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Acasti Announces Second Quarter Results

LAVAL, Quebec, Oct. 15, 2013 (GLOBE NEWSWIRE) -- Acasti Pharma ("Acasti" or the "Corporation") (Nasdaq:ACST) (TSX-V:APO), a Neptune Technologies & Bioressources Inc.'s ("Neptune") subsidiary, announces its financial results for the three and six-month periods ending August 31, 2013.

Financial Results: Three Months Ended August 31, 2013

- Revenues were $266,000 for the quarter ended August 31, 2013, versus $237,000 for the quarter ended August 31, 2012. Sales in both years were generated from the commercialization of Onemia®, the Corporation's medical food product.
- Research and development expenses were $1,526,000 for the current quarter, up from $761,000 in the corresponding prior-year quarter.
- Adjusted EBITDA was negative $(1,755,000) for the quarter ended August 31, 2013, versus negative $(1,037,000) in the corresponding prior-year quarter.
- A net loss of $(3,238,000) or $(0.04) per share was recorded for the current quarter, versus a net loss of $(1,752,000) or $(0.02) per share in the same quarter last year.

Financial Results: Six Months Ended August 31, 2013

- Revenues were $273,000 for the six-month period ended August 31, 2013, versus $251,000 for the corresponding period ended August 31, 2012. Sales in both years were generated from the commercialization of Onemia®, the Corporation's medical food product.
- Research and development expenses were $2,304,000 for the six-month period ended August 31, 2013, up from $1,321,000 in the corresponding prior-year period.
- Adjusted EBITDA was negative $(3,015,000) for the quarter ended August 31, 2013, versus negative $(1,953,000) in the corresponding prior-year period.
- A net loss of $(5,203,000) or $(0.07) per share was recorded for the current quarter, versus a net loss of $(3,328,000) or $(0.05) per share in the corresponding prior-year period.

"Acasti's position continues to grow stronger, with the Corporation reaching several significant milestones in recent months," highlighted Dr. Harlan W. Waksal, M.D., Executive Vice-President, Business & Scientific Affairs. "These include the signing of a Manufacturing Agreement with a world leader in natural based specialty chemicals for the manufacturing of CaPre® clinical material and the release of positive results in our recently completed COLT trial testing the safety and efficacy of CaPre®." These accomplishments are an important part of Acasti's drug development program geared towards obtaining market approval of CaPre®.

On top of this, Acasti and Neptune recently reached a favourable settlement with a number of respondents named in the U.S. International Trade Commission's (ITC) investigation into alleged composition of matter infringements. The ITC investigation was instituted earlier this

year following a Neptune and Acasti complaint filed with the ITC. "Our intellectual property (IP) is a valuable asset and the resolution with key industry players in the ITC investigation reflects its strength and we remain dedicated in its defense," continued Dr. Waksal. To date, Acasti and Neptune have not reached a settlement with the remaining respondents in the ITC investigation, including Aker BioMarine AS; Aker BioMarine Antarctic USA, Inc.; Aker BioMarine Antarctic AS; Enzymotec Limited and Enzymotec USA, Inc.

Clinical Trials

During the quarter, Acasti announced positive results for its randomized, open-label, dose ranging, multi-centre ("COLT") trial, designed to evaluate the safety and efficacy of different daily doses of CaPre® on patients with mild to severe hypertriglyceridemia. CaPre® was found to be safe and effective with significant mean triglyceride reductions above 20% after 8 weeks of treatment with both daily doses of 4.0 grams and 2.0 grams. No serious events were reported indicating that CaPre® is safe and tolerable at all doses tested. The efficacy of CaPre® at all doses and increased effect with dose escalation suggests that CaPre® may be titratable, allowing physicians to adjust dosage in order to better manage patients' medical needs. Going forward, the Corporation plans to release full COLT trial results at an international scientific forum.

Acasti's other Phase II study, a randomized, double-blind, placebo-controlled ("TRIFECTA") trial remains on track, with completion continued to be expected for the first half of calendar 2014. On top of this, Acasti also continues to progress with its US strategy to submit an Investigational New Drug (IND) filing to initiate PK and Phase III clinical trials of CaPre®. The Corporation intends to do this in a two-step process, initially seeking approval to conduct a PK study and subsequently amending it to include phase III studies. "The PK study will set the stage for discussions with the FDA to conduct pivotal phase III studies in the USA," highlighted Dr. Waksal. The PK IND submission is expected to be done in the current quarter ending November 30, 2013, while the amended version requesting approval to conduct Phase III trials should be completed by the end of this fiscal year.

About Acasti Pharma Inc.

Acasti is developing a product portfolio of proprietary novel long-chain omega-3 phospholipids. Phospholipids are the major component of cell membranes and are essential for all vital cell processes. They are one of the principal constituents of High Density Lipoprotein (good cholesterol) and, as such, play an important role in modulating cholesterol efflux. Acasti's proprietary novel phospholipids carry and functionalize the polyunsaturated omega-3 fatty acids EPA and DHA, which have been shown to have substantial health benefits and which are stabilized by potent antioxidants. Acasti is focusing initially on treatments for chronic cardiovascular and cardiometabolic conditions within the medical food and prescription drug markets.

"Neither NASDAQ nor 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."

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. Private Securities Litigation Reform Act of 1995 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 the Corporation 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. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in the Corporation's reports filed with the Securities and Exchange Commission and the Canadian securities commissions.

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