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Acasti Announces Third Quarter Results

LAVAL, Quebec, Jan. 14, 2014 (GLOBE NEWSWIRE) -- Acasti Pharma ("Acasti" or the "Corporation") (Nasdaq:ACST) (TSX-V:APO), a Neptune Technologies & Bioresources Inc.'s ("Neptune") subsidiary, announces its financial results for the three and nine-month periods ended November 30, 2013.

Financial Results: Three Months Ended November 30, 2013

- Revenues were \$28,000 for the quarter ended November 30, 2013, versus \$424,000 for the quarter ended November 30, 2012. Sales in both years were generated from the commercialization of Onemia[®], the Corporation's medical food product.
- Research and development (R&D) expenses were \$1,279,000 for the current quarter, up from \$770,000 in the corresponding prior-year quarter.
- Adjusted EBITDA was negative \$(1,574,000) for the quarter ended November 30, 2013, versus negative \$(1,048,000) in the corresponding prior-year quarter.
- A net loss of \$(3,856,000) or \$(0.05) per share was recorded for the current quarter, versus a net loss of \$(1,611,000) or \$(0.02) per share in the same quarter last year.

The year over year net loss increase is largely due to additional R&D contract expenses related to CaPre's[®] research and clinical development program, higher stock based compensation expenses and additional costs relating to Acasti's recent US\$23 million public offering.

Financial Results: Nine Months Ended November 30, 2013

- Revenues were \$301,000 for the nine-month period ended November 30, 2013, versus \$675,000 for the corresponding period ended November 30, 2012. Sales in both years were generated from the commercialization of Onemia[®], the Corporation's medical food product.
- Research and development expenses were \$3,584,000 for the nine-month period ended November 30, 2013, up from \$2,091,000 in the corresponding prior-year period.
- Adjusted EBITDA was negative \$(4,607,000) for the nine-month period ended November 30, 2013, versus negative \$(3,024,000) in the corresponding prior-year period.
- A net loss of \$(9,059,000) or \$(0.12) per share was recorded for the nine-month period ended November 30, 2013, versus a net loss of \$(4,940,000) or \$(0.07) per share in the corresponding prior-year period.

"Acasti recently announced a number of important milestones towards securing regulatory approval to distribute and market CaPre[®] as a prescription drug in the U.S," highlighted Mr. Henri Harland, President and CEO of Acasti. "These include clearance from the US

Food and Drug Administration (FDA) to initiate a pharmacokinetic (PK) study in the U.S. and the closing of a US\$23 million public offering to support our research and clinical development program relating to our investigational new drug CaPre[®]. With these achievements we are now moving forward with plans to seek approval from the FDA to conduct a pivotal Phase III clinical trial of CaPre[®] in the U.S. This is the critical and decisive next step in our drug development program."

"On top of these developments, Neptune continued to reach favourable settlements with the respondents named in the US International Trade Commission's (ITC) investigation into alleged composition of matter infringements of Neptune's patents, which benefits Acasti," continued Mr. Harland. "To date, Neptune has settled with eight of the ten respondents, effectively resolving the ITC investigation. These settlement agreements are a great testimonial to the strength and validity of our patent estate and demonstrate that industry peers recognize the value of our intellectual property (IP). The strategy put forward in the ITC investigation reflects our commitment to actively defend this fundamental asset. The settlements maintain IP protection for Acasti and furthermore protect its market as no licensing agreements were signed giving the right to manufacture products in the pharmaceutical field."

Clinical Trials

Acasti continues to make significant progress in its research and clinical development program. Recently, Acasti announced that the FDA had given it clearance to initiate a PK trial in the U.S. This is a significant milestone and a key first step towards securing regulatory approval to distribute and market CaPre[®] as a prescription drug in the U.S.

Quintiles, the world's largest provider of biopharmaceutical development and commercial outsourcing services, has been engaged to conduct the trial. The PK study is expected to start in the second quarter of calendar 2014 and results would be announced in the following quarter.

Going forward the Corporation intends to amend its initial PK Investigational New Drug submission with the FDA to also request approval to conduct a Phase III trial in the U.S. The amended submission should be filed by the end of February 2014.

Patient recruitment for the Phase II TRIFECTA study, a randomized, double-blind, placebo-controlled trial is on-going and special focus is being given to recruiting patients in the moderate to severe hypertriglyceridemia population (triglyceride levels over 500 mg/dL). The Corporation continues to aim for trial completion by the first half of calendar 2014. Based on the positive safety data found in the previously completed COLT trial, Acasti filed an amendment with Health Canada in December 2013, to broaden the inclusion criteria to facilitate patient recruitment for the above 500 mg/dL group. Depending on Health Canada's response, Acasti will adjust its strategy accordingly.

Major Financing Completed

In December 2013, Acasti announced the closing of a public offering totalling US\$23 million in gross proceeds. Acasti intends to use the net proceeds from the offering to support its research and clinical development program relating to its investigational new

drug candidate CaPre[®].

US Patent Application Granted by USPTO

On November 19, 2013 the United States Patent and Trademark Office (USPTO) granted Acasti's composition and use patent application entitled Concentrated Therapeutic Phospholipid Compositions (the "Patent") (Patent number: US8,586,567).

The Patent relates to concentrated therapeutic phospholipid omega-3 compositions and covers methods for treating or preventing diseases associated with cardiovascular diseases, metabolic syndrome, inflammation, neurodevelopmental diseases, and neurodegenerative diseases. It is enforceable and valid until October 29, 2029.

[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 and 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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CONTACT: Acasti Contacts:

Xavier Harland
Chief Financial Officer
+1.450.687.2262
x.harland@acastipharma.com
acastipharma.com

John Ripplinger
Investor Relations
+1.450.687.2262
j.ripplinger@acastipharma.com
acastipharma.com

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