

February 13, 2018



# Acasti Pharma Reports Third Quarter FY 2018 Financial Results

## Increased Cash Position Supports Initiation of CaPre Phase 3 Clinical Studies

LAVAL, QUÉBEC -- (Marketwired) -- 02/13/18 -- 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 December 31, 2017, which is the third quarter of Acasti's fiscal year 2018. All amounts are in Canadian dollars.

"Acasti achieved several goals in the third quarter including closing a successful \$13.6 million financing that supports the initiation of our CaPre Phase 3 clinical program. Several clinical sites are already actively screening patients, and we remain on track to begin randomization of those patients as planned early this year. We expect to continue advancing our potential best-in-class prescription omega-3 product for the treatment of severe hypertriglyceridemia through the patient enrollment process in 2018, and beyond to expected top line results by the end of 2019," said Jan D'Alvise, president and CEO of Acasti. "We also entered into a non-binding term sheet agreement this quarter with a leading Chinese pharmaceutical company for the development and commercialization of CaPre in certain Asian countries. This partnership is the first step in our worldwide strategy to maximize the value of our asset. We also benefited from the recent Biotech Showcase conference in San Francisco, which provided the opportunity for us to advance discussions with several other potential commercialization partners."

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

- ***Financing completed to support CaPre Phase 3 trials:*** In December 2017, Acasti closed a U.S. public offering of common shares together with accompanying warrants for gross proceeds of \$12.6 million. The closing of a subsequent over-allotment option in January 2018 increased the total gross proceeds to approximately \$13.6 million. The net proceeds from the offering will be used to further the development of CaPre, including additional clinical site activation; progression of patient enrollment and continued production of clinical materials (both CaPre and placebo) for the Phase 3 program; expansion of business development activities; working capital; and other general corporate purposes.

- ***The first clinical sites were activated and patient enrollment initiated for the CaPre Phase 3 program:*** This is a double-blind, placebo-controlled, 26-week, two-study Phase 3 clinical program designed to evaluate the safety and efficacy of CaPre in patients with severe hypertriglyceridemia. Additional cGMP production lots of API (known as NKPL66) and CaPre were manufactured during the third quarter, enabling Acasti to continue to

accumulate the CaPre and placebo inventory required to support the activation of clinical trial sites. Dariush Mozaffarian, M.D., Dr.P.H. is the Principal Investigator for the CaPre Phase 3 program. Dr. Mozaffarian is a highly regarded cardiologist at Tufts University and his research focuses on the influence of omega-3s, diet and lifestyle on cardiometabolic health. Acasti's clinical development plan remains on track and the company expects to randomize the first patients in the first quarter of 2018.

- **Progressed commercialization agreement with leading Chinese pharmaceutical partner:** Acasti entered into a non-binding term sheet with a leading China-based pharmaceutical company. If a definitive agreement is signed, the deal will grant an exclusive license to the Chinese pharmaceutical company to commercialize CaPre in certain Asian countries. Negotiations are ongoing with the Chinese pharmaceutical company to complete the license agreement, while Acasti continues to advance discussions with additional potential partners as part of its worldwide licensing strategy.

- **Presented at Biotech Showcase Conference:** President and chief executive officer, Jan D'Alvise provided a corporate update at the Biotech Showcase Conference in San Francisco. The webcast and presentation are available on the Acasti Pharma [website](#).

- **Board membership:** After the December 2017 financing, in light of the reduction of Neptune's percentage ownership of Acasti's total outstanding common shares below a control position, the Neptune-affiliated members of the board of directors resigned, as announced by Acasti on January 16, 2018. Acasti is currently recruiting new directors to fill these vacancies.

### **Third Quarter and Year-to-Date FY 2018 Financial Results<sup>1,2</sup> :**

- **Net loss** for the quarter ended December 31, 2017 was \$6.1 million or \$0.40 per share, compared to a net loss of \$2.4 million or \$0.22 per share for the quarter ended November 30, 2016. The higher net loss was primarily due to the planned increase in research and development expenses ("R&D") for the Phase 3 program, and financing-related expenses. The \$1.1 million in financing-related expenses were incurred as a result of the recently completed underwritten U.S. public stock offering. The net loss for the nine months ended December 31, 2017 was \$13.4 million or \$0.90 per share, compared to a net loss of \$7.9 million or \$0.74 per share for the nine months ended November 30, 2016, also driven by the planned increase in R&D expenses as well as the financing-related expenses.

- **R&D expenses** were \$4.3 million for the quarter ended December 31, 2017, up from \$1.7 million in the quarter ended November 30, 2016. The \$2.6 million increase was primarily attributable to a \$2.0 million increase in clinical research contracts combined with a \$0.3 million increase in professional fees to execute on Acasti's Phase 3 clinical development plan. The increased contract research expense primarily resulted from activities associated with Acasti's clinical research organization and contract manufacturing partners to prepare and initiate the Phase 3 clinical program. R&D expenses were \$9.6 million for the nine months ended December 31, 2017, up from \$5.7 million in the nine months ended November 30, 2016, resulting primarily from increased Phase 3 clinical program contract expenses and increased clinical development strategy professional fees.

- **General and Administrative ("G&A") expenses** were \$0.9 million for the quarter ended December 31, 2017, compared to \$0.8 million for the quarter ended November 30, 2016.

The net increase was mainly attributable to \$0.1 million in stock-based compensation resulting primarily from the additional vesting of existing grants. G&A expenses were \$2.7 million for the nine months ended December 31, 2017, up from \$2.3 million for the nine months ended November 30, 2016. The \$0.4 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 \$12.5 million as of December 31, 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 2018 to continue to finance the Phase 3 program for CaPre.

- 1 The interim unaudited financial statements and the MD&A for the quarter ended December 31, 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/>
- 2 The current periods represent the three and nine-month periods ended December 31, 2017 and the prior periods represent the three and nine-month periods ended November 30, 2016.

### ***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's CaPre Phase 3 program is currently underway.

### ***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. 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. The company is developing CaPre in a Phase 3 clinical program in patients with severe hypertriglyceridemia, a market that includes 3 to 4 million patients in the U.S. The addressable market may expand significantly if omega-3s demonstrate long-term cardiovascular benefits in on-going outcomes studies (REDUCE-IT and STRENGTH). Acasti's strategy is to commercialize CaPre in the U.S. and the company is pursuing partnerships to market CaPre in major countries around the world. 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," "potential," "should," "may," "will," "plans," "continue" or other similar expressions 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 licensing negotiations; 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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Source: Acasti Pharma Inc.