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# Acasti Pharma Reports Second Quarter FY 2018 Financial Results

LAVAL, QUÉBEC -- (Marketwired) -- 11/13/17 -- Acasti Pharma Inc. (NASDAQ:ACST)(TSX VENTURE:ACST), a biopharmaceutical innovator focused on the research, development and commercialization of its prescription drug candidate CaPre® (omega-3 phospholipid) for the treatment of severe hypertriglyceridemia, today announced its operating and financial results for the quarter ended September 30, 2017, which is the second quarter of Acasti's fiscal year 2018. All amounts are in Canadian dollars.

"Acasti met several key milestones in the second quarter, advancing our Phase 3 clinical program to evaluate CaPre in patients with severe hypertriglyceridemia. We are building the value of CaPre as a potentially best-in-class prescription omega-3 product that addresses a very large market opportunity," said Jan D'Alvise, president and CEO of Acasti. "We continue on schedule to begin site activation in our CaPre Phase 3 program before year-end, and to begin treatment of the first patients in early 2018."

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

- ***Advanced Phase 3 program for CaPre:*** Acasti obtained important confirmation from the U.S. Food and Drug Administration on its Chemistry, Manufacturing, and Controls (CMC) plan and on the clinical trial design supporting Acasti's Phase 3 program. In parallel with the clinical trial planning, several lots of CaPre were manufactured under cGMP, providing Acasti with the CaPre and placebo inventory necessary to support the activation of Phase 3 clinical trial sites by the end of 2017. Additional clinical trial lots of CaPre are planned to be manufactured in 2018 to support completion of the Phase 3 program in 2019. In addition, Acasti is working with one of the biopharmaceutical industry's largest global clinical research organizations to prepare for site activation and to conduct the Phase 3 trials for CaPre.
- ***Named principal investigator for Phase 3 program.*** Acasti announced that Dariush Mozaffarian, M.D., Dr.P.H., will be the principal investigator to oversee the Phase 3 clinical program for CaPre. Dr. Mozaffarian is a cardiologist and epidemiologist serving as the Dean of the Friedman School of Nutrition Science & Policy and the Jean Mayer Chair and Professor of Nutrition at Tufts University. His widely published research focuses on how lifestyle and diets such as those rich in omega-3s can influence cardiometabolic health. Dr. Mozaffarian is a recognized opinion leader often consulted to help develop new and effective policies to improve health and wellness.
- ***New directors elected at recent AGM:*** At Acasti's Annual and Special Meeting of Shareholders in August 2017, Richard P. Schottenfeld and Katherine Crewe were elected as new directors of Acasti. Mr. Schottenfeld and Ms. Crewe have extensive investment and pharmaceutical industry expertise, respectively, complementing the existing members of the Acasti board.

## **Second Quarter and Year-to-Date FY 2018 Financial Results<sup>1</sup> :**

- **Net loss** for the quarter ended September 30, 2017 was \$4.5 million or \$0.31 loss per share, compared to a net loss of \$2.3 million or \$0.22 loss per share for the quarter ended August 31, 2016. The higher net loss was primarily due to the increase in both research and development expenses (R&D) and general and administrative (G&A) expenses and an increase in net financial expenses driven primarily by interest expense and the transition of a foreign exchange gain in the prior period to a foreign exchange loss in the current period. The net loss for the six months ended September 30, 2017 was \$7.3 million or \$0.49 loss per share, compared to a net loss of \$5.5 million or \$0.51 loss per share for the six months ended August 31, 2016, also driven by increased R&D and G&A expenses.
- **R&D expenses** were \$3.3 million for the quarter ended September 30, 2017, up from \$1.6 million in the quarter ended August 31, 2016. The \$1.7 million increase was primarily attributable to a \$0.9 million increase in research contracts combined with a \$0.6 million increase in professional fees to execute on Acasti's clinical development strategy. The increased research contract expense primarily resulted from activities associated with Acasti's clinical research organization and contract manufacturing partners to prepare for the Phase 3 clinical program. R&D expenses were \$5.3 million for the six months ended September 30, 2017, up from \$4.0 million in the six months ended August 31, 2016, resulting primarily from increased professional fees combined with expenses related to the expansion of Acasti's full-time R&D leadership.
- **G&A expenses** were \$1.0 million for the quarter ended September 30, 2017, up from \$0.9 million for the quarter ended August 31, 2016. The net increase was mainly attributable to \$0.1 million in professional expenses to support public company activities and filings. G&A expenses were \$1.9 million for the six months ended September 30, 2017, up from \$1.4 million for the six months ended August 31, 2016. The \$0.5 million increase was primarily attributable to increased professional and legal fees and an increase in expenses related to the added full-time executive and accounting staff.
- **Cash flows** - As previously disclosed, with cash and cash equivalents of \$5.3 million as of September 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 in the third quarter to help finance the advancement of its CaPre Phase 3 program.

<sup>1</sup> The interim unaudited financial statements and the MD&A for the quarter ended September 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/>

### **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.

### ***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; the timing and the outcome of meetings and discussions with the FDA; and Acasti's ability to fund its continued operations.

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 annual report on Form 20-F and most recent management's discussion and analysis (MD&A), which 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). 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 assumptions and 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 Acasti's latest annual report on Form 20-F and most recent MD&A.

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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