

**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): August 12, 2021

ACASTI PHARMA INC.

(Exact name of registrant as specified in its charter)

Québec, Canada
(State or Other Jurisdiction of Incorporation)

001-35776
(Commission File Number)

98-1359336
(I.R.S. Employer Identification No.)

**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))

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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 2.02. Results of Operations and Financial Condition.

On August 12, 2021, Acasti Pharma Inc. (“Acasti”) issued a press release announcing its financial results for the fiscal quarter ended June 30, 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 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.

Additional Information and Where to Find It

In connection with its proposed merger with Grace Therapeutics Inc. (“Grace”), Acasti filed with the Securities and Exchange Commission (“SEC”) a registration statement on Form S-4 on June 30, 2021 (as amended on July 13, 2021) that includes the preliminary prospectus/proxy statement relating to the merger. On July 15, 2021, the registration statement was declared effective by the SEC and Acasti filed the final prospectus/proxy statement in connection with the merger with the SEC, which contains important information about the merger and related matters. The prospectus/proxy statement will be mailed to Acasti shareholders and is accessible on Acasti’s EDGAR and SEDAR profiles. **INVESTORS AND SECURITY HOLDERS OF ACASTI ARE URGED TO CAREFULLY READ THE ENTIRE PROSPECTUS/PROXY STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS TO SUCH DOCUMENTS) BEFORE MAKING ANY VOTING DECISION WITH RESPECT TO THE MERGER BECAUSE IT CONTAINS IMPORTANT INFORMATION ABOUT THE MERGER AND THE PARTIES TO THE MERGER.**

Acasti shareholders can obtain a free copy of the prospectus/proxy statement, as well as other relevant filings containing information about Acasti and the merger, including materials incorporated by reference into the prospectus/proxy statement, without charge at the SEC’s website (www.sec.gov) or from Acasti by contacting Acasti’s Secretary at 3009 boul. de la Concorde East, Suite 102 Laval, Québec, Canada H7E 2B5, telephone: (450) 686-4555.

No Offer or Solicitation

This document is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made, except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.

Participants in the Solicitation

Acasti and Grace and certain of their respective directors, executive officers and employees may be deemed to be participants in the solicitation of Acasti proxies in respect of the merger. Information regarding the persons who may, under SEC rules, be deemed participants in the solicitation of proxies to Acasti shareholders in connection with the merger is set forth in the prospectus/proxy statement. Copies of the prospectus/proxy statement may be obtained free of charge from the SEC or Acasti, as described in the preceding paragraph.

Cautionary Statement Regarding Forward-Looking Statements

This document contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and may be forward-looking information as defined under applicable Canadian securities legislation (collectively, “forward-looking statements”). These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Acasti, as well as assumptions made by, and information currently available to, management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as “may,” “will,” “should,” “would,” “expect,” “estimate,” “plan,” “believe,” “anticipate,” “intend,” “look forward,” and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance.

Forward-looking statements contained in this document may include, without limitation, statements regarding the proposed merger between Acasti and Grace; the timing and financial and strategic benefits thereof; the expected impact of the transaction on the cash balance of Acasti following the merger; Acasti’s future strategy, plans and expectations after the merger; and the anticipated timing of clinical trials and approvals for, and the commercial potential of, Acasti’s products and pipeline product candidates and those of its subsidiaries (including Grace, if the merger is completed). Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including the failure to receive, on a timely basis or otherwise, the required approvals by Acasti shareholders or Grace stockholders, as applicable, in connection with the merger; the risk that a condition to closing of the merger may not be satisfied; the possibility that the anticipated benefits of the proposed merger may not be fully realized or may take longer to realize than expected; the possibility that costs or difficulties related to the integration of the businesses of Acasti and Grace will be greater than expected; the ability of the companies following the merger to commercialize drug candidates in line with the companies’ expectations; the ability to retain and hire key personnel and maintain relationships with customers, key opinion leaders, suppliers or other business partners; the impact of legislative, regulatory, competitive and technological changes; and other risk factors relating to the companies’ businesses and the biopharmaceutical industry, as detailed from time to time in Acasti’s reports filed with the SEC and the Canadian Securities Administrators, which you are encouraged to review. Investors should not place undue reliance on forward-looking statements.

For a discussion of the factors that may cause Acasti’s, Grace’s or the combined company’s actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, and for a discussion of risks associated with the ability of Acasti and Grace to complete the merger and the effect of the merger on the business of Acasti, Grace and the combined company, see the section titled “Risk Factors” in the prospectus / proxy statement.

The forward-looking statements reflect management’s current knowledge, assumptions, beliefs, estimates and expectations and express management’s current view of future performance, results and trends. If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Acasti, Grace or the combined company could differ materially from the forward-looking statements. All forward-looking statements in this document are current only as of the date on which the statements were made, or in the case of a document incorporated by reference, as of the date of that document. Except as required by applicable law, neither Acasti nor Grace undertakes any obligation to update publicly any forward-looking statements for any reason after the date of this document or to conform these statements to actual results or to changes in expectations.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 12, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 12, 2021

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



Acasti Pharma Provides Business Update for the First Quarter of Fiscal 2022

August 4th webcast replay discussing planned acquisition of Grace Therapeutics available on the Company's website

Shareholders urged to vote in advance of upcoming shareholder meeting on August 26th

LAVAL, Québec, Aug. 12, 2021 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST and TSX-V: ACST) today provided a business update and announced its operating and financial results for the first quarter of fiscal 2022 ended June 30, 2021.

On May 7, 2021, Acasti announced that it had entered into a definitive agreement to acquire Grace Therapeutics, Inc. ("Grace"), a privately held emerging biopharmaceutical company focused on developing innovative drug delivery technologies for the treatment of rare and orphan diseases to address 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 remain encouraged and excited about the planned acquisition of Grace, as we believe this transaction will be transformative for our Company and our shareholders. Grace has developed novel drug delivery technologies and is applying them to approved pharmaceutical compounds with proven safety profiles and clinical efficacy. Grace's technologies enable them to customize the formulation of these marketed drugs in new ways that have the potential to address significant unmet medical needs in rare and orphan diseases by achieving faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery – all which can help to increase treatment compliance and improve patient outcomes. We plan to utilize the Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act for clinical development and approval, which can significantly reduce time to market, as well as cost and risk. Moreover, Orphan Drug Designation from the FDA should provide seven years of marketing exclusivity in the U.S. post-launch. In addition, Grace brings 40-plus granted and pending patents around the world, which should provide exclusivity beyond 2036."

"The proposed acquisition of Grace represents a unique opportunity for Acasti and our shareholders to build a new, late-stage specialty pharma company focused on rare and orphan diseases, by combining Acasti's drug development, manufacturing, and commercialization expertise, as well as our strong balance sheet, with Grace's drug delivery technologies and their deep clinical and preclinical product pipeline. Following the merger, we expect to have more than \$60 million in cash on our balance sheet, which should provide at least two years of operating runway and enable us to achieve meaningful catalysts including the completion of the clinical development and filing of an NDA for Grace's lead clinical asset, GTX-104, as well as advancing other drug candidates in the Grace pipeline to additional key, value-enhancing milestones," concluded, Ms. D'Alvise.

The Company has posted a presentation summarizing key highlights of the transaction, which is available on both the Acasti and Grace websites, as well as frequently asked questions regarding the transaction.

CaPre

Despite not meeting the primary endpoint in the TRILOGY 1 and TRILOGY 2 trials as previously disclosed, the triglyceride reduction was one of the highest seen among previously conducted hypertriglyceridemia studies, particularly in patients on statins. As a result, Acasti has received strong interest and continues to evaluate a variety of strategic options for CaPre. Management intends to provide additional information as developments unfold.

Conference call and Shareholder Meeting

Management hosted a business update conference call held on August 4, 2021 at 1:00 p.m. Eastern Time. A webcast replay is available on the Company's News and Investors section of the website (<https://www.acastipharma.com/investors/>) through Thursday, November 04, 2021.

Acasti strongly encourages all investors to vote in advance of the August 26, 2021 annual and special meeting of shareholders, in order to ensure the quorum requirements are met to approve the transaction. In order for shares to be voted at the annual and special meeting, a proxy must be received (whether delivered by mail, telephone or internet) by no later than 5:00 p.m. Eastern Time on August 24, 2021 by Acasti's registrar and transfer agent, Computershare Investor Services Inc., Attention: Proxy Department, 100 University Avenue, 9th Floor, Toronto, Ontario, M5J 2Y1, telephone number: 1-866-732-VOTE (8683), website: www.investorvote.com.

If investors have any questions regarding the proposals or how to vote, please contact investor relations at proxy@acastipharma.com.

Nasdaq Communication

Acasti presented a detailed plan of compliance for the NASDAQ Hearings Panel's consideration on June 17, 2021, which included Acasti's commitment to implement a share consolidation, if needed, to evidence compliance with NASDAQ's listing rules. On July 12, 2021, the NASDAQ Hearings Panel issued its decision, which extended the time for Acasti to regain compliance with Listing Rule 5550(a), subject to the following: 1) on or before August 26, 2021, Acasti will hold a shareholders meeting to obtain approval for a share consolidation at a ratio that will allow for long term compliance with Listing Rule 5550(a); and 2) on or before September 10, 2021, Acasti will have regained compliance with Listing Rule 5550(a). The approval by NASDAQ of (i) the continued listing of Acasti's common shares on NASDAQ

following the effective time of the merger and (ii) the listing of the Acasti common shares being issued to Grace stockholders in connection with the merger on NASDAQ at or prior to the effective time are conditions to the closing of the merger.

First Quarter of Fiscal 2022 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 three months ended June 30, 2021, was \$3.1 million, compared to a loss from operating activities of \$4.1 million for the three months ended June 30, 2020. The change was due mainly to a reduction in research and development, general and administrative expenses, and sales and marketing expenses.
- **Net loss** for the three months ended June 30, 2021, was \$3.1 million or \$0.01 per share, a decrease of \$1.6 million from the net loss of \$4.7 million or \$0.05 per share for the three months ended June 30, 2020. The reduction in net loss resulted primarily from a decrease in research and development expenses as the TRILOGY Phase 3 clinical program for CaPre has been completed. Sales and marketing expenses also decreased due to the discontinuation of CaPre commercialization activities due to the primary endpoint not being met in the TRILOGY 2 Phase 3 clinical trials. These decreases are offset by an increase related to general and administrative expenses from the prior period, due to legal and professional fees incurred in relation to the Proposed Transaction.
- **Research and development expenses** before depreciation, amortization and stock-based compensation expenses for the three months ended June 30, 2021 totaled \$0.42 million compared to \$1.1 million for the three months ended June 30, 2020. The net decrease was mainly attributable to a reduction in research contracts associated with the completed TRILOGY trials as well as a reduction in headcount within the research and development and marketing departments.
- **General and administration expenses** before stock-based compensation expenses for the three months ended June 30, 2021 were \$2.6 million compared to \$1.3 million for the three months ended June 30, 2020. This increase is a result of increased legal and professional fees related to the Proposed Transaction.
- **Sales and marketing expenses** before stock-based compensation expenses were nil for the three months ended June 30, 2021, compared to \$0.57 million for the three months ended June 30, 2020. The decrease was due to the discontinuation of planned pre-launch marketing activities for CaPre.
- **Cashflows, liquidity, cash, cash equivalents and short-term investments** totaled \$57.7 million as of June 30, 2021, compared to \$12.1 million at June 30, 2020.

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. The Proposed acquisition of Grace represents a unique opportunity for Acasti and its shareholders to build a new, late-stage specialty pharma company focused on rare and orphan diseases. Grace’s novel drug delivery technologies have the potential to improve the performance of currently marketed drugs by achieving faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery – all which could help to increase treatment compliance and improve patient outcomes.

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Participants in the Solicitation

Acasti and Grace and certain of their respective directors, executive officers and employees may be deemed to be participants in the solicitation of Acasti proxies in respect of the Proposed Transaction. Information regarding the persons who may, under SEC rules, be deemed participants in the solicitation of proxies to Acasti shareholders in connection with the Proposed Transaction is set forth in the prospectus/proxy statement. Copies of the prospectus/proxy statement may be obtained free of charge from the SEC or Acasti, as described in the preceding paragraph.

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The forward-looking statements reflect management’s current knowledge, assumptions, beliefs, estimates and expectations and express management’s current view of future performance, results and trends. If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Acasti, Grace or the combined company could differ materially from the forward-looking statements. All forward-looking statements in this document are current only as of the date on which the statements were made, or in the case of a document incorporated by reference, as of the date of that document. Except as required by applicable law, neither Acasti nor Grace undertakes any obligation to update publicly any forward-looking statements for any reason after the date of this document or to conform these statements to actual results or to changes in expectations.

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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