

# Acasti Announces First Quarter Results

## Appoints Jerald J. Wenker as Chairman of Board

LAVAL, Quebec, July 15, 2014 (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 financial results for the first quarter ended May 31, 2014.

"Acasti continues to make important progress in its drug development program to obtain regulatory approval to distribute and market CaPre® as a prescription drug," highlighted Mr. Andre Godin, Interim President and Chief Executive Officer of Acasti. "Recently we announced the completion of two key clinical studies, a Phase II double-blind (TRIFECTA) trial and a Pharmacokinetic (PK) trial. These trials are a key part of our expanding clinical program to evaluate the safety and efficacy of CaPre®. They are also an important component of Acasti's on-going discussion with the US food and Drug Administration (FDA) to obtain approval to conduct a Phase III study in the US. We look forward to obtaining results for the two studies in the coming months."

## Financial Results: First Quarter Ended May 31, 2014

- Revenues were \$56,000 for the quarter ended May 31, 2014, versus \$6,000 for the quarter ended May 31, 2013. Sales in both years were generated from the commercialization of Onemia®, the Corporation's medical food product
- Research and development (R&D) expenses were \$1,219,000 for the quarter, versus \$779,000 in the prior year
- Adjusted EBITDA was negative \$(1,695,000) for the quarter, versus negative \$(1,270,000) in the prior year
- Net Income was \$1,356,000 for the quarter, versus a net loss of \$(1,965,000) in the prior year.

The year-over-year decrease in adjusted EBITDA is largely due to increased R&D contract related expenses as Acasti continues to make important progress in its clinical trials. This was partially offset by lower royalties, following the royalty prepayment agreement with Neptune Technologies & Bioresources, Acasti's parent corporation.

The \$1.4 million of income recorded for the quarter is due to a 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's uses the Black-Scholes pricing model to determine fair value.

## Clinical Trials

### *Phase II TRIFECTA and PK Trial*

Top-line results for the recently completed TRIFECTA and PK trial are expected by the end of September 2014, with full data for both trials coming out in the following quarter. Top-line data for the TRIFECTA trial will include the efficacy of CaPre® in lowering triglycerides, along with its impact on other lipid markers, including high-density lipoprotein (HDL) and non-HDL as well as low-density lipoprotein (LDL).

### *Phase III Trial*

The Corporation continues to correspond with the FDA regarding its Investigational New Drug (IND) filing for a pivotal Phase III clinical trial of CaPre® in patients with severe hypertriglyceridemia in the US. Once full TRIFECTA and PK trials results are available, Acasti intends to request an End of Phase II/pre Phase III meeting with the FDA to obtain buy-in on the clinical program and to address specific questions for which Acasti is seeking final responses. Following this, Acasti is evaluating the possibility of submitting its phase III protocol to the FDA for a Special Protocol Assessment ("SPA"). A SPA is a written agreement with the FDA on the design and planned analysis for a clinical trial. It is intended to form the basis for a new drug application (NDA) and may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of new scientific or

public health concerns.

## **Jerald J. Wenker Appointed Chairman of the Board**

At Acasti's Annual & Special Meeting, held on June 19, 2014, shareholders elected a strong slate of directors, who bring deep industry experience in health, nutrition, finance, sales and marketing and a solid track record of value creation in their respective areas. Following a vote at a Board meeting held on July 15, 2014, Jerald J. Wenker was appointed Chairman of the Board of Acasti, effective immediately.

Mr. Wenker is currently President and Chief Operating Officer of Dermalogica, a leading professional skin care company based in the United States. Previously, he was President of Ther-Rx Corporation, the branded division of KV Pharmaceuticals (Lumara Health). Prior to Ther-Rx, Mr. Wenker worked at Abbott Laboratories (AbbVie Inc.) for approximately 15 years where he held several executive roles in such areas as commercial and marketing management, strategic planning, licensing and new business development as well as new product development.

"I am excited to serve as Chairman of Acasti as it continues to evolve and move to the next level of care," said Mr. Wenker. "Acasti is making important progress in its in clinical studies and research and development and I am looking forward to working with my fellow board members as Acasti continues to position itself as a leader of pharmaceutical omega-3 phospholipids. On behalf of all Board members and Acasti management I would also like to thank outgoing chairman, Ronald Denis, for his leadership and distinguished service. Over the years he has made an important contribution to Acasti's success." Mr. Denis will remain a Director of Acasti's Board.

## **[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**

*Certain statements included in this press release may be considered 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 we refer to as forward-looking statements. 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 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. Except as required by law, Acasti disclaims any intention or obligation to update or revise any forward-looking statements.*

*Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by Acasti in its public securities filings available at [www.sedar.com](http://www.sedar.com) and [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml), actual events may differ materially from current expectations. Except as required by law, Acasti disclaims any intention or obligation to update or revise any forward-looking statements.*

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Source: Acasti Pharma Inc.