

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): April 30, 2020

ACASTI PHARMA INC.

(Exact Name of Registrant as Specified in Charter)

QUEBEC, CANADA
(State or Other Jurisdiction of Incorporation)

001-35776
(Commission File Number)

98-1359336
(I.R.S. Employer Identification Number)

**545 Promenade du Centropolis
Suite 100
Laval, Québec
Canada H7T 0A3**
(Address of Principal Executive Offices) (Zip Code)

450-686-4555
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, no par value per share	ACST	NASDAQ Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On April 30, 2020, Acasti Pharma Inc. (the “Company”) issued a press release announcing that the Company has submitted its briefing package on April 29, 2020 to the Food and Drug Administration (the “FDA”) for review. The Company is currently awaiting comments and expects a formal response from the FDA on or before June 30, 2020. As previously reported, the Company filed its meeting request with the FDA at the end of March and this briefing package is now intended to provide the FDA with a review of the relevant TRILOGY 1 data and audit findings, with the objective to gain alignment on the interpretation of the TRILOGY 1 results and implications for TRILOGY 2. The Company also announced in the press release that it has received notice of issuance of a composition of matter patent to be awarded by the Intellectual Property Office in Hong Kong. This new patent grants claims for any composition containing EPA and DHA, where at least 50% of the composition consists of phospholipids.

On April 30, 2020, this press release was filed with the Canadian securities regulatory authorities in Canada on the System for Electronic Document Analysis and Retrieval. A copy of this press release is attached as Exhibit 99.1 hereto.

The information provided under this Item (including Exhibit 99.1, attached hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits****Exhibit No. Description**

99.1 [Press Release dated April 30, 2020.](#)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ACASTI PHARMA INC.

Date: April 30, 2020

By: /s/ Jan D'Alvise
Jan D'Alvise
Chief Executive Officer

April 30, 2020



Acasti Pharma Announces Submission of TRILOGY 1 Briefing Package to FDA

FDA response expected on or before June 30, 2020

Acasti also received notice of issuance of a Composition of Matter Patent in Hong Kong

LAVAL, Quebec, April 30, 2020 (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 announced that it submitted its briefing package on April 29, 2020 to the Food and Drug Administration (FDA) for review. The Company is currently awaiting comments, and expects a formal response from the FDA on or before June 30, 2020.

As previously reported, Acasti filed its meeting request at the end of March, and this briefing package is now intended to provide the FDA with a review of the relevant TRILOGY 1 data and audit findings, with the objective to gain alignment on the interpretation of the TRILOGY 1 results and implications for TRILOGY 2. The Company will also seek the FDA’s input on Acasti’s proposed revisions to the pre-specified TRILOGY 2 statistical analysis plan (SAP), and explore and hopefully reach agreement on a plan for pooling the data from TRILOGY 1 and TRILOGY 2 to support an NDA filing. Acasti continues to remain blinded to the TRILOGY 2 results, and intends to update the statistical analysis plan (SAP) with these revisions if the FDA agrees.

Jan D’Alvise, President and CEO of Acasti Pharma, commented, “We have submitted our briefing package to the FDA for their review, and are now awaiting their formal response. We remain optimistic that we may still have a viable path toward filing an NDA. We look forward to the FDA’s feedback on our briefing package, and expect that they will provide valuable guidance on the next steps to be taken towards the unblinding of TRILOGY 2. We will provide more information about our TRILOGY 1 findings, and the FDA’s response to our briefing package and our questions after we get it.”

Acasti also announced today that it has received notice of issuance of a composition of matter patent to be awarded by the Intellectual Property Office in Hong Kong. This new patent grants claims for any composition containing EPA and DHA, where at least 50% of the composition consists of phospholipids.

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 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 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.

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; CaPre’s potential to become the “best-in-class” cardiovascular drug for treating severe Hypertriglyceridemia (HTG); the timing and outcome of our requested meeting with the FDA; and Acasti’s ability to file an NDA based on the results of its TRILOGY Phase 3 program.

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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