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): May 18, 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** **(Address of Principal Executive Offices)**	**H7E 2B5** **(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 7.01 Regulation FD Disclosure.

On May 18, 2022, Acasti Pharma Inc. (the “Company”) issued a press release announcing that the top line results of its pharmacokinetic (PK) bridging study with IV GTX-104, the Company’s lead drug candidate for the treatment of Subarachnoid Hemorrhage (SAH), met all its planned study endpoints. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1, 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 in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On May 18, 2022, Acasti Pharma Inc. (the "Company") announced that the top line results of its pharmacokinetic (PK) bridging study with IV GTX-104, the Company’s lead drug candidate for the treatment of Subarachnoid Hemorrhage (SAH), met all its planned study endpoints. The primary objective of the study was to evaluate the relative bioavailability of IV GTX-104 compared to oral nimodipine in healthy adult male and female subjects, while the secondary objective was to assess its safety and tolerability. The Company plans to submit these results to the US Food and Drug Administration (FDA), along with its proposed study design for the Phase 3 safety study which is on track to start in the second half of 2022. The safety study is expected to be the final step required to seek regulatory approval under the 505(b)(2) regulatory pathway before submitting a New Drug Application to the FDA.

SAH affects an estimated 50,000 patients per year in the U.S. and represents an estimated total addressable market of more than $300 million in the US alone (Becske, 2016; NINDS, 2016; and Connolly, 2012). There are an estimated additional 55,000 patients in Europe. Based on the improved bioavailability, more convenient mode of administration, safety and tolerability, management believes GTX-104 has the potential to capture a significant share of the SAH market.

The PK study was completed at a single center in Canada and followed a 2-period crossover design where each subject received IV GTX-104 first, followed by oral nimodipine; or oral nimodipine first, followed by IV GTX-104. Fifty-eight subjects were randomized in a ratio of 1:1 between IV GTX-104 first or oral nimodipine first. IV GTX-104 and oral nimodipine were administered to all subjects over a period of 72 hours. A total of 56 and 55 subjects were included in the PK analysis at Day 1 and Day 3, respectively, as two subjects did not complete one of the 2 periods and 1 subject was excluded due to a protocol deviation, as prospectively defined in the statistical analysis plan (SAP).

The primary PK endpoints were maximum concentration (expressed as C_{max}) during the first 4 hours on Day 1 and the total amount of nimodipine in the blood (expressed as the area under the curve (AUC)) on Day 3 ($AUC_{Day\ 3,\ 0\text{-}24hr}$). The secondary endpoint was C_{max} measured over 24 hours on on Day 3. The ratio of IV/oral is presented for each endpoint with the corresponding 90% confidence interval (CI). A ratio of 1 indicates no absolute difference between IV GTX-104 and oral nimodipine.

The IV/oral ratio (%) and its corresponding 90% CI (range) for the primary and secondary endpoints in the subjects who completed each treatment period were as follows:

Day 1 C_{max}:	92% (82 – 104)
$AUC_{Day\ 3,\ 0\text{-}24hr}$:	106% (99 – 114)
Day 3 C_{max}:	92% (85 – 101)

All three endpoints indicated that statistically there was no difference in exposures between IV GTX-104 and oral nimodipine over the defined time periods for both maximum exposure and total exposure. Plasma concentrations obtained following IV administration showed significantly less variability between subjects as compared to oral administration of capsules, since IV administration is not as sensitive to some of the physiological processes that affect oral administration, such as taking the drug with and without meals, variable GI transit time, variable drug uptake from the GI tract into the systemic circulation, and variable hepatic blood flow and hepatic first pass metabolism. Previous studies have shown these processes significantly affect the oral bioavailability of nimodipine, and therefore cause oral administration to be prone to larger within and between-subject variability.

The bioavailability of oral nimodipine capsules was observed to be only 8% compared to IV GTX-104. Consequently, less than one-tenth the amount of nimodipine is delivered with GTX-104 to achieve the same blood levels as with the oral capsules. In addition, the diurnal variation associated with IV GTX-104 was approximately half of that seen with the oral nimodipine capsules. Diurnal variation takes into consideration variation in body functions (blood flow, renal function and hepatic metabolism) over the course of a day.

No serious adverse events and no adverse events (AEs) leading to withdrawal were reported during the study. More gastro-intestinal disorders were observed with oral nimodipine (16% vs 7% for IV GTX-104), and as expected in the context of a phase I trial conducted in healthy volunteers, more administration and sampling site related events were reported with IV GTX-104 (41% vs 11% for oral

nimodipine). The other most frequently reported AEs (IV/oral) were headache (36%/36%), somnolence (9%/13%) and hot flashes/flushing (10%/11%).

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 18, 2022
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: May 18, 2022

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

ACASTI PHARMA ANNOUNCES POSITIVE RESULTS FOR PHARMACOKINETIC BRIDGING STUDY, WITH INTRAVENOUS GTX-104 MEETING ALL ENDPOINTS

Bioavailability of IV GTX-104 compared favorably with the oral formulation of nimodipine, and no serious adverse events observed for GTX-104

Phase 3 remains on track to start before year-end

A conference call to discuss the results scheduled for Wednesday May 18th at 1:00 PM Eastern Time

LAVAL, Québec, May 18, 2022 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST and TSX-V: ACST) announced today that the top line results of its pharmacokinetic (PK) bridging study with IV GTX-104, the Company’s lead drug candidate for the treatment of Subarachnoid Hemorrhage (SAH), met all its planned study endpoints. The primary objective of the study was to evaluate the relative bioavailability of IV GTX-104 compared to oral nimodipine in healthy adult male and female subjects, while the secondary objective was to assess its safety and tolerability. The Company plans to submit these results to the US Food and Drug Administration (FDA), along with its proposed study design for the Phase 3 safety study which is on track to start in the second half of 2022. The safety study is expected to be the final step required to seek regulatory approval under the 505(b)(2) regulatory pathway before submitting a New Drug Application to the FDA.

SAH affects about 50,000 patients per year in the U.S. and represents an estimated total addressable market of more than $300 million in the US alone (Becske, 2016; NINDS, 2016; and Connolly, 2012). There are an estimated additional 55,000 patients in Europe. Based on the improved bioavailability, more convenient and consistent mode of administration, safety and tolerability, management believes GTX-104 has the potential to capture a significant share of the SAH market.

"We are very pleased to report the top line results for this important PK study which met all its planned study endpoints,” commented Jan D’Alvise, Acasti’s CEO. “The study completed on schedule, and we are now working with our clinical and regulatory advisors to finalize our study design and protocol for the Phase 3 safety study of GTX-104. We believe the safety study should be relatively low risk based on the favorable safety profile observed in more than 130 patients combined from this PK study and a previous PK study. We plan to submit the protocol along with our PK data to the FDA to confirm the final steps required prior to registration. Based on the improved bioavailability demonstrated in this study, we continue to believe GTX-104 delivered intravenously has the potential to be a more convenient, efficient and controlled way to deliver nimodipine to patients with SAH.

“As observed in a previous PK study with GTX-104 and now with the results of this study, the inter- and intra-subject variability was also much lower for GTX-104 as compared with oral nimodipine,” D’Alvise continued. “Importantly, because of its better absorption profile and more consistent blood levels, GTX-104 may provide physicians with a more reliable and effective treatment for patients with SAH. This is a key advantage, as we believe GTX-104 could help to reduce the incidence of hypotensive events and vasospasm, which require immediate and costly

intervention and can lead to worse outcomes for the patient. Moreover, it could provide dosing flexibility and a more consistent and convenient route of administration for the significant percentage of patients who present and remain unconscious during their ICU stay following SAH. For these reasons, we believe GTX-104 could be well-positioned to rapidly capture market share if the FDA grants approval."

The PK study was completed at a single center in Canada and followed a 2-period crossover design where each subject received IV GTX-104 first, followed by oral nimodipine; or oral nimodipine first, followed by IV GTX-104. Fifty-eight subjects were randomized in a ratio of 1:1 between IV GTX-104 first or oral nimodipine first. IV GTX-104 and oral nimodipine was administered to all subjects over a period of 72 hours. A total of 56 and 55 subjects were included in the PK analysis at Day 1 and Day 3, respectively, as two subjects did not complete one of the two periods and one subject was excluded due to a protocol deviation, as prospectively defined in the statistical analysis plan (SAP).

The primary PK endpoints were maximum concentration (expressed as C_{max}) during the first 4 hours on Day 1 and the total amount of nimodipine in the blood (expressed as the area under the curve ($AUC_{Day\ 3,\ 0\text{-}24hr}$)) on Day 3. The secondary endpoint was C_{max} measured over 24 hours on Day 3. The ratio of IV/oral is presented below for each endpoint with the corresponding 90% confidence interval (CI). A ratio of 1 indicates no absolute difference between IV GTX-104 and oral nimodipine.

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AUC $_{Day\ 3,\ 0\text{-}24hr}$: 106% (99 – 114)
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All three endpoints indicated that statistically there was no difference in exposures between IV GTX-104 and oral nimodipine over the defined time periods for both maximum exposure and total exposure. Plasma concentrations obtained following IV administration showed significantly less variability between subjects as compared to oral administration of capsules, since IV administration is not as sensitive to some of the physiological processes that affect oral administration, such as taking the drug with and without meals, variable GI transit time, variable drug uptake from the GI tract into the systemic circulation, and variable hepatic blood flow and hepatic first pass metabolism. Previous studies have shown these processes significantly affect the oral bioavailability of nimodipine, and therefore cause oral administration to be prone to larger within and between-subject variability.

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No serious adverse events (AEs) and no AEs leading to withdrawal were reported during the study. More gastro-intestinal disorders were observed with oral nimodipine (16% vs 7% for IV GTX-104), and as expected in the context of a phase I trial conducted in healthy volunteers, more

administration and sampling site related events were observed with IV GTX-104 (41% vs 11% for oral nimodipine). The other most frequently observed AEs (IV/oral) were headache (36%/36%), somnolence (9%/13%) and hot flashes/flushing (10%/11%).

Cash Update

Acasti also reports that it had $43.7M cash on hand as of March 31, 2022, which management continues to expect will fund lead drug candidate GTX-104 through NDA submission, and GTX-102 for ataxia telangiectasia and GTX-101for postherpetic neuralgia to additional key milestones.

Conference call

Acasti will host a conference call on Wednesday, May 18, 2022 at 1:00 PM Eastern Time to discuss the results of the trial. The conference call will be available via telephone by dialing toll free 888-506-0062 for U.S. callers or +1 973-528-0011 for international callers and using entry code 456498. A webcast of the call may be accessed at https://www.webcaster4.com/Webcast/Page/2210/45556 or on the Company's Investor Relations section of the website: https://www.acastipharma.com/investors/.

A webcast replay will be available on the Company's Investors News/Events section of the website (https://www.acastipharma.com/investors/) through May 18, 2023. A telephone replay of the call will be available approximately one hour following the call, through May 25, 2022, and can be accessed by dialing 877-481-4010 for U.S. callers or +1 919-882-2331 for international callers and entering conference ID: 45556.

About SAH

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 rupture of an aneurysm. The result is a relatively uncommon type of stroke that accounts for about one-in-twenty (5%) of all strokes and has an incidence of six per 100,000 person years (Becske, 2018). In contrast to more common types of strokes 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, approximately 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 the 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).

About GTX-104

GTX-104 is a clinical stage, novel 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. The addressable market in the United States for GTX-104 is estimated to be about $300 million based on market research conducted by Fletcher Spaght.

About Acasti

Acasti is a late-stage specialty pharma company with drug delivery technologies and 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—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-approval in the United States, and additional intellectual property protection with over 40 granted and pending patents. Acasti's lead clinical assets target underserved orphan diseases:

(i)GTX-104, an intravenous infusion targeting Subarachnoid Hemorrhage (SAH), a rare and lifethreatening 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 affects children, causing severe disability, and 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 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 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 press release.

The forward-looking statements in this press release 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 study for GTX-104 and Acasti's other pre-clinical and clinical trials; (ii) regulatory requirements or developments and the outcome of meetings with the FDA; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; (v) costs associated with Acasti's clinical trials 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 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.

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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