend its intellectual property rights and to avoid infringing upon the intellectual property rights of third parties.

Consequently, all the forward-looking information in this AIF 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 AIF.

## **CORPORATE STRUCTURE**

### **Company Overview**

Acasti was incorporated on February 1, 2002 under Part 1A of the *Companies Act* (Québec) under the name "9113-0310 Québec Inc". On August 7, 2008, pursuant to a Certificate of Amendment, the Corporation changed its name to "Acasti Pharma Inc.", its share capital, 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 has further revised its provisions regarding its borrowing powers. The Corporation became a reporting issuer in the Province of Québec on November 17, 2008. 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).

Acasti's head office and registered office is located at 545 Promenade du Centropolis, Suite 100, Laval, Québec H7T 0A3. The Corporation's website address is <http://www.acastipharma.com>. The Corporation does not incorporate the information on or accessible through its website into this AIF, and you should not consider any information on, or that can be accessed through, its website as part of this AIF.

### **Intercorporate Relationships**

The Corporation has no subsidiaries. As of the date of this AIF, Neptune owns 51,942,183 Class A shares of Acasti (the "**Common Shares**"), representing approximately 49% of the Common Shares issued and outstanding. The Common Shares are voting, participating and have no par value. Neptune also owns a warrant entitling it to acquire 592,500 Common Shares.

The Common Shares are listed on the TSX Venture Exchange ("**TSXV**") under the ticker symbol "APO" and on The NASDAQ Stock Market ("**NASDAQ**") under the ticker symbol "ACST".

## **ACASTI'S BUSINESS**

### **Business Overview**

Acasti is an emerging biopharmaceutical company focused on the research, development and commercialization of new krill oil-based forms of omega-3 phospholipid therapies for the treatment and prevention of certain cardiometabolic disorders, in particular abnormalities in blood lipids, also known as dyslipidemia. Because krill feeds on phytoplankton (diatoms and dinoflagellates), it is a major source of phospholipids and polyunsaturated fatty acids ("**PUFAs**"), mainly eicosapentaenoic acid ("**EPA**") and docosahexaenoic acid ("**DHA**"), which are two types of omega-3 fatty acids well known to be beneficial for human health.

CaPre®, currently Acasti's only prescription drug candidate, is a highly purified omega-3 phospholipid concentrate derived from krill oil and is being developed to help prevent and treat hypertriglyceridemia, which is a condition characterized by abnormally high levels of triglycerides in the bloodstream. Phospholipids represent approximately two-thirds of the composition of CaPre®. The majority of EPA and DHA contained in CaPre® is bound to phospholipids, allowing these PUFAs to more readily reach the small intestine where they undergo faster 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 than EPA and DHA contained in fish oil which are transported by triglycerides and must undergo additional digestion before they are ready for transport in the bloodstream. See “Acasti’s Products - Overview”.

CaPre® is designed to be used as a therapy in conjunction with positive lifestyle changes and administered either alone or with other treatment regimens such as statins (a class of drug used to reduce cholesterol levels) and potentially for use by statin-intolerant or statin-resistant patients. CaPre® is being developed for the treatment of patients with high triglycerides with levels ranging from 200 to 499 mg/dL (“**mild to moderate hypertriglyceridemia**”) and very high triglycerides with levels over 500mg/dL (“**severe hypertriglyceridemia**”). In addition to targeting the reduction of triglyceride levels, clinical data collected and reviewed by the Corporation to date has indicated that CaPre® may also normalize blood lipids by increasing high density lipoprotein (“**HDL-C**”) (good cholesterol), and reducing non-high density lipoprotein (“non-HDL-C”), which includes all cholesterol contained in the bloodstream except HDL-C. In addition, clinical data collected by Acasti to date indicates that CaPre® has no significant deleterious effect on low density lipoprotein (“LDL-C”) (bad cholesterol) levels. Future clinical trials of Acasti, which may include trials specifically designed to evaluate the effect of CaPre® on LDL-C levels, may further assist Acasti in evaluating the effect of CaPre® on LDL-C levels and validate reductions of LDL-C observed by Acasti in its nonclinical trials. See “Acasti’s Business - Clinical and Nonclinical Research - Clinical”. Due to a recent decision of the U.S. Food and Drug Administration’s (the “**FDA**”) not to grant authorization to commercialize a competitor’s drug in the mild to moderate patient population before the demonstration of clinical outcome benefits, Acasti is reassessing its clinical strategy and may put a primary and first focus on the severe hypertriglyceridemia population.

During the fiscal year ended February 29, 2012, Acasti initiated the TRIFECTA and COLT trials, two Phase II clinical trials in Canada designed to evaluate the safety and efficacy of CaPre® for the treatment of patients with levels of triglycerides ranging from 2.28 to 10.0 mmol/L (200-877 mg/dL). On August 13, 2013, Acasti announced the completion and results of its open-label COLT trial. Acasti’s double-blind TRIFECTA trial is ongoing and Acasti expects results to be available during the first half of 2014. See “Acasti’s Business - Clinical and Nonclinical Research - Clinical”.

Further to the completion of the Phase II COLT trial, and in parallel with the ongoing Phase II TRIFECTA trial, being conducted in Canada, the Corporation has filed an investigational new drug (“**IND**”) application with the FDA, to conduct a pharmacokinetic (“**PK**”) trial, which Acasti expects to conduct prior to a Phase III clinical trial that Acasti intends to conduct in the United States, with potentially a few Canadian clinical trial sites, under the guidelines and rules of the FDA. Concurrently, Acasti is corresponding with the FDA and has responded to the FDA’s recommendations regarding its upcoming IND filing for its phase III clinical trial of CaPre® in the United States. The FDA has invited Acasti to formally request an end of phase II/pre phase III meeting to allow them to provide feedback on the submission and to address specific questions for which Acasti is seeking approval and final response from the FDA. Acasti intends to seek such meeting as soon as TRIFECTA trial results are available. See “Acasti’s Business - Clinical and Nonclinical Research - Clinical - Next Steps”.

ONEMIA®, a medical food and currently Acasti’s only commercialized product, is a purified omega-3 phospholipid concentrate derived from krill oil with lower levels of phospholipids, EPA and DHA content than CaPre®. Based on nonclinical studies conducted by Acasti, supported by clinical testing conducted on Neptune Krill Oil (NKO®), Acasti believes ONEMIA® to be safe and effective for the dietary management of omega-3 phospholipid deficiency related to abnormal lipid profiles and cardiometabolic disorders. See “Acasti’s Business - Acasti’s Products - ONEMIA®”.

### **Business Strategy**

Key elements of Acasti’s strategy to commercialize therapies for dyslipidemia and other cardiometabolic disorders include: (i) completing Acasti’s Phase II TRIFECTA clinical trial in Canada, initiating and completing PK and a Phase III clinical trial and filing a New Drug Application (“**NDA**”) to obtain regulatory approval for CaPre® in the United States (initially for the treatment of severe hypertriglyceridemia and thereafter for the treatment of mild to moderate hypertriglyceridemia); (ii) strengthening Acasti’s patent portfolio and other means of protecting intellectual property exclusivity; (iii) pursuing distribution partnerships to commercialize CaPre® in the United States and elsewhere; and (iv) continuing to generate awareness of ONEMIA® throughout the medical community in an effort to build a market foundation for CaPre®. Acasti may also pursue strategic opportunities including

licensing or similar transactions, joint ventures, partnerships, strategic alliances or alternative financing transactions to provide sources of capital for Acasti. However, no assurance can be given as to when or whether Acasti will pursue any such strategic opportunities.

## **Treatments for Cardiometabolic Disorders – Acasti’s Market**

### *Lipid Disorders and Cardiovascular Disease*

Heart attacks, strokes and other cardiovascular events represent the leading cause of death and disability among men and women in the United States. According to the 2011 At-A-Glance Report from the U.S. Center for Disease Control, more than 1 out of every 3 adults in the United States (approximately 83 million) currently lives with one or more types of cardiovascular disease; an estimated 935,000 heart attacks and 795,000 strokes occur in the United States each year; and an estimated 71 million adults in the United States have high cholesterol (i.e., high levels of LDL-C). Having abnormally high levels of lipids or lipoproteins, such as cholesterol and triglycerides, which are fats carried in the bloodstream, is an important risk factor for cardiovascular disease.

According to the American Heart Association, the prevalence of hypertriglyceridemia is increasing in the United States and globally, correlating to the increasing incidence of obesity and diabetes. Market participants, including the American Heart Association, have estimated that one-third of the population in the United States has elevated levels of triglycerides, including over 40 million people diagnosed with mild to moderate hypertriglyceridemia and over 4 million people diagnosed with severe hypertriglyceridemia. 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 HDL-C and elevated levels of LDL-C. Lowering triglyceride levels is one of the primary goals to reduce a patient’s risk of atherosclerotic cardiovascular disease. Hypertriglyceridemia is due to 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.

Patients with type 2 diabetes are more susceptible to cardiovascular disease. Cardiovascular disease may be preventable in some patients with appropriate treatment of lipid abnormalities. Diabetic dyslipidemia most commonly manifests as elevated triglycerides and low levels of HDL-C, with a predominance of small, dense LDL-C particles amid relatively normal LDL-C levels. Non-HDL-C reduction is a key secondary goal of therapy under the National Cholesterol Education Program Adult Treatment Panel III national lipid treatment guidelines and, according to the American Diabetes Association and the American College of Cardiology, has been emphasized as a major goal of therapy in the consensus guidelines for lipoprotein management in patients with cardiometabolic risk. Acasti believes, based in part on a study published by Blaha MJ et al. in The Journal of Clinical Lipidology in 2008, that non-HDL-C levels may be a better indicator than LDL-C for the prediction of cardiovascular events and that non-HDL-C reduction has many other compelling advantages over LDL-C and other traditional lipid parameters. Studies have established the clinical utility of non-HDL-C as a comprehensive measure of atherogenic lipoproteins. In diabetic patients, non-HDL-C levels may be a stronger predictor of cardiovascular disease than LDL-C levels or triglycerides because it correlates highly with atherogenic lipoproteins. Target goals for LDL-C levels and non-HDL-C levels in patients with diabetes are < 100 and < 130 mg/dL, respectively. Failure to consider the importance of non-HDL-C in type 2 diabetes may result in undertreatment of patients with diabetes.

Red blood cells are made of a molecule called haemoglobin that glucose adheres to in the bloodstream. The more glucose in the blood, the more it will adhere to haemoglobin to make a glycosylated haemoglobin molecule, called haemoglobin A1C (or HbA1c). HbA1c is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. This serves as a marker for average blood glucose levels over the previous months prior to the measurement.

A National Health and Nutrition Examination Survey analysis of dyslipidemia in the United States in 2010 indicated that while LDL-C levels have actually declined since its last analysis, the percentage of patients with hypertriglyceridemia has risen by 6% along with the dramatic increases in obesity. The National Cholesterol Education Program (“NCEP”) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol recommends that the first priority for the management of hypertriglyceridemia is triglyceride reduction to decrease the risk of pancreatitis. In addition, severe hypertriglyceridemia is also associated with a markedly increased risk for

cardiovascular disease and a recent report released by the NCEP Expert Panel has claimed that elevated triglyceride levels can be regarded as an independent risk factor for cardiovascular disease-related events such as myocardial infarction, ischemic heart disease and ischemic stroke.

In a subgroup analysis of the Japan EPA Lipid Intervention Study, in 2005, in which 18,645 hypercholesterolemic patients randomly received EPA plus a statin or statin control, patients with baseline triglycerides >150 mg/dL and HDL-C <40 mg/dL receiving EPA plus a statin (7,503 patients) had a 19% reduced risk of cardiovascular disease compared to a statin alone (7,478 patients; P=0.048). In addition, in 2001, the Italian Group for the Study of the Survival of Myocardial Infarction (GISSI) trial randomly assigned 11,324 survivors of recent myocardial infarction to receive omega-3 PUFAs (1 gram per day), vitamin E (300 mg per day), both, or neither (the control group) for 3.5 years. Among the patients who received omega-3 PUFAs alone, as compared to the control group, there was a 15% reduction in the composite primary end point of death, nonfatal myocardial infarction, or nonfatal stroke (p<0.02) and a 20% reduction in the rate of death from any cause (p<0.01). The reduction in risk of sudden death was statistically significant beginning at the four month stage of treatment. A similarly significant, although more delayed, pattern after six to eight months of treatment was observed for cardiovascular, cardiac and coronary deaths.

A recent meta-analysis by Sarwar et al. in 2007 included 29 prospective studies and was the largest and most comprehensive epidemiological assessment of the association between triglyceride levels and cardiovascular disease risk in Western populations (262,525 participants; 10,158 cases). A combined analysis of the 29 studies yielded an adjusted odds ratio of 1.72 (72% higher risk) for the patients with triglyceride levels greater than or equal to 200 mg/dL compared to those with normal triglyceride levels. The conclusion of the study is that there are moderately strong associations between triglyceride levels and cardiovascular disease risk.

Several omega-3 fatty acid products derived from fish oil are currently being marketed and sold in the United States and elsewhere. Some consist of supplements that are commercialized for human health maintenance while others are prescription omega-3 fatty acids that are designed as treatments for severe hypertriglyceridemia.

#### Available Prescription Drugs

The rise in obesity over the last 20 years has led to a parallel increase in triglyceride levels among the population and awareness of medical and health practitioners about the critical role that high triglyceride levels, particularly together with abnormal levels of LDL-C, HDL-C and non HDL-C (which is collectively referred to as dyslipidemia), have as a predictor of cardiovascular events. Accordingly, the introduction of new prescription drugs and drug therapies to lower the risk of cardiovascular events by addressing dyslipidemia has become a priority. The initial treatment recommendation for patients with dyslipidemia is typically a lifestyle change (diet and increased exercise). Dyslipidemia is also treated with statins, which account for a large portion of prescriptions for dyslipidemia. However, statins alone are primarily used for reducing LDL-C and appear to have only modest effects on triglyceride levels. Recognizing that statins alone are not effective triglyceride lowering drugs, the NCEP panel recommends the use of more focused therapies to lower triglyceride levels in patients with severe hypertriglyceridemia. The first-line drug therapy in patients with severe hypertriglyceridemia is often a prescription omega-3 fatty acid or fibrates, but clinical tests have shown that fibrates may also induce side effects.

According to an investigation published by the American Medical Association in 2009, fewer than 4% of adults in the United States with hypertriglyceridemia receive prescription medication to lower their triglyceride levels, representing a significant unmet medical need. Many available treatment options have limitations in the treatment of hypertriglyceridemia which Acasti believes CaPre® can address. The use of fibrates, for example, has been shown to raise the risk of abnormal increases in liver enzymes and creatinine (a marker of kidney function) and, when combined with a statin, rhabdomyolysis (muscle breakdown). Based on the results of the COLT trial and other data collected by the Corporation, the Corporation does not believe that CaPre® produces such side effects. Furthermore, Acasti believes that CaPre® in combination with statins could become a standard of care in patients with mixed dyslipidemia because of its once per day dosing convenience. See “Acasti’s Business - Clinical and Nonclinical Research - Clinical - COLT Trial”.

There are several marketed prescription omega-3 fatty acids currently approved for treatment of dyslipidemia in the United States and elsewhere. According to the Frost Sullivan 2012 Global Overview of the EPA and DHA Omega-3 Ingredients Markets, the global revenue for the marine and algae EPA/DHA omega-3 ingredients market



in 2011 was approximately \$1.8 billion. Lovaza and Omacor, which are sold in the United States and Europe, respectively, are omega-3 ethyl-esters derived from fish oil comprised of EPA and DHA and are indicated for the treatment of severe hypertriglyceridemia in twice-daily doses of two 1-gram capsules or once-a-day dose of four 1-gram capsules. In addition, Vascepa and Epadel are two approved omega-3 ethyl-esters derived from fish oil comprised of EPA that are sold in the United States and Japan, respectively. A market research report published by Amadee & Company Inc. estimates that the total prescription omega-3 market generated over \$2 billion in sales worldwide in 2012. Acasti believes that there will be increased growth in the prescription omega-3 market based on the expected introduction, and resulting increased promotion and awareness, of new prescription omega-3 products, as well as the emergence of new clinical data regarding the efficacy of omega-3s in the treatment and prevention of cardiometabolic disorders. Other disorders that potentially benefit from the use of prescription omega 3 fatty acids include osteopenia/osteoporosis, depression, sleep disorders associated with depression and pain and inflammation.

The cardioprotective efficacy of omega-3 fatty acids is well-established. Omega-3 products have anti-thrombotic and anti-inflammatory effects that have proven to inhibit atherosclerosis in animal models as well as reduce the rate of adverse cardiovascular events in humans. Omega-3 fatty acids, particularly those with concentrated levels of EPA and DHA, have been demonstrated in multiple clinical trials to lower concentrations of triglycerides and non-HDL in the bloodstream. In a study published in the American Journal of Clinical Nutrition in 2009, it was proposed that the omega-3 index be considered a potential risk factor for coronary heart disease mortality, especially sudden cardiac death.

### Medical Foods

Medical foods are at the intersection of functional food and prescription drugs. Medical foods are regulated by the FDA and intended for specific dietary management of a disease with “distinctive nutritional requirements” under the supervision of a physician and contain ingredients that are generally recognized as safe (GRAS) or are otherwise considered acceptable for use. No market pre-authorization by the FDA or other similar international agencies is needed for medical foods to be commercialized in the United States or elsewhere.

The majority of U.S. medical food products on the market are for metabolic diseases. Protein-based medical foods are the most common. Nutrients such as omega-3s, isoflavones, vitamin D, chelated zinc, flavonoids (e.g., baicalin, catechin, pterostilbene), chromium picolinate, phytosterols and L-arginine are other leading ingredients used in this developing category, along with other vitamins and minerals such as pyridoxine, thiamine and folic acid, which are being used in combination. Acasti believes ONEMIA® is the only medical food that offers a high concentration of krill oil-derived omega-3 fatty acids.

Manufacturers are bringing more medical foods to market that address metabolic processes. In 2006, Limbrel (flavocoxid), the first medical food for the management of osteoarthritis, was launched. Axona was designated by the FDA in 2009 as a medical food, targeting metabolic deficiencies associated with Alzheimer’s disease; the well-researched VSL #3, a probiotic for ulcerative colitis and the ileal pouch, was introduced to the market in 2002; and NiteBite, a snack bar for the nutritional management of hyperglycemia, has been marketed since 1996.

### Acasti’s Products

#### Overview

Acasti believes its krill oil-based form of omega-3 phospholipid therapies have advantages over omega-3 products that are derived from fish oil. EPA and DHA in krill oil are mainly carried by phospholipids, while EPA and DHA derived from fish oil are mainly carried by triglycerides. Acasti believes that omega-3 phospholipids provide for better absorption and assimilation of EPA and DHA into the bloodstream compared to other omega-3 sources, including those derived from fish oil. Phospholipids represent approximately two-thirds of the composition of CaPre®. This high phospholipid content allows the EPA and DHA bound to the phospholipids to be absorbed into the small intestine where their transformation into complex fat molecules that are required for transport in the bloodstream occurs. Acasti believes that omega-3 fatty acids from fish oil require additional digestion before this process can occur. Once in the bloodstream, the target destinations for krill oil-based phospholipids also differ from fish oil-based omega-3 triglycerides. Krill oil is absorbed directly into the membranes of cells and tissue, which are also composed of phospholipids, whereas fish oils are stored in fat tissue as a source of energy, requiring a much higher amount of fish oil in order to provide the body with the EPA and DHA for the desired health benefits. In

addition, absorption of ethyl-ester forms of currently available prescription omega-3 fatty acids derived from fish oil requires the breakdown of fats by pancreatic enzymes that are produced in response to the consumption of high fat meals. As a low fat diet is typically a critical component for treatment of patients with severe hypertriglyceridemia, these ethyl-ester formulations have demonstrated lower absorption and bioavailability relative to those formulated as omega-3 phospholipids.

### CaPre®

CaPre® is designed to be used as a therapy in conjunction with positive lifestyle changes and administered either alone or with other treatment regimens such as statins (a class of drug used to reduce cholesterol levels) and potentially for use by statin-intolerant or statin-resistant patients. CaPre® is being developed for the treatment of mild to moderate hypertriglyceridemia and severe hypertriglyceridemia. In addition to targeting the reduction of triglyceride levels, clinical data collected by Acasti to date has indicated that CaPre® may also normalize blood lipids by increasing HDL-C (good cholesterol) and reducing non-HDL-C, which includes all cholesterol contained in the bloodstream except HDL-C. In addition, clinical data collected and reviewed by Acasti to date indicates that CaPre® has no significant deleterious effect on LDL-C (bad cholesterol) levels. Future clinical trials of Acasti, which may include trials specifically designed to evaluate the effect of CaPre® on LDL-C levels, may further assist Acasti in evaluating the effect of CaPre® on LDL-C levels and validate reductions of LDL-C observed by Acasti in its nonclinical trials. Obtaining regulatory approval for the commercialization of CaPre® requires that safety is confirmed and it is effective at reducing triglycerides at a level that would medically benefit the patient. See “Acasti’s Business - Clinical and Nonclinical Research - Clinical - COLT Trial”.

During the fiscal year ended February 29, 2012, Acasti initiated two Phase II clinical trials in Canada. On August 13, 2013, the Corporation announced the completion and results of its open-label Phase II COLT clinical trial, which was primarily designed to evaluate the safety and efficacy of CaPre® for the treatment of mild to severe hypertriglyceridemia. The results of Acasti’s Phase II COLT trial found CaPre® to be safe and effective at different doses over a 4-week treatment period in reducing triglycerides in patients with mild to severe hypertriglyceridemia. The COLT clinical trial also indicated significant statistical and clinical benefits in treating patients with mild to moderate hypertriglyceridemia. A total of 288 patients were enrolled and randomized and 270 patients completed the study, which exceeded the targeted number of evaluable patients. See “Acasti’s Business - Clinical and Nonclinical Research - Clinical - COLT Trial”.

The Corporation’s double-blind Phase II TRIFECTA clinical trial, also designed to evaluate the safety and efficacy of CaPre® for the management of mild to severe hypertriglyceridemia, is ongoing. Acasti believes the trial will be completed around the end of the second quarter of calendar 2014 and results will be available at a future date yet to be determined. See “Acasti’s Business - Clinical and Nonclinical Research - Clinical - TRIFECTA Trial”.

### ONEMIA®

ONEMIA®, a medical food and currently Acasti’s only commercialized product, is a purified omega-3 phospholipids concentrate derived from krill oil with lower levels of phospholipids, EPA and DHA content than CaPre®. The term “medical food” is defined in the United States Orphan Drug Act as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Nonclinical studies conducted by the Corporation, supported by clinical testing conducted on Neptune Krill Oil (NKO®), have shown ONEMIA® to be safe and effective for the dietary management of omega-3 phospholipids deficiency and the related abnormal lipid profiles and cardiometabolic disorders. Phospholipid deficiency and abnormal lipid profiles can lead to a number of conditions, including hyperlipidemia (which generally manifests as high LDL-C and high triglycerides), atherosclerosis (the build-up of plaque on the inside of blood vessels), diabetes, rheumatoid arthritis, certain gastroenterology disorders and metabolic syndrome.

ONEMIA® was introduced in the U.S. market in 2011. In 2012, Acasti made its first sales of ONEMIA® to a medical food distributor in the United States, which has begun distribution of ONEMIA® through its network of dispensing physicians under its own brand name. ONEMIA® is also available behind-the-counter in pharmacies. Acasti expects continued sales of ONEMIA® in the short-term to provide revenues that will contribute, in part, to the financing of Acasti’s research and development projects while continuing to generate awareness of ONEMIA®.

throughout the medical community in an effort to build a market foundation for CaPre®. During the fiscal years 2014, 2013 and 2012, Acasti generated revenues of approximately \$501,000, \$724,000 and \$10,000, respectively, from sales of ONEMIA®.

In 2012, Acasti interviewed and collected data on a voluntary basis from physicians either buying, using, or testing ONEMIA® on some of their patients. The 20 physicians (consisting of five primary care physicians and 15 cardiologists or endocrinologists) that participated are also prescribers of Lovaza and recommended ONEMIA® to 348 patients without controlling their diet, exercise or monitoring compliance with the recommended dosage. Most physicians were willing to try ONEMIA® as a potentially more cost efficient option relative to Lovaza without side effects such as reflux and other gastrointestinal disorders, and having a once per day dosing convenience making it easier to use than Lovaza, which has a dosage requirement of four 1g capsules per day. Primary care physicians participating in the survey responded favorably to features of ONEMIA® such as once-a-day dosing, bioavailability due to the element of marine phospholipids in ONEMIA® and the ability to take ONEMIA® with or without a meal.

Acasti continues to explore the benefit of combining ONEMIA® with a statin treatment. Non-clinical activities have been undertaken in order to determine whether or not ONEMIA® should be added to a statin treatment. The accumulated non-clinical data showed that it would be beneficial to explore in humans testing the positive results which were observed in animal testing to the effect that ONEMIA® may benefit patients taking statins dealing with complex and hard to manage lipid profiles.

## **Clinical and Nonclinical Research**

### **Nonclinical**

In preparation of its planned filing of an IND application with the FDA in the future to conduct a Phase III clinical trial, Acasti carried out an extensive nonclinical program to demonstrate the safety of CaPre® in a defined set of studies required by the FDA. These studies were carried out by contract research organizations with Good Laboratory Practice certification and conducted on various species of animals recommended by the FDA to investigate the long term effects of CaPre® at doses of up to 10g HED over 13 weeks. In these studies, hematological, biochemical, coagulation and overall health parameters of CaPre® were evaluated and no toxic effects were observed in any of the segments of the studies. Once overall systemic toxicity was ruled out, Acasti's studies focused on the potential toxic effects of CaPre® on vital systems, such as the cardiovascular, respiratory and central nervous system as evaluated by behavioural studies of the various species. These studies demonstrated that CaPre® did not have any adverse or toxic effects on any of the vital systems investigated, again up to doses well above the recommended clinical dose of CaPre®. To rule out any short term toxic effects of CaPre® on genes, genomic toxicity studies were undertaken on accepted cellular and animal models. These studies showed no toxic effects of CaPre® on any of the genetic markers indicative of potential gene altering toxic effects.

Acasti believes these studies clearly indicate that CaPre® was well-tolerated and showed no toxic effects on any of the physiological and vital systems of the tested animal subjects or their genes or molecules at doses well above the anticipated clinical therapeutic dose of 1.0g-4.0g daily.

Acasti is continuing its nonclinical studies to further investigate the potential therapeutic effects of CaPre® and ONEMIA® in the management of lipid disorders, in particular by studying their effects on the regulation of genes known to be implicated in the pathogenesis of atherosclerosis and lipid management. In parallel to its proposed Phase III clinical trial, Acasti intends to complete two sets of nonclinical studies.

The first set of studies, the DART (Developmental and Reproductive Toxicology), will be designed to assess safety on male and female fertility, developmental toxicity (embryo-fetal development) and pre and postnatal development in rodents and non-rodents. The second set of studies, the CARCINO, will consist of carcinogenicity testing in both rats and mice to identify a tumorigenic potential in animals and to assess the relevant risk in humans. Carcinogenicity testing is usually required under the rules of the FDA prior to conducting clinical trials that involve the administration of a pharmaceutical and biopharmaceutical product for a period of more than six months. Acasti believes that it will be necessary to complete the DART and CARCINO nonclinical studies prior to the filing of its NDA submission for CaPre® in the United States and expects to do so in the allocated time frame. The third set of studies, the long term animal toxicity studies, as defined by 6-month rodent and 9-month non-rodent, will be

conducted as a requirement to support a Phase III clinical trial or NDA. In these studies, we investigate the effects of CaPre® on blood parameters (hematology, biochemistry, coagulation), urinalysis, ophthalmological and ECG testing.

### Clinical

The Phase II COLT and TRIFECTA clinical trials were initiated during the Corporation's fiscal year ended February 29, 2012 under Canada's Natural Health Product Directorate ("NHPD") guidelines. The final results on the COLT trial were announced on August 13, 2013 and the TRIFECTA trial is currently in progress. Acasti expects the final results on the TRIFECTA trial by the first half of 2014.

The COLT trial was conducted, and the TRIFECTA is being conducted, by JSS Medical Research ("JSS"), a clinical research organization ("CRO") specializing in the pharmaceutical, biotechnology, nutraceutical and medical device industries, which is both owned and managed by Dr. John Sampalis, brother of Dr. Tina Sampalis, Chief Global Strategy Officer of Acasti. JSS was selected by Acasti following a rigorous due diligence process conducted by the Corporation's board of directors and management. Acasti's board of directors appointed an external independent auditor, SNC Lavalin Pharma, to confirm and validate the clinical trials' achievements, milestones and payments.

### **COLT Trial**

The COLT trial, a randomized, open-label, dose-ranging, multi-center trial, was designed to assess the safety and efficacy of CaPre® in the treatment of patients with triglycerides levels between 2.28 and 10.0 mmol/L (200-877 mg/dL) (clinical trial.gov identifier NCT01516151). The primary objectives of the COLT trial were to evaluate the safety and efficacy of 0.5, 1.0, 2.0 and 4.0g of CaPre® per day in reducing fasting plasma triglycerides over 4 and 8 weeks as compared to the standard of care alone.

The secondary objectives of the COLT trial were to evaluate the effect of CaPre® on fasting plasma triglycerides in patients with triglycerides between 2.28 and 5.69 mmol/L (200-499 mg/dL) (mild to moderate hypertriglyceridemia); to evaluate the dose dependent effect on fasting plasma triglycerides in patients with triglycerides > 5.7 and <10 mmol/L (500-877 mg/dL); and to evaluate the effect of CaPre® on fasting plasma levels of LDL-C (direct measurement), HDL-C, non-HDL-C, hs-CRP and omega-3 index. Non-HDL-C is the total cholesterol minus the HDL-C.

The final results of the COLT trial indicated that CaPre® was safe and effective in reducing triglycerides in patients with mild to severe hypertriglyceridemia with significant mean (average) triglyceride reductions above 20% after 8 weeks of treatment with both daily doses of 4.0g and 2.0g. Demographics and baseline characteristics of the patient population were balanced in terms of age, race and gender. A total of 288 patients were enrolled and randomized and 270 patients completed the study, which exceeded the targeted number of evaluable patients. From this patient population, approximately 90% had mild to moderate hypertriglyceridemia.

CaPre® was safe and well tolerated. The proportion of patients treated with CaPre® that experienced one or more adverse events in the COLT trial was similar to that of the standard of care group (30.0% versus 34.5%, respectively). A substantial majority of adverse events were mild (82.3%) and no severe treatment-related adverse effects have been reported. Only one patient was discontinued from the study due to an adverse event of moderate intensity. It was noted that the rate of gastrointestinal side effects were higher in the CaPre® groups compared to standard of care alone and appeared to increase in a dose-related manner. However, none of the subjects participating in the study suffered from a serious adverse event. The report concludes that even at higher doses, CaPre® is safe and well tolerated with only transient and predominantly mild adverse events occurring at low rates.

The COLT trial met its primary objective showing CaPre® to be safe and effective in reducing triglycerides in patients with mild to severe hypertriglyceridemia. After only a 4-week treatment, CaPre® achieved a statistically significant triglyceride reduction as compared to standard of care alone. Standard of care could be any treatment physicians considered appropriate in a real-life clinical setting and included lifestyle modifications as well as lipid modifying agents, such as statins, ezetimibe and fibrates. Patients treated with 4.0g of CaPre® a day over 4 weeks reached a mean triglyceride decrease of 15.4% from baseline and a mean improvement of 18.0% over the standard of care. Results also showed increased benefits after 8 weeks of treatment, with patients on a daily dose of 4.0g of

CaPre® registering a mean triglyceride decrease of 21.6% from baseline and a mean improvement of 14.4% over the standard of care. It is noteworthy that a mean triglyceride reduction of 7% was observed for the standard of care group at week 8, which may be explained by lipid lowering medication adjustments during the study, which was allowed to be administered in the standard of care group alone.

Moreover, after 8 weeks of treatment, patients treated with 1.0g for the first 4 weeks of treatment and 2.0g for the following 4 weeks, showed a statistically significant triglycerides mean improvement of 16.2% over the standard of care, corresponding to a 23.3% reduction for the 1.0-2.0g as compared to a 7.1% reduction for the standard of care. After a 8 week treatment, patients treated with 2.0g of CaPre® for the entire 8 weeks showed statistically significant triglycerides mean improvements of -14.8% over the standard of care, corresponding to a 22.0% reduction for the 2.0g as compared to a 7.1% reduction for the standard of care. Also, after 8 weeks of treatment, patients treated with 4.0g for the entire 8 weeks, showed statistically significant triglycerides, non-HDL-C and HbA1C mean improvements of, respectively, 14.4% and 9.8% and 15.0% as compared to standard of care. The 4.0g group mean improvements in (i) triglycerides of 14.4% corresponds to a reduction of 21.6% as compared to a reduction of 7.1% for the standard of care group, (ii) non-HDL-C of 9.8% corresponds to a reduction of 12.0% as compared to a reduction of 2.3% for the standard of care group, and (iii) HbA1C of 15.0% corresponds to a reduction of 3.5% as compared to an increase of 11.5% for the standard of care group. In addition, all combined doses of CaPre® showed a statistically significant treatment effect on HDL-C levels, with an increase of 7.4% as compared to standard of care. Trends (p-value < 0.1) were also noted on patients treated with 4.0g of CaPre® for the entire 8-week treatment period with mean reduction of total cholesterol of 7.0% and increase of HDL-C levels of 7.7% as compared to the standard of care. Furthermore, after doubling the daily dosage of CaPre® after an initial period of 4 weeks, the results indicate a dose response relationship corresponding to a maintained and improved efficacy of CaPre® after an 8-week period. The efficacy of CaPre® at all doses in reducing triglyceride levels and increased effect with dose escalation suggests that CaPre® may be titrable, allowing physicians to adjust dosage in order to better manage patients' medical needs.

### ***TRIFECTA Trial***

The TRIFECTA trial (clinical trial.gov identifier NCT01455844), a 12-week, randomized, double-blind, placebo-controlled study, is designed to assess the effect of CaPre®, at a dose of 1.0 or 2.0g, on fasting plasma triglycerides as compared to a placebo in patients with mild to severe hypertriglyceridemia. A total of 366 patients have been randomized over the 429 planned protocol (342 evaluable patients).

Similar to the COLT trial, the primary objective of the TRIFECTA trial is to evaluate the effect of CaPre® on fasting plasma triglycerides in patients with triglycerides between 2.28 and 10.0 mmol/L (200-877 mg/dL) and to assess the tolerability and safety of CaPre®. The secondary objectives of the TRIFECTA trial are to evaluate the effect of CaPre® on fasting plasma triglycerides in patients with triglycerides between 2.28 and 5.69 mmol/L (200-499 mg/dL); to evaluate the dose dependent effect on fasting plasma triglycerides in patients with triglycerides > 5.7 and <10 mmol/L (500-877 mg/dL); to evaluate the effect of CaPre® in patients with mild to moderate hypertriglyceridemia and severe hypertriglyceridemia on fasting plasma levels of LDL-C (direct measurement), and on fasting plasma levels of HDL-C, non-HDL-C, hs-CRP and omega-3 index.

On December 20, 2012, the TRIFECTA trial completed an interim analysis. The review committee made up of medical physicians assembled to evaluate the progress of the TRIFECTA trial reviewed the interim analysis relative to drug safety and efficacy and unanimously agreed that the study should continue as planned. All committee members agreed that there were no toxicity issues related to the intake of CaPre® and that the signals of a possible therapeutic effect, noted as reduction of triglycerides in the groups evaluated, were reassuring and sufficiently clinically significant to allow the further continuation of the TRIFECTA trial. The data was provided to the committee members blind, meaning that the identity of the three groups was not revealed. Since the data revealed a possible therapeutic effect without any safety concerns, the committee decided that it was not necessary to unblind the data. The number of targeted patients evaluable as per protocol has been reached. Acasti is currently evaluating efficacy and safety of CaPre® for the treatment of patients with mild to severe hypertriglyceridemia, which is the primary objective of the study. A secondary objective of the study was to assess the efficacy of CaPre® in two distinct patient populations: those with mild to moderate hypertriglyceridemia and those with severe hypertriglyceridemia. Based on patient information currently available, the Corporation does not expect the sample size to be large enough to conclude on the efficacy of CaPre® on severe hypertriglyceridemia as part of the TRIFECTA trial. Acasti does not expect the FDA to request efficacy data on patients with severe

hypertriglyceridemia before granting permission to conduct a phase III trial. Acasti believes the trial will be completed by the end of the second quarter of calendar 2014 and results will be available at a future date yet to be determined.

### PK Trial

On November 11, 2013, the Corporation announced that it submitted an investigational new drug application to the FDA to initiate a PK trial of CaPre® in the United States. The proposed PK trial is an open-label, randomized, multiple-dose, single-center, parallel-design study to evaluate blood profiles and bioavailability of omega-3 phospholipids on healthy volunteers taking single and multiple daily oral doses of 1.0g, 2.0g and 4.0g of CaPre®. The Corporation expects that the duration of the PK trial would likely be over a 30-day period and involve the enrollment of approximately 42 healthy subjects.

On January 9, 2014, the Corporation announced that the FDA granted Acasti approval to conduct its PK trial, having found no objections with the proposed PK trial design, protocol or safety profile of CaPre®. Acasti also announced that Quintiles, the world's largest provider of biopharmaceutical development and commercial outsourcing services, has been hired to conduct the PK trial. The Corporation expects results of its PK trial to be available by mid to late 2014.

### Next Steps

Acasti is corresponding with the FDA and has responded to the FDA's recommendations regarding its upcoming IND filing for its phase III clinical trial of CaPre® in the United States. The FDA has invited Acasti to formally request an end of phase II/pre phase III meeting to allow them to provide feedback on the submission and to address specific questions for which Acasti is seeking approval and final response from the FDA. Acasti intends to seek such meeting as soon as TRIFECTA trial results are available.

Acasti intends to conduct a phase III clinical trial in the United States, with potentially a few Canadian clinical trial sites, in a patient population with very high triglycerides (>500 mg/dL). This study would constitute the primary basis of an efficacy claim for CaPre® in an NDA submission for severe hypertriglyceridemia. Acasti is also evaluating the possibility of submitting a Special Protocol Assessment ("SPA") to the FDA in order to form the basis for the design of its intended Phase III clinical trial. An SPA is a declaration from the FDA that an uncompleted Phase III trial's design, clinical endpoints, and statistical analyses are acceptable for FDA approval. A request would be submitted for the protocol at least 90 days prior to the anticipated start of the Phase III clinical trial. See "Acasti's Business - Government Regulation".

In addition to conducting and completing the TRIFECTA, PK and a Phase III clinical trial, Acasti expects that additional time and capital will be required to complete the filing of a NDA to obtain FDA approval for CaPre® in the United States before reaching commercialization, which may initially be only for the treatment of severe hypertriglyceridemia. The FDA may require Acasti to conduct additional clinical studies to obtain FDA approval for the treatment of mild to moderate hypertriglyceridemia, which may include a cardiovascular outcomes study. See "Acasti's Business - Government Regulation" and "Acasti's Business - Sales and Marketing".

### Sales and Marketing

The Corporation has exclusive global commercial rights to CaPre®. The Corporation does not currently have in-house sales and marketing or distribution capabilities and the Corporation currently plans to seek an established commercial partner for the distribution of CaPre® if it reaches commercialization. In addition to completing the TRIFECTA, PK and a Phase III clinical trial and the DART and CARCINO nonclinical studies, the Corporation expects that additional time and capital will be required to complete the filing of a NDA to obtain FDA approval for CaPre® in the United States and to complete marketing and other pre-commercialization activities before reaching commercialization, which may initially be only for the treatment of severe hypertriglyceridemia. The FDA may also require Acasti to conduct additional clinical studies to obtain FDA approval for the treatment of mild to moderate hypertriglyceridemia, which may include a cardiovascular outcomes study. The Corporation would focus initially on specialists, cardiologists and primary care physicians who comprise the top prescribers of lipid-regulating therapies as part of the sales and marketing strategy for CaPre®. See "Risk Factors - Risks Related to Product Development, Regulatory Approval and Commercialization".

ONEMIA® is being distributed in the United States by Acasti to physicians, who then can either provide it to their patients directly or via a website by using a dedicated medical food access code. Acasti also makes ONEMIA® available via distributors and behind-the-counter in pharmacies. In 2012, Acasti made its first sales of ONEMIA® to a medical food distributor in the United States, which has begun distribution through its network of dispensing physicians under its own brand name. Acasti intends to make ONEMIA® available via additional distributors and behind-the-counter in more pharmacies in the United States and to secure distribution partners to commercialize ONEMIA® outside of the United States. Revenues of Acasti for the fiscal years 2014, 2013 and 2012 were all derived from the sale of ONEMIA® and amounted to approximately \$501,000, \$724,000 and \$10,000, respectively. During its fiscal year ended February 28, 2014, more than 94% of sales of ONEMIA® were made through Acasti's distribution partner in the United States and the remaining 6% came from direct sales by Acasti.

### **Competition**

The biopharmaceuticals industry is highly competitive. There are many public and private biopharmaceutical companies, universities, governmental agencies and other research organizations actively engaged in the research and development of products that may be similar to the Corporation's products or address similar markets. It is probable that the number of companies seeking to develop products similar to the Corporation's products will increase. Many of these and other existing or potential competitors have substantially greater financial, technical and human resources than the Corporation does and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with or superior to Acasti's. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of Acasti's products, which might render the Corporation's technology and products non-competitive or obsolete. Acasti's competitors in the United States and elsewhere include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies and specialized cardiovascular treatment companies. These companies include GlaxoSmithKline plc, which currently markets Lovaza, a prescription omega-3 for patients with severe hypertriglyceridemia, Abbott Laboratories, which currently markets Tricor and Trilipix (both fibrates) and Niaspan (niacin) for treatment of severe hypertriglyceridemia, and Amarin Corporation, which currently markets Vascepa, an ethyl-ester form of EPA, for the treatment of patients with severe hypertriglyceridemia.

In March 2011, Pronova BioPharma Norge AS, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc. to settle their patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova granted Apotex a license to enter the U.S. market with a generic version of Lovaza in the first quarter of 2015, or earlier, depending on circumstances. As a result, Acasti expects Apotex to compete against it as well. Other companies are also seeking to introduce generic versions of Lovaza.

In addition, Acasti is aware of other pharmaceutical companies that are developing products that, if approved, would compete with CaPre®. These include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) being developed by Omthera Pharmaceuticals, which was acquired by London-based AstraZeneca PLC on July 18, 2013. On May 6, 2014, AstraZeneca announced that the FDA had approved its product as an adjunct to diet to reduce triglyceride levels in adults with severe hypertriglyceridaemia. Enzymotec Ltd. also recently submitted an IND application and requested an end of Phase II meeting in order to ultimately receive a SPA from the FDA and proceed to conduct a Phase III clinical trial for its phytosterol-omega-3 drug candidate. Acasti believes other emerging biopharmaceutical companies are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids, but Acasti is unaware of the development stage of their product candidates. CaPre® may also face competition from omega-3 dietary supplements that are available without a prescription. See "Risk Factors - Risks Related to Product Development, Regulatory Approval and Commercialization - The Corporation faces competition from other biotechnology and pharmaceutical companies and its operating results will suffer if the Corporation fails to compete effectively."

There are also competitors in the medical food market. In May 2013, Pivotal Therapeutics announced positive results for its clinical trial of Vascazen, a medical food product being developed to improve patient lipid profiles and reduce cardiovascular disease risk factors.

## **Intellectual Property**

Acasti intends to obtain, maintain and enforce patent protection for its products, formulations, methods and other proprietary technologies, preserve its trade secrets and operate without infringing on the proprietary rights of other parties.

### **Patents**

Acasti owns the following portfolio of patents, filed in various jurisdictions worldwide, including the United States, Canada, Japan, Australia and Europe:

<b>Patent Family Description</b>	<b>Description</b>	<b>WO (PCT) Application Number &amp; U.S. Patent Number</b>	<b>Expiration Date of the Patent Family</b>	<b>Number of Patents Worldwide</b>
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<i>Concentrated Therapeutic Phospholipid Composition</i>	<i>Composition of Matter</i>	WO2011050474 & US8,586,567;	2028	8* (pending in approx. 40 countries)
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\* Includes 5 Australian innovation patents expiring in 2018

On November 19, 2013, the United States Patent and Trademark Office granted Acasti a concentrated phospholipid composition patent (US8,586,567) covering concentrated therapeutic phospholipid compositions useful for treating or preventing diseases associated with cardiovascular disease, metabolic syndrome, inflammation and diseases associated therewith, neurodevelopmental diseases, and neurodegenerative diseases, comprising administering an effective amount of a concentrated therapeutic phospholipid composition. The patent is valid until 2028, covers specific omega-3 phospholipid compositions, synthetic and/or natural, regardless of the extraction process, suitable for human consumption. The patent protects Acasti's phospholipid compositions, namely Capre® and Onemia®.

The corresponding US8,586,567 Acasti patent has also been granted in South Africa and Panama, and 5 innovation patents have been granted to Acasti in Australia (which innovation patents in Australia expire in 2018), while continuations have been filed in the US.

To this day, Acasti's patents and pending patent applications have not been opposed and/or challenged by third parties anywhere in the world. In Canada, the United States and Europe, a patent is generally valid for 20 years from the date of first filing. Patent terms can vary slightly for other jurisdictions, with 20 years from filing being the norm. In certain jurisdictions exclusivity can be formally extended beyond the normal patent term to compensate for regulatory delays during the pre-market approval process.

### **Licensed Rights**

In August 2008, Neptune granted to Acasti a license to rights on its intellectual property portfolio related to cardiovascular pharmaceutical applications. This license allows Acasti to exploit the subject intellectual property rights in order to develop novel active pharmaceutical ingredients ("APIs") into commercial products for the medical food and the prescription drug markets. Acasti is responsible for carrying out the research and development of the APIs, as well as required regulatory submissions and approvals and intellectual property filings relating to the cardiovascular applications. The following table summarizes the patent applications related to Acasti's license from Neptune.

<b>Patent description</b>	<b>US Patent #</b>	<b>Expiration Date of the Patent</b>	<b>Holder</b>
<b>Composition of Matter</b> (NATURAL PHOSPHOLIPIDS OF MARINE ORIGIN CONTAINING FLAVONOIDS AND POLYUNSATURATED PHOSPHOLIPIDS AND THEIR USES)	US8,030,348 <sup>(1)</sup>	2022	Neptune



Patent description	US Patent #	Expiration Date of the Patent	Holder
<b>Method of Use for Dyslipidemia</b> (KRILL AND/OR MARINE EXTRACTS FOR PREVENTION AND/OR TREATMENT OF CARDIOVASCULAR DISEASES, ARTHRITIS, SKIN CANCER, PREMENSTRUAL SYNDROME, DIABETES AND TRANSDERMAL TRANSPORT)	US8,057,825	2022	Neptune
<b>Method of Extraction!</b> ) METHOD OF EXTRACTING LIPIDS FROM MARINE AND AQUATIC ANIMAL TISSUES) !	US6,800,299	2020	Neptune

Note:

(1) Two continuations also stem from U.S. Pat. 8,030,348 (U.S. Pat. 8,278,351 and 8,383,675).

The license agreement provided that the products developed by Acasti must comply with the ranges specified in the license agreement pertaining to the concentration of phospholipids.

Under the license agreement, the Corporation was obligated under the license agreement to pay to Neptune, until the expiration of Neptune's licensed patents, a royalty equal to the sum of (a) in relation to sales of products in the licensed field, if any, the greater of: (i) 7.5% of Acasti's net sales and (ii) 15% of Acasti's gross margin; and (b) 20% of revenues from sub-licenses granted by Acasti to third parties, if any. The license will expire on the date of expiration of the last-to-expire of the licensed patent claims and/or continuation in part and/or divisional of the licensed patent claims. After the last-to expire of the licensed patents, which is currently expected to occur in 2022, the license agreement will automatically renew for an additional period of 15 years, during which period royalties were to be equal to half of those calculated according to the above formula. Notwithstanding the above, the license agreement provided for minimum royalty payments as follows: year 1 - nil; year 2 - \$50,000; year 3 - \$200,000; year 4 - \$225,000 (initially \$300,000, but reduced to \$225,000 following Acasti's abandonment of its option right to develop products for the over-the-counter market pursuant to the license); year 5 - \$700,000; and year 6 and thereafter - \$750,000. Minimum royalties were based on contract years based on the effective date of the license agreement, which is August 7, 2008.

On December 4, 2012, the Corporation announced that it entered into a prepayment agreement with Neptune pursuant to which the Corporation exercised its option under the license agreement to pay in advance all of the future royalties payable under the license. The value of the prepayment, determined with the assistance of outside valuations specialists, using the pre-established formula set forth in the license agreement, and adjusted to reflect the royalties of \$395,000 accrued from December 4, 2012 to July 12, 2013, amounts to approximately \$15.1 million. The prepayment and accrued royalties have been paid pursuant to the prepayment agreement through the issuance of 6,750,000 Common Shares, issuable at a price of \$2.30 per share, totaling \$15.5 million, upon the exercise of a warrant issued to Neptune.

On July 12, 2013, Neptune announced that it had acquired 6,750,000 Common Shares upon the exercise of a warrant issued to it by Acasti under the prepayment agreement. The prepayment agreement and the issuance of the 6,750,000 Common Shares to Neptune were approved by the TSXV and the disinterested shareholders of Acasti (excluding Neptune and non-arm's length parties to Neptune) at the annual meeting of shareholders of Acasti held on June 27, 2013. As a result of the royalty prepayment transaction, 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.

Pursuant to the terms and conditions of the license agreement, Acasti is required, at Neptune's option, to have its products, if any, manufactured by Neptune at prices determined according to different cost-plus rates for each of the product categories under the license. A copy of the license agreement is available on SEDAR at [www.sedar.com](http://www.sedar.com).

Acasti has also initiated its patent portfolio with the first application as a U.S. provisional of a composition and use patent. The invention is entitled "Concentrated Therapeutic Phospholipid Compositions (US20110160161)" and relates to concentrated therapeutic phospholipids compositions; methods for treating or preventing diseases associated with cardiovascular disease, metabolic syndrome, inflammation and diseases associated therewith, neurodevelopmental diseases, and neurodegenerative diseases, comprising administering an effective amount of a concentrated therapeutic phospholipids composition. Acasti's patent application has been filed in more than 40 jurisdictions worldwide. On August 23, 2013, Acasti was granted its first patent in South Africa in the Concentrated

Therapeutic Phospholipid Compositions family. The patent is in force and valid until October 29, 2029. See “Risk Factors - Risks 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.”

### Brand names and trademarks

Acasti has applied for worldwide trademark protection of CaPre® as well as for the trademark ONEMIA®, and is the owner of the trademark BREAKING DOWN THE WALLS OF CHOLESTEROL™ in Canada, the United States and the European Union. The trademark CaPre® is now registered in certain jurisdictions including the United States, Canada and Europe.

### Trade Secrets

In addition, Acasti protects its optimization and extraction processes through industrial trade secrets and know-how.

### Raw Materials, Manufacturing and Facility

The Corporation’s head office and operations are located at 545, Promenade Centropolis, suite 100, Laval, Québec, Canada, H7T 0A3. The Corporation leases its premises for \$6,500 per month.

Acasti uses krill oil as its primary raw material to produce CaPre® and ONEMIA®. There are two ocean regions where krill is generally harvested: the Southern Ocean (Antarctic krill *Euphausia superba*) and the Northern Pacific Ocean (Pacific krill *Euphausia pacifica*), mainly off the coasts of Japan and Canada. The total quantity of the krill species in these two oceans is estimated to be at least 500,000,000 metric tons. The World Health Organization estimates that approximately 271,000 metric tons of both krill species are harvested annually. From 2002 to 2011, between 105,000 to 212,000 metric tons originated from the Southern Ocean and, on average, 60,000 harvested metric tons originated from the Northern Pacific Ocean each year. The annual Antarctic krill catches represent an estimated 0.05% of the existing resource. Acasti’s products are derived from Antarctic krill.

According to the Commission for the Conservation of Antarctic Marine Living Resources, from 2008 to 2011, annual quotas for Antarctic krill have increased by 33%. Annual allowable quotas of 6.555 million metric tons for 2010 were increased to 8.695 million metric tons for 2011. In the areas currently being fished for krill, the Commission has established a combined annual catch suspension trigger level of 620,000 metric tons. If the trigger level is reached, the Commission may intervene to authorize additional krill harvesting and impose a stricter control on fisheries. As a result, the Corporation believes that krill is an abundant and accessible resource with potential for long-term sustainable exploitation. The average market price for whole frozen krill is approximately US\$900 per metric ton. See “Risk Factors - Risks Related to Product Development, Regulatory Approval and Commercialization.”

Acasti does not own its own manufacturing facility for the production of krill oil, CaPre® and ONEMIA® nor does it have plans to develop its own manufacturing facility in the foreseeable future. Acasti depends on third party suppliers and manufacturers for all of its required raw materials and drug substance and, if approved for distribution by the FDA, Acasti expects to rely on cGMP- compliant third parties to manufacture, encapsulate, bottle and package clinical supplies of CaPre®.

Acasti acquires all of its krill oil for the production of CaPre® and ONEMIA® from its parent company, Neptune. However, due to the incident, Acasti is currently acquiring its krill oil through purchases in the open market in order to meet production requirements for ONEMIA® and is seeking a third party to both supply krill oil on an interim basis and provide manufacturing services for the production of CaPre® in accordance with cGMP regulations imposed by the FDA. On May 28, 2013, Neptune announced that it had commenced reconstruction of its production plant, the completion of which is anticipated for early June 2014. Acasti intends to acquire its krill oil supply from Neptune upon the recommencement of Neptune’s krill oil production. See “Recent Developments”.

In July 2013, the Corporation entered into a memorandum of understanding with a third party for the manufacturing, in accordance with cGMP regulations imposed by the FDA, of CaPre® clinical material for the purposes of Acasti’s upcoming clinical trials. The memorandum of understanding remains subject to the negotiation

and execution of a detailed definitive agreement between the parties. See “Risk Factors – Risks Related to Product Development, Regulatory Approval and Commercialization – The Corporation’s supply of krill oil for commercial supply and clinical trials is dependent upon relationships with Neptune and other third party manufacturers and key suppliers” and “Risk Factors - Risks Related to Product Development, Regulatory Approval and Commercialization - The Corporation relies on third parties for the manufacturing, production and supply of CaPre® and ONEMIA® and may be adversely affected if those third parties are unable or unwilling to fulfill their obligations.”

### **Employees, Specialized Skills and Knowledge**

Acasti’s management consists of professionals experienced in business development, finance and science. The Acasti research team includes scientists with expertise in pharmaceutical development, chemistry, manufacturing and controls, nonclinical and clinical studies, pharmacology, regulatory affairs, quality assurance/quality control, intellectual property and strategic alliances. As of February 28, 2014, the Corporation employed six persons in Canada, four of whom have biology, chemistry, biochemistry or microbiology backgrounds, and two of whom serve general and administrative roles. Acasti generally requires all of its employees to enter into an invention assignment, non-disclosure and non-compete agreement. The Corporation relies, in part, on the administrative and other staff of its parent company, Neptune, and also relies on consultants from time to time. The Corporation’s employees are not covered by any collective bargaining agreement or represented by a trade union. The Corporation places special emphasis on training for its personnel.

### **Litigation**

Due to the fact that a significant portion of the Corporation’s intellectual property rights are licensed to it by Neptune, the Corporation depends on Neptune to protect a significant portion of the intellectual property rights that it uses under such license. Neptune is engaged in a number of legal actions relating to its intellectual property.

#### *U.S. Nutraceuticals LLC*

On or around January 27, 2010, the Corporation and Acasti filed a Motion for the Issuance of a Permanent Injunction before the Quebec Superior Court against US Nutraceuticals LLC (d.b.a. Valensa), a US based Corporation. Neptune and Acasti are seeking inter alia an injunction ordering Valensa to amend some patent applications filed by Valensa to add Neptune as co-owner, or in the alternative to have Valensa assign these patent applications to Neptune, as well as punitive damages, loss of profit and loss of business opportunity for an amount currently established at \$3,000,000. On or around February 3, 2014, Neptune and Valensa filed dismissals with the Court and the case was closed. There are no pending litigation in Quebec or anywhere else in the world between the Corporation and Valensa.

#### *ITC Complaint*

On January 29, 2013, Neptune filed a Complaint under Section 337 of the U.S. Tariff Act of 1930 with the ITC alleging that Aker, Enzymotec and Rimfrost are engaging in unfair trade practices by, at least, the importation, sale for importation, and sale after importation of certain krill-based products, namely krill paste and krill oils, that directly or indirectly infringe one or more claims of Neptune’s U.S. Patents No. 8,278,351 and 8,383,675. The investigation was officially instituted on April 11, 2013. On May 13, 2014, the Administrative Law Judge granted the parties’ motion and issued the Initial Determination to terminate the investigation against the last remaining Respondents Enzymotec Ltd. and Enzymotec USA, Inc. The ITC investigation is therefore over and the complaint has been settled by Neptune, Acasti and the other respondents. For more information on the settlements with each of Aker, Enzymotec and Rimfrost, see “Acasti’s Business - Litigation”.

The Corporation is not aware of any other legal proceedings or regulatory actions in which it is involved and no such proceedings or regulatory actions are known by the Corporation to be contemplated Government Regulation.

#### *Aker Biomarine ASA and others*

On November 13, 2009, Neptune filed a patent infringement lawsuit against Aker BioMarine ASA, Jedwards International, Inc and Virgin Antartic LLC, asserting its U.S. patent relating to a method of extraction of total lipids fractions from Krill. Neptune alleges that the Defendants have used solvents for the extraction of their krill oil,

which are covered by the patent (US6,800,299) licensed to Neptune. The Complaint (case 1:09-cv-11946-MLW) filed in 2009 by Neptune et al. against Aker et al. in the District of Massachusetts for the infringement of the Université of Sherbrooke's US patent licensed to Neptune (US. Pat. 6,800,299) was also dismissed on or around February 11, 2014, as per the terms of the Settlement agreement reached between Aker and the Corporation on November 28, 2013. On October 4, 2011, the Corporation filed a Complaint in the US District Court for the District of Delaware against Aker Biomarine ASA, Aker Biomarine Antarctic USA Inc., and Schiff Nutrition International Inc. (Aker et al.) for the infringement of the Corporation's US patent 8,030,348 and for damages. On December 19, 2011, Aker et al. filed Counterclaims denying any infringement, seeking the invalidity of the Corporation's patent, and seeking an award for costs and damages. This Complaint against Aker et al. will be dismissed in accordance with the Settlement agreement reached between Aker and the Corporation on November 28, 2013.

On October 2, 2012, the Corporation filed a Complaint in the US District Court for the District of Delaware against Aker Biomarine ASA, Aker Biomarine Antarctic USA Inc., Aker Biomarine Antarctic AS, Schiff Nutrition Group Inc., and Schiff Nutrition International Inc. (Aker et al.) for the infringement of the Corporation's US patent 8,278,351 and for damages. This Complaint against Aker et al. was dismissed on or around April 10, 2014 in accordance with the Settlement agreement reached between Aker and the Corporation on November 28, 2013.

On March 6, 2013, the Corporation filed a Complaint in the US District Court for the District of Delaware against Aker Biomarine ASA, Aker Biomarine Antarctic USA Inc., Aker Biomarine Antarctic AS, Schiff Nutrition Group Inc., and Schiff Nutrition International Inc. (Aker et al.) for the infringement of the Corporation's US patent 8,383,675 and for damages. This Complaint against Aker et al. was dismissed on or around April 10, 2014 in accordance with the Settlement agreement reached between Aker and the Corporation on November 28, 2013.

On December 17, 2013, Neptune and Acasti announced a settlement and license agreement with Aker which resulted in the dismissal of all Aker respondents from the then on-going claims brought by Neptune against Aker at the ITC, as well as the dismissal of all current lawsuits brought by Neptune against Aker and certain other associated companies. As part of the settlement agreement, Neptune granted a world-wide, non-exclusive, royalty-bearing license to Aker and each of their respective affiliates, allowing such licensees to market and sell its nutraceutical products. Under the terms of the settlement agreement, royalty levels are dependent on the outcome of the inter partes review proceedings requested by Aker before the USPTO regarding Neptune's '351 composition of matter patent (No. 8,278,351). Aker also agreed to pay Neptune an additional non-refundable payment for the manufacture and sale of krill products prior to the effective USPTO decision date.

#### *Enzymotec Limited and others*

On October 4, 2011, the Corporation filed a Complaint in the US District Court for the District of Delaware against Enzymotec Limited, Enzymotec USA Inc., Mercola.com Health Resources, LLC, and Azantis Inc. for the infringement of the Corporation's US patent 8,030,348 and for damages. In addition, on October 2, 2012, the Corporation filed a Complaint in the US District Court for the District of Delaware against Enzymotec Limited, Enzymotec USA Inc., Mercola.com Health Resources, LLC for the infringement of the Corporation's US patent 8,278,351 and for damages. On January 14, 2013, Enzymotec Limited, Enzymotec USA Inc., Mercola.com Health Resources, LLC filed a Counterclaim denying any infringement, seeking the invalidity of the Corporation's patent, and seeking an award for costs and damages. On March 6, 2013, the Corporation filed a Complaint in the US District Court for the District of Delaware against Enzymotec Limited, Enzymotec USA Inc., Mercola.com Health Resources, LLC for the infringement of the Corporation's US patent 8,383,675 and for damages.

On December 16, 2013, Neptune, Acasti and Enzymotec entered into a settlement term sheet to resolve the on-going ITC investigation brought by Neptune, as well as to request the dismissal of all current lawsuits brought by Neptune against Enzymotec. On December 18, 2013, Neptune announced that the administrative law judge presiding over the pending ITC investigation involving Neptune and Enzymotec granted the parties' joint motion to stay the proceedings for 30 days, which stay was further extended until February 5, 2014, in order for the parties to enter into a definitive settlement agreement resolving all pending litigation.

On April 27, 2014, Acasti and Neptune announced that a final and binding patent infringement settlement and license agreement has been signed with Enzymotec that resolves the ITC's investigation of infringement of Neptune's composition of matter patents, related federal court actions initiated by Neptune against Enzymotec and its distributors and various patent review proceedings requested by Enzymotec.

As part of the settlement, Neptune granted a world-wide, non-exclusive, royalty-bearing license to Enzymotec, allowing it to market and sell its nutraceutical products under Neptune's '348 family of patents (US Patent No. 8,030,348 and all the continuations). Under the terms of the settlement agreement, royalty levels in the United States are dependent on the outcome of pending inter partes review proceedings before the USPTO regarding certain claims of Neptune's '351 composition of matter patent (US Patent No. 8,278,351). Furthermore, royalty levels in Australia are dependent on a potential request by Enzymotec to the APO for a post-grant review of certain claims of Neptune's allowed composition of matter patent application (AU2002322233). Enzymotec also agreed to pay Neptune a non-refundable one-time upfront settlement payment.

All the Complaints against Enzymotec Limited, Enzymotec USA Inc., Mercola.com Health Resources, LLC, and Azantis Inc. will be dismissed in accordance with the settlement agreement reached on April 27, 2014 between Enzymotec and the Corporation.

#### *Rimfrost USA and others*

On March 6, 2013, Neptune filed a Complaint in the U.S. District Court for the District of Delaware against Rimfrost USA, LLC, Avoca, Inc., and Olympic Seafood AS (collectively "**Rimfrost**") for the infringement of Neptune's U.S. patents 8,030,348, 8,287,351 and 8,383,675, and for damages.

On October 2, 2013, the Corporation announced the conclusion of a settlement with Rimfrost, resolving the ITC investigation related to infringement of Neptune's composition of matter patents. As part of the settlement, Neptune granted a world-wide, non-exclusive, royalty-bearing licence to these settling respondents, allowing them to market and sell nutraceutical products containing components extracted from krill. The respondents in question also agreed to pay Neptune an additional royalty amount for the manufacture and sale of krill products prior to the effective license commencement date. Neptune also agreed to dismiss a related patent infringement case against Rimfrost filed in March of 2013. Moreover, Neptune signed a strategic non-exclusive krill oil manufacturing and supply agreement with Rimfrost giving Neptune the right to purchase, at a preferred price, up to 800 metric tons of krill oil during the first three-year term of the renewable agreement.

#### *Patent EP1,417,211*

On March 9, 2010, Neptune filed an appeal with the European Patent Office's Board of Appeal contesting a 2009 decision of the European Patent Office regarding the European composition of phospholipids and use patent EP1,417,211. On April 9, 2013, the European Opposition Board dismissed Neptune's appeal and the European patent EP1,417,211 was revoked.

#### *Henri Harland*

On May 29, 2014, Henri Harland, the former President and Chief Executive Officer of the Corporation filed a lawsuit against the Corporation, Neptune and NeuroBioPharm in connection with his departure as President and Chief Executive Officer of each of Neptune, Acasti and NeuroBioPharm. Among other things, Mr. Harland alleged that his resignation occurred as a result of a constructive dismissal and is seeking approximately \$8.5 million in damages, interest and costs. In addition, Mr. Harland is seeking from Neptune, Acasti and NeuroBioPharm, as applicable, the issuance of 500,000 shares of each of Neptune, Acasti and NeuroBioPharm as well as two blocks of 1,000,000 call options each on the shares held by Neptune in Acasti and NeuroBioPharm. As a result of the lawsuit, Mr. Harland was requested to resign as Director of the Corporation. The following day, Neptune and its subsidiaries jointly announced that they believed the claim as formulated was without merit or cause, they will vigorously defend the lawsuit and will take any steps necessary to protect their interests.

### **Government Regulation**

#### *United States Drug Development*

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products such as CaPre®. Generally, before a new drug can be

marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

### ***FDA Regulatory Process***

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development or approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a "clinical hold" on investigations intended to support FDA approval, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, debarment from government programs, restitution, disgorgement, civil or criminal penalties, or entry of consent decrees and integrity agreements. Any agency or judicial enforcement action could have a material adverse effect on Acasti.

In order to be marketed in the United States, CaPre® must be approved by the FDA through the NDA process. The process required before a drug may be marketed in the United States generally involves the following:

- completion of extensive nonclinical (animal) and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice ("GLP") regulations;
- submission of an IND, which must become effective before human clinical trials may begin in the United States;
- performance of adequate and well-controlled clinical trials in accordance with the applicable IND and other clinical study-related regulations, such as current Good Clinical Practices, to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission of an NDA for a new drug;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of potential FDA audit of the nonclinical and/or clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

The data required to support an NDA is generated in two distinct development stages: nonclinical and clinical. The nonclinical development stage generally involves synthesizing or otherwise producing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND, which is a request for authorization from the FDA to administer an investigational drug product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials. The FDA may also place the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A clinical hold may be imposed at any time before or during a clinical trial due to safety concerns or non-compliance. Accordingly, the Corporation cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the investigational drug to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, data collection, and the parameters to be used to monitor subject safety and assess the investigational drug's efficacy. Each protocol, and any subsequent amendments to the protocol or new investigator's information, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board ("IRB") at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or its legal representative. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries, as well as reporting of safety information under the IND.

Clinical studies are generally conducted in three sequential phases that may overlap, known as Phase I, Phase II and Phase III clinical trials. Phase I generally involves a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the investigational drug. The primary purpose of these studies is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug. Phase II trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase III clinical trials generally involve large numbers of patients at multiple sites, often in multiple countries (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase III clinical trials should, if possible, include comparisons with placebo and may include a comparison to approved therapies. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA (Pivotal Studies).

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. In addition, written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides oversight and will determine whether or not a trial may move forward at designated check points based on review of interim data from the study. A clinical trial may be terminated or suspended based on evolving business objectives and/or competitive climate.

The manufacturing process must be capable of consistently producing quality batches of the investigational drug and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug product. The sponsor must develop appropriate labeling that sets forth the conditions of intended use. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Post-approval studies, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase IV studies as part of a post-approval commitment, such as pediatric studies.

### ***NDA and FDA Review Process***

Nonclinical and clinical information is filed with the FDA in an NDA along with proposed labeling. The NDA is a request for approval to market the drug and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive nonclinical and clinical testing. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including

studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. FDA approval of an NDA must be obtained before marketing a drug in the United States. In addition, under the Pediatric Research Equity Act, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (“PDUFA”) the FDA has ten months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant. This review typically takes 12 months from the date the NDA is submitted to the FDA including the screening which takes a period of 60 days. The FDA does not always meet its PDUFA goal dates for standard NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product’s identity, strength, quality and purity. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions with the FDA.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with cGCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it will issue a Complete Response Letter (“CRL”). A CRL indicates that the review cycle of the application is complete and whether the application is approved and, when applicable, the CRL describes the specific deficiencies in the NDA and may require additional clinical data and/or an additional Phase III clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. The applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than the Corporation interprets the same data.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States and the Corporation may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, may condition the approval of the NDA on other changes to the proposed labeling, or may require a Risk Evaluation and Mitigation Strategy (REMS), which could limit the Corporation’s ability to market the drug once approved. The FDA may also require the development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products.

#### ***U.S. Post-Marketing Requirements***

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising,



restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (“**off-label use**”), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers and distributors may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. In some cases, these changes will require the submission of clinical data and the payment of a user fee.

### ***U.S. Patent Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of the FDA approval of Acasti’s prescription drug candidates, some of Acasti’s U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office (the “**USPTO**”) in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, Acasti intends to apply for restoration of patent term for one of its currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing and review of the relevant NDA.

### ***Non-U.S. Drug Regulation***

In Canada, biopharmaceutical product candidates are regulated by the Food and Drugs Act and the rules and regulations promulgated thereunder, which are enforced by the Therapeutic Products Directorate of Health Canada. In order to obtain approval for commercializing new drugs in Canada, the sponsor (Acasti) must satisfy many regulatory conditions. The sponsor must first complete preclinical studies in order to file a clinical trial application (“**CTA**”) in Canada. The sponsor will then receive different clearance authorizations to proceed with Phase I clinical trials, which can then lead to Phase II and Phase III clinical trials. Once all three phases of trials are completed, the sponsor must file a registration file named a New Drug Submission (“**NDS**”) in Canada. If the NDS demonstrates that the product was developed in accordance with the regulatory authorities’ rules, regulations and guidelines and demonstrates favorable safety and efficacy and receives a favorable risk/benefit analysis, then the regulatory authorities issue a notice of compliance, which allows the sponsor to market the product.

In addition to regulations in the United States and Canada, Acasti is subject to a variety of regulations governing clinical studies and commercial sales and distribution of its products in other jurisdictions around the world. These laws and regulations typically require the licensing of manufacturing and contract research facilities, carefully controlled research and testing of product candidates and governmental review and approval of results prior to marketing therapeutic product candidates. Additionally, they require adherence to good laboratory practices, good clinical practices and good manufacturing practices during production. The process of new drug approvals by regulators in the United States, Canada and the European Union are generally considered to be among the most rigorous in the world.

Whether or not the FDA or Health Canada approval is obtained for a product, Acasti must obtain approvals from the comparable regulatory authorities of other countries before it can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for the FDA or Health Canada approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. In some international markets, additional clinical trials may be required prior to the filing or approval of marketing applications within the country.

### Medical Food Regulation

Prior to 1972, medical foods that mitigated serious adverse effects of the underlying diseases were regulated by the FDA as “drugs” under the Federal Food, Drug, and Cosmetic Act. In 1972, in an effort to encourage innovation and availability of such products, the FDA revised its regulatory approach and classified these products as “foods for special dietary use.” The Orphan Drug Amendments of 1988 provided a statutory definition of a medical food, which means a food that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition, for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. In the Nutrition Labeling and Education Act of 1990, the U.S. Congress exempted medical foods from the nutrition labeling, health claim, and nutrient disclosure requirements applicable to most other foods, further distinguishing this category from conventional food products.

The regulatory status of these products in other countries varies. It is also possible that such products would be regulated in Canada as natural health products pursuant to the Natural Health Products Regulations.

### Active Pharmaceutical Ingredient Regulation

The FDA will regulate finished products containing APIs developed or under development by Acasti; however, the FDA does not actively regulate the APIs themselves. Depending on its intended uses, a finished product containing the API may be regulated as a drug or a medical food under the procedures described above. It may be possible to market a finished product containing an API developed or under development by Acasti as a dietary supplement. Dietary supplements do not require FDA premarket approval. However, it may be necessary to submit a notification to the FDA that a company intends to market a dietary supplement containing a “new dietary ingredient.” In general, the regulatory requirements in other countries also depend on the nature of the finished product and do not focus on the API itself.

## **HISTORY AND DEVELOPMENT OF THE CORPORATION**

### **Three-Year History**

The following is a summary of significant events related to the development of the Corporation and its business that have occurred in the last three completed fiscal years.

#### Fiscal Year Ended February 29, 2012

On March 31, 2011, the Common Shares were listed for trading on the TSXV under the ticker symbol “APO”.

During the fiscal year ended February 29, 2012, Acasti initiated two Phase II open label clinical trials in Canada; (i) the TRIFECTA trial for which the first patients were enrolled in October 2011, and (ii) the COLT trial, for which the first patients were enrolled in December 2011. See “Acasti’s Business – Clinical and Nonclinical Research.”

During the same period, Acasti made significant progress in its nonclinical IND-enabling program for CaPre®. This program allows Acasti to accumulate, as per FDA and Health Canada guidelines, the required animal data demonstrating the safety of CaPre®. By means of its nonclinical research and development program, Acasti reported nonclinical results indicating that CaPre® performed effectively on overall lipid management, specifically reduction of triglycerides.

On September 14, 2011, Acasti closed a rights offering pursuant to which holders of its Common Shares subscribed for 6,445,444 Common Shares at a price of \$1.25 per share, representing aggregate net proceeds of \$7,850,000 for the Corporation.

On February 13, 2012, Acasti completed a private placement pursuant to which Dr. Harlan Waksal, Acasti’s Executive Vice-President, Business & Scientific Affairs, and Neptune subscribed for an aggregate of 1,500,000 Common Shares and 750,000 warrants to purchase Common Shares exercisable at a price of \$1.50 per share for a period of three (3) years, for aggregate net proceeds of \$1,979,000.

Fiscal Year Ended February 28, 2013

On January 7, 2013, the Common Shares were listed for trading on the NASDAQ under the ticker symbol “ACST”.

On November 8, 2012, Neptune reported an explosion and fire destroyed its production plant located in Sherbrooke, Québec, Canada. Acasti announced that its day-to-day operations and business were not interrupted as a result of this tragic event and that all CaPre® materials required for its two Phase II clinical trials had already been produced and stored in other facilities outside Neptune’s affected plant. See “Risk Factors - Risks Related to Product Development, Regulatory Approval and Commercialization - The Corporation’s supply of krill oil for commercial supply and clinical trials is dependent upon relationships with Neptune and other third party manufacturers and key suppliers.”

On December 4, 2012, the Corporation announced that it entered into a prepayment agreement with Neptune pursuant to which the Corporation exercised its option to prepay all future royalties under the license granted by Neptune to Acasti. The value of the prepayment, determined with the assistance of outside valuations specialists, using the pre-established formula set forth in the license agreement, amounts to approximately \$15.5 million, which Acasti will pay through the issuance of 6,750,000 Common Shares, issuable at a price of \$2.30 per share, upon the exercise of a warrant delivered to Neptune. The prepayment and the issuance of the Common Shares to Neptune are subject to the final approval of the TSXV and the approval of the disinterested shareholders of the Corporation at its next annual meeting, which is scheduled to occur on June 27, 2013.

Fiscal Year Ended February 28, 2014

On March 19, 2013, the Corporation announced encouraging preliminary data of its “Randomized, Open-Label, Dose-Ranging, Multi-Center Trial to assess the Safety and efficacy of CaPre® in the treatment of mild-to-high hypertriglyceridemia”. Data from 157 patients who completed four weeks of treatment with 0.5, 1, 2 or 4 grams of CaPre® per day were assessed and CaPre® achieved a clinically important and statistically significant triglyceride reduction of up to 23% (p<0.05) as compared to standard of care. The results of this preliminary analysis suggested that CaPre® could be used as a safe and effective alternative for the treatment of patients with triglyceride levels ranging from 200 to 500 mg/dL.

On May 22, 2013, the Corporation announced that patient recruitment for the COLT trial had been completed. Acasti continued to make good progress on its two Phase II clinical trials, the COLT trial and the TRIFECTA trial.

On June 27, 2013, the Corporation held its Annual and Special Meeting of the shareholders, where the shareholders of the Corporation voted in favour of all items put forth at the meeting. All of the existing director nominees were re-elected and three new directors, Mr. Valier Boivin, Mr. Jean-Claude Debard and Mr. Harlan W. Waksal, were elected.

On July 15, 2013, the Corporation announced that it had received the approval of both the shareholders and the TSX Venture Exchange to become royalty free by paying in advance all future royalties owed under the license agreement through the issuance of shares to Neptune. The value of this royalty prepayment, which was confirmed by an independent valuation expert using the pre-established prepayment formula set forth in the license agreement, was approximately \$15.5 million and was paid through the issuance of 6,750,000 Acasti Class A common shares to Neptune. The prepayment increased Neptune’s equity participation in Acasti from approximately 57% to approximately 60%. Being royalty free allows Acasti to preserve cash of at least \$700,000 annually which was the current minimum royalty due under the license agreement.

On July 31, 2013, the Corporation announced that it had signed an agreement with a world leader in natural based specialty chemicals for the manufacturing of CaPre® clinical material in expectation of upcoming PK and phase III clinical trials in the United States and to substantiate its upcoming submission of an Investigational New Drug (IND) filing. Specialized krill oil raw material will first be produced by a North American company using Neptune’s proprietary production process. It will then be sent to the specialty chemicals manufacturer for further processing, including purification and formulation into CaPre® under cGMP guidelines. The Corporation also announced its intention to initiate discussions to manufacture CaPre® at full plant scale, should regulatory approval for commercialization in the United States be obtained

On August 13, 2013 the Corporation announced positive results for its Phase II randomized, open-label, dose-ranging, multi-center trial designed to assess the safety and efficacy of its investigational new drug candidate CaPre® in the treatment of mild to severe hypertriglyceridemia. CaPre® was found to be safe and effective with significant mean triglyceride reductions above 20% after 8 weeks of treatment with both daily doses of 4g and 2g. No serious adverse events were reported, indicating that CaPre® is safe and tolerable at all doses tested.

On October 2, 2013, the Corporation announced the conclusion of a settlement with respondents Rimfrost, resolving the ITC investigation related to infringement of Neptune's composition of matter patents. As part of the settlement, Neptune granted a world-wide, non-exclusive, royalty-bearing licence to these settling respondents, allowing them to market and sell nutraceutical products containing components extracted from krill. The respondents in question also agreed to pay Neptune an additional royalty amount for the manufacture and sale of krill products prior to the effective license commencement date. Neptune also agreed to dismiss a related patent infringement case against Rimfrost filed in March of 2013. Moreover, Neptune signed a strategic non-exclusive krill oil manufacturing and supply agreement with Rimfrost giving Neptune the right to purchase, at a preferred price, up to 800 metric tons of krill oil during the first three-year term of the renewable agreement. Under the agreement, Neptune has agreed to purchase certain minimum quantities of commodity grade krill oil from Rimfrost in 2013 and 2014, which purchases may be deferred to the following calendar years.

On October 29, 2013, the Corporation announced that the USPTO had allowed Acasti's composition and use patent application entitled Concentration Therapeutic Phospholipid Compositions, publication number US20110160161. The patent relates to concentrated therapeutic phospholipid omega-3 compositions and covers methods for treating or preventing diseases associated with cardiovascular diseases, metabolic syndrome, inflammation, neurodevelopmental diseases, and neurodegenerative diseases. The Corporation was granted a corresponding patent in South Africa, which is enforceable and valid until October 29, 2029.

On November 5, 2013, the Corporation announced that it had welcomed to its Board of Directors Reed V. Tuckson M.D., Managing Director of the health and medical care consulting business Tuckson Health Connections LLC. This appointment increased the number of board members to six, four of whom are independent directors.

On November 11, 2013, the Corporation announced the submission of an Investigational New Drug Application to the FDA to initiate a PK trial of CaPre® in the United States. This proposed PK trial is the first step in the Corporation's U.S. clinical strategy to initiate PK and Phase III trials of CaPre® in the United States.

On November 26, 2013, the Corporation announced that it had commenced an underwritten public offering of units of the Corporation, each Unit consisting of one Common Share and one Common Share purchase warrant of the Corporation. The offering was conducted in the United States pursuant to the effective shelf registration statement filed with the U.S. Securities and Exchange Commission (the "SEC") and in Canada pursuant to a final short form base prospectus filed with the securities regulatory authorities in the Provinces of Quebec, Ontario, Manitoba, Alberta and British Columbia. On November 27, 2013, the Corporation announced that it had priced the underwritten public offering of 16,000,000 units of Acasti at a price of US\$1.25 per Unit. Each of the Common Share purchase warrant entitled the holder to purchase one Common Share at exercise price of US\$1.50 per warrant share. On December 3, 2013, the Corporation announced the closing of the public offering and the exercise by the underwriters, prior to the closing, of the overallotment option which was exercised in full to purchase an additional 2,400,000 Units. The public offering resulted in a total 18,400,000 units being issued for gross proceeds of approximately US\$23 million.

On December 16, 2013, the administrative law judge presiding over the pending ITC investigation involving Neptune, Acasti, Enzymotec granted the parties' joint motion to stay the proceedings for thirty days. The motion to stay was filed because the parties had agreed to a settlement term sheet with the hope of concluding a binding settlement agreement before the expiration of the stay. Neptune has entered into a settlement agreement with all the other respondents named in the ITC investigation and motions to terminate the investigation as to those respondents have been submitted.

On December 17, 2013, the Corporation announced that it had concluded a settlement and license agreement with Aker. As part of the settlement, Neptune granted a world-wide, non-exclusive, royalty-bearing license to Aker to market and sell nutraceutical products in the licensed countries. Pursuant to the terms of the settlement, royalty levels hinge on the outcome of the review proceedings being conducted before the USPTO regarding Neptune's 351

Patent. Aker also agreed to pay a non-refundable one-time payment to Neptune for the manufacture and sale of krill products prior to the effective USPTO decision date.

On December 19, 2013, the Corporation announced that it had appointed Jerald J. Wenker, President and COO of Dermalogica, a leading professional skin care company, as special advisor to the Board of Directors. Mr. Wenker accepted the nomination for election to serve on the Board of Directors at the Annual Meeting to be held in 2014, subject to shareholder approval.

On January 9, 2014, the Corporation announced that the FDA had cleared its Investigational New Drug submission to imitate a PK trial of CaPre® in the United States after having found no objections with the PK trial design, protocol, or safety profile of CaPre®. Following this clearance, the Corporation engaged Quintiles, the world's largest provider of biopharmaceutical development and commercial outsourcing services, to conduct its PK study.

On February 7, 2014, the Corporation announced the closing of a private placement of CAD\$2,150,000 of units of the Corporation at a price of CAD\$1.33 per unit, each unit consisting of one Common Share and one Common Share purchase warrant of the Corporation. Each of these warrants entitles its holder to purchase one Common Share at an exercise price of CAD\$1.60. All of the units were issued to the Fiera Capital QSSP II Investment Fund Inc. under the Quebec Stock Savings Plan II, and could not be qualified under the Quebec Stock savings Plan II and subscribed for by the Fund under the Corporation's public offering completed on December 3, 2012.

On February 14, 2014, the Corporation announced that it had not been able to arrive at a final settlement agreement with Enzymotec that would resolve the ITC investigation into the infringement of Neptune's composition of matter patents, and related federal court matters. Despite the presiding administrative law judge granting an extended stay through February 5, 2014, no settlement could be achieved as the parties reached an impasse on certain fundamental settlement terms, including terms that had already been agreed to in the term sheet. As a result of this bottleneck, Neptune agreed to participate in the ITC's mediation program in a final attempt to reach a mutually satisfactory agreement. Neptune and Enzymotec requested that the administrative law judge extend the stay for an additional 60 days and reschedule the ITC hearing until after the expiration of the stay.

### **Recent Developments**

On April 27, 2014, Acasti and Neptune announced that a patent infringement settlement and license agreement has been signed with Enzymotec that resolves the ITC's investigation of infringement of Neptune's composition of matter patents, related federal court actions initiated by Neptune against Enzymotec and its distributors and various patent review proceedings requested by Enzymotec. As part of the settlement, Neptune granted a world-wide, non-exclusive, royalty-bearing license to Enzymotec, allowing it to market and sell its nutraceutical products under Neptune's '348 family of patents (US Patent No. 8,030,348 and all the continuations). Under the terms of the settlement agreement, royalty levels in the United States are dependent on the outcome of pending inter partes review proceedings before the USPTO regarding certain claims of Neptune's '351 composition of matter patent (US Patent No. 8,278,351). Furthermore, royalty levels in Australia are dependent on a potential request by Enzymotec to the APO for a post-grant review of certain claims of Neptune's allowed composition of matter patent application (AU2002322233). Enzymotec also agreed to pay Neptune a non-refundable one-time upfront settlement payment.

On April 28, 2014, Acasti announced the resignation of Mr. Henri Harland as President and Chief Executive Officer of Acasti. Acasti has begun the search for a new President and Chief Executive Officer. During the interim period, Acasti continues to be managed by a management and operations committee under the leadership of Mr. André Godin, the interim Chief Executive Officer.

On May 29, 2014, Henri Harland, the former President and Chief Executive Officer of the Corporation filed a lawsuit against the Corporation, Neptune and NeuroBioPharm in connection with his departure as President and Chief Executive Officer of each of Neptune, Acasti and NeuroBioPharm. Among other things, Mr. Harland alleged that his resignation occurred as a result of a constructive dismissal and is seeking approximately \$8.5 million in damages, interest and costs. In addition, Mr. Harland is seeking from Neptune, Acasti and NeuroBioPharm, as applicable, the issuance of 500,000 shares of each of Neptune, Acasti and NeuroBioPharm as well as two blocks of 1,000,000 call options each on the shares held by Neptune in Acasti and NeuroBioPharm. As a result of the lawsuit, Mr. Harland was requested to resign as Director of the Corporation. The following day, Neptune and its subsidiaries

jointly announced that they believed the claim as formulated was without merit or cause, they will vigorously defend the lawsuit and will take any steps necessary to protect their interests.

## **RISK FACTORS**

*Investing in the Common Shares involves a high degree of risk. Prospective and current investors should carefully consider the following risks and uncertainties, together with all other information in this AIF, as well as the Corporation's financial statements and related notes and MD&A. Any of the risk factors described below could adversely affect Acasti's business, financial condition or results of operations. The market price of the Common Shares could decline significantly if one or more of these risks or uncertainties actually occur. The risks below are not the only ones Acasti faces. Additional risks that Acasti currently does not know about or that Acasti currently believes to be immaterial may also impair its business. Certain statements below are forward-looking information. See "Cautionary Note Regarding Forward-Looking Information".*

### **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 still initiate Phase III 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 2016 at the earliest. 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 prevention and treatment of hypertriglyceridemia or 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.

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

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 Phase III clinical trials, are not successful for the prevention and treatment of hypertriglyceridemia or severe hypertriglyceridemia, and regulatory approval is not obtained in a timely fashion or at all, the Corporation's business will be materially adversely affected.

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 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 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.

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®. In addition, 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. 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.

***The Corporation may be unable to develop alternative product candidates.***

To date, the Corporation has not commercialized any prescription drug candidates and does not have any other compounds in clinical trials, nonclinical testing, lead optimization or lead identification stages besides CaPre®. The Corporation cannot be certain that CaPre® will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If the Corporation fails to successfully commercialize CaPre® as a treatment for hypertriglyceridemia and severe hypertriglyceridemia, or any other indication, whether as a stand-alone therapy or in combination with other treatments, the Corporation would have to develop, acquire or license alternative product candidates or drug compounds to expand its product candidate pipeline beyond CaPre®. In such a scenario, the Corporation may not be able to identify, and acquire product candidates that prove to be successful products, or to acquire them on terms that are acceptable to the Corporation.

***Even if the Corporation receives regulatory approval for CaPre®, the Corporation still may not be able to successfully commercialize it and the revenue that the Corporation generates from its sales, if any, may be limited.***

The commercial success of CaPre® in any indication for which the Corporation obtains marketing approval from the FDA or other regulatory authorities will depend upon its acceptance by the medical community, including physicians, patients and health insurance providers. The degree of market acceptance of CaPre® will depend on a number of factors, including:

- demonstration of clinical safety and efficacy of prescription omega-3 products generally;
- relative convenience, pill burden and ease of administration;
- the prevalence and severity of any adverse side effects;
- the willingness of physicians to prescribe CaPre® and of the target patient population to try new therapies;
- efficacy of CaPre® compared to competing products, including omega-3 dietary supplements;
- the introduction of any new products, including generic prescription omega-3 products, that may in the future become available to treat indications for which CaPre® may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications for which CaPre® shows utility;
- pricing;
- the inclusion of prescription omega-3 products in applicable treatment guidelines;
- the effectiveness of the Corporation's or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- the Corporation's ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

In addition, even if the Corporation obtains regulatory approvals, the timing or scope or conditions of any approvals may prohibit or reduce the Corporation's ability to commercialize CaPre® successfully. For example, if the approval process takes too long, the Corporation may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval the Corporation ultimately obtains may be limited or subject to restrictions or post-approval commitments that render CaPre® not commercially viable. For example, regulatory authorities may not approve the price the Corporation intends to charge for CaPre®, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve CaPre® with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Any of the foregoing scenarios could have a material adverse effect on the commercial prospects for CaPre®. If CaPre® is approved, but does not achieve an adequate level of acceptance by physicians, health insurance providers and patients, the Corporation may not generate sufficient revenue and the Corporation may not be able to ever achieve profitability.

***The Corporation faces competition from other biotechnology and pharmaceutical companies and its operating results will suffer if the Corporation fails to compete effectively.***

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. The Corporation's potential competitors both in the United States and globally include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies and specialized cardiovascular treatment companies. Many of these competitors have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than the Corporation. These companies include GlaxoSmithKline plc, which currently markets Lovaza, a prescription omega-3 for patients with severe hypertriglyceridemia, and Abbott Laboratories, which currently markets Tricor and Trilipix (both fibrates) and Niaspan (niacin) for treatment of severe hypertriglyceridemia and high triglycerides, Amarin Corporation, which currently markets Vascepa, an ethyl-ester form of EPA, for the treatment of patients with severe hypertriglyceridemia and AstraZeneca which announced on May 6, 2014 that the FDA had approved EPANOVA (omega-3-carboxylic acids) as an adjunct to diet to reduce triglyceride levels in adults with severe



hypertriglyceridaemia. In addition, Acasti is aware of other pharmaceutical companies that are developing products that, if approved, would compete with CaPre®. CaPre® may also compete with omega-3 dietary supplements that are available without a prescription. These established competitors and others may invest heavily to quickly discover and develop novel compounds that could make CaPre® obsolete or uneconomical. CaPre® may need to demonstrate compelling comparative advantages in efficacy, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic drug competition, could force the Corporation to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to CaPre®. If the Corporation is not able to compete effectively against its current and future competitors, its business will not grow and its financial condition and operations will suffer.

***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. Dietary supplements may generally be marketed without a lengthy FDA premarket review and approval process and are not subject to prescription. However, unlike prescription drug products, manufacturers of dietary supplements may not make therapeutic claims for their products; dietary supplements may be marketed with claims describing how the product affects the structure or function of the body without premarket approval, but may not expressly or implicitly represent that the dietary supplement will diagnose, cure, mitigate, treat, or prevent disease. The Corporation believes the pharmaceutical-grade purity of CaPre® has a superior therapeutic profile to naturally occurring omega-3 fatty acids and the omega-3 in commercially available dietary supplements. However, the Corporation cannot be certain that physicians or consumers will view CaPre® as superior. 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, 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®.

***Even if the Corporation obtains marketing approval for CaPre®, the Corporation will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense.***

Even if the Corporation obtains U.S. regulatory approval for CaPre® for the prevention and treatment of hypertriglyceridemia or severe hypertriglyceridemia, which would not occur until the Corporation successfully completes Phase III clinical trials, the FDA may still impose significant restrictions on its indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase IV clinical trials or clinical outcome studies, and post-market surveillance to monitor the safety and efficacy of CaPre®. Even if the Corporation secures U.S. regulatory approval, the Corporation would continue to be subject to ongoing regulatory requirements related to CaPre® governing manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with cGCPs, for any clinical trials that the Corporation conducts post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

If the Corporation or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or the Corporation or its manufacturers fail to comply with applicable regulatory requirements, the Corporation may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;

- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by the Corporation, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit the Corporation's ability to commercialize CaPre® and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase the Corporation's product liability exposure. See "Acasti's Business – Government Regulation".

***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 some foreign 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 the United States, the Medicare Modernization Act, or 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.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may possibly require the Corporation to modify its business practices with healthcare practitioners.

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. 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 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 projected value of certain development projects and reduce the Corporation's ability to achieve profitability.

***If the Corporation markets CaPre® in a manner that violates healthcare fraud and abuse laws, or if the Corporation violates government price reporting laws, the Corporation may be subject to civil or criminal penalties.***

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.

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 prescribers; 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 government litigation may include Corporate Integrity Agreements with commitments for monitoring, training, and reporting designed to prevent future violations.

***Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain the Corporation's future revenues.***

The Corporation's ability to successfully market CaPre® will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for

the cost of the Corporation's products and related treatments. Countries in which CaPre® may in the future be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. The Corporation may not be able to sell CaPre® profitably if its prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact the Corporation's development of products including:

- not approving the prices charged for health care products;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

***Termination or suspension of, or delays in the commencement or completion of, any necessary future studies of CaPre® for any indications could occur.***

The commencement and completion of clinical studies for CaPre®, including the Corporation's ongoing TRIFECTA Phase II clinical trial and PK trial in Canada, can be delayed for a number of reasons, including delays related to:

- the FDA, Health Canada or similar regulatory authorities not granting permission to proceed and placing the clinical study on hold;
- subjects failing to enroll or remain in the Corporation's trials at the rate the Corporation expects;
- a facility manufacturing CaPre® being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;
- any changes to the Corporation's manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which the Corporation is developing CaPre®, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform the Corporation's clinical trials, not performing the Corporation's clinical trials on their anticipated schedule or employing methods not consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA, Health Canada or similar regulatory authorities or IRBs finding regulatory violations that require the Corporation to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit the Corporation from using some or all of the data in support of its marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA, Health Canada or other government or regulatory authorities for violations of regulatory requirements, in which case the Corporation may need to find a substitute contractor, and the Corporation may not be able to use some or any of the data produced by such contractors in support of its marketing applications;

- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CRO and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- the addition of new clinical trial sites; and
- the inability of the CRO to execute any clinical trials for any reason.

Product development costs for CaPre® will increase if the Corporation has delays in testing or approval or if the Corporation needs to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and the Corporation may need to amend study protocols to reflect these changes. Amendments may require the Corporation to resubmit its study protocols to the FDA, Health Canada or similar regulatory authorities or IRBs for re-examination, which may impact the costs, timing or successful completion of that study. Any delays in completing the Corporation's clinical trials will increase its costs, slow down its development and approval process and jeopardize its ability to commence sales of CaPre® and generate revenues. Any of these occurrences may have a material adverse effect on the Corporation's business, financial condition and prospects.

***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.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. For example, the positive preliminary results generated to date in the Corporation's TRIFECTA Phase II clinical trial for CaPre® do not ensure that the final Phase II results or later clinical trials will produce similar results. The Corporation cannot assure you that the FDA will view the results as the Corporation does or that any future trials of CaPre® for other indications will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for CaPre® may not be successful.

A number of factors could contribute to a lack of favorable safety and efficacy results for CaPre® for other indications. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period, and due to varying patient characteristics including demographic factors and health status. There can be no assurance that the Corporation's clinical trials, including its TRIFECTA Phase II clinical trial and its PK trial, will demonstrate sufficient safety and efficacy for the FDA to approve CaPre® for the prevention and treatment of hypertriglyceridemia and severe hypertriglyceridemia, or any other indication that the Corporation may consider in any additional NDA submissions for CaPre®.

In addition, clinical trials and nonclinical studies performed by research organizations and other independent third parties may yield negative results regarding the effect of omega-3 fatty acids on cardiometabolic disorders and specifically hypertriglyceridemia and severe hypertriglyceridemia. For example, in May 2013, the New England Journal of Medicine published results on a study in which it concluded that a daily treatment of omega-3 fatty acids did not reduce the risk of cardiovascular events. The clinical trial consisted of the enrollment of 12,513 patients who were followed by a network of 860 general practitioners in Italy. Patients were randomly assigned to omega-3 fatty acids (1g daily) or placebo. Researchers reported that omega-3 fatty acid supplements did not reduce death from heart disease or heart attacks or strokes in the group and concluded that the intake of omega-3 fatty acids does not have any specific advantage in a population that is considered at high risk of cardiovascular disease. The New England Journal of Medicine study along with other future studies yielding similar results could have a negative impact on consumer perception and market acceptance of the efficacy of omega-3 fatty acids on cardiometabolic disorders, specifically the beneficial effect on triglyceride and cholesterol levels, and such impact may have a material adverse effect on the Corporation's business.

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

The Corporation has entered into agreements with a CRO 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®.

***The Corporation's supply of krill oil for commercial supply and clinical trials is dependent upon relationships with Neptune and other third party manufacturers and key suppliers***

The Corporation depends on krill oil sourced from third parties for the production of ONEMIA™ and CaPre®. The Corporation's reliance on third party suppliers of krill oil involves several risks, including potential fluctuations in supply and reduced control over production costs, delivery schedules and the quality of available krill oil. Until November 2012, Acasti purchased all of its supply of krill oil from its parent company, Neptune. On November 8, 2012, an explosion and fire destroyed Neptune's production plant located in Sherbrooke, Québec, Canada. Following the incident, Acasti is currently acquiring its krill oil through purchases in the open market in order to meet production requirements for ONEMIA™, and is also seeking a third party to both supply krill oil on an interim basis and provide manufacturing services for the production of CaPre® in accordance with cGMP regulations imposed by the FDA. However, the Corporation will have to source additional quantities of krill oil for the continued production of ONEMIA™ and its planned Phase III clinical trial for CaPre®, and, if regulatory approval is obtained, larger quantities for the commercialization and distribution of CaPre® than the Corporation is currently able to source.

Neptune is required to obtain the following two operating permits before production can resume at its new production facility:

- a certificate of authorization required under the *Environment Quality Act* (Québec) from the Québec Ministry of Sustainable Development, Environment and the Fight Against Climate Change (the "**Ministry of Environment**") relating to environmental matters relating to the new production facility's operations; and
- a *levée d'interdiction de démarrer*, or permit to lift the prohibition to begin operations, from the *Commission de la santé et de la sécurité du travail* (the "**CSST**") relating to safety in the workplace requirements.

Neptune is currently working closely with the Ministry of Environment and the CSST to obtain the operating permits. While Neptune currently expects the required permits to be issued in time for its target resumption of

production by approximately early June 2014, it is possible that the issuance of these permits could be delayed, denied or subject to additional conditions that require Neptune to make modifications to its new production facility or otherwise put procedures in place that result in a delay and increased cost of the resumption of its operations.

Acasti intends to acquire its krill oil supply from Neptune upon the commencement of krill oil production by Neptune. However, until the reconstruction of Neptune's production facility is completed, Acasti is seeking alternative suppliers of krill oil and may be required to pay higher prices for krill oil (in comparison to what it paid to Neptune or what it pays currently), or it may be unable to acquire krill oil in sufficient quantities. Further, any alternative supply of krill oil may not be of comparable quality to that previously provided by Neptune which may impact the efficacy, or the markets' perception of the efficacy, of ONEMIA™ and CaPre®. Although a prospective new supplier of krill oil to the Corporation has been identified, Acasti cannot be certain that it will be able to contract with this third party supplier on acceptable terms or at all. Disruption to the Corporation's required quantities and quality of krill oil supplies would have a material adverse effect on Acasti's business and results of operations.

***The Corporation relies on third parties for the manufacturing, production and supply of CaPre® and ONEMIA® 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® and ONEMIA®, 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® and its commercial sales of ONEMIA®. The Corporation's reliance on third-parties to produce CaPre® and ONEMIA® exposes Acasti to a number of risks. For example, Acasti may be subject to delays in or suspension of the production of CaPre® and ONEMIA® 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 III clinical trial for CaPre®, which could have a material adverse effect on Acasti's business prospects and result of operations.

***The Corporation may be subject to Product Liability Claims and Recalls of its Products.***

Drug development involves the testing of experimental drugs on human subjects. These studies subject the Corporation to liability risks relating to personal injury or, in extreme cases, death to participants as a result of an unexpected adverse reaction to the tested drug. Furthermore, the administration of these experimental drugs to humans after marketing clearance is obtained can result in product liability claims which may result from claims made directly by consumers or by regulatory agencies, pharmaceutical companies or others. There can be no assurance that insurance will be adequate or will continue to be available on terms acceptable to the Corporation. Insurance will generally not protect the Corporation against negligence.

The obligation to pay any product liability claim in excess of whatever insurance the Corporation is able to acquire, or the recall of any of its products, could have a material adverse effect on the business, financial condition and future prospects of the Corporation.

## **Risks 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.

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 intends to vigorously enforce and protect its intellectual property.

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 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®, ONEMIA® 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 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 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 use of its patents and know-how, the Corporation will not be able to manufacture and market CaPre®, which would have a material adverse affect on its business and financial condition. See “Acasti’s Business – Intellectual Property – Patents*

Acasti owns the following portfolio of patents, filed in various jurisdictions worldwide, including the United States, Canada, Japan, Australia and Europe:

<b><i>Patent Family Description</i></b>	<b><i>Description</i></b>	<b><i>WO (PCT) Application Number &amp; U.S. Patent Number</i></b>	<b><i>Expiration Date of the Patent Family</i></b>	<b><i>Number of Patents Worldwide</i></b>
<i>Concentrated Therapeutic Phospholipid Composition</i>	<i>Composition of Matter</i>	<i>WO2011050474 &amp; US8,586,567;</i>	<i>2028</i>	<i>8* (pending in approx. 40 countries)</i>
<i>* Includes 5 Australian innovation patents expiring in 2018</i>				

On November 19, 2013, the United States Patent and Trademark Office granted Acasti a concentrated phospholipid composition patent (US8,586,567) covering concentrated therapeutic phospholipid compositions useful for treating or preventing diseases associated with cardiovascular disease, metabolic syndrome, inflammation and diseases associated therewith, neurodevelopmental diseases, and neurodegenerative diseases, comprising

administering an effective amount of a concentrated therapeutic phospholipid composition. The patent is valid until 2028, covers specific omega-3 phospholipid compositions, synthetic and/or natural, regardless of the extraction process, suitable for human consumption. The patent protects Acasti's phospholipid compositions, namely Capre® and Onemia®.

The corresponding US8,586,567 Acasti patent has also been granted in South Africa and Panama, and 5 innovation patents have been granted to Acasti in Australia (which innovation patents in Australia expire in 2018), while continuations have been filed in the US.

To this day, Acasti's patents and pending patent applications have not been opposed and/or challenged by third parties anywhere in the world. In Canada, the United States and Europe, a patent is generally valid for 20 years from the date of first filing. Patent terms can vary slightly for other jurisdictions, with 20 years from filing being the norm. In certain jurisdictions exclusivity can be formally extended beyond the normal patent term to compensate for regulatory delays during the pre-market approval process.

Licensed Rights".

***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 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. 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.

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 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.

### **General Risks Related to the Corporation**

#### ***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 ever achieve profitability. The Corporation's net loss for the fiscal year ended February 28, 2014 was approximately \$11.6 million. As of February 28, 2014, the Corporation had an accumulated deficit of approximately \$31.7 million.

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.

#### ***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®. In addition to completing non-clinical and clinical trials, the Corporation expects that additional time and capital will be required to complete the filing of a 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 were approximately \$23.7 million as of February 28, 2014. 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, raise the necessary capital and make sales. 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 favourable terms, or at all, could have a material adverse effect on Acasti's business, financial condition and results of operations.

***In order to establish the Corporation's sales and marketing infrastructure, the Corporation will need to expand the size of its organization, and the Corporation may experience difficulties in managing this growth.***

As of February 28, 2014, the Corporation had six employees in Canada, four of whom have biology, chemistry, biochemistry or microbiology backgrounds and two of whom serve in general and administrative capacities. As the Corporation's development and commercialization plans and strategies develop, the Corporation expects that it will need to expand the size of its employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, the Corporation's management may have to divert a disproportionate amount of its attention away from the Corporation's day-to-day activities and devote a substantial amount of time to managing these growth activities. The Corporation's future financial performance and its ability to commercialize CaPre® and any other future product candidates and its ability to compete effectively will depend, in part, on the Corporation's ability to effectively manage any future growth.

***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.

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.

***If product liability lawsuits are brought against the Corporation, it may incur substantial liabilities and may be required to cease the sale, marketing and distribution of its products.***

The Corporation faces a potential risk of product liability as a result of its sales, marketing and distribution activities relating to ONEMIA® and any future commercialization of CaPre® or any other future product. For example, the Corporation may be sued if any product it develops allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product,

negligence, strict liability and a breach of warranties. Claims could also be asserted under U.S. state or Canadian provincial or other foreign consumer protection legislation. If the Corporation cannot successfully defend itself against product liability claims, it may incur substantial liabilities or be required to cease the sale, marketing and distribution of its products. Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for ONEMIA®, CaPre® or any future products that the Corporation may develop;
- injury to the Corporation's reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and the Corporation's resources;
- substantial monetary awards to consumers, trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize CaPre®;
- the inability to continue the sale, marketing and distribution of ONEMIA®; and
- a decline in the price of the Common Shares.

If the Corporation is unable to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, the commercialization of products it develops could be hindered or prevented. The Corporation currently carries product liability insurance in the amount of \$5.0 million in the aggregate. In addition, the Corporation currently carries liability insurance covering its clinical trials in the amount of \$5.0 million in the aggregate. Although the Corporation maintains such insurance, any claim that may be brought against the Corporation could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by the Corporation's insurance or that is in excess of the limits of the Corporation's insurance coverage. The Corporation's insurance policies also have various exclusions, and the Corporation may be subject to a product liability claim for which it has no coverage. In the event of a successful product liability claim against it, the Corporation may have to pay from its own resources any amounts awarded by a court or negotiated in a settlement that exceed its coverage limitations or that is not covered by the Corporation's insurance, and the Corporation may not have, or be able to obtain, sufficient capital to pay such amounts.

***The Corporation may acquire businesses or products or form strategic alliances in the future and the Corporation may not realize the benefits of such acquisitions.***

The Corporation may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that the Corporation believes will complement or augment its existing business. If the Corporation acquires businesses with promising markets or technologies, it may not be able to realize the benefit of acquiring such businesses if the Corporation is unable to successfully integrate them with its existing operations and company culture. The Corporation may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent the Corporation from realizing their expected benefits.

***The Corporation may not achieve its publicly announced milestones on time.***

From time to time, the Corporation publicly announces the timing of certain events it expects to occur, such as the anticipated timing of results from its clinical trials. These statements are forward-looking and are based on the best estimate of management at the time relating to the occurrence of such events. However, the actual timing of

such events may differ from what has been publicly disclosed. The timing of events such as completion of a clinical trial, discovery of a new product candidate, filing of an application to obtain regulatory approval, beginning of commercialization of certain products, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. For example, the Corporation cannot provide assurances that the TRIFECTA Phase II clinical trial and the PK trial in Canada will be completed on schedule or at all, that it will conduct Phase III clinical trial for CaPre®, that it will make regulatory submissions or receive regulatory approvals as planned, or that it will be able to adhere to plans for the scale-up of manufacturing and launch of any of its products. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, problems with a supplier or a distribution partner or any other event having the effect of delaying the publicly announced timeline. The Corporation undertakes no obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on the Corporation's business plan, financial condition or operating results and the trading price of the Common Shares.

### ***Neptune could lose its control of Acasti***

Neptune currently owns approximately 49.07% of Acasti's outstanding common shares, five members of Neptune's Board of Directors are also members of Acasti's Board of Directors, and Neptune's Chief Executive Officer is also the Chief Executive Officer of Acasti. As a result, Neptune exercises control over Acasti as of February 28, 2014. However, if all outstanding warrants, call options and restrictive share units of Acasti were to be exercised, Neptune's ownership interest in Acasti's common shares would fall to approximately 34.34%. 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;
- Acasti making decisions in connection with the development and commercialization of Acasti's products with less or no involvement and approval from Neptune; and
- a different presentation of Neptune's financial statements as it relates to Acasti, including assets and any future revenues generated by Acasti would not be directly included in Neptune's consolidated financial statements.

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

### **Risks Related to the Corporation's Status as a Foreign Private Issuer/Emerging Growth Company**

***As a foreign private issuer, the Corporation is subject to different U.S. securities laws and regulations than a domestic U.S. issuer, which may limit the information publicly available to the Corporation's U.S. shareholders.***

The Corporation is a foreign private issuer under applicable U.S. federal securities laws, and therefore, it is not required to comply with all the periodic disclosure and current reporting requirements of the U.S. Securities and Exchange Act of 1934, as amended (the "Exchange Act"). As a result, the Corporation does not file the same reports that a U.S. domestic issuer would file with the SEC, although the Corporation is required to file with or furnish to the SEC the continuous disclosure documents that the Corporation is required to file in Canada under Canadian securities laws. In addition, the Corporation's officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions of Section 16 of the Exchange Act. Therefore, the Corporation's shareholders may not know on as timely a basis when the Corporation's officers, directors and principal shareholders purchase or sell common shares as the reporting periods under the corresponding Canadian insider reporting requirements are longer. In addition, as a foreign private issuer, the Corporation is exempt from the proxy rules under the Exchange Act.

***The Corporation may lose its foreign private issuer status in the future, which could result in significant additional costs and expenses to the Corporation.***

The Corporation may in the future lose its foreign private issuer status if a majority of the Common Shares are held in the United States and it fails to meet the additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to the Corporation under U.S. federal securities laws as a U.S. domestic issuer would be significantly more than the costs the Corporation incurs as a Canadian foreign private issuer. If the Corporation is not a foreign private issuer, it would not be eligible to use foreign issuer forms and would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. In addition, the Corporation may lose the ability to rely upon exemptions from NASDAQ corporate governance requirements that are available to foreign private issuers. If the Corporation loses foreign private issuer status, compliance with more enhanced disclosure requirements and other U.S. securities laws may increase our legal and financial compliance costs, make some activities more difficult and time-consuming, increase demand on our systems and resources and divert management's attention from other business concerns, all of which could have a material adverse effect on our business, financial condition and results of operations.

Currently, the Corporation does not satisfy the eligibility criteria to use MJDS to conduct public securities offerings and to meet its periodic disclosure requirements in the United States. As a result, if the Company conducts future public securities offerings in the United States, it may have to do so without the use of MJDS, which could involve additional time and cost.

***As an “emerging growth company”, Acasti is exempt from the requirement to comply with the auditor attestation requirements of the Sarbanes-Oxley Act.***

Acasti is an “emerging growth company”, as defined in the U.S. Jumpstart Our Business Start-ups Act, and intends to avail itself of the exemption provided to emerging growth companies from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Therefore, Acasti's internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are not using an exemption. In addition, Acasti cannot predict if investors will find the Common Shares less attractive because it relies on this exemption. If some investors find the Common Shares less attractive as a result, there may be a less active trading market for the Common Shares and trading price for the Common Shares may be negatively affected.

***U.S. investors may be unable to enforce certain judgments.***

The Corporation is a company existing under the Business Corporations Act (Québec). The majority of the Corporation's directors and officers are residents of Canada, and substantially all of the Corporation's assets are located outside the United States. As a result, it may be difficult to effect service within the United States upon the Corporation or upon its directors and officers. Execution by U.S. courts of any judgment obtained against the Corporation or any of its directors or officers in U.S. courts may be limited to the assets of such companies or such persons, as the case may be, located in the United States. It may also be difficult for holders of securities who reside in the United States to realize in the United States upon judgments of U.S. courts predicated upon civil liability and the civil liability of the Corporation's directors and executive officers under the U.S. federal securities laws. The Corporation has been advised that a judgment of a U.S. court predicated solely upon civil liability under U.S. federal securities laws or the securities or “blue sky” laws of any state within the United States, would likely be enforceable in Canada if the United States court in which the judgment was obtained has a basis for jurisdiction in the matter that would be recognized by a Canadian court for the same purposes. However, there may be doubt as to the enforceability in Canada against these non-U.S. entities or their controlling persons, directors and officers who are not residents of the United States, in original actions or in actions for enforcement of judgments of U.S. courts, of liabilities predicated solely upon U.S. federal or state securities laws.

***The Corporation does not expect that it will be a passive foreign investment company, or PFIC, for the current taxable year, but PFIC classification is fundamentally factual in nature, determined annually and subject to change.***

Based on the projected composition of its income and assets, the Corporation does not expect that it will be a PFIC for the current taxable year ending February 28, 2015. However, whether the Corporation is a PFIC depends on complex U.S. federal income tax rules whose application to the Corporation is uncertain, and, since the PFIC status of the Corporation will depend upon the composition of its income and assets and the fair market value of its assets from time to time and generally cannot be determined until the end of a taxable year, there can be no assurance that the Corporation will not be a PFIC for the current or subsequent taxable years. If the Corporation is a PFIC or if it were to become a PFIC in future taxable years while a U.S. Holder (defined as a beneficial owner of Common Shares that, for U.S. federal income tax purposes, is (a) an individual who is a citizen or resident of the U.S., (b) a corporation, or other entity classified as a corporation for U.S. federal income tax purposes, that is created or organized in or under the laws of the U.S., any state in the U.S. or the District of Columbia, (c) an estate if the income of such estate is subject to U.S. federal income tax regardless of the source of such income, or (d) a trust if (i) such trust has validly elected to be treated as a U.S. person for U.S. federal income tax purposes or (ii) a U.S. court is able to exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of such trust) holds Common Shares, such U.S. Holder would generally be subject to adverse U.S. federal income tax consequences, including the treatment of gain realized on the sale of Common Shares as ordinary (rather than capital gain) income, potential interest charges on those gains and certain other distributions made by the Corporation and ineligibility for the preferential tax rates on dividends paid by qualified foreign corporations generally available to certain non-corporate U.S. Holders.

Each U.S. purchaser is urged to consult its own tax advisor with respect to the U.S. federal, state, local and non-U.S. tax consequences of the acquisition, ownership, and disposition of the Common Shares as may be applicable to that purchaser's particular circumstances.

## **DIVIDENDS**

The Corporation does not anticipate paying any cash dividend on the Common Shares in the foreseeable future. The Corporation presently intends to retain future earnings to finance the expansion and growth of the Corporation's business. Any future determination to pay dividends will be at the discretion of the Corporation's Board of Directors and will depend on the Corporation's financial condition, results of operations, capital requirements and other factors the Board of Directors deems relevant. In addition, the terms of any future debt or credit facility may preclude the Corporation from paying dividends.

## **DESCRIPTION OF CAPITAL STRUCTURE**

The Corporation's authorized capital consists of an unlimited number of no par value Common Shares and an unlimited number of no par value Class B, Class C, Class D and Class E preferred shares (collectively the "**Preferred Shares**"), issuable in one or more series.

As of February 28, 2014, there were (i) a total of 105,862,179 Common Shares issued and outstanding and no Preferred Shares issued and outstanding, (ii) 4,911,000 options to purchase Common Shares issued and outstanding, at a weighted average exercise price of \$1.57 per Common Share, and (iii) 20,766,542 warrants (including 592,500 warrants held by Neptune) to purchase Common Shares issued and outstanding, at a weighted average exercise price of \$1.65 per Common Share.

The following is a brief description of the rights, privileges, conditions and restrictions attaching to the Common Shares and Preferred Shares.

### **Common Shares**

#### *Voting Rights*



Each Common Share entitles its holder to receive notice of, and to attend and vote at, all annual or special meetings of the shareholders of the Corporation. Each Common Share entitles its holder to one vote at any meeting of the shareholders, other than meetings at which only the holders of a particular class or series of shares are entitled to vote due to statutory provisions or the specific attributes of this class or series.

#### Dividends

Subject to the prior rights of the holders of Preferred Shares ranking before the Common Shares as to dividends, the holders of Common Shares are entitled to receive dividends as declared by the Board of Directors of the Corporation from the Corporation's funds that are available for the payment of dividends.

#### Winding-up and Dissolution.

In the event of the Corporation's voluntary or involuntary winding-up or dissolution, or any other distribution of the Corporation's assets among its shareholders for the purposes of winding up its affairs, the holders of Common Shares shall be entitled to receive, after payment by the Corporation to the holders of Preferred Shares ranking prior to Common Shares regarding the distribution of the Corporation's assets in the case of winding-up or dissolution, share for share, the remainder of the property of the Corporation, with neither preference nor distinction. The order of priority, applicable to all classes of shares of the Corporation with respect to the redemption, liquidation, dissolution or distribution of property (the "**Order of priority**") is as follows:

First, the Class E non-voting shares;

Second, the Class D non-voting shares;

Third, the Class B multiple voting shares and Class C non-voting shares, *pari passu*; and

Fourth, the Common Shares.

Notwithstanding the above-mentioned Order of priority, shareholders of a class of shares may renounce the above-mentioned Order of priority by unanimous approval by all shareholders of that class of shares.

#### **Preferred Shares**

##### Class B multiple voting shares

Each Class B multiple voting share entitles the holder thereof to ten (10) votes per share in all shareholder meetings of the Corporation.

#### ***Dividends***

Holders of Class B multiple voting shares are entitled to receive, as and when such dividends are declared, an annual non-cumulative dividend of five percent (5%) on the amount paid for the said shares, payable at the time and in the manner which the Directors may determine and subject to the Order of priority.

#### ***Participation***

Subject to the provisions of subsection 5.2.2 of the of the Corporation's articles, dated February 1, 2002, as amended (the "**Articles**"), holders of Class B multiple voting shares do not have the right to participate in the profits or surplus assets of the Corporation.

#### ***Conversion***

Holders of Class B multiple voting shares have the right, at their entire discretion, to convert, part or all of the Class B multiple voting shares they hold into Common Shares on the basis of one (1) Common Share for each Class B multiple voting share converted.

#### ***Redemption***

Subject to the provisions of the BCA and the Order of priority, holders of Class B multiple voting shares have the right to demand from the Corporation, upon a thirty (30) day written notice, that the Corporation redeem the Class B multiple voting shares at a price equivalent to the amount paid for such shares plus the redemption premium, as defined in subsection 5.2.4.1 of the Articles, and any and all declared but yet unpaid dividends on same.

### ***Liquidation***

In the event of the dissolution or liquidation of the Corporation or any other distribution of its property, the Class B voting shareholders shall have the right to be reimbursed for the amount paid on Class B multiple voting shares plus the redemption premium, as defined in subsection 5.2.4.1 of the Articles as well as the amount of any and all declared but yet unpaid dividends on said shares, subject to the Order of priority.

### ***Class C Non-Voting Shares***

Subject to the provisions of the BCA, holders of Class C non-voting shares are neither be entitled to vote at any meeting of the shareholders of the Corporation, nor to receive a notice of such meeting nor to attend any such meeting.

### ***Dividend***

Holders of Class C non-voting shares are entitled to receive, as and when such dividends are declared, an annual non-cumulative dividend of five percent (5%) on the amount paid for the said shares, plus a redemption premium as defined in subsection 5.3.6.1 of the Articles, payable at the time and in the manner which the Directors may determine and subject to the Order of priority.

### ***Participation***

Subject to the provisions of subsection 5.3.2 of the Articles, holders of Class C non-voting shares do not have the right to participate in the profits or surplus assets of the Corporation.

### ***Conversion***

Holders of Class C non-voting shares have the right, at their entire discretion, to convert, part or all of the Class C non-voting shares they hold into Common Shares on the basis of one (1) Common Share for each Class C non-voting share converted.

### ***Forced Conversion***

All of the Corporation's Class C non-voting shares shall automatically be converted in Common Shares upon the request of an unrelated third party investor in the Corporation, investing more than \$500,000, or any other amount to be determined by the Board of directors of the Corporation, in the Corporation and requesting as a condition to the investment that the Class C non-voting shares be converted into Common Shares on the basis of one Common Share for each Class C non-voting share converted.

### ***Redemption***

Subject to the provisions of the BCA and the Order of priority, holders of Class C non-voting shares have the right to demand from the Corporation, upon a thirty (30) day written notice, that the Corporation redeem the Class C non-voting shares at a price equivalent to the amount paid for said shares plus the redemption premium, as defined in subsection 5.3.6.1 of the Articles, and any and all declared but yet unpaid dividends on same.

### ***Liquidation***

In the event of the dissolution or liquidation of the Corporation or any other distribution of its property, the shareholders have the right to be reimbursed for the amount paid on Class C non-voting shares plus the redemption

premium, as defined in subsection 5.3.6.1 of the Articles, as well as the amount of any and all declared but yet unpaid dividends on said shares, subject to the Order of priority.

*Class D Non-Voting Shares*

Subject to the provisions of the BCA, holders of Class D non-voting shares shall neither be entitled to vote at any meeting of the shareholders of the Corporation, nor to receive a notice of such meeting nor to attend any such meeting.

***Dividend***

Holders of Class D non-voting shares are entitled to receive, as and when such dividends are declared, a monthly non-cumulative dividend of half of one percent to two percent (0.5% to 2%) on the amount paid for such shares, plus a redemption premium as defined in subsection 5.4.6.1 of the Articles, payable at the time and in the manner which the Directors may determine and subject to the Order of priority.

***Participation***

Subject to the provisions of subsection 5.4.2 of the Articles, holders of Class D non-voting shares shall not have the right to participate in the profits or surplus assets of the Corporation.

***Conversion***

Holders of Class D non-voting shares shall have the right, at their entire discretion, to convert, part or all of the Class D non-voting shares they hold into Common Shares on the basis of a number of Common Shares equal to the number of Class D non-voting shares converted multiplied by the conversion ratio, calculated as follows:

$$\text{Conversion Ratio} = \frac{\text{The product obtained by multiplying a factor to be agreed at the time of the issuance of the Class D non-voting shares by the average amount paid per share for the Class D non-voting shares plus the redemption premium per share, as defined in subsection 5.4.6.1 of the Articles as well as the amount of any and all declared but yet paid dividends per said shares}}{\text{Fair Market Value of the Common Shares at the date of any conversion of Class D non-voting shares in Common Shares}}$$

***Forced Conversion***

All of the Corporation's Class C non-voting shares shall automatically be converted in Common Shares upon the request of an unrelated third party investor in the Corporation, investing more than \$500,000, or any other amount to be determined by the Board of directors of the Corporation, in the Corporation and requesting as a condition to the investment that the Class C non-voting shares be converted into Common Shares in all cases, on the basis of a number of Common Shares equal to the number of Class D non-voting shares converted multiplied by the conversion ratio, calculated as follows :

$$\text{Conversion Ratio} = \frac{\text{The product obtained by multiplying a factor to be agreed at the time of the issuance of the Class D non-voting shares by the average amount paid per share for the Class D non-voting shares plus the redemption premium per share, as defined in subsection 5.4.6.1 of the Articles as well as the amount of any and all declared but yet paid dividends per said shares}}{\text{Fair Market Value of the Common Shares at the date of any conversion of Class D non-voting shares in Common Shares}}$$

### ***Redemption***

Subject to the provisions of the BCA and the Order of priority, holders of Class D non-voting shares have the right to demand from the Corporation, upon a thirty (30) day written notice, that the latter redeem the Class D non-voting shares that are held by the shareholder(s) at a price equivalent to the amount paid for said shares plus the redemption premium, as defined in subsection 5.4.6.1 of the Articles, and any and all declared but yet unpaid dividends on same.

### ***Liquidation***

In the event of the dissolution or liquidation of the Corporation or any other distribution of its property, the shareholders shall have the right to be reimbursed for the amount paid on Class D non-voting shares plus the redemption premium, as defined in subsection 5.4.6.1 of the Articles as well as the amount of any and all declared but yet unpaid dividends on said shares, subject to the Order of priority.

### ***Class E Non-Voting Shares***

Subject to the provisions of the BCA, holders of Class E non-voting shares shall neither be entitled to vote at any meeting of the shareholders of the Corporation, nor to receive a notice of such meeting nor to attend any such meeting.

### ***Dividend***

Holders of Class E non-voting shares are entitled to receive, as and when such dividends are declared, a monthly non-cumulative dividend of half of one percent to two percent (0.5% to 2%) on the amount paid for the said shares, payable at the time and in the manner which the Directors may determine and subject to the Order of priority.

### ***Participation***

Subject to the provisions of subsection 5.5.2 of the Articles, holders of Class E non-voting shares shall not have the right to participate in the profits or surplus assets of the Corporation.

### ***Conversion***

Holders of Class E non-voting shares shall have the right, at their entire discretion, to convert, part or all of the Class E non-voting shares they hold into Common Shares on the basis of a number of Common Shares equal to the number of Class E non-voting shares converted multiplied by the conversion ratio, calculated as follows:

$$\text{Conversion Ratio} = \frac{\text{The product obtained by multiplying a factor to be agreed at the time of the issuance of the Class E non-voting shares by the average amount paid per share for the Class E non-voting shares plus the amount of any and all declared but yet paid dividends per said shares}}{\text{Fair Market Value of the Common Shares at the date of any conversion of Class E non-voting shares in Common Shares}}$$

### ***Redemption***

Subject to the provisions of the BCA and the Order of priority, the Corporation has the right to demand from holders of Class E non-voting shares, upon a thirty (30) day written notice, that the latter redeem the Class E non-voting shares that are held by the shareholder(s) at a price equivalent to the amount paid for said shares and any and all declared but yet unpaid dividends on same.

## **Liquidation**

In the event of the dissolution or liquidation of the Corporation or any other distribution of its property, the shareholders shall have the right to be reimbursed for the amount paid on Class E non-voting shares as well as the amount of any and all declared but yet unpaid dividends on said shares, subject to the Order of priority.

## **MARKET FOR SECURITIES**

Since March 31, 2011, the Common Shares have been listed on the TSXV under the ticker symbol APO. Since January 7, 2013, the Common Shares have been listed on the NASDAQ Stock Market under the ticker symbol ACST.

As at February 28, 2014, there were 105,862,179 issued and outstanding Common Shares of Acasti, each share entitling its holder to one (1) vote per Common Share.

### **Trading Prices and Volumes for Acasti**

The price ranges and trading volume of the Common Shares for the most recently completed fiscal year on the TSX and the NASDAQ was as follows:

<b>Period</b>	<b>TSX-V (CDN\$)</b>			<b>NASDAQ (US\$)</b>		
	<b>High</b>	<b>Low</b>	<b>Volume (daily average)</b>	<b>High</b>	<b>Low</b>	<b>Volume (daily average)</b>
February 2014	1.54	1.32	22,300	1.39	1.20	576,679
January 2014	1.69	1.30	53,726	1.56	1.18	762,590
December 2013	1.52	1.20	37,512	1.44	1.15	331,360
November 2013	2.14	1.15	38,865	2.10	1.09	140,735
October 2013	2.57	1.86	33,084	2.55	1.86	40,246
September 2013	3.05	2.10	57,460	2.90	2.00	106,858
August 2013	4.20	2.45	26,870	4.11	2.39	34,298
July 2013	4.32	2.92	20,446	4.20	2.78	26,721
June 2013	2.96	2.57	10,392	2.85	2.47	15,889
May 2013	2.80	2.30	15,359	2.74	2.35	19,730
April 2013	2.52	2.05	23,738	2.48	2.08	32,037
March 2013	2.57	2.00	25,988	3.15	1.97	39,738

## **ESCROWED SECURITIES AND SECURITIES SUBJECT TO RESTRICTION ON TRANSFER**

Certain securities of Acasti were deposited with Computershare Investor Services Inc. (the “**Escrow Agent**”) pursuant to the TSXV Policy 5.4 and a securities escrow agreement entered into on March 31, 2011 (the listing date of the Corporation’s Common Shares on the TSXV) between the Corporation and the Escrow Agent (the “**Escrow Agreement**”). The Escrow Agreement was terminated on March 31, 2014. As of the date hereof, these securities of the Corporation are no longer subject to the Escrow Agreement.

## DIRECTORS AND OFFICERS

### Name, Occupation and Security Holding of Directors and Executive Officers

The following table sets forth each director and executive officer's name, province and country of residence, his/her principal occupation, including the committees of the Board, the year in which he or she first became a director. All members of the Board of Directors herein below will hold their positions until the next annual meeting of shareholders of the Corporation.

Name, Province and Country of Residence	Principal Occupation	Position Within the Corporation	Year of Nomination as a Director of the Corporation
Henri Harland <sup>(3,4)</sup> Québec, Canada	President and Chief Executive Officer of Neptune <sup>(4)</sup>	President, Secretary and Chief Executive Officer and Director <sup>(4)</sup>	2008
Ronald Denis <sup>(1,2,3)</sup> Québec, Canada	Chief of Surgery at Hôpital du Sacré-Coeur, Montréal	Independent Director and Chairman of the Board	2008
Valier Boivin <sup>(1,2,3)</sup> Québec, Canada	Chief Operating Officer of Neptune <sup>(4)</sup>	Independent Director	2013
Jean-Claude Debard <sup>(1,2,3)</sup> Saint Ouen l'Aumône, France	President, Hodran Consultants	Independent Director	2013
Harlan W. Waksal <sup>(3)</sup> New York, United States	Executive Vice-President, Business and Scientific Affairs of the Corporation	Executive Vice-President, Business and Scientific Affairs	2013
Reed V. Tuckson Washington, United States	Managing Director, Tuckson Health Connections, LLC	Independent Director	2013
Tina Sampalis Québec, Canada	Chief Global Strategy Officer of the Corporation	Chief Global Strategy Officer	-
Pierre Lemieux Québec, Canada	Chief Operating Officer of Acasti	Chief Operating Officer	-
Xavier Harland Québec, Canada	Chief Financial Officer of the Corporation	Chief Financial Officer	-

Notes:

- (1) Member of the Audit Committee of the Corporation
- (2) Member of the Compensation Committee of the Corporation
- (3) Member of the Corporate Governance Committee of the Corporation
- (4) Mr. Harland resigned as President and Chief Executive Officer of Neptune as well as President, Secretary and Chief Executive Officer of the Corporation on April 28, 2014

As of February 28, 2014, the directors and executive officers of the Corporation, as a group, beneficially owned or exercised control or direction over approximately 2,492,169 (2%) of the outstanding Common Shares.

Following are brief biographies of Acasti's directors and executive officers:

#### ***Mr. Henri Harland – Director and President and Chief Executive Officer***

Mr. Henri Harland is an Actuary and holds a MBA (Finance) from Laval University. Mr. Henri Harland has been a Director, President and Chief Executive Officer of the Corporation since 2008. His principal occupation is President and Chief Executive Officer of Neptune, a position he has held since Neptune's incorporation on October 9, 1998. He is the founder of the Corporation and has been involved in the krill research project since 1991. For more than ten years he has also held the position of President and Chief Executive Officer of Groupe Conseil Harland Inc., a financial engineering group. Previously, he acted as an independent financial consultant guiding companies from different industrial sectors in both North America and Europe in their capital restructure, financing and business development.

***Dr. Ronald Denis - Chairman of the Board and Director***

Dr. Ronald Denis is Chairman of the Board and has been a Director of the Corporation since 2008. His principal occupation is Chief of Surgery and Co-Director of the Trauma Program at Hôpital du Sacré-Coeur in Montréal. Also, since 1987, Dr. Denis has been medical co-director of the Canadian Formula 1 Grand Prix. Dr. Denis sits on several scientific boards and management committees.

***Mr. Valier Boivin – Director***

Mr. Valier Boivin holds a bachelor's degree in Economic and Administrative Sciences (UQAC-1973), a master's degree in Taxation (Université de Sherbrooke, 1978) and a law degree (Université de Montréal, 1985). Furthermore, he is a member of the “Barreau du Québec” since 1986 and the “Ordre des comptables agréés du Québec” since 1974. He held the position of Professor at the Université du Québec à Chicoutimi until 1978 and then joined the master's degree in taxation program as Professor, at the Université de Sherbrooke until 1987. Founder (in 1987) of Boivin O'Neil, s.e.n.c., he practices business law. Specialized in Mergers & Acquisitions and corporate financing, he acts as legal and strategic counsel to many private and public companies. Since January 2009, he is President of the regional economic intervention fund, FIER Ville-Marie L.P. Mr. Boivin is also socially involved with various professional associations, non-profit organizations and charitable foundations.

***Mr. Jean-Claude Debard – Director***

Mr. Jean-Claude Debard has been President of M Motors Automobiles France, Subaru France, Daihatsu France, SsangYong France since 2012 and FEA Services as well as an officer of Frey Accessories and Parts since 1999 and most recently Executive President of Group Emil Frey France since 2008. Since 1999, Mr. Debard has served on the Oversight Committee of Holding (SERGESA), SsangYong France and Hyundai Finances. Mr. Debard also has a graduate degree in Management and Strategic Management.

***Dr. Harlan W. Waksal – Director and Vice-President, Business and Scientific Affairs***

Dr. Harlan W. Waksal is the Vice-President, Business and Scientific Affairs at the Corporation. Dr. Waksal is a retired physician, he received his B.A. from Oberlin College and M.D. from Tufts University School of Medicine, and his post graduate training in Internal Medicine and in Pathology. In addition, he conducted research in immunology at the Weizmann Institute of Science. Dr. Waksal was a founder of Imclone Systems Incorporated, a New York based pharmaceutical company specializing in developing new treatment for various forms of cancer. He served as the Chief Operating Officer and member of the board of directors from 1986 until 2001 and as President/Chief Executive Officer from 2001 until 2002. During his tenure, he was responsible for building the scientific and operation infrastructure of the company. Dr. Waksal is the author of over 50 scientific publications and has also authored multiple patents and patent applications. Dr. Waksal currently serves on the boards of the Oberlin College, Senesco Technologies, Inc. He also serves on the Advisory Board of Northern Rivers Funds.

***Reed V. Tuckson, M.D. – Director***

Dr. Tuckson is a graduate of Howard University, Georgetown University School of Medicine, and the Hospital of the University of Pennsylvania's General Internal Medicine Residency and Fellowship Programs, where he was also a Robert Wood Johnson Foundation Clinical Scholar studying at the Wharton School of Business. Dr. Tuckson is currently the Managing Director of Tuckson Health Connections, LLC, a health and medical care consulting business. Previously, he served a long tenure as Executive Vice President and Chief of Medical Affairs for UnitedHealth Group, a Fortune 25 health and well-being company. Dr. Tuckson is member of the Advisory Committee to the Director of the National Institutes of Health and is also an active member of the Institute of Medicine of the National Academy of Sciences. He also serves on the Boards of the American Telemedicine Association, Howard University and Cell Therapeutics Inc., a public corporation.

***Dr. Pierre Lemieux Ph.D. – Chief Operating Officer***

Dr. Pierre Lemieux has been the Chief Operating Officer of the Corporation since April 12, 2010. He holds a post-doctoral degree in Oncology from the Health Science Center, University of Texas (San Antonio), United States, and a PhD in biochemistry from Laval University, Canada, jointly with University of Nottingham, England. Prior to

joining the Corporation, Dr. Lemieux was the President, Chief Executive Officer and the chairman of the board as well as being the founder of Technologie Biolactis Inc., a late-stage biotechnology company specialized in the valorization of proteins to better serve the nutraceutical, cosmetic and pharmaceutical industries.

***Mr. Xavier Harland – Chief Financial Officer***

Mr. Xavier Harland joined the Corporation as Chief Financial Officer on in March of 2011. He graduated from Laval University in Actuarial Science in 2003. He is also a CFA charter holder since 2007 and FRM holder since 2006. Xavier Harland was the Director of Finance for Neptune from 2004 to 2011. Mr. Harland works full time for the Neptune group, which also includes NeuroBioPharm, Acasti's sister company.

***Dr. Tina Sampalis M.D., Ph.D. – Chief Global Strategy Officer***

Dr. Tina Sampalis is the Chief Global Strategy Officer of the Corporation. Dr. Sampalis is an Oncology Surgeon, trained in Physiology at McGill University, Medicine at the University of Patras (Greece), Dermatology at Göttingen University (Germany) and Marselisborg University (Denmark), Pediatric, General and Oncology Surgery at the University of Athens (Greece), graduate training (PhD) in Surgical Research at the University of Athens and a second PhD in Epidemiology and Experimental Surgery at McGill University. Between May 2000 and June 2007, she held the position of Vice-President of Research and Business Development at Neptune and since June 2007 the position of Chief Scientific Officer of the Corporation. She ceased to occupy these positions following her nomination as Chief Global Strategy Officer for Neptune and Acasti, which was announced on May 25, 2012.

**CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS**

To the knowledge of Acasti, none of the directors or executive officers of the Corporation:

- (a) is, or has been, within the last ten years, a director, chief executive officer or chief financial officer of any Corporation that:
  - (i) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant Corporation access to any exemption under applicable securities legislation, that was in effect for a period of more than 30 consecutive days (an "Order"), which Order was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer; or
  - (ii) was subject to an Order that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer; or

To the knowledge of Acasti, no director or executive officer of the Corporation, or shareholder holding a sufficient number of securities of the Corporation to affect materially the control of the Corporation:

- (a) is, or has been, within the last ten years, a director or executive officer of any Corporation that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver manager or trustee appointed to hold its assets; or
- (b) has, within the last ten years, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold his or its assets of the proposed director.

To the knowledge of Acasti, no director, executive officer or shareholder holding a sufficient number of securities of the Corporation to affect materially the control of the Corporation has been subject to:



- (a) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
- (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable security holder in deciding whether to vote for a proposed director.

### LEGAL PROCEEDINGS AND REGULATORY ACTIONS

The Corporation is not aware of any legal proceedings or regulatory actions in which it is involved and no such proceedings or regulatory actions are known by the Corporation to be contemplated, except in the section entitled “Acasti’s Business – Litigation.”

### INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

None of the insiders of the Corporation, the Directors, or any of their respective associates or affiliates, has or has had any material interest, direct or indirect, in any material transaction whether proposed or concluded, since the beginning of the Corporation’s most recently completed fiscal year and for the three (3) last completed fiscal years.

### TRANSFER AGENTS AND REGISTRARS

Computershare Trust Company of Canada, at its offices in Montreal, is the transfer agent and registrar for the Corporation’s Common Shares.

### MATERIAL CONTRACTS

*The Corporation has not entered into any material contract, other than those entered into in the normal course of business, within the most recently completed fiscal year, or before the most recently completed fiscal year, which is still in effect except for the license agreement entered into with Neptune on August 7, 2008 and the prepayment agreement entered into with Neptune on December 4, 2012. See “Acasti’s Business – Intellectual Property – Intellectual Property - Patents*

Acasti owns the following portfolio of patents, filed in various jurisdictions worldwide, including the United States, Canada, Japan, Australia and Europe:

<i>Patent Family Description</i>	<i>Description</i>	<i>WO (PCT) Application Number &amp; U.S. Patent Number</i>	<i>Expiration Date of the Patent Family</i>	<i>Number of Patents Worldwide</i>
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<i>Concentrated Therapeutic Phospholipid Composition</i>	<i>Composition of Matter</i>	<i>WO2011050474 &amp; US8,586,567;</i>	<i>2028</i>	<i>8* (pending in approx. 40 countries)</i>
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\* Includes 5 Australian innovation patents expiring in 2018

On November 19, 2013, the United States Patent and Trademark Office granted Acasti a concentrated phospholipid composition patent (US8,586,567) covering concentrated therapeutic phospholipid compositions useful for treating or preventing diseases associated with cardiovascular disease, metabolic syndrome, inflammation and diseases associated therewith, neurodevelopmental diseases, and neurodegenerative diseases, comprising administering an effective amount of a concentrated therapeutic phospholipid composition. The patent is valid until 2028, covers specific omega-3 phospholipid compositions, synthetic and/or natural, regardless of the extraction process, suitable for human consumption. The patent protects Acasti’s phospholipid compositions, namely Capre® and Onemia®.

The corresponding US8,586,567 Acasti patent has also been granted in South Africa and Panama, and 5 innovation patents have been granted to Acasti in Australia (which innovation patents in Australia expire in 2018), while continuations have been filed in the US.

To this day, Acasti's patents and pending patent applications have not been opposed and/or challenged by third parties anywhere in the world. In Canada, the United States and Europe, a patent is generally valid for 20 years from the date of first filing. Patent terms can vary slightly for other jurisdictions, with 20 years from filing being the norm. In certain jurisdictions exclusivity can be formally extended beyond the normal patent term to compensate for regulatory delays during the pre-market approval process.

Licensed Rights.”

## **INTEREST OF EXPERTS**

KPMG LLP (“KPMG”), has audited the Corporation's consolidated financial statements for the years ended as at February 28, 2014 and February 28, 2013. KPMG is independent with respect to Neptune Technologies & Bioresources Inc. and Acasti Pharma Inc. within the meaning of the relevant rules and related interpretations prescribed by the relevant professional bodies in Canada.

## **REPORT ON AUDIT COMMITTEE**

### **Audit Committee's Charter**

The Charter of the Audit Committee is annexed to this circular as Schedule A. The Charter was adopted by the Board of Directors on June 6, 2007.

### **Composition of the Audit Committee**

The Audit Committee is currently composed of three (3) members of Board of Directors: Dr. Ronald Denis, Mr. Valier Boivin, Mr. Jean-Claude Debard. From the experience set forth below, the Corporation believes that these persons have sufficient knowledge and background to actively participate on the Audit Committee. Under National Instrument 52-110 Audit Committees (“NI 52-110”), a member of an Audit Committee is “independent” if he or she has no direct or indirect material relationship with the issuer, that is, a relationship which could, in the view of the Board of Directors, reasonably interfere with the exercise of the member's independent judgment.

All members of the Audit Committee are considered to be “financially literate” within the meaning of applicable Canadian securities regulations in that they each have the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Corporation financial statements.

### ***Relevant Education and Experience***

The following describes the relevant education and experience of each member of the Audit Committee that shows their (a) understanding of the accounting principles used by the Corporation to prepare its financial statements, (b) ability to assess the general application of such accounting principles, (c) experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to those that can reasonably be expected to be raised by the Corporation's financial statements or experience actively supervising one or more persons engaged in such activities, and (d) understanding of internal controls and procedures for financial reporting.

**Dr. Ronald Denis** – Dr. Denis has been Chief of Surgery and Director of the Trauma Program at Hôpital Sacré-Coeur since 1997. In his duties, Dr. Denis has to manage Sacré-Coeur Hospital Trauma Program budget and staff, also he has had to regularly review and analyze financial statements. Dr. Denis' experience has contributed to the development of his ability to analyze financial statements and understand GAAP.

**Mr. Valier Boivin** – Mr. Valier Boivin holds a bachelor’s degree in Economic and Administrative Sciences (UQAC-1973), a master’s degree in Taxation and a law degree. Furthermore, he is a member of the “Barreau du Québec” since 1986 and the “Ordre des comptables agréés du Québec” since 1974. He held the position of Professor at the Université du Québec à Chicoutimi until 1978 and then joined the master’s degree in taxation program as Professor, at the Université de Sherbrooke until 1987. He practices business law. Specialized in Mergers & Acquisitions and corporate financing, he acts as legal and strategic counsel to many private and public companies. Since January 2009, he is President of the regional economic intervention fund, FIER Ville-Marie L.P. Mr Boivin’s experience required and contributed to the development of his ability to analyze financial statements and understand IFRS.

**Mr. Jean-Claude Debard** – Mr. Debard has been President of Hyundai Automobile France and FEA Services as well as an officer of Frey Accessories and Parts since 1999 and most recently Executive President of Group Emil Frey France since 2008. Since 1999, Mr. Debard has served on the Oversight Committee of Holding (SERGESA), SsangYong France and Hyundai Finances. Mr. Debard also has a graduate degree in Management and Strategic Management. Mr. Debard’s experience required and contributed to the development of his ability to analyze financial statements and understand IFRS.

### **External Auditor Fees**

#### **Audit Fees**

“Audit fees” consist of fees for professional services for the audit of the Corporation’s annual financial statements, interim reviews and limited procedures on interim financial statements, securities filings and consultations on accounting or disclosure issues. For the fiscal year ended February 28, 2014, KPMG LLP, the Corporation’s external auditors, billed \$214,500 to the Corporation for audit fees. For the fiscal year ended February 28, 2013, the audit fees were \$68,500 to the Corporation.

#### **Audit-Related Fees**

“Audit-related fees” consist of fees for professional services that are reasonably related to the performance of the audit or review of the Company’s financial statements and which are not reported under “Audit Fees” above. For the fiscal year ended February 28, 2014, KPMG LLP, the Corporation’s external auditors, billed \$14,000 to the Corporation (translation). No fees were billed as to this matter for the fiscal years ended February 28, 2013.

#### **Tax Fees**

“Tax fees” consist of fees for professional services for tax compliance, tax advice and tax planning. KPMG LLP, the Corporation’s external auditors, billed a total of \$25,500 to the Corporation for tax fees for fiscal year ended February 28, 2014 and a total of \$7,500 to the Corporation for the fiscal period ended February 28, 2013. Tax fees include, but are not limited to, preparation of tax returns.

#### **All Other Fees**

The “other fees” include all other fees billed for professional services other than those mentioned hereinabove. KPMG LLP, the Corporation’s external auditors, billed no fees as to this matter the fiscal years ended February 28, 2014 and February 28, 2013.

### **ADDITIONAL INFORMATION**

Additional information relating to the Corporation may also be found on the SEDAR website at [www.sedar.com](http://www.sedar.com), and on EDGAR at [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml).

Additional information, including directors’ and officers’ remuneration and indebtedness, principal holders of the Corporation’s securities, options to purchase securities and interests of informed persons in material transactions, if applicable, is contained in Acasti’s Management Proxy Circular dated May 22, 2014 and available on SEDAR. Additional financial information is also provided in the Corporation’s financial statements and MD&A for the most recently completed fiscal year.

## **SCHEDULE “A”**

### **CHARTER OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS**

The Audit Committee of the Board of Directors assists the Board in fulfilling its oversight responsibilities relating to the quality and integrity of the accounting, auditing and reporting practices of the Corporation and such other duties as directed by the Board of Directors or imposed by legislative authorities or stock exchanges.

#### **Structure and Organization**

1. The membership of the Committee will consist of at least three independent members of the Board of Directors, the majority of whom will not be employees, controlling shareholders or executives of the Corporation or of any associates or affiliates of the Corporation. Committee members and the Committee Chairman shall be designated by and serve at the pleasure of the Board of Directors. All members must be financially literate and at least one member must have accounting or related financial management expertise, in each case in the judgment of the Board of Directors.
2. The Committee shall meet at least four times per year or more frequently as circumstances require. The Committee may ask members of management or others to attend meetings and provide pertinent information as necessary. The required quorum for the Committee will be the majority of the members forming the Committee.
3. The Committee is expected to maintain free and open communication with management and the external auditors.
4. The Committee has the authority to investigate any matter brought to its attention and to retain outside counsel for this purpose if, in its judgment, that is appropriate.

#### ***General Responsibilities***

The Committee shall:

1. Meet periodically with representatives of the external auditors, the internal audit manager (if any) and management in separate sessions to discuss any matters that the Committee or these groups believe should be discussed privately with the Committee. Provide sufficient opportunity for the external auditors to meet with the Audit Committee as appropriate without members of management being present.
2. Prepare the minutes of all Committee meetings and report of such meetings to the Board of Directors.
3. Review and reassess the adequacy of this Charter annually.

#### ***Responsibilities for Engaging External Auditors***

The Committee shall:

1. Recommend for approval by the Board of Directors and ratification by the shareholders the selection and retention of an independent firm of chartered professional accountants as external auditors, approve compensation of the external auditors, and review and approve in advance the discharge of the external auditors.
2. Review the independence of the external auditors. In considering the independence of the external auditors, the Committee will review the nature of the services provided by the external auditors and the fees charged, and such other matters as the Committee deems appropriate.

3. Ensure that the external auditors are in good standing with the Canadian Public Accountability Board (CPAB) and that the CPAB has not imposed any sanction on them. The Audit Committee is also responsible for ensuring that the external auditors comply with the rotation requirements with respect to partners involved in the audit of the Corporation.
4. Arrange for the external auditors to be available to the Board of Directors at least annually to help provide a basis for the Board's approval of the external auditors' appointment.
5. Approve all allowable non-audit related services to be provided to the Corporation or one of its subsidiaries by the Corporation's external auditors if applicable.
6. Non-audit services of minimal amount satisfy the pre-approval requirements on the following conditions:
  - (a) that the aggregate amount of all non-audit services that were not pre-approved is reasonably expected to constitute no more than five per cent of the total amount of fees paid by the Corporation and its subsidiaries to the Corporation's external auditors during the fiscal year in which the services are provided;
  - (b) that the Corporation or its subsidiaries, as the case may be, did not recognize the services as non-audit services at the time of the engagement; and
  - (c) that the services are promptly brought to the attention of the Audit Committee and approved, prior to the completion of the audit, by the Audit Committee or by one or more of its members to whom authority to grant such approvals had been delegated by the Audit Committee.

#### **Responsibilities for Oversight of the Quality and Integrity of Accounting, Auditing and Reporting Practices of the Corporation**

The Committee shall:

1. Directly review the work of the external auditors engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attestation services for the Corporation. The Committee shall be directly responsible of the resolution of disagreements between management and the external auditors regarding financial reporting.
2. Review the Corporation's financial statements, management's discussion and analysis (MD&A) and annual and interim earnings press releases together with management and the external auditors, if applicable, before the Corporation publicly discloses this information. This review should cover the quality of the financial reporting and such other matters as the Committee deems appropriate.
3. Review with the external auditors and management the audit plan of the external auditors for the current year and the following year.
4. Review with financial and accounting personnel, the adequacy and effectiveness of the accounting, financial, and computerized information systems controls of the Corporation, and the results of any external audit procedures, if applicable.
5. Establish procedures for the receipt, retention and treatment of complaints received regarding accounting, internal accounting controls or auditing matters. Such complaints are to be treated confidentially and anonymously.
6. Review and approve all related party transactions undertaken by the Corporation.

### ***Periodic Responsibilities***

The Committee shall:

1. Review periodically with management any legal and regulatory matters that may have a material impact on the Corporation's financial statements, compliance policies and compliance programs.
2. Review with management and approve transactions involving management and/or members of the Board of Directors, which would require disclosure under TSX Venture Exchange rules.
3. Supervise the corporate compliance program and periodically review whether any improvements should be made thereto and make appropriate recommendations to management.
4. Perform such other functions assigned by law, the Corporation's Articles or bylaws, or by the Board of Directors.
5. Review services and related fees for work done by the external auditors as well as an updated projection of the total costs for the fiscal year.
6. Review and approve the engagement policy of the Corporation with respect to partners, employees, former partners and employees of the current and previous external auditors of the Corporation.
7. Implement a process for the identification of the principal business risks and monitor the implementation of appropriate methods of risk management. This process will require consultation with management in order to determine how risks are handled and to solicit the opinion of the internal audit department with respect to the effectiveness of the risk limitation strategies.

### ***Authority of the Audit Committee***

The Committee shall have the authority to:

1. Engage independent counsel and other advisors as it determines necessary to carry out its duties.
2. Pay the compensation for any advisors employed by the Committee. The Committee shall notify the Board of Directors on the extent of the financing required to pay for the compensation of the independent expert advisors retained to advise the Committee.
3. Communicate directly with the internal and external auditors.