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 22, 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”) today announced that preliminary topline results for its single-dose, pharmacokinetic (PK) bridging study to evaluate the relative bioavailability of GTX-101 compared to the reference listed drug in the U.S., bupivacaine subcutaneous injectable, met all primary outcome measures for the study. The final clinical study report is anticipated to be received by the Company in the first half of 2023. This PK study was the next step in the proposed 505(b)(2) regulatory pathway for GTX-101 and provides important information on the dose and dosing frequency in humans for future planned clinical studies.

GTX-101 is a novel formulation of bupivacaine hydrochloride (HCl) for topical administration via a bio-adhesive, film-forming polymer, for relief of pain associated with Postherpetic Neuralgia (PHN), a persistent and often debilitating neuropathic pain caused by nerve damage from the varicella zoster virus (shingles), which may persist for months and even years. The potential benefits of GTX-101 could include faster onset of action and a longer duration of pain relief as compared to the lidocaine patch. GTX-101 can be conveniently sprayed on the skin wherever the pain is located, and based on the PK profile of bupivacaine, the Company believes that GTX-101 may only need to be applied once or twice a day to the affected area for 24/7 pain relief, although this dosing schedule will need to be confirmed in future clinical studies.

The Single Dose PK study for GTX-101 was a Phase 1, Randomized, Single-Dose, 4-Cohort, Parallel study to evaluate the pharmacokinetics, dose proportionality, safety and tolerability of GTX-101 (bupivacaine hydrochloride metered dose spray) and subcutaneous injectable bupivacaine in 48 healthy subjects. The primary objective was to assess the pharmacokinetics of 3 dose levels of GTX-101 (50, 100, and 200 mg) given as a single-dose topical application (metered spray).

The study enrolled 48 healthy adult subjects (24 males/24 females, mean age = 36 years), in 12 subjects per cohort. Subjects in Cohorts 1, 2, and 3 received GTX-101 as either 5, 10, or 20 sprays (50, 100, or 200 mg, respectively). Subjects in Cohort 4 received a single 10 mg subcutaneous injection of the active control. It is important to note that one of the secondary objectives of this study was to compare the bioavailability of these two very different modes of administration. The first subject / first dose was administered on July 26th and the dosing phase of the study was completed on August 21st, 2022.

Following GTX-101 topical administration, bupivacaine is expected to diffuse into the skin and act locally, while a limited fraction of bupivacaine is expected to diffuse into the systemic circulation as measured in the blood. This circulating level of bupivacaine in the blood stream is not anticipated to contribute significantly to the analgesic effect but should be monitored to avoid any risk of toxicity.

GTX-101 PK Study Outcome Definitions and Preliminary Topline Findings Are as Follows:

- Primary outcome measures and their definitions include:
  - C_{max} is the maximum concentration occurring at Tmax between 0 hour to 240 hours after study drug administration.
  - T_{max} is the time of maximum concentration between 0 hour to 240 hours after study drug administration.
  - AUC_{last} is the area under the concentration time curve from the time of last dosing to the time of last quantifiable concentration.
  - AUC_{∞} is the area under the concentration time curve extrapolated to infinity.
  - T_{half} is the time required for the plasma concentration to decrease by 50%.
- The median time to reach the maximum concentration of bupivacaine in plasma (T_{max}) following GTX-101 single-dose topical applications of 50, 100 and 200 mg ranged between 18 to 24 hours depending on dose, while the median T_{max}following the subcutaneous injection of 10 mg of bupivacaine was only 23 minutes. This finding suggests that the bupivacaine delivered by GTX-101 remains in the skin for a long period of time, potentially inducing prolonged analgesic effect in the sprayed area.
- The exposure to bupivacaine based on C_{max} and AUC_{∞}following GTX-101topical application as a single-dose of 50, 100 and 200 mg, increased with increasing dose. This was predictable and expected.
- The systemic exposure to bupivacaine following a 200mg dose of GTX-101 was:
  - Approximately 29-fold less than a single subcutaneous dose of 10mg of bupivacaine based on C_{max} and,
  - Approximately 6-fold less than a single subcutaneous dose of 10mg of bupivacaine based on AUC_{∞}.
  - These results are predicted to correspond to an increased safety margin for GTX-101 with regards to toxicity risk.
- The mean half-life (T_{half}) following GTX-101 single-dose topical application of 50, 100 and 200 mg ranged between 24 to 37 hours depending on dose, suggesting a slow elimination and potentially long duration of effect, while the mean T_{half} following the subcutaneous injection of 10 mg of bupivacaine was only 8 hours.
- Adverse events judged as related to the study drug by the investigator were (1 case each):

- oFollowing GTX-101 topical application: headache (3%) and numbness (3%) at the sprayed area, and
- oFollowing bupivacaine subcutaneous injection: dizziness (8%) and nausea (8%).

In conclusion, this Single Dose PK study was conducted successfully, and it achieved all its primary outcome measures. The data provides Acasti with key information to help characterize the PK parameters, and safety and tolerability of GTX-101, and supports additional future clinical development. The full clinical study report will be received in the first half of calendar 2023, and the company intends to eventually publish this data.

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 22, 2022

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