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): August 11, 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 2.02 Results of Operations and Financial Condition.

The following information is furnished pursuant to Item 2.02, "Results of Operations and Financial Condition."

On August 11, 2022, Acasti Pharma Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information in this Item 2.02, 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 they be deemed incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, 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	Description
99.1	Press Release dated August 11, 2022
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: August 11, 2022

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

Acasti Pharma Reports First Quarter 2023 Operational Results

Company to Host Conference Call Today at 1:00pm ET

LAVAL, Québec, August 11, 2022 -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST and TSX-V: ACST), a late-stage, specialty pharma company with drug delivery capability and technologies addressing rare and orphan diseases, today announced financial and operational results for the first quarter ended June 30, 2022.

Recent Highlights

- The Company is preparing the GTX-104 PK bridging study results for submission to the U.S. Food and Drug Administration (FDA) in calendar Q3. The Company also plans to submit the proposed design for the Phase 3 safety study along with a request for a Type C meeting with the FDA to confirm the Phase 3 plans and obtain the agency’s feedback before initiating the study in the first half of calendar 2023. The Phase 3 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 (NDA) to the FDA.

- The Company initiated its planned pharmacokinetic (PK) bridging study to evaluate the relative bioavailability of GTX-101 compared to the reference listed drug bupivacaine in 48 healthy subjects. This study is expected to be completed on schedule by the end of calendar 2022, and it will provide important information on the dose and dosing frequency in humans.

- The Company remains on track to initiate the PK bridging study of GTX-102 in the third calendar quarter of 2022 and is expected to report out topline results on schedule before the end of calendar 2022. Assuming the PK bridging study meets its primary endpoint, and based on the FDA’s subsequent guidance, the Company plans to conduct a Phase 3 safety and efficacy trial in Ataxia Telangiectasia (A-T) patients. The Phase 3 study is expected to be initiated in the second half of calendar 2023.

- Company finished the first fiscal quarter ending June 30, 2022, with $38.4 million in cash, cash equivalents and short-term investments. Given certain cost savings and overall efficiencies implemented across the organization, management believes that it now has sufficient capital to fund operations through at least March 2024, allowing for the advancement of GTX-104 through Phase 3 and advancing GTX-102 and GTX-101 to key value inflection points.

Management Discussion

Jan D’Alvise, Chief Executive Officer of Acasti said, “We are making excellent progress on all three of our clinical programs, each of which have important clinical trials underway or to be initiated this fiscal year. All of our drug candidates have already received Orphan Drug Designation from the FDA, and each has the potential to be considered for fast-track review and approval. We are currently planning the Phase 3 safety trial for our lead drug candidate, GTX-104, a novel IV formulation of nimodipine designed to treat patients with subarachnoid hemorrhage (SAH). We also recently initiated a single dose study for GTX-101, a novel topical spray form of the analgesic bupivacaine, which is designed to treat Postherpetic Neuralgia (PHN), the severe and often debilitating nerve pain that can persist following a shingles infection. Very

shortly in calendar Q3, we expect to initiate a PK bridging study for GTX-102, a concentrated oral mucosal spray form of betamethasone, designed to improve the neurological symptoms of patients with Ataxia Telangiectasia (A-T). We are excited about the progress we are making to deliver innovative new treatments to thousands of patients who currently lack effective therapies. We look forward to reporting on the progress and results of these studies."

Program Updates

GTX-104: GTX-104 is a clinical stage, novel formulation of nimodipine for IV infusion in SAH patients. In May 2022, the Company announced that the top line results from its pharmacokinetic (PK) bridging study for GTX-104 had met all its planned study endpoints. The primary objective of the study was to evaluate the relative bioavailability of 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 results showed statistically no difference in maximum and total exposure between GTX-104 and the oral formulation of nimodipine, and no serious adverse events were observed. This means that GTX-104 can be considered essentially bioequivalent to oral nimodipine. Importantly, the inter- and intra-subject variability was also much lower for GTX-104 as compared with oral nimodipine.

The Company believes that 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 could be a key advantage, as 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.

The Company plans to submit its recent PK Bridging study results to the FDA in calendar Q3. The Company also plans to submit its proposed design for the Phase 3 safety study and will request a Type C meeting with the FDA to review the Phase 3 plans and obtain the FDA's feedback and guidance before initiating the Phase 3 safety study in the first half of calendar 2023. The Phase 3 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 for GTX-104 for the treatment of SAH patients.

GTX-102: GTX-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve neurological symptoms of A-T, for which there are currently no FDA-approved therapies. GTX-102 is comprised of a proprietary formulation of the gluco-corticosteroid betamethasone that can be sprayed conveniently over the tongue of the A-T patient.

The Company plans to initiate a PK bridging study of GTX-102 in the third calendar quarter of 2022 and anticipates reporting out the topline results as planned before the end of calendar 2022. Assuming the PK bridging study meets its primary endpoint, the final development step is to conduct a Phase 3 safety and efficacy trial in A-T patients. The Company plans to request a Type B meeting with the FDA following the completion of the PK study to confirm the Phase 3 study design, and the Phase 3 study is expected to be initiated in the second half of calendar 2023. If both studies meet their primary endpoints, an NDA filing for GTX-102 under Section 505(b)(2) would follow.

GTX-101: GTX-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to treat PHN, the severe and often debilitating nerve pain that can persist following a shingles infection. The data from a single dose Phase 1 clinical trial for GTX-101 along with regulatory guidance from the FDA's Division of Anesthesiology has informed the design of additional preclinical toxicology studies, and a proposed

clinical and regulatory pathway to approval. On July 26, 2022, the Company initiated its PK bridging study to evaluate the relative bioavailability of GTX-101 compared to the reference listed drug bupivacaine in 48 healthy subjects. This PK study is the next step in the Company's proposed 505(b)(2) regulatory pathway for GTX-101. The PK study is expected to be completed by the end of calendar 2022 as planned, and it will provide important information on the dose and dosing frequency for additional clinical studies of GTX-101 in humans in 2023.

Fiscal 2022 Financial Results (U.S. Dollars)

The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America.

Research and development expenses, net of government assistance for the three months ended June 30, 2022, totaled $2.6 million compared to $0.5 million for the three months ended June 30, 2021. Our research and development during the quarter ended June 30, 2022, was focused primarily on our clinical development programs for GTX-104, GTX-102, and GTX-101 drug candidates, which were acquired in the merger with Grace Therapeutics Inc. which closed on August 27, 2021. Research and development expenses during the three months ended June 30, 2021, related to the completion of our TRILOGY Phase 3 clinical program for our former drug candidate CaPre.

General and administrative expenses for the quarter ended June 30, 2022, were $1.9 million compared to $2.7 million for the quarter ended June 30, 2021. This reduction was a result of decreased legal, tax, accounting and other professional fees that had been incurred in connection with the Grace merger and the renewal of our at-the-market program during the three months ended June 30, 2021. The decrease in professional fees was partly offset by an increase in salaries and benefits due to the renewed accrual for our employee incentive bonus program in FY'23.

Loss from operating activities for the quarter ended June 30, 2022, was $4.7 million compared to a $3.1 million loss for the quarter ended June 30, 2021.

Net loss and total comprehensive loss for the quarter June 30, 2022, was $4.5 million, or a loss of $0.10 per share, compared to a net loss of $3.1 million, or a loss of $0.12 per share, for the quarter ended June 30, 2021.

Cash, cash equivalents and short-term investments totaled $38.4 million as of June 31, 2022, compared to $43.7 million in cash, cash equivalents and short-term investments as of March 31, 2022. Based on management's current projections, current cash is expected to fund our lead asset GTX-104 through to NDA submission, and GTX-102 and GTX-101 to additional important milestones.

Financing Activities

As previously disclosed, Acasti entered into an amended and restated ATM sales agreement on June 29, 2020 (the "Sales Agreement") with B. Riley FBR Inc., Oppenheimer & Co. Inc. and H.C. Wainwright & Co., LLC (collectively, the "Agents"), to implement an "at-the market" equity offering program under which Acasti may issue and sell from time to time its common shares having an aggregate offering price of up to $75 million through the Agents (the "ATM Program"). Pursuant to the ATM Program, as required pursuant to the policies of the TSX Venture Exchange ("TSXV"), since the last distributions reported on June 22, 2021, Acasti issued an aggregate of 206,010 common shares (the "ATM Shares") over the NASDAQ Stock Market for aggregate gross proceeds to the Company of US $200,000. The ATM Shares

were sold at prevailing market prices averaging US $0.97 per share. No securities were sold through the facilities of the TSXV or, to the knowledge of the Company, in Canada. The ATM Shares were sold pursuant to a U.S. registration statement on Form S-3 (No. 333-239538) as made effective on July 7, 2020, as well as the Sales Agreement. Pursuant to the Sales Agreement, a cash commission of 3.0% on the aggregate gross proceeds raised was paid to the Agents in connection with their services. The recent ATM sales have been made in the months of May 2022 and June 2022. No sales were made under the ATM Program during the fiscal year ended March 31, 2022. As a result of the recent ATM sales since March 2022, Acasti has a total of 44,494,193 common shares issued and outstanding as of August 10, 2022.

Conference Call Details

Acasti will host a conference call on Thursday, August 11, 2022, at 1:00 PM Eastern Time to discuss the Company's corporate progress and other developments, as well as financial results for its quarter ended June 30, 2022.

The conference call will be available via telephone by dialing toll free 844-836-8745 for U.S. callers or +1 412-317-6797 for international callers. A webcast of the call may be accessed at https://app.webinar.net/972kwK4obMY or on the Company's Investor Relations section of its website: https://www.acastipharma.com/investors/.

A webcast replay will be available on the Investors News/Events section of the Company's website (https://www.acastipharma.com/investors/) through August 10, 2023. A telephone replay of the call will be available approximately one hour following the call, through August 18, 2022, and can be accessed by dialing 877-344-7529 for U.S. callers or +1 412-317-0088 for international callers and entering replay access code: 7767644.

About Acasti

Acasti is a 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 provides the assets with seven years of marketing exclusivity post-launch in the United States, and have 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 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 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,” “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 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 and Acasti’s other pre-clinical and clinical trials for GTX-102 and GTX-101; (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) actual costs associated with Acasti’s clinical trials as compared to management’s current expectations; 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 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. 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.

For more information, please contact:

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ACASTI PHARMA INC.
Condensed Consolidated Interim Balance Sheet
(Unaudited)

(Expressed in thousands of U.S. dollars except share data)	June 30, 2022 $	March 31, 2022 $
Assets		
Current assets:		
Cash and cash equivalents	38,377	30,339
Short-term investments	16	13,322
Receivables	964	548
Assets held for sale	352	352
Prepaid expenses	1,539	720
Total current assets	41,248	45,281
Right of use asset	819	315
Equipment	90	250
Intangible assets	69,810	69,810
Goodwill	12,964	12,964
Total assets	124,931	128,620
Liabilities and shareholders' equity		
Current liabilities:		
Trade and other payables	3,062	3,156
Lease liability	645	104
Total current liabilities	3,707	3,260
Derivative warrant liabilities	—	10
Lease Liability	174	191
Deferred tax liability	16,647	16,889
Total liabilities	20,528	20,350
Shareholders' equity:		
Common shares	258,185	257,990
Additional paid-in capital	12,618	12,154
Accumulated other comprehensive loss	(6,039)	(6,037)
Accumulated deficit	(160,361)	(155,837)
Total shareholder's equity	104,403	108,270
Commitments and contingencies		
Total liabilities and shareholders' equity	124,931	128,620

ACASTI PHARMA INC.
Condensed Consolidated Interim Statements of Loss and Comprehensive Loss
(Unaudited)

Three months ended June 30, 2022 and 2021

	Three-month ended	
	June 30, 2022	June 30, 2021
(Expressed in thousands of U.S dollars, except per share data)	$	$
Operating expenses		
Research and development expenses, net of government assistance	(2,590)	(469)
General and administrative expenses	(1,919)	(2,676)
Sales and marketing expenses	(221)	—
Loss from operating activities	(4,730)	(3,145)
Financial income (expenses)	(36)	27
Loss before income tax recovery	(4,766)	(3,118)
Income tax recovery	242	—
Net loss and total comprehensive loss	(4,524)	(3,118)
Basic and diluted loss per share	(0.10)	(0.12)
Weighted average number of shares outstanding	44,328,049	26,046,950