

June 27, 2018



## **Acasti Pharma Business Update for the Fourth Quarter and Fiscal 2018**

*Patient enrollment in the two TRILOGY Phase 3 studies is progressing as planned: 463 patients enrolled and 41 patients randomized at 110 clinical sites as of June 26<sup>th</sup>*

*Phase 3 topline results tracking on schedule to be reported by the end of 2019*

*Public offering completed in May 2018 with gross proceeds of CAD\$11.5M*

*Brian Groch appointed as Chief Commercial Officer to drive global commercialization strategy including US launch planning and execution, and partnering activities in the rest of the world*

*Partnering discussions progressing in several territories*

LAVAL, Québec, June 27, 2018 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (NASDAQ:ACST) (TSX-V: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 provided a business update and announced its operating and financial results for the fourth quarter and fiscal year ending March 31, 2018. All amounts are in Canadian dollars.

Jan D'Alvise, president and CEO of Acasti Pharma, commented, "Fiscal 2018 was a transformative year for the Company, culminating in the initiation of our pivotal Phase 3 program ("TRILOGY") to demonstrate the effectiveness of CaPre in lowering triglyceride levels (TGs) in patients with severe hypertriglyceridemia (HTG), as well as the potential to improve these patients' broader lipid profile. If our phase 3 data replicates our phase 2 results, it could position CaPre as best-in-class in the marketplace. I am pleased to report that as of June 26<sup>th</sup>, 2018 we had reached the 35% enrollment milestone, with 463 patients enrolled, and 41 patients randomized at 110 clinical sites across North America that continue to actively screen and enroll patients. We remain on track to obtain topline data from TRILOGY by the end of 2019. Notably, we also recently completed a successful public offering, which generated over \$11.5 million in gross proceeds with the over-allotment fully exercised."

"At the same time, we continue to evaluate and explore a variety of potential commercialization partnerships due to the growing interest in CaPre as a Phase 3 asset. This interest was clearly evident at the Biotech Showcase at JP Morgan in January 2018, the ChinaBIO meeting in Suzhou China in May 2018, and the BIO International Convention in Boston in June 2018. While we continue to advance our discussions with several potential partners in China, in order to maximize shareholder value, we have kept our options open with a view to reaching a deal with the best possible commercialization partner

there. Active partnering discussions are on-going with companies in other parts of the world as well.”

“Acasti participated in several international conferences throughout the fiscal year, which reinforced the growing global interest in CaPre. The presentations highlighted the clinical data on CaPre, and compare CaPre’s safety and efficacy profile with commercially available omega-3 prescription drugs. These conferences were excellent venues for introducing physicians to the unique benefits of CaPre as a potential new therapeutic tool, and our presentations were very well received. The scientific and clinical team have showcased CaPre at the following conferences: the National Lipid Association Scientific Sessions in Philadelphia; the International Academy of Cardiology Annual Scientific Sessions; the 22nd World Congress on Heart Disease in Vancouver; and the International Atherosclerosis Meeting in Toronto.”

“Throughout fiscal 2018, Acasti continued to expand its IP portfolio. Additional composition of matter and method of use patents were granted in various territories including Canada, Taiwan, Australia, and South Korea. These new patents help to safeguard valuable potential market expansion opportunities and support our global commercial strategies as well as the related ongoing partnering and licensing activities.”

#### **Recent Developments:**

- **As of June 26<sup>th</sup>, 110 clinical sites have been activated, 463 patients have been enrolled and 41 patients have been randomized for the CaPre TRILOGY 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 active pharmaceutical ingredient (API) and CaPre were manufactured during the fourth quarter, enabling Acasti to continue to accumulate the CaPre and placebo inventory required to support the TRILOGY trials.
- **Acasti hosted a well-attended investigators meeting for the TRILOGY Phase 3 studies** on April 20-21, 2018 in Fairfax, VA. The aim of the investigators meeting was to ensure that the clinical studies are conducted in compliance with the clinical study protocol, guidelines and applicable regulations. Approximately 200 attendees participated in this meeting which gathered physicians, study nurses and study coordinators representing 90 of the TRILOGY clinical sites together with the clinical team of Acasti, the Company’s contract research organization, and the lead Principal Investigator for the TRILOGY studies, Dariush Mozaffarian, M.D., Dr.P.H. who also presented at this meeting. 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.
- **Financing completed to support CaPre Phase 3 Program:** In May 2018, Acasti closed a Canadian public offering of common shares together with accompanying warrants for gross proceeds of \$11.5 million, including a full exercise of the over-allotment option. 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 randomization, 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.

- **Senior management:** Brian Groch was appointed as Chief Commercial Officer and brings over 25 years of senior experience in the healthcare and life science industries, including product commercialization, developing and executing global sales strategies, business development, and operations. Mr. Groch will drive global commercialization strategy including US launch planning and execution and partnering activities in the rest of the world. Mr. Laurent Harvey, VP of Clinical and Non-Clinical Affairs, announced he will resign effective July 9, 2018. With planning of the TRILOGY program completed and enrollment progressing according to schedule, we do not plan to replace Mr. Harvey as we have a strong clinical team in place that is well supported by our CRO.
- **Board membership:** Mr. Donald Olds was appointed as a new, independent director in April 2018 and was also appointed to each of the Audit Committee and the Governance & Human Resources Committee. Mr. Olds is an experienced biotech senior executive and director, and is currently the CEO of the NEOMED Institute, located in Montreal, Quebec. With Mr. Olds joining the Audit Committee, Acasti regained compliance with Nasdaq Listing Rule 5605(c), which requires that a company's Audit Committee be comprised of at least three independent directors.

#### **Fourth Quarter and Annual FY 2018 Financial Results<sup>1, 2</sup>:**

- **Net loss** for the quarter ended March 31, 2018 was \$8.1 million or \$0.32 per share, compared to a net loss of \$2.6 million or \$0.23 per share for the three-month period ended February 28, 2017. The higher net loss was primarily due to the planned increase in research and development expenses ("R&D") for the TRILOGY Phase 3 program. The net loss for the year ended March 31, 2018 was \$21.5 million or \$1.23 per share, compared to a thirteen-month net loss of \$11.2 million or \$1.01 per share for the thirteen-month period ended March 31, 2017, also driven by the planned increase in R&D expenses as well as the \$1.1 million in financing-related expenses offset by the additional month of expenses in the prior year.
- **R&D expenses** were \$6.1 million for the quarter ended March 31, 2018, up from \$1.6 million in the three months ended February 28, 2017. The \$4.5 million increase was primarily attributable to a \$4.3 million increase in clinical research contracts. The increased contract research expense primarily resulted from activities associated with Acasti's clinical research organization and contract manufacturing activities to support the Phase 3 clinical program. R&D expenses were \$15.7 million for the year ended March 31, 2018, up from \$7.7 million for the thirteen-month period ended March 31, 2017, also resulting primarily from increased Phase 3 clinical program contract expenses offset by the additional month of R&D expenses in the prior year.
- **General and Administrative ("G&A") expenses** were \$1.3 million for the quarter ended March 31, 2018, compared to \$1.0 million for the three months ended February 28, 2017. The net increase was mainly attributable to a \$0.1 million increase in expenses related to the added full-time executive and accounting staff and a \$0.2 million increase in legal and accounting fees. G&A expenses were \$4.0 million for the year ended March 31, 2018, up from \$3.6 million for the thirteen-month period ended March 31, 2017. The \$0.4 million net 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 offset by the additional month of G&A expenses in the prior year.
- **Cash flows** – Cash and cash equivalents totaled \$8.2 million as of March 31, 2018,

and increased with \$11.5 million in gross proceeds from the May 2018 underwritten public offering in Canada with full exercise of the overallotment option. As previously disclosed, there exists a material uncertainty about the company's ability to continue as a going concern and to 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 later in 2018 to continue to finance the Phase 3 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. Acasti believes that EPA and DHA are more efficiently transported by phospholipids sourced from krill oil than the EPA and DHA contained in fish oil that are transported either by triglycerides (as in dietary supplements) or as ethyl esters in other prescription omega-3 drugs, which must then undergo additional digestion before they are ready for transport in the bloodstream. 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 may need to conduct at least one additional clinical trial to expand CaPre's indications to this segment. Acasti's strategy is to commercialize CaPre in the U.S. and the company is pursuing development and distribution 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 information" within the meaning of Canadian securities laws and "forward-looking statements" within the meaning of U.S. federal securities laws (collectively, "forward-looking statements"). 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 statements in this press release include, but are 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; CaPre's potential to become the "best-in-class" cardiovascular drug for treating severe Hypertriglyceridemia (HTG), 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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<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).

<sup>2</sup> The current periods represent the three and twelve-month periods ended March 31, 2018 and the prior periods, based on last year's change to a March year end, represent for

comparability, the three-month period ended February 28, 2017 and the thirteen-month period ended March 31, 2017 (though last year's fourth quarter of this thirteen-month period was a four-month period as disclosed in the MD&A).



Source: Acasti Pharma, Inc.