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): December 28, 2022

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.

Acasti Pharma Inc. ("Acasti" or the "Company") announces that the preliminary topline results of the pharmacokinetic (PK) bridging study for GTX-102 met all outcome measures. The objectives of the study were to evaluate the bioavailability, pharmacokinetics, and safety of GTX-102, a novel, concentrated oral-mucosal metered spray of betamethasone in healthy volunteers. This new formulation is intended to improve the neurological symptoms of Ataxia Telangiectasia (A-T) in a pediatric population for which there are currently no FDA-approved therapies. GTX-102 can be sprayed conveniently over the tongue of A-T patients, who often have difficulties swallowing. This PK study was the next step in the proposed 505(b)(2) regulatory pathway for GTX-102.

This PK bridging study is a Phase 1, randomized, open-label, crossover study in healthy adult subjects to evaluate the comparative bioavailability, PK, and safety of GTX-102 administered as an oral spray compared to intramuscular (IM) betamethasone (which is expected to be the reference product for bridging purposes), and to an oral solution (OS) of betamethasone, which is available in Europe but not approved in the US. The betamethasone OS was shown to reduce neurological symptoms in children with A-T in a published multicenter, double-blind, randomized, placebo-controlled crossover trial conducted in Italy (Zannolli et al, 2012).

The primary objective of this PK bridging study was to evaluate and characterize the PK profile of GTX-102 as an oral spray.

A total of 48 healthy adult subjects (27 males and 21 females) were enrolled in this single center, 5-treatment, 8-sequence, 2-period cross-over study. The 5 treatments assessed in the study were:

- GTX-102: low dose at 0.0125 mg/kg, medium dose at 0.05 mg/kg, and high dose at 0.1 mg/kg
- OS betamethasone at 0.1 mg/kg
- IM betamethasone at 0.1 mg/kg

Each subject received a single dose of 2 treatments in a cross-over fashion, in a randomized sequence over 2 treatment periods separated by 15 days. The dosing started on September 13, 2022 and ended on November 24, 2022. Betamethasone blood levels were compared between all treatment groups.

GTX-102 PK study outcome measures definitions and preliminary topline findings are as follows:

- Primary outcome measures and their definitions include:
  - AUC_{0-72} is the area under the concentration time curve up to 72 hours post-dose
  - AUC_{∞} is the area under the concentration time curve extrapolated to infinity
  - C_{max} is the maximum concentration occurring between 0 hour to 72 hours after study drug administration.
- GTX-102 given at doses of 0.0125 (low), 0.5 (medium) or 0.1 (high) mg/kg, showed betamethasone blood concentrations that were highly predictable and consistent based on AUC and C_{max}, indicating good linearity and dose-proportionality.
- Following the high dose of GTX-102 (0.1 mg/kg), betamethasone blood concentrations were within the same range of exposure as IM betamethasone (0.1 mg/kg), based on AUC. The IM formulation of betamethasone will serve as a bridge for GTX-102 in the context of the proposed 505(b)(2) regulatory pathway.
- In addition, Betamethasone blood concentrations following the high dose of GTX-102 (0.1 mg/kg) were within the same range of exposure as OS betamethasone (0.1 mg/kg), based on AUC. This OS formulation was the same one that was used by Zannolli et al and may serve as a clinical comparator for further clinical development of GTX-102.
- There was statistically no significant difference ($p>0.05$) between GTX-102 (0.05 mg/kg) when comparing a fast rate of administration (each spray immediately following the preceding one) to a slow rate (1 spray/minute), as indicated by C_{max} and AUC. This is important because being able to use the fast or the slow rate of administration may provide greater flexibility for patients and caregivers.
- The Cmax of GTX-102 was within the same range of exposure as the OS, but the Cmax for the IM formulation was lower than both GTX-102 and the OS, as well as what has been reported previously for the IM in the literature. It is important to note that achieving bioequivalence with the IM was not an objective of this study, nor was it expected.
- No serious adverse events (AE) were reported during the study. AEs leading to study discontinuation consisted of cough/fever/body pain/stuffy nose (1 case), Covid-19 (1 case) and elevated creatinine kinase (1 case), and all events occurred prior to receiving the second treatment. None were judged as being related to the study drugs by the investigator. The most frequent drug-related AE was mild headache (4 cases).
- Based on this data, Acasti will work with its clinical experts and the FDA to determine the best final dosing regimen for GTX-102 to incorporate into its Phase 3 study design.

The Company expects that the final development step for GTX-102 will be to conduct a Phase 3 safety and efficacy trial in A-T patients using a treatment regimen similar to the one already proved effective by Zannolli, et al. The Company plans to request a Type B meeting with the FDA following the receipt of the full PK study dataset sometime in calendar H1 2023 to confirm the proposed Phase 3 study design. If all proceeds as planned, the Phase 3 study is expected to be initiated in the second half of calendar 2023. If the Phase 3 program meets the primary endpoints, an NDA filing for GTX-102 under Section 505(b)(2) is expected to follow.

Forward-Looking Statements

Statements in this report 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 (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 containing 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 report. The forward-looking statements in this report 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 each of the planned Type B meeting with the FDA and the anticipated Phase 3 safety and efficacy trial for GTX-102, (ii) the success and timing of regulatory submissions of the PK bridging study and Phase 3 safety study protocol for GTX-104, and Acasti's other pre-clinical and clinical trials; (iii) regulatory requirements or developments; (iv) changes to clinical trial designs and regulatory pathways; (v) legislative, regulatory, political and economic developments, and (vi) the effects of COVID-19 on clinical programs and business operations. 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 may be filed by Acasti from time to time with the Securities and Exchange Commission. All forward-looking statements contained in this report 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.

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 hereunto duly authorized.

Acasti Pharma Inc.

Date: December 28, 2022

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