

October 14, 2014



## Acasti Announces Second Quarter Results

LAVAL, Quebec, Oct. 14, 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 results for the three and six-months ended August 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 Andre Godin, Acasti's Interim President and Chief Executive Officer. "Recently, positive clinical results for both our Phase II double-blind TRIFECTA and Pharmacokinetic (PK) trials were announced. Most importantly, CaPre® was shown to be safe and effective in the treatment of patients with hypertriglyceridemia."

Not only did CaPre® demonstrate a statistically significant improvement in lowering triglycerides (TG) and non-HDL-C (considered the most accurate marker for cardiovascular disease), no increases in LDL-C (bad cholesterol) and slight increases in HDL-C (good cholesterol) were found. In addition, clinically meaningful reductions in VLDL-C (considered a highly significant predictor of coronary artery disease) were seen. On top of this, results from the PK study confirmed the bioavailability of CaPre® was not meaningfully affected by the fat content of a meal. This is an important finding as a low fat diet is often part of the management of hypertriglyceridemic patients.

### Financial Results: Three Months Ended August 31, 2014

- Revenues were \$8,000 for the second quarter ended August 31, 2014, versus \$266,000 for the quarter ended August 31, 2013
- Research and development (R&D) expenses were \$1,803,000 for the quarter, versus \$1,526,000 in the prior year
- Adjusted EBITDA was negative \$(2,449,000) for the quarter, versus negative \$(1,763,000) in the prior year
- Net loss was \$(3,712,000) for the quarter, versus a net loss of \$(3,238,000) in the prior year.

Sales continue to be generated from the commercialization of Onemia®, the Corporation's medical food product. Acasti relies on a limited number of distributors and clients and therefore revenues may vary significantly from quarter to quarter.

The year-over-year increase in R&D expenses is largely due to higher contract and regulatory expenses as Acasti continues to make important progress in its clinical trials.

The decrease in adjusted EBITDA was attributable to higher R&D expenses, along with increased general and administrative costs, largely associated with salaries and benefits. The higher net loss is due to the aforementioned factors along with a quarterly increase 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.

### **Financial Results: Six Months Ended August 31, 2014**

- Revenues were \$64,000 for the six-months ended August 31, 2014, versus \$273,000 for the corresponding period ended August 31, 2013.
- Research and development (R&D) expenses were \$3,022,000 for the six-month period, compared to \$2,304,000 in the prior year
- Adjusted EBITDA was negative \$(4,144,000), versus negative \$(3,033,000) in the prior year
- Net loss was \$(2,356,000), versus a net loss of \$(5,203,000) in the prior year.

The six-month year-over-year variances are mainly attributable to the factors listed above for the three-months ended August 31, 2014. As well, the lower net loss over the prior year is due to a year-to-date decrease in the fair value of Acasti's derivative warrant liability.

### **Next Steps: Leading Towards Full Regulatory Approval of CaPre®**

With the positive results for the TRIFECTA and PK trials, Acasti is moving one step closer to the potential commercialization of CaPre®. As previously announced, full data for the TRIFECTA and PK trials is expected by the end of 2014. Once available, Acasti will meet with the US Food and Drug Administration (FDA) to finalize next steps in the clinical development of CaPre®. The focus will be on patients with severe hypertriglyceridemia, the only indication currently recognized by the FDA for Omega-3 products.

### **Dr. Harlan W. Waksal, M.D. Steps Down As EVP at Acasti, But Remains on BOD**

Dr. Waksal has stepped down as Executive Vice-President, Business & Scientific Affairs at Acasti, following his recent appointment as President and CEO of Kadmon Corporation. He remains a Director on Acasti's Board. "Over the years Dr. Waksal has made a valuable contribution to Acasti's success and we look forward to his continued leadership and guidance on Acasti's Board," highlighted Mr. Jerald J. Wenker, Chairman of Acasti.

### **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 [www.sedar.com](http://www.sedar.com), on EDGAR at [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml) and on the investor section of Acasti's website at [acastipharma.com](http://acastipharma.com) (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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Source: Acasti Pharma Inc.