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 2, 2021

ACASTI PHARMA INC.

(Exact name of registrant as specified in its charter)

Québec, Canada	**001-35776**	**98-1359336**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 7.01. Regulation FD Disclosure.

On December 2, 2021, Acasti Pharma Inc. (the "Company") issued a press release announcing positive interim data for a pivotal pharmacokenetic study for its GTX-104 drug candidate. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information in this Item 7.01, 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 it 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 December 2, 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: December 2, 2021

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

Acasti Pharma Announces Interim Data Meets All Primary Endpoints for Pivotal PK Study for GTX-104

Bioavailability of GTX-104 compares favorably with the oral formulation of nimodipine; full PK study expected to report out as planned in H1'22

LAVAL, Québec, Dec. 02, 2021 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST and TSX-V: ACST), today announced positive results for GTX-104 based on its interim analysis of the first 20 of 50 normal healthy subjects in its pivotal pharmacokinetic (PK) bridging study. GTX-104 met both primary endpoints for Maximum Concentration (Cmax) on Day 1 and Area Under the Concentration-Time Curve (AUC 0-24 hours) on Day 3, allowing the study to continue under the current infusion protocol to its completion. GTX-104 is a novel, aqueous formulation of nimodipine developed as an IV infusion for patients experiencing Subarachnoid Hemorrhage, or bleeding over the surface of the brain triggered by a ruptured aneurysm (aSAH).

The Company believes that the tight correlation of the primary endpoint data for the first 20 patients is a strong indication that GTX-104 could achieve comparable bioavailability with oral nimodipine in the full study cohort of 50 subjects. As observed in a previous PK study, the inter- and intra-subject variability in the interim analysis was much lower for GTX-104 as compared with oral nimodipine. So far, there have been no serious adverse events observed, and only mild adverse events were reported in both groups such as headaches, that were resolved with common medications.

"This interim data is very encouraging, as it suggests that our current infusion protocol is on track to meet the objectives for this pivotal PK study. As previously disclosed, we expect to report the final study results sometime in the first half of 2022. If the final study results are consistent with these interim results, we could proceed quickly to finalize the study design and protocol for the Phase 3 Safety Study of GTX-104 with the FDA, and initiate the study in the second half of 2022," commented Jan D'Alvise, Acasti's CEO. "Importantly, we believe the follow-up safety study has the potential to be relatively fast, low cost and low risk based on the favorable safety profile observed to date. Moreover, this clinical study is expected to be the final step required to seek regulatory approval under the 505(b)(2) regulatory pathway before submitting our New Drug Application (NDA) to the FDA.

"We believe GTX-104 delivered intravenously has the potential to be a more convenient, efficient and controlled way to deliver nimodipine. Importantly, because of its better absorption profile and more consistent blood levels, GTX-104 may provide physicians with a more reliable and effective tool for hypotension management. This is a key advantage, as GTX-104 could help to reduce the incidence of vasospasm, which requires immediate and costly intervention and can lead to worse outcomes for the patient. For these reasons, we believe GTX-104 could be well positioned to rapidly capture market share if we are granted FDA approval.

"This interim data is further validation of our strategic decision to acquire Grace Therapeutics. In just three months since completing the acquisition, we launched this pivotal PK bridging study for GTX-104 and already have positive interim data with more data to follow in the first half of 2022. We are also working diligently to rapidly advance the clinical programs for GTX-102 and GTX-101. As a result, we remain encouraged by the outlook for our business and look forward to reporting on a number of key upcoming milestones that we believe could drive significant value for our shareholders," concluded Ms. D'Alvise.

The PK bridging study for GTX-104 is being conducted in a total of 50 healthy subjects as a single center, randomized, two-period crossover study. The overall objective of the study is to evaluate and compare the relative bioavailability of GTX-104, with the currently marketed oral nimodipine capsules, which are the standard of care, while a secondary objective of the study is to assess the safety and tolerability of GTX-104, as compared to oral nimodipine capsules. Throughout the study, safety evaluations are being conducted, which include capturing any treatment-emergent adverse events, serious adverse events, electrocardiogram data, clinical laboratory evaluations, physical examinations and resting vital signs, including blood pressure. Subjects are admitted to the clinical research unit on the day prior to dosing, and they remain domiciled in the clinical research unit (CRU) for the duration of each study period.

Per the study protocol, subjects are being randomly assigned in a 1:1 ratio to one of two treatment sequences, with a cross over design: Group A switching to Group B, where GTX-104 is administered first, or Group B switching to Group A, where oral nimodipine capsules are administered first. In both groups, GTX-104 nimodipine is administered intravenously over a 72-hour period, and nimodipine is administered orally with water every 4 hours for 72 hours.

About SAH

Subarachnoid Hemorrhage (SAH) 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. The result is a relatively uncommon type of stroke that accounts for about 5% of all strokes and has an incidence of six per 100,000 person years (Becske, 2018).

In contrast to common types of stroke in elderly individuals, SAH often occurs at a relatively young age, with half the affected patients being younger than 60 years (Becske, 2018). Particularly devastating for patients younger than 45, around 10% to 15% of aneurysmal SAH (aSAH) patients die before reaching the hospital (Rinkel, 2016), and those who survive the initial hours post hemorrhage are admitted or transferred to tertiary neurointensive care centers to manage the high risk of complications, including rebleeding and delayed cerebral ischemia (DCI). Systemic manifestations affecting cardiovascular, pulmonary, and renal function are common, and often complicate management of DCI. Approximately 70% of aSAH patients experience death or dependence, and half die within one month after the hemorrhage. Of those who

survive the initial month, half remain permanently dependent on someone else to maintain daily living (Becske, 2018).

Nimodipine, a calcium channel blocker, is currently the only FDA approved therapy to improve neurological outcomes associated with DCI in SAH patients. Its use is recommended in the current guidelines for the management of SAH, as published by the American Heart Association and American Stroke Association.

About GTX-104

GTX-104 is a clinical stage, novel aqueous formulation of nimodipine being developed for IV infusion in SAH patients. It incorporates surfactant micelles as the drug carrier to solubilize nimodipine. This nimodipine injectable formulation is comprised of a nimodipine base, an effective amount of a hydrophilic surfactant, and a pharmaceutically acceptable carrier for injection. GTX-104 is an aqueous solution substantially free of organic solvents, such that the nimodipine is contained in a concentrated injection solution, suspension, emulsion or complex as a micelle, a colloidal particle or an inclusion complex, and the formulation is stable and clear. Acasti estimates the addressable market in the United States for GTX-104 to be approximately $300 million based on approximately 50,000 patients being affected by aSAH per year.

About Acasti

Acasti is a specialty pharma company with drug delivery capability and technologies 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—all which could help to increase treatment compliance and improve patient outcomes.

Acasti's three lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provide the assets with seven years of marketing exclusivity post-launch in the United States and protection by over 40 granted and pending patents. The lead assets target underserved orphan diseases: (i) GTX-104, an intravenous infusion targeting Subarachnoid Hemorrhage (SAH), 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; (ii) GTX-102, an oral mucosal spray targeting Ataxia-Telangiectasia (A-T), a progressive, neurodegenerative genetic disease that primarily impacts children causing severe disability, for which no treatment currently exists; and (iii) GTX-101, a topical spray, targeting 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. 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 information" within the meaning of Canadian securities laws and "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 labelled with the terms "believes," "belief," "expects," "intends," "anticipates," "potential," "should," "may," "will," "plans," "continue", "targeted", "estimates" 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.

These forward-looking statements 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 and pre-clinical and clinical trials; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments, (v) the final outcome of Acasti's PK bridging study for GTX-104; and (vi) the effects of COVID-19 on clinical programs and business operations. The foregoing review 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 SEC. 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 under applicable securities laws.

Neither NASDAQ, the TSXV nor its Regulation Services Provider (as that term is defined in the policies of the TSXV) accepts responsibility for the adequacy or accuracy of this release.

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