

# Acasti Pharma Reports Third Quarter 2017 Financial Results

## Key Developments Include Advancement of Drug Candidate CaPre and New CFO

LAVAL, QUÉBEC -- (Marketwired) -- 01/12/17 -- Acasti Pharma Inc. ("Acasti" or the "Corporation") (NASDAQ:ACST)(TSX VENTURE:ACST) today announced its operating and financial results for the third quarter of its 2017 fiscal year, which ended November 30, 2016. All amounts are in Canadian dollars.

"A highlight of Acasti's third quarter was the reporting of positive data from our Phase 2 Bridging Study for CaPre®, which gives us confidence that we'll proceed with the U.S. Food and Drug Administration's (FDA) more expedited 505(b)(2) pathway, pending the outcome of our end of Phase 2 meeting with the agency," said Jan D'Alvise, president and CEO of Acasti Pharma. "More recently, we secured a Q1 date for the end of Phase 2 meeting with the FDA, and completed the first engineering production run of CaPre, both important milestones in our CaPre development program. We also welcomed Linda O'Keefe as our new CFO, augmenting our executive team that is focused on advancing CaPre towards a Phase 3 clinical trial later this year."

### **Key Developments**

- The full report of Acasti's completed Bridging Study for CaPre was submitted to the FDA. The Corporation has an End of Phase 2 meeting scheduled with the FDA in the first quarter of 2017, and plans to discuss the Bridging Study results with the agency and to gain their guidance on Acasti's development program and planned Phase 3 clinical study protocol in patients with severe hypertriglyceridemia.
- Acasti advanced the process leading to the cGMP manufacturing of CaPre for the planned Phase 3 clinical trial with qualified and experienced pharmaceutical CMOs, including the installation and qualification of the Acasti owned proprietary extraction and purification equipment, which led to the first engineering production run of CaPre in December 2016.
- Acasti appointed Linda P. O'Keefe as chief financial officer effective November 25, 2016. Ms. O'Keefe is an accomplished CFO and finance executive with experience in public small cap and multi-national companies, private start-ups in the life sciences industry, as well as with venture capital and private equity firms. Her track-record includes finance, accounting and back office administrative leadership roles.

### **Third Quarter 2017 and Year-to-Date Financial Results<sup>1</sup>**

- **Net loss** was \$2.4 million or \$0.22 loss per share for the third quarter, compared to a net loss of \$2.2 million or \$0.21 loss per share in the third quarter of last fiscal year. Net loss was \$7.9 million or \$0.74 loss per share for the first nine months of fiscal

2017, compared to a net loss of \$4.4 million or \$0.41 loss per share for the same period of the last fiscal year. The higher net loss for the current nine-month period was primarily based on last year's net loss being reduced by a \$2.0 million incremental decreased value of derivative warrant liabilities, a \$1.0 million change from a foreign exchange gain last year to a foreign exchange loss in the current year, and increased general and administrative (**G&A**) expenses.

- **Research and development (R&D) expenses** were \$1.7 million for the third quarter, down from \$2.2 million in the third quarter of fiscal 2016. The current quarter's lower R&D expenses are primarily attributed to the change in the year-to-year mix of clinical and production activities and the timing of related expenses, including the current year's project expenses not all being incurred during the full quarter. As Acasti continues as planned on its previously announced timeline for the conduct of its clinical program, R&D expenses were \$5.7 million for the first nine months of fiscal 2017, a decrease from \$5.8 million for the same period last year.
- **General and administrative expenses** were \$0.8 million for the third quarter, up from \$0.5 million in the third quarter of fiscal 2016. The increase in G&A expenses during the current quarter was primarily made up of project expenses for the reactivation of the public and investor relations programs and achievement of business development milestones as well as nonrecurring legal professional fees associated primarily with the Corporation's year-end change and immigration activities for its U.S. executives. For the first nine months of fiscal 2017, G&A expenses were \$2.3 million, an increase from \$1.6 million for the same period last year, resulting primarily from the increased cost of the expanded executive team, led by the stock-based compensation impact, and an increase in the Corporation's market research expenses based on a change in expense classification.
- **Cash Flows** - With cash and short-term investments of \$5.8 million as of November 30, 2016, if Acasti does not raise additional funds, there exists a material uncertainty that casts substantial doubt about the Corporation's ability to continue as a going concern and, therefore, realize its assets and discharge its liabilities in the normal course of business. Management has reasonable expectation that the Corporation should be able to raise additional funds, assuming the successful completion of Acasti's previously announced financing initiatives.

<sup>1</sup> The quarterly unaudited financial statements with footnotes and the MD&A are 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 [www.acastipharma.com](http://www.acastipharma.com).

### **About Acasti Pharma**

Acasti Pharma is a biopharmaceutical innovator advancing a potentially best-in-class cardiovascular drug, CaPre® (omega-3 phospholipid), for the treatment of hypertriglyceridemia, a chronic condition affecting an estimated one third of the U.S. population. The Corporation's strategy is to initially develop and commercialize CaPre for the 3 to 4 million patients in the U.S. with severe hypertriglyceridemia. Since its founding in 2008, Acasti Pharma has focused on addressing a critical market need for an effective, safe and well-absorbing omega-3 therapeutic that can make a positive impact on the major blood lipids associated with cardiovascular disease risk. For more information, visit [www.acastipharma.com](http://www.acastipharma.com).

## ***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. Forward-looking information in this press release includes, but is not limited to, information or statements about Acasti's strategy, future operations, prospects and the plans of management; the completion of Acasti's previously announced financing initiatives in the timeframe anticipated; whether Acasti's previously announced financing initiatives will be successful; the timing of future meetings and discussions with the FDA and the outcome thereof.

The forward-looking statements contained in this news release are expressly qualified in their entirety by this cautionary statement, 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 [www.acastipharma.com](http://www.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, including, without limitation, the failure to receive regulatory approvals (including stock exchange) or otherwise satisfy the conditions to the completion of Acasti's previously announced financing initiatives and the funds thereof not being available to the Corporation; anticipated studies and submissions to the FDA may not occur as currently anticipated, or at all; rejection by the FDA of Acasti's 505(b)(2) regulatory pathway approach; difficulties, delays or failures in obtaining regulatory approvals for the initiation of clinical trials; uncertainties related to the regulatory approval process; failure to achieve Acasti's publicly announced milestones on time; the net proceeds from Acasti's previously announced financing initiatives and existing cash, together with interest thereon, may not be sufficient to fund Acasti's operations through December 31, 2017; Acasti has a history of negative operating cash flow and may never become profitable or be able to sustain profitability; Acasti will have significant additional future capital needs and may not be able to raise additional financing required to fund further research and development, clinical studies, obtain regulatory approvals, and to meet ongoing capital requirements to continue current operations on commercially acceptable terms or at all.

Certain important assumptions by Acasti in making forward-looking statements include, but are not limited to, the satisfaction of all conditions to completion of Acasti's previously announced financing initiatives; the receipt of required regulatory approvals (including stock

exchange approvals) and successful completion of Acasti's previously announced financing initiatives in the time frame anticipated; confirmation by the FDA of Acasti's 505(b)(2) regulatory pathway approach and finalization of the protocol for the Phase 3 trial for CaPre within the anticipated timeframe; the Corporation's ability to achieve its publicly announced milestones on time; the Corporation's ability to continue as a going concern; and Acasti's ability to obtain additional capital and financing as needed on favorable terms. Additional information about these assumptions and risks and uncertainties is contained in the AIF and in the Corporation's most recent management's discussion and analysis (MD&A), in each case under the heading "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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