

November 14, 2018



Acasti Pharma Provides Business Update for Second Quarter of Fiscal 2019

Reports over \$52 million of cash-on-hand with Company now fully funded beyond completion of the TRILOGY Phase 3 studies

Both TRILOGY studies surpass 90% enrollment and remain on track to report topline results in 2019

Acasti management to host conference call at 11AM ET today

LAVAL, Québec, Nov. 14, 2018 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti or the "Company") (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 fiscal second quarter ended September 30, 2018. All amounts are in Canadian dollars.

Jan D'Alvise, president and CEO of Acasti Pharma, commented, "Following our recent capital raises in the U.S. and Canada, I am pleased to report as of November 1, we had over \$52 million of cash on hand. Based on management's current projections, we are now fully funded to complete our TRILOGY Phase 3 studies. This capital will also enable us to initiate work on our New Drug Application (NDA) assuming our Phase 3 is successful. It will also fund expanded business development activities, and allow us to initiate several important prelaunch marketing programs in the U.S."

Acasti's two TRILOGY Phase 3 studies remain on track to complete enrollment this year. As of October 31, 2018, TRILOGY had surpassed 90% enrollment with greater than >50% of patients randomized at more than 150 clinical sites across the U.S., Canada, and Mexico. The Company continues to project that the studies will be completed on schedule in the second half of calendar 2019, with topline results targeted to report before the end of calendar 2019.

The recent results of Amarin's REDUCE-IT outcome trial demonstrated a meaningful reduction in major adverse CV events (MACE) in the patient population treated with Vascepa as compared to placebo. Acasti believes that these results further validate the importance of therapeutic omega-3 (OM3) products for patients with elevated triglycerides (TGs), and together with Astra Zeneca's pending STRENGTH trial, could hold the potential to expand the addressable market to the roughly 36 million patients with high triglycerides (blood levels between 200 – 499 mg/dL)¹.

"We remain confident that CaPre has the potential to become the best-in-class OM3 for the treatment of severe hypertriglyceridemia (blood levels above 500 mg/dL) based on the data from our earlier trials, and we are currently seeking to replicate and expand on this data in our TRILOGY Phase 3 program," further commented Ms. D'Alvise. "An important differentiator of CaPre versus other therapeutic OM3 products is that unlike our competitors, CaPre does not require a fatty meal to improve bioavailability and absorption. We believe that CaPre's proprietary formulation combining both EPA and DHA, delivered as a mixture of free fatty acids and bound to phospholipids, makes them more readily absorbed by the body. Consequently, we believe patients taking CaPre can remain on their physician recommended low fat diet and still get full efficacy benefit. Furthermore, we believe it is the combination of EPA, DHA and phospholipids in CaPre's composition that is responsible for CaPre's "trifecta effect". In our prior studies, CaPre showed a significant reduction of triglycerides (TG) and non-high-density lipoprotein cholesterol (non-HDL-C) levels in the blood of patients with mild to severe HTG, and showed no safety concerns. Unlike other OM3 therapeutic products, CaPre also showed the potential to reduce LDL-C ("bad cholesterol"). We believe that the phospholipids in CaPre not only help to improve the absorption, distribution, and metabolism of OM3s, but could also decrease the synthesis of LDL-C in the liver, impede cholesterol absorption, and stimulate lipid secretion from bile. CaPre has also shown the potential to increase high-density lipoprotein cholesterol (HDL-C), at the therapeutic dose of 4 grams/day in our Phase 2 studies. Furthermore, patients in our Phase 2 studies showed a significant reduction of HbA1c, indicating that CaPre, again due to its unique OM3/phospholipid composition, may improve long-term glucose metabolism."

Recent Developments:

- On September 24, 2018, the Company announced that Mr. Jean-François Boily was appointed as the Vice President of Finance and Mrs. Linda O’Keefe, the Company’s former Chief Financial Officer, announced her retirement.
- On October 11, 2018, the Company announced the closing of its underwritten public offering in the United States of 19,090,000 Common Shares (which includes the exercise in full by the underwriters of their over-allotment option to purchase 2,490,000 additional Common Shares, at the same public offering price of US\$1.00 per Common Share for gross proceeds to the Company of \$24.7 million (US\$19.1 million) generating net proceeds to the Company of approximately \$22.5 million (US\$17.4 million).
- On October 23, 2018, the Company announced the closing of its underwritten public offering in Canada of 21,562,000 Common Shares (which includes the exercise in full by the underwriters of their over-allotment option to purchase 2,812,500 additional Common Shares), at the same public offering price of \$1.28 per Common Share for gross proceeds to the Company of \$27.6 million generating net proceeds to the Company of approximately \$25.4 million. Based on management’s current projections, Acasti believes that the total of approximately \$47.9 million in net proceeds from the two October 2018 public offerings, together with existing cash, will fully fund the Company’s operations beyond the completion of our Phase 3 clinical trials.

Second Quarter 2019 Financial Results:

- **Loss from operating activities** for the second quarter ended September 30, 2018 was \$10.4 million, compared to a loss from operating activities of \$4.4 million for the quarter ended September 30, 2017, which was primarily due to the planned increase of approximately \$6.0 million related to research and development expenses (“R&D”) for the TRILOGY Phase 3 program.
- **Net loss** for the second quarter ended September 30, 2018 was \$22.7 million or \$0.62 per share, compared to a net loss of \$4.5 million or \$0.31 per share for the quarter ended September 30, 2017. The higher net loss of \$18.2 million was primarily due, in addition to the \$6.0 million R&D above, to \$12.2 million in non-cash financial expenses due mostly to an increase in loss related to the change in fair value of the derivative warrant liabilities.
- **R&D expenses** were \$9.1 million for the quarter ended September 30, 2018, up from \$3.3 million in the quarter ended September 30, 2017. The \$5.8 million increase was primarily attributable to a \$6.4 million increase in clinical research contracts offset mainly by a decrease in other professional fees. The increased contract research expense primarily resulted from the planned patient enrollment and randomization activities combined with the contract manufacturing production activities to support the Phase 3 clinical program.
- **General and Administrative expenses** were \$1.3 million for the quarter ended September 30, 2018, compared to \$1.0 million for the quarter ended September 30, 2017. The net increase was mainly attributable to the expansion of business development and pre-commercialization activities and a \$0.1 million increase in stock based compensation expenses.
- **Cash flows** – Cash and cash equivalents totaled \$6.0 million as of September 30, 2018 increased by \$0.6 million compared to the quarter ended September 30, 2017. The increase was generated from gross proceeds from the May 2018 underwritten public offering in Canada with the full exercise of the over-allotment option offset with the cash used in operating activities. Based on management’s current projections, and as stated above, Acasti believes that the total of approximately \$47.9 million in net proceeds from the two October 2018 public offerings, together with existing cash, will fully fund the Company’s operations beyond the completion of our Phase 3 clinical trials. Acasti may need to raise additional capital in the future to complete the funding of its NDA preparations, and pre-commercialization activities. If Acasti does not raise additional funds, it may not be able to realize its assets and discharge its liabilities in the normal course of business. As a result, there exists a material uncertainty about the Acasti’s ability to continue as a going concern and to realize its assets and discharge its liabilities in the normal course of business.

Conference Call

Acasti will host a conference call today, Wednesday, November 14, 2018 at 11:00 AM Eastern Time to discuss the Company’s financial results for the second quarter ended September 30, 2018, as well as the Company’s corporate progress and other developments.

The conference call will be available via telephone by dialing toll free 877-407-8031 for U.S. callers or +1 201-689-8031 for international callers, or on the Company’s News and Investors section of the website: <https://www.acastipharma.com/investors/>.

A webcast replay will be available on the Company’s News and Investors section of the website (<https://www.acastipharma.com/investors/>) through February 14, 2019. A telephone replay of the call will be available approximately one hour following the call, through November 28, 2018, and can be accessed by dialing 877-481-4010 for U.S. callers or +1 919-882-2331 for international callers and entering conference ID: 39708.

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 third party outcomes studies. Acasti may need to conduct at least one additional clinical trial to support FDA approval of a supplemental New Drug Application 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.

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," "targeted" 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), Acasti's ability to commercially launch CaPre, 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, on EDGAR at www.sec.gov/edgar/shtml, and on the investor section of Acasti's website at 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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¹ The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease, 2011

Source: Acasti Pharma, Inc.