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): June 21, 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 June 21, 2022, Acasti Pharma Inc. issued a press release announcing its financial results for the fiscal year ended March 31, 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 it be 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 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 June 21, 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: June 21, 2022

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

Acasti Pharma Reports Fiscal Year 2022 Operational Results

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

For Immediate Release

LAVAL, Québec, June 21, 2022 (PR NEWSWIRE) -- 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 fiscal year ended March 31, 2022.

Recent Highlights

- Acasti's 3 lead programs are on schedule to initiate new clinical trials in the second half of calendar 2022 including:
  - GTX-104 – Initiate Phase 3 safety trial (Q4 calendar year)
  - GTX-102 – Initiate PK Bridging Study (Q3 calendar year)
  - GTX-101 – Initiate Single Dose and Multiple Ascending Dose PK studies (Q3 calendar year)
- Company ended the year (March 31, 2022) with $43.7 million in cash, cash equivalents and short-term investments.
- Achieved positive top line results for the pharmacokinetic (PK) bridging study with IV GTX-104, our lead drug candidate for the treatment of Subarachnoid Hemorrhage (SAH), with the study having met all its planned endpoints.
- Preparing the GTX-104 PK bridging study results for submission to the U.S. Food and Drug Administration (FDA), along with the Company's proposed design for the Phase 3 safety study, which remains on track to start in the second half of calendar 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.
- European Patent Office provided notice of allowance of the Company's composition of matter patent for GTX-104. The patent is expected to be valid until 2037.
- United States Patent and Trademark Office issued a notice of allowance for the Company's composition of matter patent for GTX-102, a novel, easy-to-use oral mucosal formulation of betamethasone, intended to improve symptoms of ataxia-telangiectasia (A-T). The patent is expected to be valid until 2037.
- Japanese Patent Office granted a composition of matter patent for the Company's GTX-101 topical spray targeting postherpetic neuralgia (PHN). The granted patent is valid until 2036.
- Appointed Michael L. Derby to our board of directors.

Management Discussion

Jan D'Alvise, Chief Executive Officer of Acasti said, "Fiscal year 2022 was a truly transformative year for Acasti, and I am extremely pleased with all our team has accomplished over the last 12 months. In FY'22, we pivoted as a company, and acquired Grace Therapeutics in August 2021. This gave us a new mission of leveraging Grace's proprietary drug delivery technologies to reformulate and repurpose marketed medicines for indications in rare and orphan diseases, where significant unmet medical needs exist. We now have three drug candidates advancing in clinical development, and all three have already received Orphan Drug Designation by the FDA, which could grant us 7 years of market exclusivity in the US. Just a few weeks ago we announced that GTX-104, a novel IV formulation of nimodipine, met all its PK Bridging Study endpoints, and we are now working with the FDA to commence a Phase 3 study, which we expect to be the final step required to seek regulatory approval. We also advanced our other drug candidates, GTX-102 and GTX-101, into the clinic with significant potential milestones expected later this calendar year."

D'Alvise continued, "We are confident that our strong balance sheet, which shows $43.7 million of cash and short-term investments as of March 31, 2022, will allow us to advance GTX-104 through Phase 3 and to potential FDA submission, while similarly advancing GTX-102 and GTX-101 to key value inflection points. We look forward to the coming fiscal year with tremendous excitement."

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 top line results of its pharmacokinetic (PK) bridging study with IV GTX-104 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. Importantly, the inter- and intra-subject variability was also much lower for GTX-104 as compared with oral nimodipine. The Company believes 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 data results to the FDA, along with its proposed study design for the Phase 3 safety study, which remains on schedule to start in the second half of calendar 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 treat SAH patients to the FDA.

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 the glucocorticoid betamethasone that can be sprayed conveniently over the tongue of the A-T patient. The Company plans to initiate the PK bridging study of GTX-102 in the third calendar quarter of 2022 and is expected to report out results before the end of calendar 2022. Based on the FDA's guidance and assuming the PK bridging study meets its primary endpoint, the Company plans to conduct a Phase 3 safety and efficacy trial in A-T patients. The Phase 3 study is expected to be initiated in the first half of calendar 2023. If both studies meet their primary endpoints, an NDA filing 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. The Company plans to initiate both a single dose study and a multiple ascending dose study in healthy human volunteers in calendar Q3, 2022. Results for these studies are expected to report out before the end of calendar 2022. Results from these pre-clinical and clinical studies are required before the Company can initiate its Phase 2 program in PHN patients, which is expected to start in early calendar 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 ("U.S. GAAP").

Research and development expenses, net of government assistance for the twelve months ended March 31, 2022 totaled $5.6 million compared to $4.2 million for the twelve months ended March 31, 2021. Our research and development during the year ended March 31, 2022 was focused primarily on advancing the clinical development programs for our GTX 104, GTX 102, and GTX 101 drug candidates, which were acquired in the Grace merger completed on August 27, 2021. Research and development expenses during the year ended March 31, 2021 related to the completion of our TRILOGY Phase 3 clinical program for CaPre, and due diligence activities on various strategic options under review prior to the Grace merger announcement.

General and administrative expenses for the year ended March 31, 2022 were $9.3 million compared to $5.5 million for the year ended March 31, 2021. This increase was a result of increased legal, tax, accounting and other professional fees related to the Grace merger, and the renewal of our at-the-market program.

Loss from operating activities for the year ended March 31, 2022 was $15.6 million compared to a $16.4 million loss for the year ended March 31, 2021.

The Company incurred net financial income (expenses) gain for the year ended March 31, 2022 of $5.1 million compared to $(3.3) million for the year ended March 31, 2021. The change is primarily due to change in fair value of derivative warrant liabilities.

Net loss and total comprehensive loss for the year ended March 31, 2022 was $9.8 million, or $0.27 loss per share, compared to a net loss of $19.7 million, or $1.33 loss per share for the year ended March 31, 2021.

Cash, cash equivalents and short-term investments totaled $43.7 million as of March 31, 2022 compared to $60.7 million in cash, cash equivalents and short-term investments as of March 31, 2021. 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 key milestones.

Conference Call Details

Acasti will host a conference call on Tuesday, June 21, 2022, at 1:00 PM Eastern Time to discuss the Company's corporate progress and other developments, as well as financial results for its fiscal year ended March 31, 2022.

The conference call will be available via telephone by dialing toll free 844-836-8745 for U.S. callers or +1 412-317-5499 for international callers and using entry code 316432. A webcast of the call may be accessed at https://app.webinar.net/RLkpwLG5mAx 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 June 21, 2023. A telephone replay of the call will be available approximately one hour following the call, through June 28, 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: 1970306.

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; (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 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.

CONSOLIDATED BALANCE SHEET

(Expressed in thousands of U.S. dollars)	March 31, 2022 $	March 31, 2021 $
Assets		
Total current assets	45,531	62,372
Right of Use Asset	315	86
Intangible assets	69,810	—
Goodwill	12,964	—
Total assets	**128,620**	**62,458**
Liabilities and Shareholders' equity		
Total current liabilities	3,260	1,579
Derivative warrant liabilities	10	5,219
Lease Liability	191	—
Deferred tax liability	16,889	—
Total liabilities	**20,350**	**6,798**
Shareholders' Equity:		
Common shares	257,990	197,194
Additional paid-in capital	12,154	10,817
Accumulated other comprehensive loss	(6,037)	(6,333)
Accumulated deficit	(155,837)	(146,018)
Total Shareholder's equity	**108,270**	**55,660**
Total liabilities and shareholders' equity	**128,620**	**62,458**

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended		
(Expressed in thousands of U.S. dollars except share data)	March 31, 2022 $	March 31, 2021 $	Increase (Decrease) $
Revenue	—	196	(196)
Operating expenses			
Cost of sales of products	—	76	(76)
Research and development expenses, net of government assistance	5,559	4,173	1,386
General and administrative expenses	9,263	5,521	3,742
Sales and marketing expenses	518	1,142	(624)
Impairment of Intangible assets	—	3,706	(3,706)
Impairment of Equipment	—	1,584	(1,584)
Impairment of Other assets and prepaids	249	413	(164)
Loss from operating activities	(15,589)	(16,419)	(830)
Financial income (expenses)	5,122	(3,259)	8,381
Income tax recovery	648	—	648
Net loss	(9,819)	(19,678)	(9,859)

For more information, please contact:

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