

June 26, 2019



## **Acasti Pharma Provides Fiscal 2019 Year-End Business Update**

*Both Phase 3 TRILOGY studies at 100% randomization*

*>60% of patients have completed the 6-month trial*

*Release of topline results remain on track*

*Fully funded beyond completion of Phase 3 studies*

*Conference call to be held today, Wednesday, June 26<sup>th</sup> at 1 PM ET*

LAVAL, Québec, June 26, 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<sup>®</sup> (omega-3 phospholipid) for the treatment of severe hypertriglyceridemia (HTG), today provided a business update and announced its financial results for the fiscal year ending March 31, 2019. All amounts are in Canadian dollars.

Jan D'Alvise, president and CEO of Acasti Pharma, commented, "Fiscal 2019 was an eventful year for the Company as we achieved several key milestones related to our ongoing Phase 3 clinical trials, which remain on schedule and within budget. We recently announced that we had achieved 100% patient randomization in both TRILOGY clinical studies, and more than 60% of patients have now completed the trial. As a result, we remain on track to report topline results for our primary endpoint of lowering triglycerides for TRILOGY 1 in December 2019, and for TRILOGY 2 in January 2020. In addition to our preliminary topline data, we will seek to present the full data set, which will include results for our key secondary and exploratory endpoints of interest such as LDL-C, VLDL, HDL-C and HbA1c, as a late breaker presentation at the American College of Cardiology meeting at the end of March 2020."

The Company had \$34.4 million of cash, cash equivalents and marketable securities as of March 31, 2019. With clinical activities now decelerating, management believes Acasti is sufficiently capitalized beyond completion of the Phase 3 trials. This includes funding to continue work on the New Drug Application (NDA) for CaPre, which management plans to submit to the FDA mid-2020, assuming Phase 3 is successful, as well as on-going business and US commercial launch activities. Discussions continued in Q4 with a number of major pharma companies for commercialization partnerships in key countries around the globe, and management expects those discussions to gain momentum next year after Phase 3 results are announced, assuming positive results. Management is also exploring a variety of strategic and non-dilutive funding options to further extend the Company's current cash runway.

Jan D'Alvise continued, "Given the positive results we saw from our Phase 2 trials in a total of 675 patients, we eagerly await the completion of the results from our two TRILOGY clinical studies. It is important to note some key differences that we believe have optimized the design of our TRILOGY studies compared to our Phase 2 studies. The approximately 500 severe HTG patients enrolled in our TRILOGY Phase 3 clinical studies all have much higher baseline triglyceride levels (above 500 mg/dl) versus our Phase 2 studies, where most had baseline triglycerides significantly below 500 mg/dl. Typically, the higher the baseline level, the greater the potential for lowering triglycerides with a therapeutic omega-3. Furthermore, patients randomized to CaPre in TRILOGY will receive 4 grams per day and remain on drug for 6 months, while our phase 2 studies included patients receiving a range of doses from 1 gram, 2 grams and 4 grams per day for only 8 to 12 weeks. We generally saw a dose response in these Phase 2 studies, where the higher the CaPre dose, the greater the triglyceride reduction. All of these factors give us further confidence that CaPre has the potential to meet or exceed the target primary endpoint of reducing triglycerides by 20% compared to placebo. Given that our two Phase 3 protocols are very similar in design, this will also enable us to combine data from both studies to further explore the efficacy of CaPre in a variety of important patient subgroups, which we hope will further validate what we refer to as the "Trifecta Effect" that we saw in Phase 2. In addition to hypertriglyceridemia, data from Acasti's Phase 2 studies indicated that CaPre may have a positive effect on other major lipid markers such as VLDL, LDL-C, and HDL-C, diabetes and other inflammatory diseases, and this is being further explored in the TRILOGY Phase 3 program. Based on the results, Acasti may also seek to identify new potential indications for CaPre that may be appropriate for future studies and claim expansion."

The CaPre bioavailability bridging study was recently published in a leading peer reviewed journal, which illustrated the superior absorption of CaPre compared to LOVAZA, an omega-3 ethyl ester. Since patients with severe HTG should adhere to a low-fat diet, these findings suggest preserved exposure and perhaps retained efficacy, in patients taking CaPre. As a result, management believes that CaPre has the potential to become the best-in-class omega-3 for the treatment of severe HTG.

Based on recent third-party outcome data, management also believes the potential exists to expand CaPre's initial indication to the roughly 70 million patients with elevated triglycerides in the mild to moderate range (e.g. 150 – 499 mg/dl), although this would likely require at least one additional study.

Throughout the year, the Company also continued to expand the IP portfolio for CaPre. In May 2019, Notices of Allowance for additional patents were received for both composition of matter and method of use from the Mexican, Chilean and Israeli Patent Offices. This follows broad composition-of-matter and method of use claims that were awarded by the European Patent Office earlier this year. In addition, Acasti just received Notice of Allowance for its second Chinese patent, which has broadened our existing claims by covering a composition containing 50-70% phospholipids. The granting of these additional patents provides long-term protection of Acasti's products in important markets, which management believes will support ongoing global partnering and licensing activities.

#### **Recent Developments:**

- **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.

- **On February 21, 2019**, the Company announced it had been recognized by the TSX Venture Exchange in its “2019 Venture 50,” a ranking of the strongest companies on TSX Venture Exchange by share price, trading volume and market capitalization.
- **On April 1, 2019**, the Company announced the publication of the CaPre bioavailability study in the March 2019 issue of Journal of Clinical Therapeutics, a leading peer-reviewed journal in the field of clinical pharmacology and therapeutics. Acasti’s open-label, randomized, four-way, cross-over, bioavailability study compared CaPre, given as a single dose of 4 grams in fasting and fed states, with the approved hypertriglyceridemia drug LOVAZA (omega-3-acid ethyl esters or OM3-EE) in 56 healthy volunteers. Among subjects in the fasting state, CaPre demonstrated better bioavailability than LOVAZA, as measured by blood levels of EPA and DHA.
- **On April 1, 2019**, the Company announced it had reached 100% of the required total randomized patients for TRILOGY 1 with no severe adverse events associated with CaPre and a lower drop-out rate than anticipated.
- **On May 15, 2019**, the Company announced that it has received Notices of Allowance for both composition of matter and method of use patents by the Mexican, Chilean and the Israeli Patent Offices. The granted patents are valid until 2030 and relate to a concentrated phospholipid composition and method of using the same for modulating blood lipids.
- **On June 3, 2019**, the Company announced that its TRILOGY 2 trial achieved 100% patient randomization. The fact that both studies have reached full randomization means that the “last patient, last visit” in the TRILOGY 1 trial is on track to take place in November, and the “last patient, last visit” in the TRILOGY 2 trial is on track to take place in December. It is then anticipated to take approximately 1 month for data clean-up prior to moving to database lock. Once the database is locked, the Company expects topline results for TRILOGY 1 to be released in December 2019 and TRILOGY 2 to be released in January 2020.
- **On June 24, 2019**, the Company announced that it has received Notice of Allowance from the Chinese Patent Office for a new patent covering both composition of matter and methods of using the same for modulating blood lipids. This is the second patent to be allowed in China, and both patents are valid until 2030.

#### **Annual FY 2019 Financial Results:**

- **Net loss** for the year ended March 31, 2019 was \$51.6 million or \$0.95 per share, compared to a net loss of \$21.5 million or \$1.23 per share for the year ended March 31, 2018. The higher net loss was primarily due to the \$24 million of planned increase in research and development expenses (“R&D”) for the TRILOGY Phase 3 program and \$6 million in non-cash, financial expenses related to increased value of the

warrant derivative liability.

- **R&D expenses** were \$38.4 million for the year ended March 31, 2019, up from \$15.7 million for the year ended March 31, 2018. The \$22.7 million increase was primarily attributable to a \$22.5 million rise in clinical research contracts. The increased contract research expense primarily resulted from Phase 3 CRO contract expenses and research contracts from the planned scale-up of CaPre manufacturing activities for the year ended March 31, 2019.
- **General and Administrative (“G&A”) expenses** were \$6.6 million for the year ended March 31, 2019, up from \$4.0 million for the year ended March 31, 2018. The \$2.6 million net increase was primarily attributable to \$1.0 million in compensation expense paid in shares as a legal settlement to the former CEO, with the remainder due to increased professional and legal fees, an increase in salaries and benefits related to the added full-time business development and commercialization staff, and pre-launch market development activities.
- **Cash flows.** As at March 31, 2019, Acasti had total cash of \$34.4 million, an increase of \$26.2 million over last year, due to net proceeds from the May and October public offerings, partially offset by the cash used in operating activities. Acasti believes that the current cash on hand will fully fund the Company’s operations beyond the completion of the Phase 3 clinical trials for CaPre. Acasti will need to raise additional capital in the future to complete the funding of its NDA preparations and US commercial launch activities, which could be in the form of dilutive and/or non-dilutive financings. 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.

### **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 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.

## **Investor Conference Call**

The Company will host a conference call at 1:00 PM Eastern Time today, Wednesday, June 26, 2019, to discuss the Company's financial results for the fourth quarter and year-ended March 31, 2019, 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 September 26, 2019. A telephone replay of the call will be available approximately one hour following the call, through July 10, 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: 49452.

## **About Acasti Pharma**

Acasti Pharma is a biopharmaceutical innovator advancing a potentially best-in-class cardiovascular drug, CaPre<sup>®</sup> (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. Acasti Pharma 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 Pharma 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 Pharma's strategy is to commercialize CaPre in the U.S. and Acasti Pharma 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); CaPre's potential to meet or exceed the target primary endpoint of reducing triglycerides by 20% compared to placebo, 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.*

**Acasti Contact:**

Jan D'Alvise  
Chief Executive Officer  
Tel: 450-686-4555  
Email: [info@acastipharma.com](mailto:info@acastipharma.com)  
[www.acastipharma.com](http://www.acastipharma.com)

**U.S. Contact:**

Crescendo Communications, LLC  
Tel: 212-671-1020  
Email: [ACST@crescendo-ir.com](mailto:ACST@crescendo-ir.com)



Source: Acasti Pharma, Inc.