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

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**FORM 8-K**

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**CURRENT REPORT**

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

Date of Report (Date of earliest event Reported): November 16, 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)

**3009, boul. de la Concorde East  
Suite 102  
Laval, Québec  
Canada H7E 2B5**

(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))

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.

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

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

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**Item 2.02. Results of Operations and Financial Condition.**

The following information is furnished pursuant to Item 2.02, "Results of Operations and Financial Condition."

On November 16, 2020, Acasti Pharma Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information in this Item 2.02, 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 they be deemed incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such a filing or document.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

**Exhibit No.      Description**

99.1                      Press release issued by Acasti Pharma Inc. on November 16, 2020

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**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: November 16, 2020

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



## Acasti Pharma Provides Business Update for the Second Quarter of Fiscal 2021

LAVAL, Quebec, Nov. 16, 2020 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti or the "Company") (NASDAQ: ACST – TSX-V: ACST) today provided a business update and announced its operating and financial results for the second quarter of fiscal 2021 ended September 30, 2020.

### Recent Events:

**TRILOGY 1 & 2 Topline Results.** The Company's two Phase 3 clinical trials, designated as TRILOGY 1 & 2, were designed to evaluate the efficacy, safety and tolerability of CaPre in patients with severe hypertriglyceridemia. The top-line results were announced on January 13, 2020 and August 31, 2020 respectively, and neither TRILOGY 1 nor TRILOGY 2 independently reached statistical significance, and therefore they did not meet their primary endpoint for lowering triglycerides. Although the triglyceride reduction in the CaPre arm was one of the largest seen amongst previously conducted triglyceride reduction studies, the Company will not file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for patients with severe hypertriglyceridemia and does not plan to conduct additional clinical trials for CaPre.

**Engaged Oppenheimer & Co. Inc. to Assist in Strategic Review.** On September 29, 2020, the Company announced that it had engaged Oppenheimer & Co. Inc. as its financial advisor to assist in the strategic review process. Potential strategic alternatives that may be explored or evaluated as part of this review include, but are not limited to, a merger, business combination or other strategic transaction involving Acasti and/or CaPre. There is no defined timeline for completion of the review process.

**Reduction in Headcount and Discontinuation of Substantially all Commercial and R&D Activities.** The Company initiated a plan in September 2020 to reduce personnel and expenses to preserve cash and further reduce its operations consistent with the decision to discontinue substantially all commercialization and research and development activities. The Company expects to devote significant time and resources to identifying and evaluating strategic alternatives, however, there can be no assurance that such activities will result in any agreements or transactions that will enhance shareholder value.

Jan D'Alvise, Chief Executive Officer of Acasti, commented, "We remain committed to maximizing value for our shareholders, and as previously disclosed, we are actively exploring and evaluating a range of strategic options. We have also taken a number of proactive steps to preserve our cash by reducing staff, discontinuing all commercialization activities and putting R&D activities on hold. This has resulted in certain one-time and non-cash charges as reflected in our financial statements this quarter. While we continue to pursue strategic alternatives, we plan to complete the full data analyses for TRILOGY as contemplated in the Statistical Analysis Plan, including the pooling of the data from TRILOGY 1 and 2. As previously disclosed, we plan to provide an update on the final TRILOGY data when feasible."

### Second Quarter of Fiscal 2021 Financial Results (US dollars):

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

- **Loss from operations** for the three months September 30, 2020 was \$7.8 million, compared to a loss from operations of \$6.3 million for the three months ended September 30, 2019. The increase was due mainly to impairment charges of \$5.3 million, \$3.7 million related to intangible assets and \$1.6 million related to production and lab equipment, offset by a reduction in R&D, general and administrative expenses, and sales and marketing expenses.
- **Net loss** for the three months ended September 30, 2020 was \$6.1 million or \$0.06 per share, compared to a net loss of \$21.2 million or \$0.25 per share for the three months ended September 30, 2019. The reduction in net loss, resulted primarily from net financial expenses decreasing to a gain of \$1.9 million for the three months ended September 30, 2020, as compared to net financial expenses of \$14.9 million for the three months ended September 30, 2019. This is due mostly to a decreased impact from the change in fair value of the derivative warrant liability as compared to the comparative fiscal quarter in 2019, caused by a proportionately higher decrease in the quarter over quarter closing share price partly offset by a reduction in the number of warrants outstanding due to exercises during the prior year.
- **R&D expenses** before depreciation, amortization and stock-based compensation expenses were \$0.8 million for the three months ended September 30, 2020, compared to \$3.3 million for the three months ended September 30, 2019. The net decrease was mainly attributable to a reduction in salaries and research contracts with the reduction in R&D activities.
- **General and Administrative expenses** before stock-based compensation expenses were \$1.1 million for the three months ended September 30, 2020, compared to \$1.1 million for the three months ended September 30, 2019. This reflects a \$0.27 million increase related to legal fees related offset by a decrease of \$0.23 million related to salaries, due to a reversal of bonus accruals.
- **Sales and Marketing expenses** before stock-based compensation expenses were \$0.02 million for the three months ended September 30, 2020, compared to \$0.66 million for the three months ended September 30, 2019. The decrease was mostly due to a reduction in professional fees as a result of a reclassification of professional and other expenses to R&D.
- **Cash flows** Cash and cash equivalents totaled \$11.6 million as of September 30, 2020, compared to \$14.2 million at March 31, 2020. Acasti believes that existing cash will fully fund the Company's operations through the second calendar quarter of 2021 or through to an eventual completion of the evaluation of strategic options, but there can be no assurance as to when or whether Acasti will complete any strategic transaction, collaboration or non-dilutive financings. If the Company cannot raise additional funds or find one or more strategic partners, it may not be able to realize its assets and discharge its liabilities in the normal course of business. As a result, there exists

substantial doubt about the Company's ability to continue as a going concern, and therefore, realize its assets and discharge its liabilities in the normal course of business.

### **NASDAQ Minimum Bid Price Rule**

On February 28, 2020, Acasti received written notification from the NASDAQ Listing Qualifications Department for failing to maintain a minimum bid price of \$1.00 per share for the preceding 30 consecutive business days, as required by NASDAQ Listing Rule 5550(a)(2) – bid price (the “Minimum Bid Price Rule”). Under NASDAQ Listing Rule 5810(c)(3)(A) – compliance period, Acasti initially had 180 calendar days to regain compliance.

On April 17, 2020, Acasti was informed that NASDAQ had granted temporary regulatory relief related to the Minimum Bid Price Rule due to the COVID-19 pandemic for all NASDAQ-listed companies and therefore extended the deadline for Acasti to regain compliance to November 9, 2020.

On November 11, 2020, Acasti was further informed that NASDAQ had granted an additional 180 calendar days, or until May 10, 2021, for Acasti to regain compliance with the Minimum Bid Price Rule.

### **Retention Agreements**

In connection with its strategic review process, the Company also announces that, upon the recommendation of the Governance and Human Resources Committee of the board of directors, it has entered into retention incentive agreements with Ms. Jan D’Alvise, the Company’s President and Chief Executive Officer, and Mr. Pierre Lemieux, the Company’s Chief Operating Officer and Chief Scientific Officer (the “Retention Agreements”).

The Retention Agreements provide that the Company will pay Ms. D’Alvise an employment retention incentive of US \$100,000 provided that she remains employed with the Company until the earlier of April 30, 2021 or the closing of a merger or like transaction with a third party.

In addition, the Retention Agreements also provide that the Company will pay each of Ms. D’Alvise and Mr. Lemieux an amount of up to US \$125,000 in the event that certain milestones are met in relation to the monetization by the Company of its assets relating to the Company’s drug candidate, CaPre.

The Company also announces the upcoming departure of Mr. Brian Groch, its Chief Commercial Officer, from his position with the Company effective December 31, 2020, until which date he is continuing in his role with Acasti. The Company would like to thank Mr. Groch for his contributions to the Company and wishes him well in his future endeavors.

### **About Acasti**

Acasti is a biopharmaceutical innovator that has historically focused on the research, development and commercialization of prescription drugs using OM3 fatty acids delivered both as free fatty acids and bound-to-phospholipid esters, derived from krill oil. OM3 fatty acids have extensive clinical evidence of safety and efficacy in lowering triglycerides in patients with hypertriglyceridemia, or HTG. CaPre, an OM3 phospholipid therapeutic, was being developed for patients with severe HTG.

### **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; the outcome of the strategic review process to explore and evaluate strategic alternatives to enhance shareholder value; and Acasti’s ability to successfully consummate a strategic transaction.*

*The forward-looking statements contained in this press release are expressly qualified in their entirety by this cautionary statement, the “Special Note Regarding Forward-Looking Statements” section contained in Acasti’s latest annual report on Form 10-K and quarterly report on Form 10-Q, which are available on EDGAR at [www.sec.gov/edgar/shtml](http://www.sec.gov/edgar/shtml), on SEDAR at [www.sedar.com](http://www.sedar.com) 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 10-K and quarterly report on Form 10-Q under the caption “Risk Factors”.*

*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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