July 13, 2015



# Acasti Announces First Quarter Results

LAVAL, Quebec, July 13, 2015 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (**Acasti**" or the **"Corporation**") (NASDAQ:ACST) (TSX-V:APO), 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, announces its results for the first quarter ended May 31, 2015.

"During the quarter, Acasti continued to make important progress in its discussions with the US Food and Drug Administration (FDA) to determine next steps concerning a pivotal phase III trial of CaPre®," highlighted Pierre Lemieux, PhD, Acasti's Chief Operating Officer. "These discussions should also allow us to have a clearer picture on the requirements and projected timeline leading towards the eventual filing of a New Drug Application (NDA) to obtain regulatory approval of CaPre® in the United States."

### First Quarter Financial Results

- Revenues were \$5,000 for the three-month period ended May 31, 2015, versus \$56,000 for the quarter ended May 31, 2014
- Research and development (R&D) expenses were \$1,347,000 for the quarter, versus \$1,219,000 in the corresponding prior-year period
- Adjusted EBITDA was negative \$(1,946,000) for the quarter, versus negative \$(1,695,000) in the prior year
- Net loss was \$(966,000) for the quarter, versus a net profit of \$1,356,000 in the prior year
- Cash and short-term investments were \$17.2 million as at May 31, 2015.

R&D expenses for the current quarter were up slightly over the prior year largely due to higher professional and regulatory expense fees, partially offset by lower contract expenses.

The year-over-year decrease in adjusted EBITDA was mainly due to the higher R&D expenses.

The quarterly net loss over the prior year's net profit was mainly attributable to the factors mentioned above, along with a decrease in finance income associated with the change in the fair value of Acasti's derivative warrant liability arising from its 2013 public offering. The warrants are derivative liabilities, for accounting purposes, due to the currency of the exercise price (US dollars) being different from Acasti's functional currency (Canadian dollars). The derivative warrant liabilities are required to be measured at fair value at each reporting date with changes in fair value recognized in earnings. The Corporation uses the Black-Scholes pricing model to determine fair value.

#### **Clinical Trials**

Acasti is now corresponding with the FDA concerning next steps in the clinical development

plan of CaPre®. Such correspondence is meant to allow the FDA to provide its feedback on Acasti's plans and to clarify or answer specific questions that the FDA may have prior to such next steps, including a special protocol assessment and an Investigational New Drug (IND) amendment.

Acasti intends to conduct a phase III clinical trial in the US, with potentially a few Canadian clinical trial sites, in a patient population with very high triglycerides (>500 mg/dL). The trial is to be pursued under an IND application.

## About Acasti Pharma Inc.

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. 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®.

#### **Forward Looking Statements**

Statements in this press release that are not statements of historical or current fact constitute "forward-looking statements" within the meaning of the U.S. securities laws and Canadian securities laws. Such forward-looking statements involve known and unknown risks, uncertainties, and other unknown factors that could cause the actual results of Acasti to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labeled with the terms "believes," "belief," "expects," "intends," "anticipates," "will," or "plans" to be uncertain and forward-looking. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release.

The forward-looking statements contained in this news release are expressly qualified in their entirety by this cautionary statement and the "Cautionary Note Regarding Forward-Looking Information" section contained in Acasti's latest Annual Information Form, which also forms part of Acasti's latest annual report on Form 20-F, and which is available on SEDAR at <u>www.sedar.com</u>, on EDGAR at <u>www.sec.gov/edgar.shtml</u> and on the investor section of Acasti's website at <u>acastipharma.com</u> (the "AIF"). All forward-looking statements in this press release are made as of the date of this press release. Acasti does not undertake to update any such forward-looking statements whether as a result of new information, future events or otherwise, except as required by law. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in Acasti's public securities filings with the Securities and Exchange Commission and the Canadian securities commissions. Additional information

about these assumptions and risks and uncertainties is contained in the AIF under "Risk Factors".

Neither NASDAQ, the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

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