
United States
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM F-10
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ACASTI PHARMA INC.

(Exact name of Registrant as specified in its charter)

Québec, Canada
(Province or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial Classification)
Code Number (if applicable)

Not Applicable
(I.R.S. Employer
Identification Number (if applicable))

545 Promenade du Centropolis, Suite 100
Laval, Québec H7T 0A3
(450) 687-2262
(Address and telephone number of the Registrant's principal executive offices)

CT Corporation System
111 Eighth Avenue, New York, NY 10011
(212) 894-8440
(Name, address (including zip code) and telephone number (including area code) of agent for service in the United States)

Copies to:

Jean-Daniel Bélanger
Acasti Pharma Inc.
545 Promenade de Centropolis,
Suite 100
Laval, Québec
Canada H7T 0A3
(450) 687-2262

François Paradis
Osler, Hoskin & Harcourt LLP
1000 De La Gauchetière Street West
Suite 2100
Montréal, Québec, Canada H3B 4W5
(514) 904-8100

Jason Comerford
Osler, Hoskin & Harcourt LLP
620 Eighth Avenue
36th Floor
New York, New York 10018
(212) 867-5800

Approximate date of commencement of proposed sale of the securities to the public:
From time to time after the effective date of this Registration Statement.

Province of Quebec, Canada
(Principal jurisdiction regulating this offering (if applicable))

It is proposed that this filing shall become effective (check appropriate box):

- A. ☐ Upon the filing with the Commission, pursuant to Rule 467(a) (if in connection with an offering being made contemporaneously in the United States and Canada)
- B. ☒ At some future date (check the appropriate box below):
1. ☐ Pursuant to Rule 467(b) on (date) at (time) (designate a time not sooner than 7 calendar days after filing)

2. ☐ Pursuant to Rule 467(b) on (date) at (time) (designate a time 7 calendar days or sooner after filing) because the securities regulatory authority in the review jurisdiction has issued a receipt or notification of clearance on (date).
3. ☒ Pursuant to Rule 467(b) as soon as practicable after notification of the Commission by the Registrant or the Canadian securities regulatory authority or the review jurisdiction that a receipt or notification of clearance has been issued with respect hereto.
4. ☐ After the filing of the next amendment to this Form (if preliminary material is being filed).

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to the home jurisdiction's shelf prospectus offering procedures, check the following box. ☒

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per unit	Proposed maximum aggregate offering price(2)	Amount of registration fee
Common Shares	-	-	-	-
Warrants	-	-	-	-
Units	-	-	-	-
Total	US\$150,000,000	100%	US\$150,000,000	US\$19,320

- (1) There are being registered under this Registration Statement such indeterminate number of common shares, warrants to purchase common shares, and units (all of the foregoing collectively, the "Securities") of the Registrant as shall have an aggregate initial offering price of up to US\$150,000,000. Any Securities registered by this Registration Statement may be sold separately or as units with other Securities registered under this Registration Statement. The proposed maximum initial offering price per Security will be determined, from time to time, by the Registrant in connection with the sale of the Securities under this Registration Statement.
- (2) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457 of the Securities Act of 1933.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registration statement shall become effective as provided in Rule 467 under the Securities Act of 1933 or on such date as the Commission, acting pursuant to Section 8 (a) of the Act, may determine.

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PART 1 – INFORMATION REQUIRED TO BE DELIVERED TO OFFEREES OR PURCHASERS

This short form prospectus shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any State in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such State.

No securities regulatory authority has expressed an opinion about these securities and it is an offence to claim otherwise.

This short form prospectus constitutes a public offering of these securities only in those jurisdictions where they may be lawfully offered for sale and therein only by persons permitted to sell such securities.

The information in this short form prospectus is not complete and may be changed. The securities may not be sold in the United States until the Registration Statement filed with the U.S. Securities and Exchange Commission is effective.

This short form prospectus has been filed under legislation in securities regulatory authorities in the provinces of Québec, Ontario, Manitoba, Alberta and British Columbia that permits certain information about these securities to be determined after this prospectus has become final and that permits the omission from this prospectus of that information. The legislation requires the delivery to purchasers of a prospectus supplement containing the omitted information within a specified period of time after agreeing to purchase any of these securities.

Information has been incorporated by reference in this short form prospectus from documents filed with securities commissions or similar authorities in Canada. Copies of the documents incorporated herein by reference may be obtained on request without charge from the secretary of Acasti Pharma Inc. at 545 Promenade du Centropolis, Suite 100, Laval, Québec H7T 0A3, telephone: 1-855-314-5747 and are also available electronically at www.sedar.com.

Short Form Base Shelf Prospectus

New Issue and Secondary Offering

October 25, 2013



Acasti Pharma Inc.
US\$150,000,000

Common Shares
Warrants
Units

Acasti Pharma Inc. (“**Acasti**”, “**it**”, “**its**” or the “**Corporation**”) may offer and issue from time to time Class A shares of the Corporation (“**Common Shares**”), warrants to purchase Common Shares (“**Warrants**”), any combination of Common Shares and Warrants (“**Units**”) or any combination thereof (all of the foregoing collectively, the “**Securities**”) up to an aggregate initial offering price of US\$150,000,000 (or the equivalent thereof if the Securities are denominated in any other currency or currency unit) during the 25-month period that this short form base shelf prospectus (this “**Prospectus**”), including any amendments hereto, remains effective. Securities may be offered in amounts, at prices and on terms to be determined based on market conditions at the time of sale and set forth in one or more accompanying prospectus supplements (collectively or individually, as the case may be, a “**Prospectus Supplement**”). One or more securityholders (each a “**Selling Securityholder**”) of the Corporation may also offer and sell Securities under this Prospectus. See “Selling Securityholder”.

All information permitted under applicable laws to be omitted from this Prospectus will be contained in one or more Prospectus Supplements that will be delivered to purchasers together with this Prospectus. Each Prospectus

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Supplement will be incorporated by reference into this Prospectus for the purposes of securities legislation as of the date of the applicable Prospectus Supplement and only for the purposes of the distribution of the Securities to which the applicable Prospectus Supplement pertains.

The outstanding Common Shares are listed and posted for trading on the TSX Venture Exchange (“TSXV”) under the ticker symbol “APO” and on The Nasdaq Stock Market (“NASDAQ”) under the ticker symbol “ACST”. Unless otherwise specified in the applicable Prospectus Supplement, Securities other than Common Shares will not be listed on any securities exchange. **There is no market through which the Securities, other than the Common Shares, may be sold and purchasers may not be able to resell such Securities purchased under this Prospectus and any applicable Prospectus Supplement. This may affect the pricing of such Securities in the secondary market, the transparency and availability of trading prices, the liquidity of the Securities, and the extent of issuer regulation. See “Risk Factors – Risks Related to the Offering and the Securities”.** Certain legal matters related to the offering of Securities hereunder will be passed upon by Osler, Hoskin & Harcourt LLP with respect to Canadian and U.S. legal matters.

Investing in the Securities involves significant risks. Investors should carefully read the “Risk Factors” section in this Prospectus beginning on page 26, in the documents incorporated by reference herein and in the applicable Prospectus Supplement.

This offering is made by a Canadian issuer that is permitted, under a multijurisdictional disclosure system (“MJDS”) adopted by the United States and Canada, to prepare this Prospectus in accordance with Canadian disclosure requirements. Investors should be aware that such requirements are different from those of the United States. The annual and interim financial statements incorporated by reference herein have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board and are subject to Canadian auditing and auditor independence standards and thus may not be comparable to financial statements of United States companies.

The enforcement by investors of civil liabilities under United States federal securities laws may be affected adversely by the fact that Acasti is incorporated or organized under the laws of Canada, that the majority of the Corporation’s officers and directors are residents of Canada, that all or a substantial portion of the Corporation’s assets and all or a substantial portion of the assets of said persons are located outside the United States and that some or all of the underwriters or experts identified herein or in any Prospectus Supplement may be residents of Canada.

Harlan Waksal and Jean-Claude Debard, both directors and/or officers of the Corporation, reside outside of Canada and each of them has appointed Acasti Pharma Inc., 545 Promenade du Centropolis, Suite 100, Laval, Québec H7T 0A3, as their agent for service of process in Canada. Purchasers are advised that it may not be possible for investors to enforce judgments obtained in Canada against any person or company that is incorporated, continued or otherwise organized under the laws of a foreign jurisdiction or resides outside of Canada, even if the party has appointed an agent for service of process.

THE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION (“SEC”) NOR HAS THE SECURITIES COMMISSION OF ANY STATE OF THE UNITED STATES OR ANY CANADIAN SECURITIES REGULATOR APPROVED OR DISAPPROVED THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The specific terms of the Securities with respect to a particular offering will be set out in the applicable Prospectus Supplement and may include, where applicable: (i) in the case of Common Shares, the number of shares offered, the offering price, the currency and any other terms specific to the Common Shares being offered; (ii) in the case of Warrants, the designation, number and terms of the Common Shares issuable upon exercise of the Warrants, the offering price, the currency, any procedures that will result in the adjustment of these numbers, the exercise price, dates and periods of exercise, and any other terms specific to the Warrants being offered, and (iii) in the case of Units, the designation, number of Common Shares and Warrants comprising the Units, the offering price, the currency and any other terms specific to the Units being offered. A Prospectus Supplement may include specific terms pertaining to the Securities that are not within the alternatives and parameters set forth in this Prospectus.

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Where required by statute, regulation or policy, and where Securities are offered in currencies other than United States dollars, appropriate disclosure of foreign exchange rates applicable to the Securities will be included in the Prospectus Supplement describing the Securities.

Prospective investors should be aware that the acquisition of the Securities described herein may have tax consequences both in the United States and Canada. This Prospectus does not discuss U.S. or Canadian tax consequences and any applicable Prospectus Supplement may not describe these tax consequences fully. Prospective investors should read the tax discussion in any applicable Prospectus Supplement.

No underwriter has been involved in the preparation of this Prospectus nor has any underwriter performed any review of the contents of this Prospectus.

This Prospectus constitutes a public offering of Securities only in those jurisdictions where they may be lawfully offered for sale and therein only by persons permitted to sell the Securities. The Corporation and the Selling Securityholder may offer and sell Securities to, or through, underwriters and also may offer and sell certain Securities directly to other purchasers or through agents pursuant to exemptions from registration or qualification under applicable securities laws. A Prospectus Supplement relating to each issue of Securities offered thereby will set forth the names of any underwriters or agents involved in the offering and sale of the Securities, the name or names of any Selling Securityholder, and will set forth the terms of the offering of the Securities, the method of distribution of the Securities including, to the extent applicable, the proceeds to the Corporation and the Selling Securityholder and, any fees, discounts or any other compensation payable to underwriters or agents and any other material terms of the plan of distribution.

In connection with any offering of the Securities (unless otherwise specified in a Prospectus Supplement), the underwriters or agents may over-allot or effect transactions which stabilize or maintain the market price of the Securities offered at a higher level than that which might exist in the open market. Such transactions, if commenced, may be interrupted or discontinued at any time. See “Plan of Distribution”.

The Corporation’s head and registered office is located at 545, Promenade du Centropolis, Suite 100, Laval, Québec, Canada, H7T 0A3.

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ABOUT THIS PROSPECTUS

The Corporation is subject to the information requirements of the United States Securities Exchange Act of 1934, as amended (the “**U.S. Exchange Act**”), and applicable Canadian securities legislation, and in accordance therewith files reports and other information with the SEC and with the securities regulators in Canada. Under a multijurisdictional disclosure system adopted by the United States and Canada, documents and other information that the Corporation files with the SEC may be prepared in accordance with the disclosure requirements of Canada, which are different from those of the United States. As a foreign private issuer, the Corporation is exempt from the rules under the U.S. Exchange Act prescribing the filing, delivery and content of proxy statements, and its officers, directors and principal shareholders are exempt from the insider reporting and short-swing profit recovery provisions contained in Section 16 of the U.S. Exchange Act. In addition, the Corporation may not be required to publish financial statements as promptly as a comparable U.S. company.

You may read any document that the Corporation has filed with the SEC at the SEC’s public reference room in Washington, D.C. You may also obtain copies of those documents from the public reference room of the SEC at 100 F Street, N.E., Washington, D.C. 20549 by paying a fee. You should call the SEC at 1-800-SEC-0330 or access its website at www.sec.gov for further information about the public reference room. You may read and download some of the documents the Corporation has filed with the SEC’s Electronic Data Gathering and Retrieval (“**EDGAR**”) system at www.sec.gov/edgar.shtml. You may read and download any public document that the Corporation has filed with the Canadian securities regulatory authorities at www.sedar.com.

This Prospectus and the documents incorporated by reference contain company names, product names, trade names, trademarks and service marks of Acasti and other organizations, all of which are the property of their respective owners.

Market data and certain industry data and forecasts included in this Prospectus were obtained from internal company surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. Acasti has relied upon industry publications as its primary sources for third-party industry data and forecasts. Industry surveys, publications and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. Acasti has not independently verified any of the data from third-party sources, nor has Acasti ascertained the underlying economic assumptions relied upon therein. Similarly, internal surveys, industry forecasts and market research, which Acasti believes to be reliable based upon management’s knowledge of the industry, have not been independently verified. By their nature, forecasts are particularly subject to change or inaccuracies, especially over long periods of time. In addition, Acasti does not know what assumptions regarding general economic growth were used in preparing the forecasts cited in this Prospectus. 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 Prospectus. 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 Prospectus may only be used for the purpose for which it has been published.

In this Prospectus and in any Prospectus Supplement, unless the context otherwise requires, references to “Acasti”, the “Corporation”, “it”, “its” or similar terms refer to Acasti Pharma Inc. and references to “Neptune” refer to Acasti’s parent company, Neptune Technologies & Bioresources Inc.

EXCHANGE RATE INFORMATION

The financial information of the Corporation contained in the documents incorporated by reference herein are presented in Canadian dollars. All references in this Prospectus to “dollars”, “CDN\$” and “\$” refer to Canadian dollars, and references to “US\$” refer to United States dollars, unless otherwise expressly stated. Potential purchasers should be aware that foreign exchange rate fluctuations are likely to occur from time to time and that the Corporation does not make any representation with respect to future currency values. Investors should consult their own advisors with respect to the potential risk of currency fluctuations.

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The following table sets forth (i) the rate of exchange for the Canadian dollar, expressed in United States dollars, in effect at the end of the periods indicated; (ii) the average exchange rates for the Canadian dollar expressed in United States dollars, on the last day of each month during such periods; and (iii) the high and low exchange rates for the Canadian dollar, expressed in United States dollars, during such periods, each based on the noon rate of exchange as reported by the Bank of Canada for conversion of Canadian dollars into United States dollars:

	Six-month period ended	Fiscal Year Ended February 29/28	
	August 31, 2013	2013	2012
Rate at the end of period	0.9476	0.9723	1.0136
Average rate during period	0.9637	1.0012	1.0084
Highest rate during period	0.9833	1.0299	1.0583
Lowest rate during period	0.9455	0.9599	0.9430

On October 24, 2013, the closing exchange rate for the Canadian dollar, expressed in United States dollars, as quoted by the Bank of Canada, was CDN\$1.00 = US\$0.9592.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION

This Prospectus 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 Prospectus 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 Prospectus includes, but is not limited to, information or statements about:

- Acasti’s use of the net proceeds from any proposed offering;
- Acasti’s ability to complete its current Phase II double blind clinical trial (the TRIFECTA trial) and conduct future additional clinical trials for CaPre®, such as Phase III clinical trials, including the timing and results of those clinical trials;
- Acasti’s ability to commercialize and distribute CaPre® and ONEMIA® in the United States and elsewhere;
- Acasti’s estimates of the size of the potential markets for CaPre® and ONEMIA® and the rate and degree of market acceptance of CaPre® and ONEMIA®;
- the benefits of CaPre® and ONEMIA® 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 obtain from a third-party supplier sufficient raw materials for its operations, including krill oil used to manufacture CaPre® and ONEMIA®;
- Acasti’s ability to obtain manufactured CaPre® from a third party 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;

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- 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 Prospectus 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 Prospectus is subject to a number of known and unknown risks, uncertainties and other factors, including those described in this Prospectus 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 obtain from third parties krill oil in sufficient quantities and quality and manufactured CaPre® produced 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 and, accordingly, continue as a going concern;
- 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 Prospectus 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

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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 Prospectus.

GLOSSARY OF TERMS

“**Acasti**” or the “**Corporation**” means Acasti Pharma Inc.;

“**APIs**” means active pharmaceutical ingredients;

“**cGCP**” means current Good Clinical Practices, as further described under “Government Regulation—United States Drug Development—FDA Regulatory Process”;

“**Common Shares**” means the Class A shares of Acasti;

“**CRL**” means Complete Response Letter, as described under “Government Regulation—United States Drug Development—FDA Regulatory Process”;

“**CRO**” means clinical research organization;

“**CTA**” means a clinical trial application in Canada, as described under “Government Regulation—United States Drug Development—Non-U.S. Drug Regulation”;

“**DHA**” means docosahexaenoic acid which is a type of omega-3 fatty acid and is, together with EPA, the main PUFAs found in krill;

“**EDGAR**” means the SEC’s Electronic Data Gathering and Retrieval system;

“**EPA**” means eicosapentaenoic acid which is a type of omega-3 fatty acid and is, together with DHA, the main PUFAs found in krill;

“**FDA**” means the U.S. Food and Drug Administration;

“**FINRA**” means the Financial Industry Regulatory Authority Inc. (United States);

“**GLP**” means the FDA’s Good Laboratory Practice, as more fully described under “Government Regulation—United States Drug Development—FDA Regulatory Process”;

“**HDL-C**” means high density lipoprotein (good cholesterol);

“**IND**” means investigational new drug, for which an FDA application needs to be filed prior to any clinical trial, as described under “Government Regulation—United States Drug Development—FDA Regulatory Process”;

“**IRB**” means the Independent Institutional Review Board (United States), whose roles are described under “Government Regulation—United States Drug Development—FDA Regulatory Process”;

“**JSS**” means JSS Medical Research, as described under “Acasti’s Products—Clinical and Nonclinical Research—Clinical—COLT Trial”;

“**KPMG**” means KPMG LLP.;

“**LDL-C**” means low density lipoprotein (bad cholesterol);

“**mild to moderate hypertriglyceridemia**” means high levels of triglycerides ranging from 2.28 to 5.69 mmol/L (200-499 mg/dL);

“**mild to severe hypertriglyceridemia**” means high to very high levels of triglycerides and includes all levels in excess of 2.28 mmol/L (>200 mg/dL);

“**MJDS**” means the multijurisdictional disclosure system adopted by the United States and Canada;

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“**MMA**” means the Medicare Modernization Act (United States), as amended from time to time;

“**NASDAQ**” means The Nasdaq Stock Market;

“**NCEP**” means The National Cholesterol Education Program (United States);

“**NDA**” means new drug application, as described under “Government Regulation—United States Drug Development—FDA Regulatory Process”;

“**NDS**” means the new drug submission, as more fully described under “Government Regulation—United States Drug Development—Non-U.S. Drug Regulation”;

“**NHPD**” means the Natural Health Product Directorate (Canada);

“**non-HDL-C**” means non-high density lipoprotein, which includes all cholesterol contained in the bloodstream except HDL-C;

“**off-label use**” means uses for drugs that are not described in the drug’s approved labeling, as more fully described under “Government Regulation—United States Drug Development—FDA Regulatory Process”;

“**PDUFA**” means the Prescription Drug User Fee Act (United States), as amended from time to time;

“**PK**” means pharmacokinetic and is used throughout this Prospectus in the context of a pharmacokinetic trial or study, which is a clinical trial described under “Acasti’s Products—Clinical and Nonclinical Research—Next Steps”;

“**Preferred Shares**” means the Class B, Class C, Class D and Class E preferred shares of the Corporation, as described under “Description of the Common Shares”;

“**Prospectus Supplement**” means, collectively or individually, a prospectus supplement accompanying this Prospectus;

“**Prospectus**” means this short form base shelf prospectus;

“**PUFAs**” means polyunsaturated fatty acids;

“**SEC**” means the United States Securities and Exchange Commission;

“**Securities**” means, collectively, Common Shares, Warrants and Units;

“**Selling Securityholder**” means each of the securityholders of the Corporation, which may offer and sell Securities under this Prospectus, as more fully described under “Selling Securityholder”;

“**severe hypertriglyceridemia**” means very high levels of triglycerides of over 5.69 mmol/L (>500 mg/dL);

“**SPA**” means special protocol assessment, as described fully under “Acasti’s Products—Clinical and Nonclinical Research—Next Steps”;

“**TSVX**” means the TSX Venture Exchange;

“**U.S. Exchange Act**” means the Securities Exchange Act of 1934 (United States), as amended from time to time;

“**Unit Agreement**” means a unit agreement between the Corporation and a unit agent as described under “Description of the Units”;

“**Units**” means any combination of Common Shares and/or Warrants, as more fully described under “Description of the Units”;

“**Warrant Indenture**” means each of the warrant indentures between the Corporation and the Warrant Trustee under which Warrants are issued and governed, as more fully described under “Description of the Warrants”;

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“**Warrant Trustee**” means each warrant trustee that is party to a Warrant Indenture with the Corporation, as described under “Description of the Warrants”; and

“**Warrants**” means warrants to purchase Common Shares of Acasti, as more fully described under “Description of the Warrants”.

DOCUMENTS INCORPORATED BY REFERENCE

Information has been incorporated by reference into this Prospectus from documents filed with securities commissions or similar authorities in Canada. Copies of the documents incorporated herein by reference may be obtained on request without charge from the secretary of Acasti at 545, Promenade du Centropolis, Suite 100, Laval, Québec H7T 0A3, telephone: 1-855-314-5747. These documents are also available through the internet on SEDAR, which can be accessed online at www.sedar.com, and on EDGAR, which can be accessed at www.sec.gov/edgar.shtml.

The following documents, filed by Acasti with the securities commissions or similar authorities in the provinces of Canada, and as amended from time to time, are specifically incorporated by reference into, and form an integral part of, this Prospectus:

- (a) audited financial statements of the Corporation as at February 28, 2013 and February 29, 2012, and for the years ended February 28, 2013 and February 29, 2012, together with the notes thereto and the auditors’ report thereon, and with the management’s discussion and analysis thereon;
- (b) unaudited interim financial statements of the Corporation as at August 31, 2013 and for the three-month and six-month periods ended August 31, 2013 and 2012, together with the notes thereto and with the management’s discussion and analysis thereon;
- (c) annual information form of the Corporation dated May 29, 2013; and
- (d) management information circular of the Corporation dated May 22, 2013 prepared in connection with the Corporation’s annual meeting of shareholders held on June 27, 2013.

Any annual information form, annual or quarterly financial statements, annual or quarterly management’s discussion and analysis, management proxy circular, material change report (excluding confidential material change reports), business acquisition report, information circular or other disclosure document required to be incorporated by reference into a prospectus filed under National Instrument 44-101- *Short Form Prospectus Distributions* filed by Acasti with the securities commissions or similar authorities in Canada after the date of this Prospectus and prior to 25 months from the date hereof shall be deemed to be incorporated by reference into this Prospectus.

In addition, to the extent that any document or information incorporated by reference into this Prospectus pursuant to the foregoing paragraph is also included in any report filed with or furnished to the SEC by Acasti on Form 6-K or on Form 40-F (or any respective successor form) after the date of this Prospectus, it shall be deemed to be incorporated by reference as an exhibit to the registration statement of which this Prospectus forms a part. Further, Acasti may incorporate by reference into the registration statement of which this Prospectus forms a part, any report on Form 6-K furnished to the SEC, including the exhibits thereto, if and to the extent provided in such report.

A Prospectus Supplement containing the specific terms of any offering of the Securities will be delivered to purchasers of the Securities together with this Prospectus and will be deemed to be incorporated by reference in this Prospectus as of the date of the applicable Prospectus Supplement and only for the purposes of the offering of the Securities to which that Prospectus Supplement pertains.

Any statement contained in this Prospectus or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for the purposes of this Prospectus to the extent that a statement contained herein, or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein, modifies or supersedes that statement. The modifying or superseding statement need not state that it has modified or superseded a prior statement or include any

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other information set forth in the document that it modifies or supersedes. The making of a modifying or superseding statement shall not be deemed an admission for any purposes that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of a material fact or an omission to state a material fact that is required to be stated or that is necessary to make a statement not misleading in light of the circumstances in which it was made. Any statement so modified shall not constitute a part of this Prospectus except as so modified. Any statement so superseded shall not constitute a part of this Prospectus.

Upon a new annual information form and the related annual audited comparative financial statements and accompanying management's discussion and analysis being filed with and, where required, accepted by, the securities commissions or similar authorities in Canada during the currency of this Prospectus, the previous annual information form, the previous annual audited comparative financial statements and accompanying management's discussion and analysis and all interim financial statements and accompanying management's discussion and analysis, and all material change reports, information circulars and business acquisition reports filed prior to the commencement of the then current fiscal year, will be deemed no longer to be incorporated into this Prospectus for purposes of future offers and sales of Securities hereunder. Upon an interim financial statement and accompanying management's discussion and analysis being filed by Acasti with and, where required, accepted by, the securities commissions or similar authorities in Canada during the currency of this Prospectus, all interim financial statements and accompanying management's discussion and analysis filed prior to the new interim financial statement shall be deemed no longer to be incorporated into this Prospectus for purposes of future offers and sales of Securities hereunder.

In addition, certain marketing materials (as that term is defined in applicable securities legislation) may be used in connection with a distribution of Securities under this Prospectus and the applicable Prospectus Supplement(s). Any template version of marketing materials (as those terms are defined in applicable securities legislation) pertaining to a distribution of Securities, and filed by the Corporation after the date of the Prospectus Supplement for the offering and before termination of the distribution of such Securities, will be deemed to be incorporated by reference in that Prospectus Supplement for the purposes of the distribution of Securities to which the Prospectus Supplement pertains.

CORPORATE STRUCTURE

Overview of the Corporation

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

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

Intercorporate Relationships

The Corporation has no subsidiaries. As of the date of this Prospectus, Neptune owns 51,349,683 Common Shares, representing approximately 60% of the Common Shares issued and outstanding. The Common Shares are voting, participating and have no par value.

The Common Shares are listed on the TSXV under the ticker symbol "APO" and on the 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 500 mg/dL (“**severe hypertriglyceridemia**”). In addition to targeting the reduction of triglyceride levels, clinical data collected and reviewed by Acasti 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”.

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, Acasti intends to file an investigational new drug (“**IND**”) application with the U.S. Food and Drug Administration (“**FDA**”) to conduct a pharmacokinetic (“**PK**”) trial, which Acasti expects to conduct prior to two Phase III clinical trials 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. Acasti intends to amend the IND application used for the PK trial to conduct its two Phase III clinical trials, which would respectively be to investigate the safety and efficacy profile of CaPre[®] in a patient population with high triglycerides (200-499 mg/dL) and in a patient population with very high triglycerides (>500 mg/dL). 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[®]”.

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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 Phase III clinical trials 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

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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

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combined with a statin, rhabdomyolysis (muscle breakdown). Based on the results of the COLT trial and other data collected by Acasti, Acasti 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 Epanel 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-C 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

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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®, currently Acasti's only prescription drug candidate, is a highly purified omega-3 phospholipid concentrate derived from krill oil and is being developed to prevent and treat hypertriglyceridemia. The active ingredient of CaPre® is a mixture of concentrated omega-3 fatty acids purified from crude krill oil and developed as an oral formulation. CaPre® contains EPA and DHA bound to phospholipids as well as free EPA and DHA for a total concentration of approximately two-thirds phospholipids and approximately 30% EPA and DHA. The Corporation's near term strategy is to develop and commercialize CaPre® in the United States as a prescription drug with a claim for the treatment of severe hypertriglyceridemia and, as a next step, the treatment of mild to moderate hypertriglyceridemia.

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 and Acasti expects final results to be available during the first half of 2014. See "Acasti's Business—Clinical and Nonclinical Research—Clinical".

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

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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®. For the six-month period ended August 31, 2013, the 2013 fiscal year and the 2012 fiscal year, Acasti generated revenues of approximately \$273,000, \$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.

Clinical and Nonclinical Research

Clinical

The Phase II COLT and TRIPECTA 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 TRIPECTA trial is currently in progress. Acasti expects the final results on the TRIPECTA trial by the first half of 2014.

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

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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 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.

The following table outlines some of the key data collected from the COLT trial.

CaPre®
Phase II COLT trial
Lipid and glycemic profiles
Mean percent change at 8 weeks versus baseline

Parameter	Standard of Care			0.5-1.0g ^a CaPre®			1.0- 2.0g ^b CaPre®			2.0g ^c CaPre®			2.0-4.0g ^d CaPre®			4.0g ^e CaPre®		
	N=29			N=52			N=56			N=32			N=57			N=62		
	BL	EOT	Mean % Change	BL	EOT	Mean % Change	BL	EOT	Mean % Change	BL	EOT	Mean % Change	BL	EOT	Mean % Change	BL	EOT	Mean % Change
Triglyceride^f (mg/dL)	364.0	330.4	-7.1	388.8	347.2	-8.8	395.0	300.3	-23.3(1)	342.8	257.8	-22.0(2)	339.2	279.9	-13.6	341.0	257.8	-21.6(3)
TC (mg/dL)	211.5	207.7	-1.5	223.1	209.6	-4.1	212.7	203.0	-3.1	210.0	197.6	-5.0	204.6	198.8	0.4	215.0	195.3	-8.4(4)
LDL-C (mg/dL)	112.9	114.1	3.3	126.1	115.2	-6.6	106.3	106.3	8.8	123.0	112.5	-4.3	113.0	109.8	6.5	125.7	116.0	-7.2
HDL-C^g (mg/dL)	42.2	43.3	2.6	45.2	41.8	4.1	38.3	42.2	10.0	38.7	42.5	10.5	44.5	46.4	5.4	40.6	44.1	10.4(5)
Non-HDL-C (Calculated) (mg/dL)	169.4	164.4	-2.3	177.9	167.8	-5.6	174.4	160.9	-5.7	171.3	155.1	-8.2	160.1	152.4	-0.3	174.4	151.2	-12.0(6)
HbA1c (%)	4.14	4.19	11.5	4.7	4.8	4.9	4.6	4.8	7.9	4.49	4.52	4.7	5.21	4.81	-6.8(7)	4.9	4.6	-3.5(8)
Glucose (mg/dL)	98.8	99.0	0	97.2	96.5	3.9	94.9	92.2	-1.4	91.4	89.3	-2.2	104.8	105.3	1.2	102.4	105.1	2.6

BL = Baseline, EOT = End of treatment, Mean % change = Unadjusted mean percent change from baseline, SOC = Standard of care, TG = Triglycerides, TC = Total cholesterol.

- (1) TG mean SOC- adjusted % difference (-16.2%, p-value=0.021)
- (2) TG mean SOC- adjusted % difference (-14.8%, p-value=0.06)
- (3) TG mean SOC- adjusted % difference (-14.4%, p-value=0.038)
- (4) TC mean SOC- adjusted % difference (- 7.0%, p-value=0.06)
- (5) HDL-C mean SOC- adjusted % difference (7.7%, p-value=0.07)
- (6) Non-HDL-C mean SOC- adjusted % difference (-9.8%, p-value=0.036)
- (7) HbA1c mean SOC- adjusted % difference (-18.2%, p-value=0.013)
- (8) HbA1c mean SOC- adjusted % difference (-15.0%, p-value=0.039)
- a Four weeks of treatment with 0.5g per day followed by an additional four week with 1.0g
- b Four weeks of treatment with 1g per day followed by an additional four week with 2.0g
- c Eight weeks of treatment with 2.0g per day
- d Four weeks of treatment with 2.0g per day followed by an additional four weeks with 4.0g
- e Eight weeks of treatment with 4.0g per day
- f TG mean % difference between all CaPre® groups and SOC (-15.2%, p-value=0.015)
- g HDL-C mean % difference between all CaPre® groups and SOC (7.5%, p-value=0.04)

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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 Corporation currently expects the TRIFECTA trial to be completed 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.

Next Steps

Further to the completion of the Phase II COLT trial and in parallel with the ongoing Phase II TRIFECTA trial being conducted in Canada, Acasti intends to file an IND with the FDA to conduct a pharmacokinetic study (PK trial), which Acasti expects to conduct prior to two Phase III clinical trials 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. The PK trial would be designed to enable Acasti to better evaluate the bioavailability and the pharmacokinetic parameters of DHA/EPA in humans following single and multiple doses of CaPre[®]. Acasti expects that the duration of a PK trial would likely be over a 30-day period and involve the enrollment of approximately 42 healthy subjects.

Acasti intends to amend the IND application used for the PK trial to conduct two Phase III clinical trials, which Acasti intends to conduct in the United States, with potentially a few Canadian clinical trial sites, one in a patient population with high triglycerides (200-499 mg/dL) and a second in a patient population with very high triglycerides (>500 mg/dL). Each of these two studies would constitute the primary basis of an efficacy claim for CaPre[®] in NDA submissions, one for mild to moderate hypertriglyceridemia and one 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 trials. 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 separate request would be submitted for each specific protocol at least 90 days prior to the anticipated start of the Phase III clinical trials. See “Acasti’s Business—Government Regulation”.

In addition to conducting and completing the TRIFECTA, PK and Phase III clinical trials, 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

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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. See “Acasti’s Business—Government Regulation” and “Acasti’s Business—Sales and Marketing”.

Nonclinical

In preparation of its planned filing of an IND application with the FDA in the future to conduct Phase III clinical trials, 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 two proposed Phase III clinical trials, Acasti intends to complete two set 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 testings in both rats and mice to identify a tumorigenic potential in animals and to assess the relevant risk in humans. Carcinogenicity testings are 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.

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. Based on the results of the completed COLT trial, the current status of the TRIFECTA trial and assuming research and development for the TRIFECTA trial proceeds as planned, Acasti estimates that the completion of the TRIFECTA, PK and Phase III clinical trials and DART and CARCINO nonclinical studies for CaPre® will take at least an additional 18 to 24 months and cost between \$40 million and \$50 million. In addition to completing the TRIFECTA, PK and Phase III clinical trials 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”.

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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. For the six-month period ended August 31, 2013, the 2013 fiscal year and the 2012 fiscal year, revenues of Acasti were all derived from the sale of ONEMIA® and amounted to approximately \$273,000, \$724,000 and \$10,000, respectively. During its fiscal year ended February 28, 2013, more than 90% of sales of ONEMIA® were made through Acasti's distribution partner in the United States and the remaining 10% 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 noncompetitive 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 announced on July 9, 2013 that it had filed an NDA submission to the FDA seeking approval for the marketing and sale of its product for the treatment of patients with severe hypertriglyceridemia. On July 18, 2013, Omthera Pharmaceuticals was acquired by London-based AstraZeneca PLC. 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 pivotal 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 intense 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.

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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 and 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 active pharmaceutical ingredients (“**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.

Patent description	US Patent #	Expiration Date of the Patent	Holder
Composition of Matter (NATURAL PHOSPHOLIPIDS OF MARINE ORIGIN CONTAINING FLAVONOIDS AND POLYUNSATURATED PHOSPHOLIPIDS AND THEIR USES)	US8,030,348 ⁽¹⁾	2022	Neptune
Method of Use for Dyslipidemia (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
Method of Extraction (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 provides 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 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.

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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.

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."

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 \$6,000 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 tonnes. The World Health Organization estimates that approximately 271,000 metric tonnes of both krill species are harvested annually. From 2002 to 2011, between 105,000 to 212,000 metric tonnes originated from the Southern Ocean and, on average, 60,000 harvested metric tonnes 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 tonnes for 2010 were increased to 8.695 million tonnes 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 tonne. See "Risk Factors—Risks Related to Product Development, Regulatory Approval and Commercialization—The Corporation's ability to obtain krill oil may be affected by conservation regulation or initiatives."

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. On May 28, 2013, Neptune announced that it commenced reconstruction of its production plant, further to the explosion that occurred on November 8, 2012 and destroyed Neptune's plant, with an anticipated completion by or before the end of Neptune's fiscal year ending February 28, 2014. Until Neptune resumes its own production, the krill oil required for the production of CaPre® and ONEMIA® is being acquired through arrangements that Neptune has with third parties.

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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 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 production 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 October 24, 2013, the Corporation employed eight persons in Canada and one in the United States, six of whom have biology, chemistry, biochemistry or microbiology backgrounds, and three 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.

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;

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- 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 (“cGCP”), 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 cGCP, 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.

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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 suspended or terminated 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

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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 pivotal 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, 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

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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.

RISK FACTORS

Investing in the Securities involves a high degree of risk. Prospective investors should carefully consider the following risks, as well as the other information contained in this Prospectus, any applicable Prospectus Supplement and the documents incorporated by reference herein before investing in the Securities. If any of the following risks actually occurs, the Corporation’s business, financial condition, liquidity, results of operation and prospects could be materially harmed. Additional risks and uncertainties, including those of which the Corporation is currently unaware or that it deems immaterial, may also adversely affect the Corporation’s business, financial condition, liquidity, results of operation and prospects.

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 PK and 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 mild to moderate 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 mild to moderate 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;

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- 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®. Further, 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 mild to moderate hypertriglyceridemia or 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;

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- 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 intense 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, and Amarin Corporation, which currently markets Vascepa, an ethyl-ester form of EPA, for the treatment of patients with severe hypertriglyceridemia. 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 announced on July 9, 2013 that it had filed an NDA submission to the FDA seeking approval for the marketing and sale of its product for the treatment of patients with severe hypertriglyceridemia. On July 18, 2013, Omthera Pharmaceuticals was acquired by London-based AstraZeneca PLC. 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 pivotal Phase III clinical trial for its phytosterol-omega-3 drug candidate.

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

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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 mild to moderate 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 cGCP, 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;

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

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

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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:

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- 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 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 or not reviewing and responding to IND application requests due to the current or any future U.S. federal government shutdown;
- 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;

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- 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 reexamination, 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 final results of the Corporation's Phase II COLT clinical trial and the preliminary results generated to date in the Corporation's TRIPECTA Phase II clinical trial for CaPre® do not ensure that the final Phase II TRIPECTA trial 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 will demonstrate sufficient safety and efficacy for the FDA to approve CaPre® for the prevention and treatment of mild to moderate hypertriglyceridemia or 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 mild to moderate 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 trial. The Corporation relies heavily on the CRO for execution of clinical studies for CaPre® and controls only certain aspects of the CRO's 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

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its CROs are required to comply with cGCP, 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 cGCP, 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 cGCP regulations. 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 its 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 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. Acasti currently acquires all of its krill oil for the production of CaPre® and ONEMIA® from its parent company, Neptune.

On May 28, 2013, Neptune announced that it commenced reconstruction of its production plant, further to the explosion that occurred on November 8, 2012 and destroyed Neptune's plant, with an anticipated completion by or before the end of Neptune's fiscal year ending February 28, 2014. Until Neptune resumes its own production, the krill oil required for the production of CaPre® and ONEMIA® is being acquired through arrangements that Neptune has with third parties.

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.

Acasti will have to source additional quantities of krill oil for the continued production of ONEMIA® and its planned PK and Phase III clinical trials for CaPre®, and, if regulatory approval is obtained for the commercialization of CaPre®, larger quantities for the commercialization and distribution of CaPre®. Until the reconstruction of Neptune's production plant is completed, Acasti may be required to pay higher prices for krill oil (in comparison to what it paid Neptune), or it may be unable to acquire krill oil in sufficient quantities or of a sufficient quality. Any alternative supply of krill oil may not be of comparable quality to that provided by Neptune prior to the explosion of its production plant, which may impact the efficacy, or the markets' perception of the efficacy, of ONEMIA® and CaPre®. 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's ability to obtain krill oil may be affected by conservation regulation or initiatives.

All of the Corporation's products require the use of krill oil. Limits on krill harvesting established by the Commission for the Conservation of Antarctic Marine Living Resources may limit Acasti's ability to manufacture its products. The commission limits the amount of krill that may be harvested in Antarctic waters according to specific ocean areas. Additionally, the Commission regulates the licensing of vessels eligible to harvest krill in these specific Antarctic Ocean areas. 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

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authorize additional krill harvesting and impose a striker control on fisheries. The Commission has established limits because increases in krill catches could have a negative effect on the ecosystem, including other marine life, particularly birds, seals and fish which mainly depend on krill for food. The lowering of these quotas or other developments impacting the ability to source krill, such as adoption of additional conservation measures, may reduce the future availability of krill and cause significant increases in its price. Any such development could harm the Corporation's ability to successfully commercialize ONEMIA® or CaPre®.

The Corporation relies on third parties for production 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 cGMP regulations;
- experiences manufacturing problems or other operational failures, such as equipment failures or unplanned facility shutdowns required to comply with cGMP regulations or damage from any event, including fire, flood, earthquake, labor disruptions, 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.

Until recently, the Corporation had contracted with one third party manufacturer in the United States to produce CaPre® for the Corporation's clinical trials and ONEMIA® for distribution and commercialization. However, the FDA requires manufacturers of drug products and their facilities to comply with cGMP, and other requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. The Corporation has been advised that this manufacturer is not cGMP compliant and, as a result, the Corporation is seeking to enter into a definitive agreement with another manufacturer that complies with these FDA standards. 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.

Any third-party manufacturer of CaPre® clinical material will be required to familiarize itself with the production techniques for CaPre®, a process which could prove to be time consuming. Any delay in the manufacturing of CaPre® clinical material could delay the initiation of the Corporation's planned PK and Phase III clinical trials for CaPre®, which could materially adversely affect Acasti's business prospects.

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

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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.

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

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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 U.S. Patent and Trademark Office, 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 six-month period ended August 31, 2013 and fiscal year ended February 28, 2013 was approximately \$5.2 million and \$6.9 million, respectively. As of August 31, 2013, the Corporation had an accumulated deficit of approximately \$25.2 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 will require additional funding to continue as a going concern.

The Corporation will require substantial additional funds to conduct further research and development, scheduled clinical testing, regulatory approvals and the commercialization of CaPre®. Based on the results of the

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completed COLT trial, the current status of the TRIFECTA trial and assuming research and development for the TRIFECTA trial proceeds as planned, Acasti estimates that the TRIFECTA, PK and Phase III clinical trials and DART and CARCINO nonclinical studies for CaPre® will take at least an additional 18 to 24 months to complete and cost approximately between \$40 million and \$50 million, as described in further detail under “Sales and Marketing” and “Acasti’s Business—Clinical and Nonclinical Research—Clinical—Next Steps” and “Acasti’s Business—Clinical and Nonclinical Research—Nonclinical”. In addition to completing the TRIFECTA, PK and Phase III clinical trials 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’s cash and short term investments were approximately \$4.0 million as of August 31, 2013. The Corporation will require additional capital to fund its operating needs.

The Corporation has incurred operating losses and negative cash flows from operations since inception. As at August 31, 2013, the Corporation’s current liabilities and expected level of expenses in the research and development phase of its drug candidate significantly exceed current assets. The Corporation’s liabilities at August 31, 2013 include amounts due to Neptune of approximately \$2.5 million. The Corporation plans to rely on the continued support of Neptune to pursue its operations, including obtaining additional funding, if required. The continuance of this support is outside of the Corporation’s control. If the Corporation does not receive the continued financial support from its parent or the Corporation does not raise additional funds through public or private equity or debt financing, joint venture arrangements, and collaborative arrangements with other pharmaceutical companies, and/or from other sources, it may not be able to realize its assets and discharge its liabilities in the normal course of business. There can be no assurance that any additional funding from Neptune or 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®. As a result, there exists a material uncertainty that casts substantial doubt about the Corporation’s ability to continue as a going concern and, therefore, realize its assets and discharge its liabilities in the normal course of business.

Furthermore, 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.

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 October 24, 2013, the Corporation had eight employees in Canada and one in the United States, six of whom have biology, chemistry, biochemistry or microbiology backgrounds and three 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

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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

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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 in Canada will be completed on schedule or at all, that it will conduct PK and Phase III clinical trials 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 market price of the Common Shares.

The interests of the Corporation's controlling shareholder, which exerts significant influence over the Corporation, may conflict with the Corporation's interests and those of its public shareholders.

The Corporation's parent company, Neptune, currently owns approximately 60% of the issued and outstanding Common Shares. As its controlling shareholder, the interests of Neptune may conflict or even compete with the Corporation's interests and those of its other shareholders. As a result of its substantial ownership of the outstanding Common Shares, Neptune is able to influence or control matters requiring approval by the Corporation's shareholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. Neptune may also have interests that differ from those of other Acasti shareholders and may vote in a way with which other shareholders may disagree and which may be adverse to their interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of the Corporation, could deprive its shareholders of an opportunity to receive a premium for their shares as part of a sale of the Corporation, and might ultimately affect the market price of the Common Shares. Conversely, this concentration may facilitate a change in control at a time when other shareholders may prefer not to sell.

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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. 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 U.S. 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 U.S. 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 eligible to use MJDS. If the Corporation is not a foreign private issuer, it would not be eligible to use the MJDS or other 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 or no longer satisfies the criteria for MJDS eligibility, compliance with more enhanced disclosure requirements and other U.S. securities laws may increase the Corporation's legal and financial compliance costs, make some activities more difficult and time-consuming, increase demand on the Corporation's systems and resources and divert management's attention from other business concerns, all of which could have a material adverse effect on the Corporation's business, financial condition and results of operations.

As an "emerging growth company", the Corporation is exempt from the requirement to comply with the auditor attestation requirements of the Sarbanes-Oxley Act.

The Corporation is an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups 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, the Corporation'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, the Corporation 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 the market price of 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

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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.

Risks Related to the Offering and the Securities

Except as otherwise disclosed in any applicable prospectus supplement for any particular issuance of Securities, the following risk factors apply with respect to the Securities.

The price of the Securities may fluctuate.

Market prices for securities in general, and that of biopharmaceutical companies in particular, tend to fluctuate. Factors such as the announcement to the public or in various scientific or industry forums of technological innovations, new commercial products, patents, patent infringement claims (whether brought by the Corporation against third parties or claimed against the Corporation), exclusive rights obtained by the Corporation or others, results of pre-clinical and clinical studies by the Corporation or others, a change of regulations, publications, financial results, public concerns over the risks of pharmaceutical products, future sales of securities by the Corporation or its shareholders and many other factors could have considerable effects on the price of the Corporation’s securities.

The market price of the Common Shares could decline as a result of future issuances or actual or potential sales.

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

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

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

- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing of regulatory submissions and approvals;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize the Corporation’s products;
- the outcome of any litigation;
- changes in foreign currency fluctuations;
- competition;
- the timing of achievement and the receipt of milestone payments from current or future third parties;
- failure to enter into new or the expiration or termination of current agreements with third parties; and

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- failure to introduce the Corporation's products to the market in a manner that generates anticipated revenues.

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

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

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

There can be no assurance that an active market for the Common Shares will be sustained.

There can be no assurance that an active market for the Common Shares will be sustained. Holders of Common Shares may be unable to sell their investments on satisfactory terms. As a result of any risk factor discussed herein, the market price of the Common Shares at any given point in time may not accurately reflect the long-term value of the Corporation. Furthermore, responding to these risk factors could result in substantial costs and divert management's attention and resources. Substantial and potentially permanent declines in the value of the Common Shares may result and adversely affect the liquidity of the market for the Common Shares.

Other factors unrelated to the performance of the Corporation that may have an effect on the price and liquidity of the Common Shares include: extent of analyst coverage; lessening in trading volume and general market interest in the Common Shares; the size of the Corporation's public float; and any event resulting in a delisting of the Common Shares.

An active market may not develop for the Warrants or Units, which may hinder holders' ability to liquidate their investment.

Each issuance of Warrants and Units will be a new issue of Securities with no established trading market, and the Corporation does not currently intend to list them on any securities exchange. A dealer may intend to make a market in the Warrants or Units after their issuance pursuant to this Prospectus; however, a dealer may not be obligated to do so and may discontinue such market making at any time. As a result, the Corporation cannot assure that an active trading market will develop for any series of the Warrants or Units. In addition, subsequent to their initial issuance, the Securities may trade at a discount to their initial offering price, depending upon the value of the underlying Common Shares and upon the Corporation's prospects or the prospects for companies in its industry generally and other factors, including those described herein.

A large number of Common Shares may be issued and subsequently sold upon the exercise of the Warrants. The sale or availability for sale of these and existing warrants or other securities convertible in Common Shares may depress the price of the Common Shares.

As of October 24, 2013, there were (i) 4,899,750 options to purchase Common Shares issued and outstanding, at a weighted average exercise price of \$1.57 per Common Share, (ii) 750,000 warrants to purchase Common Shares issued and outstanding, at a weighted average exercise price of \$1.50 per Common Share, and (iii) 1,035,000 restricted shares units issued and outstanding.

In addition, the number of Common Shares that will be initially issuable upon the exercise of Warrants that may be issued pursuant hereto will be determined by the particular terms of each issue of Warrants and will be described in the relevant Prospectus Supplement. To the extent that purchasers of Warrants and existing holders of warrants

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sell Common Shares issued upon the exercise of those warrants, the market price of the Common Shares may decrease due to the additional selling pressure in the market. The risk of dilution from issuances of Common Shares underlying existing warrants and the Warrants that may be issued pursuant hereto may cause shareholders to sell their Common Shares, which could further contribute to any decline in the Common Share market price.

The sale of Common Shares issued upon the exercise of warrants or other security could encourage short sales by third parties which could further depress the price of the Common Shares.

Any downward pressure on the price of Common Shares caused by the sale of Common Shares issued upon the exercise of warrants or other security could encourage short sales by third parties. In a short sale, a prospective seller borrows Common Shares from a shareholder or broker and sells the borrowed Common Shares. The prospective seller anticipates that the Common Share price will decline, at which time the seller can purchase Common Shares at a lower price for delivery back to the lender. The seller profits when the Common Share price declines because it is purchasing Common Shares at a price lower than the sale price of the borrowed Common Shares. Such sales could place downward pressure on the price of the Common Shares by increasing the number of Common Shares being sold, which could further contribute to any decline in the market price of the Common Shares.

The Corporation cannot predict the actual number of Common Shares that it will issue upon the exercise of the Warrants.

The actual number of Common Shares that the Corporation will issue upon the exercise of the Warrants is uncertain and will be determined, or made determinable, by the particular terms of each issue of Warrants and will be described in the relevant Prospectus Supplement. The number of Common Shares issuable upon the exercise of the Warrants may fluctuate based on the market price of the Common Shares. Holders of Warrants may receive more Common Shares if the Common Share price declines.

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

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

In addition, any such future corporate development may be accompanied by certain risks, including exposure to unknown liabilities of the strategic opportunities and transactions, higher than anticipated transaction costs and expenses, the difficulty and expense of integrating operations and personnel of any acquired companies, disruption of the Corporation's ongoing business, diversion of management's time and attention, and possible dilution to shareholders. The Corporation may not be able to successfully overcome these risks and other problems associated with any future acquisitions and this may adversely affect the Corporation's business and financial condition.

CONSOLIDATED CAPITALIZATION

Other than the issuance of 5,311,100 Common Shares from the exercise of warrants and 15,000 Common Shares from the exercise of stock-options, there have been no material changes in the share or loan capitalization of the Corporation since August 31, 2013. As a result of the issuance of Securities which may be distributed under this Prospectus, the share or loan capital of the Corporation may increase by up to a maximum of US\$150,000,000.

USE OF PROCEEDS

Acasti is an emerging biopharmaceutical company with one prescription drug candidate, CaPre®, and one commercialized product, ONEMIA®. For the six-month period ended August 31, 2013 and the 2013 fiscal year, revenues of Acasti were all derived from the sale of ONEMIA® and amounted to approximately \$273,000 and \$724,000, respectively.

The Corporation had negative operating cash flows of approximately \$1.2 million and \$2.5 million, respectively, during the six-month period ended August 31, 2013 and its financial year ended February 28, 2013, incurring a net loss of approximately \$5.2 million and \$6.9 million, respectively. The Corporation's cash and short term investments were approximately \$4.0 million as of August 31, 2013. For the remainder of fiscal 2014, the Corporation expects that it will require approximately \$1.3 million, excluding non-cash stock-based compensation expenses, to fund anticipated general and administrative expenses. As the Corporation continues progressing its research and development programs, supporting its clinical programs and advancing and protecting its technology, Acasti expects to incur negative operating cash flow for the foreseeable future and expects to finance negative operating cash flow from various sources including its existing cash balances and any net proceeds that it receives from the sale of its securities.

Based on the results of the completed COLT trial, the current status of the TRIFECTA trial and assuming research and development for the TRIFECTA trial proceeds as planned, Acasti estimates that the completion of the TRIFECTA, PK and Phase III clinical trials and DART and CARCINO nonclinical studies for CaPre® will take at least an additional 18 to 24 months and cost between \$40 million and \$50 million, as described under "Sales and Marketing" and "Acasti's Business—Clinical and Nonclinical Research—Clinical—Next Steps" and "Acasti's Business—Clinical and Nonclinical Research—Nonclinical".

In addition to completing the TRIFECTA, PK and Phase III clinical trials 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. See "Sales and Marketing" and "Acasti's Business—Clinical and Nonclinical Research—Clinical—Next Steps".

The aggregate cost for completing the TRIFECTA trial, which the Corporation expects to complete by the first half of 2014, is expected to be approximately \$1 million. Acasti will require additional financing in order to finance its next clinical trials and nonclinical studies, as described under "Sales and Marketing" and "Acasti's Business—Clinical and Nonclinical Research". Acasti expects that (i) approximately \$2 million will be required to initiate and complete the PK trial, all of which is expected to be required for the next 12 months, (ii) approximately \$25 million will be required to initiate and complete the two Phase III clinical trials, of which approximately \$15 million is expected to be required for the next 12 months, and (iii) approximately \$5 million will be required to initiate and complete the DART and CARCINO nonclinical studies, of which approximately \$2.5 million is expected to be required for the next 12 months.

The above projections are based on management estimates and judgements and financing requirements may vary significantly depending on results of Acasti's clinical trials and subsequent discussions with regulatory authorities. If additional funding is not available, the pace of the Corporation's development plan may be reduced. See "Risk Factors".

Unless otherwise indicated in a Prospectus Supplement, the Corporation anticipates that the primary use of the net proceeds received by the Corporation from the sale of securities under this Prospectus will be to finance the Phase III clinical trials for CaPre®, the PK trial, the completion and filing of a NDA to obtain FDA approval CaPre® in the United States, to completing marketing and precommercialization activities and for general and administrative expenses.

More detailed information regarding the use of proceeds from the sale of Securities will be described in the applicable Prospectus Supplement. The Corporation may, from time to time, issue Common Shares or other

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securities otherwise than through the offering of Securities pursuant to this Prospectus. All expenses relating to an offering of Securities and any compensation paid to underwriters, dealers or agents, as the case may be, will be paid out of the Corporation's general funds, unless otherwise stated in the applicable Prospectus Supplement.

PLAN OF DISTRIBUTION

General

The Corporation may offer and sell the Securities, separately or together: (a) to one or more underwriters; (b) through one or more agents; or (c) directly to one or more other purchasers. Similarly, one or more Selling Securityholder of the Corporation may offer and sell certain Securities to or through underwriters purchasing as principals and also may offer and sell certain Securities directly to other purchasers or through agents pursuant to exemptions from registration or qualification under applicable securities laws. See "Selling Securityholder".

The Securities offered pursuant to any Prospectus Supplement may be sold from time to time in one or more transactions at: (i) a fixed price or prices, which may be changed from time to time; (ii) market prices prevailing at the time of sale; (iii) prices related to such prevailing market prices; or (iv) other negotiated prices. The Corporation may only offer and sell the Securities pursuant to a Prospectus Supplement during the period that this Prospectus, including any amendments hereto, remains effective. The Prospectus Supplement for any of the Securities being offered thereby will set forth the terms of the offering of such Securities, including the type of Security being offered, the name or names of any underwriters or agents, the name or names of any Selling Securityholder, as well as the purchase price of such Securities, to the extent applicable, the proceeds to the Corporation and the Selling Securityholder from such sale and, any underwriting commissions or discounts and other items constituting underwriters' compensation. Only underwriters so named in the Prospectus Supplement are deemed to be underwriters in connection with the Securities offered thereby.

By Underwriters

If underwriters are used in the sale, the Securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Unless otherwise set forth in the Prospectus Supplement relating thereto, the obligations of underwriters to purchase the Securities will be subject to certain conditions, but the underwriters will be obligated to purchase all of the Securities offered by the Prospectus Supplement if any of such Securities are purchased. The Corporation may offer the Securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. The Corporation may agree to pay the underwriters a fee or commission for various services relating to the offering of any Securities. Any such fee or commission will be paid out of the Corporation's general corporate funds. The Corporation may use underwriters with whom it has a material relationship. The Corporation will describe in the Prospectus Supplement, naming the underwriter, the nature of any such relationship.

In compliance with the guidelines of the Financial Industry Regulatory Authority ("FINRA"), the maximum aggregate value of all compensation to be received by any FINRA member or independent broker-dealer will not exceed 8% of the gross proceeds from the sale of Securities pursuant to this Prospectus and any applicable Prospectus Supplement. If 5% or more of the net proceeds of any offering of Securities made under this Prospectus will be received by a FINRA member participating in the offering or affiliates or associated persons of such FINRA member, the offering will be conducted in accordance with FINRA Rule 5121 (or any successor rule).

By Agents

The Securities may also be sold through agents designated by the Corporation. Any agent involved will be named, and any fees or commissions payable by the Corporation to such agent will be set forth in the applicable Prospectus Supplement. Any such fees or commissions will be paid out of the Corporation's general corporate funds. Unless otherwise indicated in the Prospectus Supplement, any agent will be acting on a best efforts basis for the period of its appointment.

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Direct Sales

Securities may also be sold directly by the Corporation at such prices and upon such terms as agreed to by the Corporation and the purchaser. In this case, no underwriters or agents would be involved in the offering.

General Information

Underwriters or agents who participate in the distribution of Securities may be entitled under agreements to be entered into with the Corporation to indemnification by it against certain liabilities, including liabilities under Canadian provincial and United States securities legislation, or to contribution with respect to payments which such underwriters or agents may be required to make in respect thereof. Such underwriters or agents may be customers of, engage in transactions with, or perform services for, the Corporation in the ordinary course of business.

The Corporation may enter into derivative transactions with third parties, or sell securities not covered by this Prospectus to third parties in privately negotiated transactions. If the applicable Prospectus Supplement indicates, in connection with those derivatives, the third parties may sell Securities covered by this Prospectus and the applicable Prospectus Supplement, including in short sale transactions. If so, the third parties may use Securities pledged by the Corporation or borrowed from the Corporation or others to settle those sales or to close out any related open borrowings of stock, and may use Securities received from the Corporation in settlement of those derivatives to close out any related open borrowings of stock. The third parties in such sale transactions will be identified in the applicable Prospectus Supplement.

One or more firms, referred to as “remarketing firms,” may also offer or sell the Securities, if the Prospectus Supplement so indicates, in connection with a remarketing arrangement upon their purchase. Remarketing firms will act as principals for their own accounts or as agents for the Corporation. These remarketing firms will offer or sell the Securities in accordance with the terms of the Securities. The Prospectus Supplement will identify any remarketing firm and the terms of its agreement, if any, with the Corporation and will describe the remarketing firm’s compensation. Remarketing firms may be deemed to be underwriters in connection with the Securities they remarket.

In connection with any offering of Securities, underwriters may over-allot or effect transactions which stabilize or maintain the market price of the Securities offered at a level above that which might otherwise prevail in the open market. Such transactions may be commenced, interrupted or discontinued at any time.

SELLING SECURITYHOLDER

This Prospectus may also, from time to time, relate to the offering of the Corporation’s Securities by way of a secondary offering by certain Selling Securityholders.

The terms under which the Securities will be offered by any Selling Securityholder will be described in the applicable Prospectus Supplement. A Prospectus Supplement for or including any offering of the Securities by a Selling Securityholder will include, without limitation, where applicable: (i) the name or names of any Selling Securityholder; (ii) the number and type of Securities owned, controlled or directed by each Selling Securityholder; (iii) the number of Securities being distributed for the accounts of each Selling Securityholder; (iv) the number of Securities to be owned, controlled or directed by each Selling Securityholder after the distribution and the percentage that number or amount represents out of the total number of outstanding Securities; (v) whether the Securities are owned by each Selling Securityholder both of record and beneficially, of record only or beneficially only; (vi) if the Selling Securityholder purchased any of the Securities held by it in the 12 months preceding the date of the applicable Prospectus Supplement, the date or dates each Selling Securityholder acquired the Securities; and (vii) if the Selling Securityholder acquired the Securities held by it in the 12 months preceding the date of the applicable Prospectus Supplement, the cost thereof to each Selling Securityholder in the aggregate and on a per security basis.

DESCRIPTION OF THE COMMON SHARES

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 October 24, 2013, there were (i) a total of 85,586,388 Common Shares issued and outstanding and no Preferred Shares issued and outstanding, (ii) 4,899,750 options to purchase Common Shares issued and outstanding, at a weighted average exercise price of \$1.57 per Common Share, (iii) 750,000 warrants to purchase Common Shares issued and outstanding, at a weighted average exercise price of \$1.50 per Common Share, and (iv) 1,035,000 restricted shares units issued and outstanding.

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

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.

DESCRIPTION OF THE WARRANTS

The following description, together with the additional information the Corporation may include in any applicable Prospectus Supplements, summarizes the material terms and provisions of the Warrants that the Corporation may offer under this Prospectus, which will consist of Warrants to purchase Common Shares and may be issued in one or more series. Warrants may be offered independently or together with other Securities, and may be attached to or separate from those Securities. While the terms the Corporation summarized below will apply generally to any Warrants that the Corporation may offer under this Prospectus, the particular terms of any series of Warrants that the Corporation may offer will be described in more detail in the applicable Prospectus Supplement. The terms of any Warrants offered under a Prospectus Supplement may differ from the terms described below. The Corporation undertakes that it will not offer Warrants for sale separately pursuant to the Prospectus to any member of the public in Canada unless the Prospectus Supplement containing the specific terms of the Warrants to be offered separately is first approved for filing by the Autorité des marchés financiers on behalf of the securities commissions or similar regulatory authorities in the provinces of Canada where the Warrants will be offered for sale.

General

Warrants will be issued under and governed by the terms of one or more warrant indentures (a "**Warrant Indenture**") between the Corporation and a warrant trustee (the "**Warrant Trustee**") that the Corporation will

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name in the relevant Prospectus Supplement, if applicable. Each Warrant Trustee will be a financial institution organized under the laws of Canada or any province thereof and authorized to carry on business as a trustee.

This summary of some of the provisions of the Warrants is not complete. The statements made in this Prospectus relating to any Warrant Indenture and Warrants to be issued under this Prospectus are summaries of certain anticipated provisions thereof and do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all provisions of the Warrant Indenture and the Warrant certificate. Prospective investors should refer to the Warrant Indenture and the Warrant certificate relating to the specific Warrants being offered for the complete terms of the Warrants. The Corporation will file a Warrant Indenture describing the terms and conditions of Warrants it is offering concurrently with the filing of the applicable Prospectus Supplement under which such Warrants are offered.

The applicable Prospectus Supplement relating to any Warrants offered by the Corporation will describe the particular terms of those Warrants and include specific terms relating to the offering. This description will include, where applicable:

- the designation and aggregate number of Warrants;
- the price at which the Warrants will be offered;
- the currency or currencies in which the Warrants will be offered;
- the date on which the right to exercise the Warrants will commence and the date on which the right will expire;
- the number of Common Shares that may be purchased upon exercise of each Warrant and the price at which and currency or currencies in which the Common Shares may be purchased upon exercise of each Warrant;
- the designation and terms of any Securities with which the Warrants will be offered, if any, and the number of the Warrants that will be offered with each Security;
- the date or dates, if any, on or after which the Warrants and the other Securities with which the Warrants will be offered will be transferable separately;
- whether the Warrants will be subject to redemption and, if so, the terms of such redemption provisions;
- whether the Corporation will issue the Warrants as global securities and, if so, the identity of the depository of the global securities;
- whether the Warrants will be listed on any exchange; and
- any other material terms or conditions of the Warrants.

Rights of Holders Prior to Exercise

Prior to the exercise of their Warrants, holders of Warrants will not have any of the rights of holders of the Common Shares issuable upon exercise of the Warrants.

Exercise of Warrants

Each Warrant will entitle the holder to purchase Common Shares, as specified in the applicable Prospectus Supplement at the exercise price that the Corporation describes therein. Unless otherwise specified in the applicable Prospectus Supplement, holders of the Warrants may exercise the Warrants at any time up to the specified time on the expiration date set forth in the applicable Prospectus Supplement. After the close of business on the expiration date, unexercised Warrants will become void.

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Holders of the Warrants may exercise the Warrants by delivering the Warrant certificate representing the Warrants to be exercised together with specified information, and paying the required amount to the Warrant Trustee, if any, or to the Corporation, as applicable, in immediately available funds, as provided in the applicable Prospectus Supplement. The Corporation will set forth on the Warrant certificate and in the applicable Prospectus Supplement the information that the holder of the Warrant will be required to deliver to the Warrant Trustee, if any, or to the Corporation, as applicable.

Upon receipt of the required payment and the Warrant certificate properly completed and duly executed at the corporate trust office of the Warrant Trustee, if any, to the Corporation at its principal offices, as applicable, or any other office indicated in the applicable Prospectus Supplement, the Corporation will issue and deliver the securities purchasable upon such exercise. If fewer than all of the Warrants represented by the Warrant certificate are exercised, then the Corporation will issue a new Warrant certificate for the remaining amount of Warrants. If so indicated in the applicable Prospectus Supplement, holders of the Warrants may surrender securities as all or part of the exercise price for Warrants.

Anti-Dilution

The Warrant Indenture, if any, and the Warrant certificate will specify that upon the subdivision, consolidation, reclassification or other material change of the Common Shares or any other reorganization, amalgamation, merger or sale of all or substantially all of the Corporation's assets, the Warrants will thereafter evidence the right of the holder to receive the securities, property or cash deliverable in exchange for or on the conversion of or in respect of the Common Shares to which the holder of a Common Share would have been entitled immediately after such event. Similarly, any distribution to all or substantially all of the holders of Common Shares of rights, options, warrants, evidences of indebtedness or assets will result in an adjustment in the number of Common Shares to be issued to holders of Warrants.

Global Securities

The Corporation may issue Warrants in whole or in part in the form of one or more global securities, which will be registered in the name of and be deposited with a depository, or its nominee, each of which will be identified in the applicable Prospectus Supplement. The global securities may be in temporary or permanent form. The applicable Prospectus Supplement will describe the terms of any depository arrangement and the rights and limitations of owners of beneficial interests in any global security. The applicable Prospectus Supplement will describe the exchange, registration and transfer rights relating to any global security.

Modifications

The Warrant Indenture, if any, and the Warrant certificate will provide for modifications and alterations to the Warrants issued thereunder by way of a resolution of holders of Warrants at a meeting of such holders or a consent in writing from such holders. The number of holders of Warrants required to pass such a resolution or execute such a written consent will be specified in the Warrant Indenture, if any, and the Warrant certificate.

The Corporation may amend any Warrant Indenture and the Warrants, without the consent of the holders of the Warrants, to cure any ambiguity, to cure, correct or supplement any defective or inconsistent provision, or in any other manner that will not materially and adversely affect the interests of holders of outstanding Warrants.

DESCRIPTION OF THE UNITS

The following description, together with the additional information the Corporation may include in any applicable Prospectus Supplement, summarizes the material terms and provisions of the Units that the Corporation may offer under this Prospectus. While the terms summarized below will apply generally to any Units that the Corporation may offer under this Prospectus, the particular terms of any series of Units will be described in more detail in the applicable Prospectus Supplement. The terms of any Units offered under a Prospectus Supplement may differ from the terms described below.

The Corporation will file the form of unit agreement ("**Unit Agreement**"), if any, between the Corporation and a unit agent that describes the terms and conditions of the series of Units offered, and any supplemental agreements,

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concurrently with the filing of the applicable Prospectus Supplement under which such series of Units are offered. The following summaries of material terms and provisions of the Units are subject to, and qualified in their entirety by reference to, all the provisions of the Unit Agreement, if any, and any supplemental agreements applicable to a particular series of Units. The Corporation urges you to read the applicable Prospectus Supplement related to the particular series of Units offered under this Prospectus, as well as the complete Unit Agreement, if any, and any supplemental agreements that contain the terms of the Units.

General

The Corporation may issue Units comprising one or more of Common Shares and Warrants in any combination. Each Unit will be issued so that the holder of the Unit is also the holder of each security included in the Unit. Thus, the holder of a Unit will have the rights and obligations of a holder of each included security. The Unit Agreement under which a Unit may be issued may provide that the securities included in the Unit may not be held or transferred separately, at any time or at any time before a specified date.

The Corporation will describe in the applicable Prospectus Supplement the terms of the series of Units, including:

- the designation and terms of the Units and of the securities comprising the Units, including whether and under what circumstances those securities may be held or transferred separately;
- provisions of the governing Unit Agreement, if any; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the Units or of the securities comprising the Units.

The provisions described in this section, as well as those described under “Description of the Common Shares” and “Description of the Warrants” will apply to each Unit and to any Common Share or Warrant included in each Unit, respectively.

Issuance in Series

The Corporation may issue Units in such amounts and in numerous distinct series as it determines appropriate.

MARKET FOR SECURITIES

The Corporation's Common Shares are listed and posted for trading on (i) the TSXV under the symbol "APO", and (ii) the NASDAQ (since January 7, 2013) under the symbol "ACST". The price ranges and trading volume of Corporation's Common Shares for the twelve-month period before the date of this Prospectus on the TSXV and the NASDAQ was as follows:

Period	TSX (CDN\$)			NASDAQ (US\$)		
	High	Low	Volume (daily average)	High	Low	Volume (daily average)
October 2013 (until October 24)	2.50	1.97	36,509	2.55	1.90	43,009
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	2.74	2.30	13,144	2.74	2.35	17,106
April 2013	2.52	2.05	23,773	2.48	2.08	32,068
March 2013	2.57	2.00	26,045	3.15	1.97	39,780
February 2013	2.65	2.04	25,926	2.69	2.00	52,353
January 2013	2.68	2.16	22,409	3.99	2.21	30,122
December 2012	2.76	2.00	35,405	—	—	—
November 2012	2.68	1.60	35,455	—	—	—
October 2012	2.60	1.98	37,536	—	—	—
September 2012	2.21	1.96	16,795	—	—	—

PRIOR SALES

In the 12 months preceding the date of this Prospectus, the Corporation issued the following Common Shares and granted the following Common Share purchase warrants and stock options under its stock option plan:

<u>Date of Issuance</u>	<u>Number of Common Shares Issued</u>	<u>Issue Price per Common Share</u>
October 24, 2012	10,000	\$ 0.25
November 14, 2012	6,250	\$ 0.25
November 16, 2012	2,500	\$ 0.25
December 3, 2012	8,750	\$ 1.40
December 11, 2012	12,500	\$ 0.25
January 22, 2013	36,250	\$ 0.25
January 28, 2013	165,000	\$ 0.80
February 11, 2013	50,000	\$ 0.25
February 13, 2013	6,250	\$ 0.25
February 21, 2013	50,000	\$ 0.25
March 1, 2013	37,500	\$ 0.25
April 8, 2013	26,250	\$ 0.25
May 7, 2013	10,000	\$ 0.25

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<u>Date of Issuance</u>	<u>Number of Common Shares Issued</u>	<u>Issue Price per Common Share</u>
May 17, 2013	7,500	\$ 0.25
June 18, 2013	10,000	\$ 1.40
July 12, 2013	6,750,000	\$ 2.30
July 16, 2013	10,000	\$ 1.40
July 22, 2013	11,250	\$ 0.25
July 31, 2013	67,500	\$ 0.59
August 8, 2013	151,500	\$ 1.64
August 13, 2013	71,250	\$ 1.10
September 5, 2013	1,526,250	\$ 0.25
September 9, 2013	56,500	\$ 0.25
September 19, 2013	55,000	\$ 0.25
September 26, 2013	2,500	\$ 0.25
October 2, 2013	10,000	\$ 0.25
October 3, 2013	94,850	\$ 0.25
October 4, 2013	135,000	\$ 0.25
October 7, 2013	37,250	\$ 0.25
October 8, 2013	3,408,750	\$ 0.25

<u>Date of Grant</u>	<u>Number of Common Share Purchase Warrants Granted</u>	<u>Exercise Price per Warrant</u>
December 3, 2012	6,750,000	\$ 2.30

<u>Date of Grant</u>	<u>Number of Stock Options Granted</u>	<u>Exercise Price per Stock Option</u>
October 25, 2012	50,000 ⁽¹⁾	\$ 2.50
December 14, 2012	50,000	\$ 2.75
January 15, 2013	20,000 ⁽²⁾	\$ 2.75
April 3, 2013	5,000	\$ 2.75
April 5, 2013	100,000	\$ 2.20
April 29, 2013	10,000	\$ 2.75
June 3, 2013	25,000	\$ 2.75
October 1, 2013	25,000	\$ 2.50

(1) Of the 50,000 stock options granted on October 25, 2012, 25,000 have been cancelled due to termination of employment.

(2) The 20,000 stock options granted on January 15, 2013 have all been cancelled due to termination of employment.

The Corporation also has an equity incentive plan, pursuant to which it may grant certain share-based awards to its employees, directors and consultants. Common Shares are issued to participants in the equity incentive plan upon vesting (or lapse of restrictions) of the awards, in accordance with the terms of the equity incentive plan. In the 12 months preceding the date hereof, Acasti has issued 1,060,000 restricted share units pursuant to the equity incentive plan (25,000 of which have been cancelled due to termination of employment).

REGISTRATION AND TRANSFER

Other than in the case of book-entry-only Securities, Securities may be presented for registration of transfer (with the form of transfer endorsed thereon duly executed) in the city specified for such purpose at the office of the registrar or transfer agent designated by the Corporation for such purpose with respect to any issue of Securities referred to in the Prospectus Supplement. No service charge will be made for any transfer, conversion or exchange of the Securities but the Corporation may require payment of a sum to cover any transfer tax or other governmental charge payable in connection therewith. Such transfer, conversion or exchange will be effected upon such registrar or transfer agent being satisfied with the documents of title and the identity of the person making the request. If a Prospectus Supplement refers to any registrar or transfer agent designated by the Corporation with respect to any issue of Securities, the Corporation may at any time rescind the designation of any such registrar or transfer agent and appoint another in its place or approve any change in the location through which such registrar or transfer agent acts.

In the case of book-entry-only Securities, the Securities may be represented by one or more global certificates or be represented by uncertificated securities and may be held by a designated depository for its participants. The Securities must be purchased or transferred through such participants, which includes securities brokers and dealers, banks and trust companies. The depository will establish and maintain book-entry accounts for its participants acting on behalf of holders of the Securities. The interests of such holders of Securities will be represented by entries in the records maintained by the participants. Holders of Securities issued in book-entry-only form will not be entitled to receive a certificate or other instrument evidencing their ownership thereof, except in limited circumstances. Each holder will receive a customer confirmation of purchase from the participants from which the Securities are purchased in accordance with the practices and procedures of that participant.

ENFORCEABILITY OF CIVIL LIABILITIES

Acasti is a company incorporated under and governed by the *Business Corporations Act* (Québec). A majority of the directors and officers of Acasti, and some of the experts named in this Prospectus, are residents of Canada or otherwise reside outside the United States and all or a substantial portion of their assets, and substantially all of Acasti's assets, are located outside the United States. Acasti has appointed an agent for service of process in the United States, but it may be difficult for holders of Securities who reside in the United States to effect service within the United States upon those directors, officers and experts of Acasti who are not residents of 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 courts of the United States predicated upon the Corporation's civil liability and the civil liability of the directors and officers of Acasti and experts under U.S. federal securities laws.

Acasti has been advised by its Canadian counsel, Osler, Hoskin & Harcourt LLP, that a judgment of a U.S. court predicated solely upon civil liability under U.S. federal securities laws would probably be enforceable in Canada if the U.S. 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. Acasti has also been advised by Osler, Hoskin & Harcourt LLP, however, that there is substantial doubt whether an action could be brought in Canada in the first instance on the basis of liability predicated solely upon U.S. federal securities laws.

Acasti expects to file a registration statement on Form F-10 to register the Securities in the United States. Concurrently with the filing of the registration statement on Form F-10, Acasti will make an appointment of an agent for service of process on Form F-X. Under the Form F-X, Acasti expects to appoint CT Corporation as its agent for service of process in the United States in connection with any investigation or administrative proceeding conducted by the SEC, and any civil suit or action brought against or involving Acasti in a U.S. court arising out of or related to or concerning the offering of the Securities under this Prospectus.

CERTAIN INCOME TAX CONSIDERATIONS

The applicable Prospectus Supplement may describe the principal Canadian federal income tax considerations generally applicable to investors described therein of purchasing, holding and disposing of the Securities offered thereunder. The applicable Prospectus Supplement may also describe certain U.S. federal income tax considerations generally applicable to the purchase, holding and disposition of those Securities by an investor who is a U.S. person.

LEGAL MATTERS

Certain legal matters relating to the Securities offered by this Prospectus will be passed upon on the Corporation's behalf by Osler, Hoskin & Harcourt LLP, its Canadian and U.S. counsel. As of the date of this Prospectus, the partners and associates of Osler, Hoskin & Harcourt LLP beneficially own, directly or indirectly, less than 1% of outstanding securities of any class issued by the Corporation. In addition, certain legal matters in connection with any offering of Securities will be passed upon for any underwriters, dealers or agents by counsel to be designated at the time of the offering by such underwriters, dealers or agents with respect to matters of Canadian and United States law.

AUDITORS

The Corporation's independent auditors are KPMG LLP ("**KPMG**"), 1500-600, de Maisonneuve Boulevard West, Montréal, Québec, Canada, H3A 0A3. KPMG is independent with respect to the Corporation within the meaning of the relevant rules and related interpretations prescribed by the relevant professional bodies in Canada and any applicable legislation or regulation. The audited financial statements of the Corporation as at February 28, 2013 and February 29, 2012, and for the years ended February 28, 2013 and February 29, 2012 incorporated in this Prospectus by reference, have been audited by KPMG as stated in their report, which is incorporated herein by reference.

DOCUMENTS FILED AS PART OF THE REGISTRATION STATEMENT

Upon filing of a registration statement with the SEC, the following documents will be filed with the SEC as part of the Registration Statement of which this Prospectus is a part: (i) the documents referred to under "Documents Incorporated by Reference"; (ii) the consents of auditors and counsel; and (iii) powers of attorney from directors and officers of the Corporation.

PART II – INFORMATION NOT REQUIRED TO BE DELIVERED TO OFFEREEES OR PURCHASERS

Indemnification of Directors and Officers

Under the *Business Corporations Act* (Québec) (the “BCA”), a corporation must indemnify a director or officer of the corporation, a former director or officer of the corporation or any other person who acts or acted at the corporation’s request as a director or officer of another group, against all costs, charges and expenses reasonably incurred in the exercise of their functions, including an amount paid to settle an action or satisfy a judgment, or arising from any investigative or other proceeding in which the person is involved if (1) the person acted with honesty and loyalty in the interest of the corporation or, as the case may be, in the interest of the other group for which the person acted as director or officer or in a similar capacity at the corporation’s request; and (2) in the case of a proceeding that is enforced by a monetary penalty, the person had reasonable grounds for believing that his or her conduct was lawful. The corporation must also advance moneys to such a person for the costs, charges and expenses of a proceeding referred to above. In the event that a court or any other competent authority judges that the conditions set out in (1) and (2) are not fulfilled, the corporation may not indemnify the person and the person must repay to the corporation any moneys advanced for such purposes. Furthermore, the corporation may not indemnify such person if the court determines that the person has committed an intentional or gross fault. In such a case, the person must repay to the corporation any moneys advanced. A corporation may also, with the approval of the court, in respect of an action by or on behalf of the corporation or other group as referred to above, against such a person, advance the necessary moneys to the person or indemnify the person against all costs, charges and expenses reasonably incurred by the person in connection with the action, if the person fulfills the conditions set out in this paragraph.

In accordance with and subject to the BCA, the by-laws of the Registrant provide that the Registrant shall indemnify a director or officer of the Registrant, a former director or officer of the Registrant, or a person who acts or acted at the Registrant’s request as a director or officer of a body corporate of which the Registrant is or was a shareholder or creditor, and his or her heirs and legal representatives, to the extent permitted by the BCA, as set forth above.

The Registrant maintains directors’ and officers’ liability insurance which insures the directors and officers of the Registrant and its subsidiaries against certain losses resulting from any wrongful act committed in their official capacities for which they become obligated to pay, to the extent permitted by applicable law.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the Registrant pursuant to the foregoing provisions, the Registrant has been informed that, in the opinion of the U.S. Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

EXHIBITS

The following exhibits have been filed as part of this Registration Statement.

<u>Exhibit Number</u>	<u>Description</u>
4.1	Annual Information Form of the Registrant dated May 29, 2013 for the fiscal year ended February 28, 2013 (incorporated by reference to Exhibit 99.1 of the Registrant's Annual Report on Form 40-F filed with the Commission on May 29, 2013)
4.2	Financial Statements as at February 28, 2013 and February 29, 2012 and for the years then ended, and the accompanying auditors' report (incorporated by reference to Exhibit 99.2 of the Registrant's Annual Report on Form 40-F filed with the Commission on May 29, 2013)
4.3	Management Analysis of the Financial Situation and Operating Results – Management Discussion and Analysis for the fiscal year ended February 28, 2013 (incorporated by reference to Exhibit 99.3 of the Registrant's Annual Report on Form 40-F filed with the Commission on May 29, 2013)
4.4	Interim Financial Statements for the three-month and six-month periods ended August 31, 2013 and 2012 (incorporated by reference to Exhibit 99.1 of the Registrant's Report on Form 6-K filed with the Commission on October 15, 2013)
4.5	Management Analysis of the Financial Situation and Operating Results – Three and six-month periods ended August 31, 2013 and 2012 (incorporated by reference to Exhibit 99.2 of the Registrant's Report on Form 6-K filed with the Commission on October 15, 2013)
4.6	Management Proxy Circular prepared in connection with the Registrant's Annual and Special Meeting of Shareholders held on June 27, 2013 (incorporated by reference to Exhibit 99.2 to the Registrant's report on Form 6-K filed with the Commission on May 28, 2013).
5.1*	Consent of KPMG LLP
5.2*	Consent of Osler, Hoskin & Harcourt LLP
6.1*	Powers of Attorney (included in Part III of this Registration Statement)

* filed herewith

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PART III – UNDERTAKING AND CONSENT TO SERVICE OF PROCESS

Item 1. Undertaking

The Registrant undertakes to make available, in person or by telephone, representatives to respond to inquiries made by the Commission staff, and to furnish promptly, when requested to do so by the Commission staff, information relating to the securities registered pursuant to Form F-10 or to transactions in said securities.

Item 2. Consent to Service of Process

Concurrently with the filing of this Registration Statement, the Registrant is filing with the Commission a written irrevocable consent and power of attorney on Form F-X. Any change to the name or address of the agent for service of the Registrant or the trustee shall be communicated promptly to the Commission by amendment to Form F-X referencing the file number of this Registration Statement.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-10 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Laval, Province of Quebec, Canada, on October 25, 2013.

ACASTI PHARMA INC.

By: /s/ Henri Harland

Name: Henri Harland

Title: President and Chief Executive Officer

POWERS OF ATTORNEY

Each person whose signature appears below constitutes and appoints Henri Harland, Xavier Harland and Jean-Daniel Belanger, or any of them, his true and lawful attorneys-in-fact and agents, each of whom may act alone, with full powers of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to this Registration Statement, including post-effective amendments, and to file the same, with all exhibits thereto, and other documents and in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, and hereby ratifies and confirms all his said attorneys-in-fact and agents or any of them or his substitute or substitutes may lawfully do or cause to be done by virtue hereof. This Power of Attorney may be executed in multiple counterparts, each of which shall be deemed an original, but which taken together shall constitute one instrument.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed below by the following persons in the capacities indicated on the dates indicated.

Signature	Title	Date
<u>/s/ Henri Harland</u> Henri Harland	President, Chief Executive Officer and Director (Principal Executive Officer)	October 25, 2013
<u>/s/ Xavier Harland</u> Xavier Harland	Chief Financial Officer (Principal Financial and Accounting Officer)	October 25, 2013
<u>/s/ Ronald Denis</u> Ronald Denis	Director and Chairman of the Board	October 25, 2013
<u>/s/ Jean-Claude Debard</u> Jean-Claude Debard	Director	October 25, 2013
<u>/s/ Valier Boivin</u> Valier Boivin	Director	October 25, 2013

AUTHORIZED REPRESENTATIVE

Pursuant to the requirements of Section 6(a) of the Securities Act of 1933, as amended, the undersigned has signed this Registration Statement, solely in the capacity of the duly authorized representative of Acasti Pharma Inc. in the United States, in the City of New York, State of New York, on October 25, 2013.

CT Corporation System
(Authorized Representative)

By: /s/ JoAn Tolosa

Name: JoAn Tolosa

Title: Assistant Secretary

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
4.1	Annual Information Form of the Registrant dated May 29, 2013 for the fiscal year ended February 28, 2013 (incorporated by reference to Exhibit 99.1 of the Registrant's Annual Report on Form 40-F filed with the Commission on May 29, 2013)
4.2	Financial Statements as at February 28, 2013 and February 29, 2012 and for the years then ended, and the accompanying auditors' report (incorporated by reference to Exhibit 99.2 of the Registrant's Annual Report on Form 40-F filed with the Commission on May 29, 2013)
4.3	Management Analysis of the Financial Situation and Operating Results – Management Discussion and Analysis for the fiscal year ended February 28, 2013 (incorporated by reference to Exhibit 99.3 of the Registrant's Annual Report on Form 40-F filed with the Commission on May 29, 2013)
4.4	Interim Financial Statements for the three-month and six-month periods ended August 31, 2013 and 2012 (incorporated by reference to Exhibit 99.1 of the Registrant's Report on Form 6-K filed with the Commission on October 15, 2013)
4.5	Management Analysis of the Financial Situation and Operating Results – Three and six-month periods ended August 31, 2013 and 2012 (incorporated by reference to Exhibit 99.2 of the Registrant's Report on Form 6-K filed with the Commission on October 15, 2013)
4.6	Management Proxy Circular prepared in connection with the Registrant's Annual and Special Meeting of Shareholders held on June 27, 2013 (incorporated by reference to Exhibit 99.2 to the Registrant's report on Form 6-K filed with the Commission on May 28, 2013).
5.1*	Consent of KPMG LLP
5.2*	Consent of Osler, Hoskin & Harcourt LLP
6.1*	Powers of Attorney (included in Part III of this Registration Statement)

* filed herewith



KPMG LLP
600 de Maisonneuve Blvd. West
Suite 1500
Tour KPMG
Montréal (Québec) H3A 0A3

Telephone	(514) 840-2100
Fax	(514) 840-2187
Internet	www.kpmg.ca

CONSENT OF INDEPENDENT AUDITORS

The Board of Directors
Acasti Pharma Inc.

We consent to the use of our audit report dated May 21, 2013, on the financial statements of Acasti Pharma Inc. (the "Company"), which comprise the statements of financial position as at February 28, 2013 and February 29, 2012, the statements of earnings and comprehensive loss, changes in equity and cash flows for each of the years then ended, and notes, comprising a summary of significant accounting policies and other explanatory information, incorporated by reference in the Company's registration statement on Form F-10, which reports appear in the annual report on Form 40-F of the Company for the fiscal year ended February 28, 2013. Our report contains an emphasis of matter paragraph that states that the Company has incurred operating losses and negative cash flows from operations since inception, and the existence of a material uncertainty that casts substantial doubt about the Company's ability to continue as a going concern. We also consent to the reference to our firm under the heading "Auditors" in the prospectus forming a part of the Registration Statement.

/s/ KPMG LLP*

October 25, 2013
Montreal, Canada

* CPA, auditor, CA, public accountancy permit No. A119178

KPMG LLP is a Canadian limited liability partnership and a member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. KPMG Canada provides services to KPMG LLP.

CONSENT OF OSLER, HOSKIN & HARCOURT LLP

October 25, 2013

Acasti Pharma Inc.
545 Promenade du Centropolis, Suite 100
Laval, Québec H7T 0A3

Dear Ladies and Gentlemen:

Re: Registration Statement on Form F-10 of Acasti Pharma Inc.

We have acted as Canadian counsel to Acasti Pharma Inc. (the “Registrant”) in connection with the registration statement on Form F-10 (the “Registration Statement”) filed on October 25, 2013 by the Registrant with the Securities and Exchange Commission under the United States Securities Act of 1933, as amended (the “Act”). We acknowledge that we are referred to under the headings “Enforcement of Civil Liabilities” and “Legal Matters” in the prospectus forming a part of the Registration Statement and we hereby consent to such use of our name in the Registration Statement. In giving this consent, we do not thereby admit that we come within the category of persons whose consent is required by the Act or the rules and regulations promulgated thereunder.

Yours very truly,

/s/ Osler, Hoskin & Harcourt LLP

Osler, Hoskin & Harcourt LLP