

# Acasti Pharma Reports Fourth Quarter and Full-Year 2017 Financial Results

## Company Achieves Multiple Milestones to Advance Drug Candidate CaPre Towards Phase 3 Trials

LAVAL, QUÉBEC -- (Marketwired) -- 06/06/17 -- Acasti Pharma Inc. (NASDAQ:ACST)(TSX VENTURE:ACST) today announced its operating and financial results for the fiscal year ended March 31, 2017. The company announced on July 15, 2016 that it would transition to a new fiscal year-end in 2017 to better align Acasti with industry comparables and standard quarters. Accordingly, Acasti's fiscal year ended on March 31, 2017 rather than on February 28, 2017. For the purpose of its regulatory filings, Acasti is reporting results for the thirteen-month transition period ended March 31, 2017, reflecting its fourth quarter period covering the four months of December 1, 2016 to March 31, 2017. All amounts are in Canadian dollars.

"We had an extremely productive fourth quarter, firing on all cylinders to set the stage for us to initiate the Phase 3, registration trials for our product candidate CaPre®, for the treatment of patients with severe hypertriglyceridemia," said Jan D'Alvise, president and CEO of Acasti Pharma. "We raised additional capital and achieved critical clinical, regulatory, manufacturing, and other value-building milestones, and we're all keenly focused on advancing CaPre into Phase 3 clinical trials as planned in the second half of this year."

### ***Key Fourth Quarter, Fiscal Year and Recent Developments***

- **Phase 3 Program Plan** - Following an end-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA"), Acasti finalized the details of its registration program for CaPre® (omega-3 phospholipid). The company plans to conduct two pivotal, double-blind, placebo-controlled studies to evaluate the efficacy and safety of CaPre in a total of approximately 400 patients with severe hypertriglyceridemia (~200 patients per study). The program is designed to satisfy the requirements of the 505(b)(2) regulatory pathway for a new drug application. The company expects to initiate the Phase 3 program on schedule in the second half of 2017.
- **Financing** - On February 21, 2017, Acasti completed a public offering of units, and private placement of convertible debentures and warrants, for aggregate gross proceeds of approximately \$7.7 million. The company is using the net proceeds to fund completion of its initial manufacturing scale-up and the clinical and regulatory preparation necessary for the Phase 3 clinical program for CaPre.
- **Production Scale Up** - During this quarter, Acasti completed the scale up and manufacturing of the first cGMP batches of CaPre. This was a significant milestone and paves the way for the Phase 3 clinical program and supply of future commercial product.
- **Bridging Study Presentation** - Acasti scientists presented results from the CaPre bridging study at the National Lipid Association Scientific Sessions in May, 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 superior bioavailability when compared to LOVAZA (omega-3 ethyl ester). In addition, the bioavailability of CaPre is not significantly reduced when taken with a low-fat meal versus a high-fat meal. Since most patients with hypertriglyceridemia must follow a restricted low-fat diet, Acasti believes that CaPre's strong bioavailability profile could provide a more effective clinical solution for these patients.

- **IP Expansion** - The company expanded its intellectual property position with the addition of new patents allowed in multiple jurisdictions related to both composition of matter and method of treatment.
- **Acasti Team Expansion** - Throughout the thirteen months ended March 31, 2017, Acasti readied for its planned late-stage development and future potential commercialization with the expansion of the company's leadership and management team. Experienced executives and professionals joined the board, executive leadership team, and senior management, including, a new fulltime and dedicated CEO and CFO, a full-time and dedicated director of finance, and key hires to bolster process development, regulatory affairs, quality and R&D capabilities.
- **Scientific Advisory Board** - Barry A. Franklin, Ph.D. and Robert Hegele, M.D., two leading cardiovascular disease experts, were appointed to Acasti's newly-formed Scientific Advisory Board, lending their expertise in scientific matters and the clinical development of CaPre.

#### ***Financial Results for the Three-month Period Ended February 28, 2017 Compared to Three-month Period Ended February 29, 2016***<sup>1</sup>

- **Net loss** for the three-month period ended February 28, 2017 was \$2.6 million or \$0.23 loss per share, compared to \$1.9 million or \$0.18 loss per share for the three-month period ended February 29, 2016. The higher net loss for the current period was primarily due to an increase in general and administrative (G&A) expenses with the expanded executive and other headcount compared to the prior period.
- **R&D expenses** were approximately \$1.6 million for the three months ended February 28, 2017, compared to approximately \$1.7 million for the same period in 2016. This \$0.1 million decrease is composed of an increase of \$0.2 million on critical clinical and production scale-up spending offset by a \$0.3 million prior-year, one-time intangible asset impairment expense.
- **G&A expenses** were approximately \$1.0 million for the current three-month period ended February 28, 2017, compared to approximately \$0.4 million for the same period in fiscal year 2016. The net increase was mainly attributable to \$0.4 million in expense increases for the expanded executive, finance and accounting staff headcount and \$0.2 million incremental expenses for the reactivated investor and public relations programs.

#### ***Thirteen-month Period Ended March 31, 2017 Compared to the Year Ended February 29, 2016***

- **Net loss** for the thirteen-month period ended March 31, 2017 was \$11.2 million or \$1.01 loss per share, compared to \$6.3 million or \$0.59 loss per share for the year ended February 29, 2016. The \$4.9 million increase was primarily due to twelve-month changes combined with the incremental one-month period net loss of \$0.8 million. The

twelve-month changes included the impact of the \$3.4 million reduction in net financial income of the prior period transitioning to a net financial expense for the current period and \$1.2 million in increased G&A expenses offset by a \$0.3 million reduction in R&D expenses. The \$3.4 million increased net financial expenses resulted from a \$2.2 million change in the fair value of the warrant liabilities and the \$1.2 million transition from an exchange rate gain in the prior year to an exchange rate loss in the current period.

- **R&D expenses** were \$7.7 million for the thirteen-month period ended March 31, 2017, or slightly higher than the \$7.6 million for the year ended February 29, 2016. The net increase resulted primarily from the incremental one-month of R&D expenses which totaled \$0.4 million for March 2017 offset by the non-recurring \$0.3 million prior-year intangible asset impairment expense. Additionally, while being offset by other reduced project expenses, increased salaries and benefits for the expanded R&D team, led by the full-time dedicated management (only part time in prior years) needed for the company to continue its pharmaceutical process and analytical development and chemistry manufacturing scale-up, was implemented as planned on Acasti's previously announced timeline.
- **G&A expenses** were \$3.6 million for the thirteen-month period ended March 31, 2017, compared to \$2.0 million for the year ended February 29, 2016. The increase was primarily attributable to a \$0.6 million net increase in compensation expenses (including a \$0.2 million stock-based compensation increase) offset by a \$0.3 million reduction in the Neptune administrative fees. This increased expense was incurred for the added new full-time executive and managerial headcount to lead the development and implementation of the company's business and commercialization strategy while also operating a more independent public company back office. This increase was also represented by \$0.4 million in increased professional fees for investor and public relations programs and business development expenses, and \$0.3 million for the incremental one-month period expenses.
- **Cash Flows** - As previously disclosed, with cash and cash equivalents of \$9.8 million as of March 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 reasonable expectation that the company should be able to raise additional funds.

### ***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.

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, risks related to timing and possible difficulties, delays or failures in the Company'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; ; the company's ability to achieve its publicly announced milestones on time; the company'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 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.

<sup>1</sup> The annual audited financial statements 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).

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