

February 14, 2019



Acasti Pharma Provides Business Update for the Third Quarter of Fiscal 2019

Planned Enrollment targets achieved in both TRILOGY studies with over 74% of patients randomized at more than 150 clinical sites

24% of randomized patients have already completed the studies

On track to report topline results by end of 2019

Fully funded beyond completion of Phase 3 studies

Acasti management to host conference call at 1 PM ET today

LAVAL, Québec, Feb. 14, 2019 (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 third quarter ended December 31, 2018. All amounts are in Canadian dollars.

Jan D'Alvise, president and CEO of Acasti Pharma, commented, "We continue to make rapid progress on our TRILOGY Phase 3 trials, and based on current trends we remain on track to report topline results by the end of this year. Importantly, we achieved our enrollment targets in December 2018, however additional patients will continue to be enrolled through the first calendar quarter of 2019 to attain final randomization targets as needed. We now have more than 74% of patients randomized at more than 150 clinical sites across the U.S., Canada, and Mexico. Following our recent capital raises in the U.S. and Canada, as of December 31, 2018 we have over \$45.6 million of cash on hand, and based on management's projections, we are funded beyond completion of our Phase 3 trials, including funding to initiate work on our New Drug Application (NDA) assuming our Phase 3 is successful, as well as expanded business and US commercial launch activities."

"I am also pleased to report we recently announced a Certificate for a European Patent has been issued by the European Patent Office that is valid until 2030. This patent contains broad claims, and is in addition to our 20 plus patents allowed in major countries around the rest of the world, which provide us with equivalent claims and strong protection in each of our key markets. We believe that CaPre's proprietary and patented 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. As a result, CaPre does not require a fatty meal to improve bioavailability and absorption unlike currently marketed prescription omega-3s, which we believe would allow patients taking CaPre to remain on their physician recommended low fat diet and still get full efficacy benefit. The phospholipids in CaPre may not only help to improve the absorption, distribution, and metabolism of omega-3s, but could

also decrease the synthesis of LDL-C in the liver, impede cholesterol absorption, and stimulate lipid secretion from bile. Given these combined benefits, we believe the combination of EPA, DHA and phospholipids in CaPre's composition contribute to CaPre's potential "trifecta effect," by: (a) lowering triglycerides; (b) reducing non-high-density lipoprotein cholesterol (non-HDL-C) levels including LDL-C ("bad cholesterol"); and (c) increasing high-density lipoprotein cholesterol (HDL-C) ("good cholesterol"), as demonstrated at the therapeutic dose of 4 grams/day in our Phase 2 studies. In addition, patients in our Phase 2 studies showed a significant reduction of HbA1c, indicating that CaPre, again due to its unique omega-3/phospholipid composition, may improve long-term glucose metabolism. As a result, we remain confident CaPre has the potential to become the best-in-class omega-3 for the treatment of severe hypertriglyceridemia (blood levels above 500 mg/dL)."

Recent Developments:

- **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 CDN\$1.28 per Common Share for gross proceeds to the Company of \$27.6 million (US\$ 21.3 million) generating net proceeds to the Company of approximately \$25.4 million (US\$ 19.6 million).
- **On January 9, 2019**, the Company announced a Certificate for a European Patent had been issued by the European Patent Office. The granted patent is valid until 2030 and relates to a concentrated phospholipid composition and method of using the same for modulating blood lipids. This patent was validated in Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, United Kingdom, Italy, Netherlands, Norway, Portugal and Sweden.
- **As of February 12, 2019**, more than 74% of the required total patients for the two studies have been randomized, and more than 24% of patients who had previously been randomized in the TRILOGY program have already completed their 6 month treatment plans. This progress further supports management's confidence in announcing topline results before the end of calendar 2019.

Third Quarter Fiscal 2019 Financial Results:

- **Loss from operating activities** for the third quarter ended December 31, 2018 was \$10.7 million, compared to a loss from operating activities of \$5.2 million for the quarter ended December 31, 2017. The approximately \$5.5 million increase was related to the planned research and development expenses ("R&D") for the TRILOGY Phase 3

program.

- **Net loss** for the third quarter ended December 31, 2018 was \$4.6 million or \$0.07 per share, compared to a net loss of \$6.1 million or \$0.40 per share for the quarter ended December 31, 2017. The lower net loss of \$1.5 million was primarily due to a \$7.0 million increase in financial income due mostly to a gain related to the reduction in value of the warrant derivative liability offset primarily from the \$5.3 million increase in planned R&D expenses.
- **R&D expenses** were \$9.6 million for the quarter ended December 31, 2018, up from \$4.3 million in the quarter ended December 31, 2017. The \$5.3 million increase was primarily attributable to a \$5.8 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 \$1.2 million for the quarter ended December 31, 2018, compared to \$0.9 million for the quarter ended December 31, 2017. The net increase was mainly due to the expansion of the administrative staff and business development and US commercial launch activities.
- **Cash flows** – Cash and cash equivalents of \$28.9 million and marketable securities of \$16.7 million totaled \$45.6 million as December 31, 2018 increased by \$37.4 million compared to the quarter ended December 31, 2017. The increase was generated from gross proceeds from the May 2018 underwritten public offering in Canada and the two October public offerings with the full exercise of the over-allotment options 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 public offerings, together with existing cash, will fully fund the Company's operations beyond the completion of our Phase 3 clinical trials. Acasti will need to raise additional capital in the future to complete the funding of its NDA preparations, and US commercial launch 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, Thursday, February 14, 2019 at 1:00 PM Eastern Time to discuss the Company's financial results for the fiscal third quarter ended December 31, 2018, as well as the Company's corporate progress and other developments.

The conference call will be available via telephone by dialing toll free 866-682-6100 for U.S. callers or +1 862-298-0702 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 May 14, 2019. A telephone replay of the call will be available approximately one hour following the call, through February 28, 2019, 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: 42051.

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, which 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. Clinically, the phospholipids may not only improve the absorption, distribution, and metabolism of omega-3s, but they may also decrease the synthesis of LDL cholesterol in the liver, impede or block cholesterol absorption, and stimulate lipid secretion from bile. In two Phase 2 studies, CaPre achieved a statistically significant reduction of triglycerides and non-HDL cholesterol levels in patients across the dyslipidemia spectrum from patients with mild to moderate hypertriglyceridemia (patients with TG blood levels between 200mg/dl and 500mg/dl) to patients with severe hypertriglyceridemia (those with TG levels above 500mg/dl). Furthermore, in the Phase 2 studies, CaPre demonstrated the potential to actually reduce LDL, or "bad cholesterol", as well as the potential to increase HDL, or "good cholesterol", especially at the therapeutic dose of 4 grams/day. The Phase 2 data also showed a significant reduction of HbA1c at a 4 gram dose, suggesting that due to its unique omega-3/phospholipid composition, CaPre may actually improve long-term glucose metabolism. Acasti's TRILOGY 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 <https://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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