

**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): June 22, 2021

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

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 June 22, 2021, Acasti Pharma Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended March 31, 2021. 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 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 June 22, 2021

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: June 22, 2021

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



Acasti Pharma Provides Fiscal 2021 Year-End Business Update

Update on Acquisition of Grace Therapeutics and Strategic Plans for CaPre

LAVAL, Québec, June 22, 2021 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST and TSX-V: ACST) today announced its operating and financial results for the fiscal year ended March 31, 2021, and provided an update on its plans to acquire Grace Therapeutics and the ongoing strategic process for CaPre.

As part of Acasti’s formal process to explore and evaluate a range of strategic alternatives to enhance shareholder value, management and the board evaluated dozens of companies and conducted an extensive and thorough due diligence process on several finalist candidates. Acasti’s management and board believed that Grace Therapeutics (Grace), a privately held emerging biopharmaceutical company focused on developing innovative drug delivery technologies for the treatment of rare and orphan diseases, stood out from the field of acquisition targets because of several important factors, including their diversified drug pipeline with multiple, high quality clinical assets; significant addressable market opportunities; three later stage assets with a potentially shorter timeline to key milestones; efficient and low-cost clinical and regulatory pathway; and a strong and growing intellectual property portfolio. Grace’s novel drug delivery technologies are designed to enable the rapid development of new therapies that could improve upon currently marketed compounds with known safety profiles. Grace’s most advanced drug candidates may also have a fast path to regulatory approval and commercialization via the 505(b)(2) pathway.

On May 7, 2021, Acasti announced that it had entered into a definitive agreement to acquire Grace and their pipeline of drug candidates addressing critical unmet medical needs (“Proposed Transaction”). The Proposed Transaction has been approved by the boards of directors of both companies and is supported by Grace’s shareholders through voting and lock-up agreements with Acasti. The transaction remains subject to approval of Acasti stockholders, as well as applicable stock exchanges.

Jan D’Alvise, Acasti’s chief executive officer stated, “We are very excited about the planned acquisition of Grace, as we believe their product portfolio has the potential for delivering better patient solutions with enhanced efficacy, faster onset of action, reduced side effects, and more convenient delivery with the potential to increase patient compliance. The planned merger with Grace will result in the creation of a rare and orphan disease company that we believe will allow us to not only rapidly advance their existing assets through the clinic, but also continue to develop new innovative therapies that leverage Grace’s novel drug delivery technologies. Following the merger, we expect to have more than \$60 million in cash, which should provide at least two years of operating runway and enable us to complete clinical development and file an NDA for GTX-104, and significantly advance other key drug candidates in the Grace pipeline.

In connection with the Proposed Transaction, Acasti will acquire Grace’s entire therapeutic pipeline consisting of three unique clinical stage and multiple pre-clinical stage assets supported by an intellectual property portfolio consisting of more than 40 granted and pending patents in various jurisdictions worldwide. Grace’s product candidates aim to improve clinical outcomes by applying proprietary formulation and drug delivery technologies to existing pharmaceutical compounds to achieve improvements over the current standard of care, or they could provide treatment for diseases with no currently approved therapy. Grace’s three lead programs have all received Orphan Drug Designation from the U.S. Food & Drug Administration (FDA), which could provide up to seven years of marketing exclusivity in the United States upon FDA approval of the New Drug Application (NDA), provided that certain conditions are met.

The Company has posted a presentation summarizing key highlights of the transaction, which is available on both the Acasti and Grace websites.

D’Alvise continued, “In parallel with progressing the acquisition of Grace, we have received interest and are evaluating a variety of strategic options for CaPre. We remain highly encouraged by the outlook for our overall business prospects and look forward to providing further updates to shareholders on our strategic processes as it relates to both the Grace acquisition as well as our plans for CaPre.”

Conference call and Shareholder Meeting

As previously disclosed, Acasti plans to file a Form S-4 proxy statement with the U.S. Securities & Exchange Commission (SEC), which will include detailed disclosure regarding the Proposed Transaction in the next few weeks. Following the SEC granting the Form S-4 to be effective, Acasti and Grace management plan to host an investor conference call to further discuss the anticipated benefits of the acquisition and answer investor questions. Acasti will call a shareholder meeting, which will be combined with our FY’21 AGM, to approve the transaction following the public filing of the Form S-4 proxy statement. More information will be provided on the timing and logistics for both events as soon as it is available.

Nasdaq Communication

On May 11, 2021, the Company received notice from the Nasdaq Listing Qualifications Department indicating that, based upon the Company’s non-compliance with the \$1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a) as of May 10, 2021, the Company’s shares were subject to delisting unless the Company timely requests a hearing before the Nasdaq Hearings Panel.

The Company requested and was granted a hearing before the Nasdaq Hearing Panel on June 17, 2021, which has stayed any further action by Nasdaq pending the conclusion of the hearing process. At the hearing, the Company presented a detailed plan of compliance for the Panel’s consideration, including the Company’s commitment to implement a share consolidation concurrently with the completion of its proposed

acquisition of Grace. Acasti expects to receive the Panel's decision within 30 days of the hearing and is prepared to take definitive action to regain compliance with Nasdaq's minimum bid price rule to ensure the Company's continued listing on Nasdaq.

Fiscal Year 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 operating activities** for the year ended March 31, 2021, was \$16.4 million, compared to a loss from operating activities of \$24.4 million for the year ended March 31, 2020. The change was due mainly to a reduction in R&D, general and administrative expenses, and sales and marketing expenses.
- **Net loss** for the year ended March 31, 2021, was \$19.7 million or \$0.17 per share, a decrease of \$5.8 million from the net loss of \$25.5 million or \$0.30 per share for the year ended March 31, 2020. The reduction in net loss resulted in part from a decrease in research and development expenses as the TRILOGY Phase 3 clinical program for CaPre was winding down. General and administrative expenses decreased from the comparative period due to decreased stock-based compensation. Sales and marketing expenses also decreased as a result of the termination of any CaPre commercialization activities due to the TRILOGY 2 Phase 3 clinical trial results. Furthermore, operational events related to the TRILOGY outcome resulted in an impairment of equipment, intangible and other assets of \$5.7M. The net loss was also impacted from financial expenses of \$3.3 million for the year ended March 31, 2021, as compared to net financial expenses of \$1.0 million for the year ended March 31, 2020, due mostly to the change in fair value of the warrant derivative liability.
- **R&D expenses** before depreciation, amortization and stock-based compensation expenses for the year ended March 31, 2021, totaled \$2.9 million compared to \$13.2 million for the year ended March 31, 2020. The net decrease was mainly attributable to a reduction in research contracts with the completion of the CaPre R&D activities as well as a reduction in headcount within the department.
- **General and Administration expenses** before stock-based compensation expenses for the year ended March 31, 2021, were \$4.7 million compared to \$4.6 million for the year ended March 31, 2020. This increase was mainly attributable to an increase associated with the Company's insurance policies, as well as an increase in legal fees, which was offset by a decrease in salaries.
- **Sales and Marketing expenses** before stock-based compensation expenses were \$1.1 million for the year ended March 31, 2021, compared to \$2.4 million for the year ended March 31, 2020. The decrease was mostly a result of a reduction in headcount, as well as a reduction in professional fees and other marketing activities resulting from the termination of the planned pre-launch marketing activities for CaPre.
- **Cash flows** Cash and cash equivalents totaled \$50.9 million as of March 31, 2021, compared to \$14.2 million at March 31, 2020.

Financing Activities

As previously disclosed, Acasti entered into an amended and restated ATM sales agreement on June 29, 2020 (the "Sales Agreement") with B. Riley FBR Inc., Oppenheimer & Co. Inc. and H.C. Wainwright & Co., LLC (collectively, the "Agents"), to implement an "at-the market" equity offering program under which Acasti may issue and sell from time to time its common shares having an aggregate offering price of up to \$75 million through the Agents (the "ATM Program"). Pursuant to the ATM Program, as required pursuant to the policies of the TSX Venture Exchange ("TSXV"), since the last distributions reported on March 8, 2021, Acasti issued an aggregate of 8,255,890 common shares (the "ATM Shares") over the NASDAQ Stock Market for aggregate gross proceeds to the Company of US \$5,849,567 million. The ATM Shares were sold at prevailing market prices averaging US \$0.71 per share. No securities were sold through the facilities of the TSXV or, to the knowledge of the Company, in Canada. The ATM Shares were sold pursuant to a U.S. registration statement on Form S-3 (No. 333-239538) as made effective on July 7, 2020, as well as the Sales Agreement. Pursuant to the Sales Agreement, a cash commission of 3.0% on the aggregate gross proceeds raised was paid to the Agents in connection with their services. As a result of the recent ATM sales, Acasti has a total of 208,375,549 common shares issued and outstanding as of June 22, 2021. During the three-month period ended March 31, 2021, Acasti sold an aggregate of 51,837,057 shares under the ATM Program at an average price per share of \$0.6873 for total net proceeds of \$34,495,532, and for the year ended March 31, 2021, Acasti sold an aggregate of 117,724,769 shares under the ATM Program at an average price per share of \$0.5213 for total net proceeds of \$59,332,476. No additional shares have been sold by Acasti under the ATM Program since March 2021.

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.

Cautionary Statement Regarding 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, statements relating to the timing and completion of the Proposed Transaction and benefits of the Proposed Transaction; future product development plans and the efficacy of drug candidates; the potential market opportunities and value of drug candidates; other statements regarding future product development and regulatory strategies, including with respect to specific indications;

statements regarding expectations of continued NASDAQ listing and compliance; and any other statements regarding Acasti's and Grace's future expectations, beliefs, plans, objectives, financial conditions, assumptions or future events or performance, and Acasti's ability to obtain a further extension from the Panel and its ability to evidence compliance with the Nasdaq Rule within any extension period that may be granted by the Panel.

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/, on SEDAR at www.sedar.com 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 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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