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, 2024

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.)**
103 Carnegie Center Suite 300 Princeton, New Jersey		**08540**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 818 839-4378

(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, 2024, Acasti Pharma Inc. issued a press release announcing its financial results for the fiscal year ended March 31, 2024. 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 Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release, dated June 21, 2024.
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, 2024

By: /s/ Prashant Kohli

Prashant Kohli
Chief Executive Officer

acasti

Exhibit 99.1

Acasti Announces Year-End 2024 Financial Results, Provides Business Update

- *Patient Enrollment in Pivotal STRIVE-ON Phase 3 Safety Trial for GTX-104 On-Track for Potential NDA Submission in 1H Calendar 2025*
- *Projected Cash Runway into Second Calendar Quarter 2026*

Princeton, NJ, June 21, 2024 (GLOBE NEWSWIRE)-- Acasti Pharma Inc. (Nasdaq: ACST) (Acasti or the Company), a late-stage, biopharma company advancing GTX-104, its novel injectable formulation of nimodipine that addresses high unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH), today announced financial results and business highlights for the year ended March 31, 2024.

"During the past year we continued to execute our focused strategy around our biggest value driver program GTX-104 and its pivotal Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial–NCT05995405)," said Prashant Kohli, CEO of Acasti. "Since initiating STRIVE-ON and dosing the first patient last October, enrollment has proceeded steadily, and we believe the trial is on track for a potential NDA submission to the FDA in the first half of calendar 2025. With our balance sheet enhanced by the $7.5 million private placement secured in September 2023, and disciplined execution of the strategic realignment plan we announced in May 2023, our cash runway is expected to extend into the second calendar quarter of 2026, well beyond our planned submission of the GTX-104 NDA."

2024 Corporate Highlights

- Overview of STRIVE-ON trial, a prospective, open-label, randomized (1:1 ratio), parallel group trial of GTX-104 compared with oral nimodipine, in patients hospitalized for aSAH, presented as a poster at the *2024 International Stroke Conference*
- Enrollment of STRIVE-ON trial on track for potential NDA submission to FDA anticipated in the first half of calendar 2025
- Conducted a meeting of STRIVE-ON trial investigators in April 2024; the in-person/virtual meeting provided an excellent opportunity to energize the principal investigators from all sites, engage in an interactive discussion about the trial inclusion/exclusion criteria, and to review key procedures to ensure quality data collection
- In October 2023 hosted a Key Opinion Leader Event GTX-104: A Potential New Treatment Standard for Rare and Life-Threatening aneurysmal Subarachnoid Hemorrhage (aSAH)
- Completed $7.5 million private placement equity financing led by ADAR1 Partners, LP in September 2023
- Presented a pharmacokinetic comparison of GTX-104 with oral nimodipine at the 2023 *Neurocritical Care Society* annual meeting in August 2023.

Fiscal Year 2024 Financial Results

The Company reported a net loss of $12.9 million, or $1.35 loss per share, for the year ended March 31, 2024, a decrease of $29.5 million from the net loss of $42.4 million or $5.71 per share for the year ended March 31, 2023. The decrease in net loss was primarily due to asset impairments, net of income tax benefit, totaling $25.3 million during the year ended March 31, 2023 that did not recur during the year ended March 31, 2024, the impact of the Company's strategic realignment in May 2023 to align the organizational and management cost structure to prioritize resources to GTX-104, and the change in fair value of the Company's derivative warrant liabilities that was primary attributable to an increase in stock price.

Research and development expenses for the year ended March 31, 2024 were $4.7 million, compared to $10.0 million for the year March 31, 2023. The decrease from the prior year period was mainly attributable to the Company's strategic realignment in May 2023, which resulted in reduced clinical development and salaries and benefits expenses.

General and administrative expenses were $6.4 million for the year ended March 31, 2024, a decrease of $1.2 million from $7.6 million for the year ended March 31, 2023. The decrease was primarily a result of decreased salaries and benefits due to a reduction in general and administrative headcount as a result of the restructuring and reorganization of our management structure offset by increased legal, tax, accounting and other professional fees related to the restructuring and private placement.

At March 31, 2024 the Company had cash and cash equivalents of $23.0 million, as compared to $27.9 million as of March 31, 2023. The Company believes it has sufficient cash to support operations into the second calendar quarter of 2026.

About aneurysmal Subarachnoid Hemorrhage (aSAH)

aSAH 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. Approximately 70% of aSAH patients experience death or dependence, and more than 30% die within one month of hemorrhage. Approximately 50,000 patients in the United States are affected by aSAH per year, based on market research. Outside of the United States, annual cases of aSAH are estimated at approximately 60,000 in the European Union, and approximately 150,000 in China.

About the Acasti Asset Portfolio

GTX-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous (IV) infusion in aSAH patients to address significant unmet medical needs. The unique nanoparticle technology of GTX-104 facilitates aqueous formulation of insoluble nimodipine for a standard peripheral IV infusion.

GTX-104 provides a convenient IV delivery of nimodipine in the Intensive Care Unit potentially eliminating the need for nasogastric tube administration in unconscious or dysphagic patients. Intravenous delivery of GTX-104 also has the potential to lower food effects, drug-to-drug interactions, and eliminate potential dosing errors. Further, GTX-104 has the potential to better manage hypotension in aSAH patients. GTX-104 has been administered in over 150 healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine. The addressable market in the United States for GTX-104 is estimated to be about $300 million, based on market research.

GTX-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve neurological symptoms of Ataxia-Telangiectasia (A-T), for which there are currently no FDA-approved therapies. GTX-102 is a stable, concentrated oral spray formulation comprised of the gluco-corticosteroid betamethasone that, together with other excipients can be sprayed conveniently over the tongue of the A-T patient and is rapidly absorbed. The further development of GTX-102 has been deprioritized in favor of our focus on development of GTX-104. It is also possible that we may out-license or sell our GTX-102 drug candidate.

GTX-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to ease the symptoms of patients suffering with postherpetic neuralgia ("PHN"). GTX-101 is administered via a

metered-dose of bupivacaine spray and forms a thin bio-adhesive topical film on the surface of the patient's skin, which enables a touch-free, non-greasy application. It also comes in convenient, portable 30 ml plastic bottles. Unlike oral gabapentin and lidocaine patches, we believe that the biphasic delivery mechanism of GTX-101 has the potential for rapid onset of action and continuous pain relief for up to eight hours. No skin sensitivity was reported in a Phase 1 trial. The further development of GTX-101 has been deprioritized in favor of our focus on development of GTX-104. It is also possible that we may out-license or sell our GTX-101 drug candidate.

About Acasti

Acasti is a late-stage biopharma company with 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. Acasti's lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provides seven years of marketing exclusivity post-launch in the United States, and additional intellectual property protection with over 40 granted and pending patents. Acasti's lead clinical asset, GTX-104, is an intravenous infusion targeting aneurysmal Subarachnoid Hemorrhage (aSAH), 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.

For more information, please visit: www.acasti.com.

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 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, including statements regarding the Company's anticipated cash runway, the timing of the planned NDA submission with the FDA in connection with the Company's STRIVE-ON trial, GTX-104's commercial prospects, GTX-104's potential to bring enhanced treatment options to patients suffering from aSAH, and the anticipated benefits and future development, license or sale of the Company's other drug candidates 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 Phase 3 safety trial for GTX-104; (ii) regulatory requirements or developments and the outcome and timing of the proposed NDA application for GTX-104; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; and (v) actual costs associated with Acasti's clinical trials as compared to management's current expectations. 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.

For more information, please contact:

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---tables to follow---

Exhibit 99.1

ACASTI PHARMA INC.
Consolidated Balance Sheets

(Expressed in thousands except share data)	March 31, 2024 $	March 31, 2023 $
Assets		
Current assets:		
Cash and cash equivalents	23,005	27,875
Short-term investments	—	15
Receivables	722	802
Prepaid expenses	283	598
Total current assets	24,010	29,290
Operating lease right of use asset	—	463
Equipment, net	24	104
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	73,300	79,123
Liabilities and Shareholders' equity		
Current liabilities:		
Trade and other payables	1,684	3,336
Operating lease liability	—	75
Total current liabilities	1,684	3,411
Derivative warrant liabilities	4,359	—
Operating lease liability	—	410
Deferred tax liability	5,514	7,347
Total liabilities	11,557	11,168
Commitments and contingencies		
Shareholders' equity:		
Class A common shares, no par value per share; unlimited shares authorized; 9,399,404 and 7,435,533 shares issued and outstanding as of March 31, 2024 and 2023, respectively	261,038	258,294
Class B, C, D and E common shares, no par value per share; unlimited shares authorized; none issued and outstanding	—	—
Additional paid-in capital	17,862	13,965
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(211,119)	(198,266)
Total shareholders' equity	61,743	67,955
Total liabilities and shareholders' equity	73,300	79,123

Exhibit 99.1

ACASTI PHARMA INC.
Consolidated Statements of Operations and Comprehensive Loss

(Expressed in thousands, except share and per data)	Year ended March 31, 2024 $	Year ended March 31, 2023 $
Operating expenses		
Research and development expenses, net of government assistance	(4,683)	(9,972)
General and administrative expenses	(6,432)	(7,614)
Sales and marketing	(252)	(661)
Restructuring cost	(1,485)	—
Impairment of intangible assets	—	(28,682)
Impairment of goodwill	—	(4,826)
Impairment of assets held for sale	—	(400)
Loss from operating activities	(12,852)	(52,155)
Foreign exchange loss	(16)	(72)
Change in fair value of derivative warrant liabilities	(2,728)	10
Interest income and other expense, net	911	246
Total other income (expense), net	(1,833)	184
Loss before income tax benefit	(14,685)	(51,971)
Income tax benefit	1,832	9,542
Net loss and total comprehensive loss	(12,853)	(42,429)
Basic and diluted loss per share	(1.35)	(5.71)
Weighted average number of shares outstanding	9,529,123	7,435,472