

August 14, 2017



## Acasti Pharma Reports First Quarter FY 2018 Financial Results

LAVAL, QUÉBEC -- (Marketwired) -- 08/14/17 -- Acasti Pharma Inc. (NASDAQ:ACST)(TSX VENTURE:ACST), a biopharmaceutical innovator focused on the research, development and commercialization of CaPre® (omega-3 phospholipid) for the treatment of severe hypertriglyceridemia, today announced its operating and financial results for the quarter ended June 30, 2017, which is the first quarter of Acasti's fiscal year 2018. All amounts are in Canadian dollars.

"We sustained our positive business performance in the first quarter, working efficiently to advance our lead drug candidate CaPre towards initiation of our planned Phase 3 program in patients with severe hypertriglyceridemia, an indication that is significantly undertreated," said Jan D'Alvise, president and CEO of Acasti. "We are in the process of finalizing the selection of the clinical research organization that will assist Acasti in conducting the trials, as well as identifying the principal investigator. We are pleased with the caliber of clinical researchers who have expressed interest in participating, and Acasti remains on track to commence the Phase 3 program in the second half of this year."

### **Key First Quarter FY 2018 and Recent Developments:**

- **cGMP scale-up and manufacturing of CaPre was completed:** During the quarter ended June 30, 2017, Acasti completed the scale-up of its novel continuous manufacturing process for CaPre, conducted under good manufacturing practice (cGMP) with qualified and experienced pharmaceutical CMOs. The first clinical production lots of CaPre have been completed, which will support the Phase 3 program that Acasti plans to initiate in the second half of 2017. This was a significant milestone, advancing the Phase 3 clinical program and future commercial supply of CaPre.
- **CaPre bridging study data was presented at major scientific conferences:** Acasti scientists presented results from the CaPre pharmacokinetics bridging study at the National Lipid Association Conference (NLA) in May 2017, highlighting the fact that when taken on an empty stomach, the phospholipid and free fatty acid forms of EPA and DHA found in CaPre demonstrated better bioavailability when compared to LOVAZA (omega-3 ethyl esters), as measured by significantly higher blood levels of EPA and DHA. Additionally, in July, results from the CaPre Phase 1 and Phase 2 clinical studies were included in an oral presentation at the International Academy of Cardiology Annual Scientific Sessions 22<sup>nd</sup> World Congress on Heart Disease (WCHD). Select data from these studies will be submitted for publication in a peer-reviewed journal. Both the NLA and WCHD presentations can be found on the [Acasti website](#).
- **Continued expansion of IP:** In April 2017, Acasti was granted additional patents by the Taiwanese and Australian patent offices, further expanding the global intellectual

property position of CaPre to protect both composition of matter and methods of treatment.

- **Neptune announcement:** On August 8, 2017, Neptune Technologies & Bioresources Inc. (Neptune) announced the sale of its krill oil inventory and intellectual property to Aker BioMarine Antarctic AS (Aker). Acasti is assessing in more detail what impact, if any, this transaction may have on its future activities.

### **First Quarter FY 2018 Financial Results<sup>1</sup> :**

- **Net loss** for the quarter ended June 30, 2017 was \$2.8 million or \$0.19 loss per share, compared to a net loss of \$3.2 million or \$0.29 loss per share for the quarter ended May 31, 2016. The lower net loss for the first quarter of fiscal year 2018 was primarily due to a decrease in research and development expenses (R&D) offset by an increase in general and administrative (G&A) expenses and a reduction in net financial expenses driven primarily by a reduced foreign exchange loss in the current period.
- **R&D expenses** were \$2.0 million for the quarter ended June 30, 2017, down from \$2.4 million in the first quarter of fiscal year 2017. The \$0.4 million net decrease was primarily attributable to a \$0.9 million reduction in research contracts, offset by a \$0.3 million increase in professional fees. The expense mix changed with the transition from completed clinical contracts for the successful Phase 1 bioavailability bridging study to professional fees related to business development and regulatory activities associated with the planning of the Phase 3 program for CaPre.
- **G&A expenses** were \$0.8 million for the quarter ended June 30, 2017, up from \$0.6 million in the first quarter of fiscal year 2017. The net increase was mainly attributable to \$0.1 million in expense increases for expanded, full-time executive, finance and accounting staff and \$0.1 million incremental expenses for business development activities and the reactivation of Acasti's investor and public relations programs.
- **Cash Flows** - As previously disclosed, with cash and cash equivalents of \$7.6 million as of June 30, 2017, if Acasti does not raise additional funds, there exists a material uncertainty that casts substantial doubt about the company'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 a reasonable expectation that the company should be able to raise additional funds to help finance its planned Phase3 program for CaPre.

### **About CaPre (omega-3 phospholipid)**

Acasti's prescription drug candidate, CaPre, is a highly purified omega-3 phospholipid concentrate derived from krill oil and is being developed to treat severe hypertriglyceridemia, a metabolic condition that contributes to increased risk of cardiovascular disease and pancreatitis. Its omega-3s, principally EPA and DHA, are either "free" or bound to phospholipids that allows for better absorption into the body. This allows for enhanced bioavailability and EPA and DHA blood levels compared to the "esterified" fish-oil omega-3 options such as LOVAZA. Acasti plans to conduct two pivotal, double-blind, placebo-controlled Phase 3 studies to evaluate the efficacy and safety of CaPre in patients with severe hypertriglyceridemia. The program is designed to satisfy the requirements of the 505(b)(2) regulatory pathway for a new drug application.

### **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 company'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; Acasti's ability to conduct all required clinical and non-clinical trials for CaPre, including the timing and results of those trials; and the timing and the outcome of meetings and discussions with the FDA.

The forward-looking statements contained in this press release are expressly qualified in their entirety by this cautionary statement, the "Cautionary Note Regarding Forward-Looking Information" section contained in Acasti's latest 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). 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, risks related to timing and possible difficulties, delays or failures in the Acasti's Phase 3 program for CaPre; anticipated pre-clinical and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of CaPre; anticipated studies and submissions to the FDA may not occur as currently anticipated, or at all; outcome study data from two of Acasti's competitors in mild to moderate HTG patients may be negative, which could also negatively affect the market perception of CaPre; difficulties, delays or failures in obtaining regulatory approvals for the initiation of clinical trials or to market CaPre; uncertainties related to the regulatory approval process;

failure to achieve Acasti's publicly announced milestones on time; 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 and to meet ongoing capital requirements. Certain important assumptions by Acasti in making forward-looking statements include, but are not limited to, the successful and timely completion of all required clinical and nonclinical trials that may be necessary for regulatory approval of CaPre; the successful enrollment of patients in clinical trials as projected; the timeline and costs for Acasti's clinical programs are not incorrectly estimated or affected by unforeseen circumstances; minimal impact to Acasti as a result of Neptune's sale of its krill oil inventory and intellectual property to Aker; the company's ability to continue as a going concern; and Acasti's ability to obtain additional capital and financing as needed on acceptable terms. Additional information about these assumptions and risks and uncertainties is contained in the Annual Report and in the company'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.

- 1 The interim unaudited financial statements and the MD&A for the quarter ended June 30, 2017 are available on SEDAR at <http://www.sedar.com/> on EDGAR at <http://www.sec.gov/edgar.shtml> and on the investor section of Acasti's website at <http://www.acastipharma.com/>

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