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): July 05, 2023

ACASTI PHARMA INC.

(Exact name of Registrant as Specified in Its Charter)

Quebec	**001-35776**	**98-1359336**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3009, boul. de la Concorde East **Suite 102** **Laval, Quebec**	**H7E 2B5**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 450 686-4555

(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	The Nasdaq Stock Market LLC

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 8.01 Other Events.

On July 5, 2023, Acasti Pharma Inc. (the "Company") issued a press release announcing alignment with the U.S. Food and Drug Administration on the Company's GTX-104 pivotal Phase 3 safety trial protocol. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release dated July 5, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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 thereunto duly authorized.

ACASTI PHARMA INC.

Date: July 5, 2023

By: /s/ Prashant Kohli
Prashant Kohli
Chief Executive Officer

Acasti Announces Alignment with FDA on GTX-104 Pivotal Phase 3 Safety Trial Protocol and Confirms Planned Initiation of STRIVE-ON in aSAH Patients in Calendar Q4 2023

STRIVE-ON is the pivotal Phase 3 trial of GTX-104 to evaluate its comparable safety and tolerability profile relative to oral nimodipine in patients hospitalized with aSAH

GTX-104 has been administered in over 150 healthy volunteers to-date and has demonstrated comparable safety profile to oral nimodipine

Company confirms its projected cash runway through a potential GTX-104 New Drug Application (NDA) submission in the first half of calendar 2025

LAVAL, QC, July 5, 2023 /PRNewswire/ -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST), a late-stage, biopharma company advancing GTX-104, its novel injectable nimodipine formulation for intravenous infusion (IV) that addresses high unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH), today announced that the Company has aligned with the U.S. Food and Drug Administration (FDA) on the protocol for its pivotal Phase 3 trial of GTX-104 and the FDA also provided guidance for a potential GTX-104 New Drug Application (NDA) package.

Acasti has all the necessary information from the FDA to initiate its recently named STRIVE-ON (Safety, Tolerability, Randomized, IV and Oral Nimodipine) pivotal Phase 3 trial of GTX-104 to evaluate its safety and tolerability profile relative to oral nimodipine.

"We greatly appreciate FDA's guidance on the STRIVE-ON trial design and are pleased with the agency's confirmation that the proposed dosing regimen, which mirrors the one used in the pivotal PK bridging study GTX-104-002, appears reasonable," commented Prashant Kohli, CEO of Acasti. "We are moving full speed ahead with anticipated first patient dosing in the fourth calendar quarter of this year and a potential NDA submission in the first half of calendar 2025. GTX-104 has a strong established safety profile having already been administered to over 150 healthy volunteers to-date. We look forward to the completion of the STRIVE-ON trial, and if approved by the FDA, GTX-104 could bring enhanced options for physicians treating patients suffering from aSAH."

STRIVE-ON will be a prospective, open-label, randomized (1:1 ratio), parallel group trial of GTX-104 compared with oral nimodipine, in patients hospitalized for aSAH. Key trial design features include:

- Approximately 100 patients will be enrolled at an estimated 25 hospitals in the U.S.
- The primary endpoint is safety and will be measured as comparative adverse events, including hypotension, between the two groups.
- GTX-104 will be administered as a continuous IV infusion of 0.15 mg/hour, and a 30-minute IV bolus of 4 mg every 4 hours. Oral nimodipine will be administered as 60 mg (two 30 mg capsules) every 4 hours.
- Both groups will receive their assigned GTX-104 or oral nimodipine for up to 21 consecutive days and will be evaluated from commencement of patient treatment through a 90-day follow-up period.

Kohli concluded, "Based on recent proactive measures taken to position ourselves for future success, we believe our current cash runway to be sufficient to achieve a potential NDA submission for GTX-104 in the first half of calendar 2025."

About aneurysmal Subarachnoid Hemorrhage (aSAH)

aSAH is bleeding over the surface of the brain in the subarachnoid space between the brain and the skull, which contains blood vessels that supply the brain. A primary cause of such bleeding is the rupture of an aneurysm. Approximately 70% of aSAH patients experience death or dependence, and more than 30% die within one month of hemorrhage. Approximately 50,000 patients in the United States are affected by aSAH per year, based on market research.

About GTX-104

GTX-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous infusion (IV) in aSAH patients to address significant unmet medical needs. The unique nanoparticle technology of GTX-104 facilitates aqueous formulation of insoluble nimodipine for a standard peripheral IV infusion.

GTX-104 provides a convenient IV delivery of nimodipine in the Intensive Care Unit eliminating the need for nasogastric tube administration in unconscious or dysphagic patients. Intravenous delivery of GTX-104 also has the potential to lower food effects, drug-to-drug interactions, and eliminate potential dosing errors. Further, GTX-104 has the potential to better manage hypotension in aSAH patients. GTX-104 has been administered in over 150 healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine. The addressable market in the United States for GTX-104 is estimated to be about $300 million, based on market research.

About Acasti

Acasti is a late-stage biopharma company with drug candidates addressing rare and orphan diseases. Acasti'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. Acasti's lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provides seven years of marketing exclusivity post-launch in the United States, and additional intellectual property protection with over 40 granted and pending patents. Acasti's lead clinical asset, GTX-104, is an intravenous infusion targeting aneurysmal Subarachnoid Hemorrhage (aSAH), a rare and life-threatening medical emergency in which bleeding occurs over the surface of the brain in the subarachnoid space between the brain and skull.

For more information, please visit: https://www.acastipharma.com/en.

Forward-Looking Statements

Statements in this press release that are not statements of historical or current fact constitute "forward-looking statements" within the meaning of the U.S. 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 "forward-looking information" within the meaning of Canadian securities laws (collectively, "forward-looking statements"). Such forward looking statements involve known and unknown risks, uncertainties, and other 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 containing the terms "believes," "belief," "expects," "intends," "anticipates," "estimates", "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. The forward-looking statements in this press release, including on the Company's anticipated cash runway, the timing of the planned initiation of the Company's STRIVE-ON trial, anticipated NDA submission with the FDA, GTX-104's potential to bring enhanced treatment options to patients suffering from aSAH, and the anticipated trail design of STRIVE-ON are based upon Acasti's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions of the planned Phase 3 safety study for GTX-104; (ii) regulatory requirements or developments and the outcome and timing of the proposed IND application for GTX-104; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; and (v) actual costs associated with Acasti's clinical trials as compared to management's current expectations. The foregoing list of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and are filed by Acasti from time to time with the Securities and Exchange Commission and Canadian securities regulators. All forward-looking statements contained in this press release speak only as of the date on which they were made. Acasti undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by applicable securities laws. NASDAQ does not accept responsibility for the adequacy or accuracy of this release.

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