

**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 09, 2024

ACASTI PHARMA INC.

(Exact name of Registrant as Specified in Its Charter)

Quebec
(State or Other Jurisdiction
of Incorporation)

001-35776
(Commission File Number)

98-1359336
(IRS Employer
Identification No.)

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

08540
(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 August 9, 2024, Acasti Pharma Inc. issued a press release announcing its financial results for the fiscal quarter ended June 30, 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**

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release, dated August 9, 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: August 9, 2024

By: /s/ Prashant Kohli
Prashant Kohli
Chief Executive Officer

Acasti Announces First Fiscal Quarter 2025 Financial Results, Provides Business Update

- *Surpassed 50% Enrollment Milestone in Pivotal Phase 3 STRIVE-ON Safety Trial of GTX-104*
- *Company Anticipates Completion of Patient Enrollment in the STRIVE-ON Trial in Late 2024 to Early 2025, with NDA Submission on Track for 1H Calendar 2025*
- *Projected Cash Runway into Second Calendar Quarter 2026*

Princeton, NJ, August 9, 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 quarter ended June 30, 2024.

"As a result of unrelenting focus on patient enrollment by the Acasti team and participating clinical trial sites, we surpassed the 50% enrollment milestone in our Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial--NCT05995405)," said Prashant Kohli, CEO of Acasti. "Investigators continue to be very enthusiastic about the potential of GTX-104 for the treatment of aSAH. These patients require intensive management and present with a variety of complications that make consistent administration of oral nimodipine difficult, and GTX-104 may provide an effective IV alternative to the current standard of care. Based on enrollment trends and ongoing engagement with investigators, we anticipate randomizing all 100 patients in late 2024 to early 2025. We believe that the STRIVE-ON trial is on track for a potential New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) in the first half of calendar 2025."

First Fiscal Quarter 2025 Highlights

- Pivotal Phase 3 STRIVE-ON safety trial surpassed the 50% enrollment milestone.
- 100% patient enrollment of STRIVE-ON trial projected for late calendar 2024 or early 2025.
- NDA submission to FDA for GTX-104 anticipated in the first half of calendar 2025.
- Conducted a meeting of STRIVE-ON trial investigators in April 2024.

First Fiscal Quarter 2025 Financial Results

The Company reported a net loss of \$2.6 million, or \$0.24 loss per share, for the quarter ended June 30, 2024, a decrease of \$1.4 million from the net loss of \$4.0 million or \$0.54 per share for the quarter ended June 30, 2023. The decrease in net loss was primarily due to restructuring costs of \$1.5 million during the three months ended June 30, 2023 and a \$1.4 million decrease to the fair value of our derivative warrant liabilities, offset in part by a \$1.6 million increase in research and development expenses.

Total research and development expenses for the quarter ended June 30, 2024 were \$2.7 million, compared to \$1.1 million for the quarter ended June 30, 2023. This increase of \$1.6 million was primarily due to the increase in our research activities for our GTX-104 pivotal Phase 3 STRIVE-ON safety clinical trial.

General and administrative expenses were \$2.3 million for the quarter ended June 30, 2024, an increase of \$0.4 million from \$1.9 million for the year quarter ended June 30, 2023. The increase was primarily a result of increased legal, tax, accounting and other professional fees related to the proposed change in the jurisdiction of incorporation of Acasti from the Province of Québec in Canada to the State of Delaware in the United States.

At June 30, 2024 the Company had cash and cash equivalents of \$19.4 million, as compared to \$23.0 million, as of March 31, 2024. 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 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 license or sell our GTX-101 drug candidate.

About Acasti



Exhibit 99.1

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 completing full patient enrollment in its Phase 3 STRIVE-ON safety trial of GTX-104, the timing of the Company's planned NDA submission with the FDA in connection with the Company's Phase 3 STRIVE-ON safety trial, GTX-104's commercial prospects; the size of the addressable market for GTX-104, the Company's beliefs regarding the potential benefits of GTX-104, including 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 STRIVE-ON 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:

Acasti Contact:



Exhibit 99.1

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---tables to follow---

**Exhibit 99.1****ACASTI PHARMA INC.**
Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2024	March 31, 2024
	\$	\$
<i>(Expressed in thousands except share data)</i>		
Assets		
Current assets:		
Cash and cash equivalents	19,394	23,005
Short-term investments	15	—
Receivables	398	722
Prepaid expenses	622	283
Total current assets	20,429	24,010
Equipment, net	23	24
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	69,718	73,300
Liabilities and Shareholders' equity		
Current liabilities:		
Trade and other payables	2,600	1,684
Total current liabilities	2,600	1,684
Derivative warrant liabilities	2,964	4,359
Deferred tax liability	4,790	5,514
Total liabilities	10,354	11,557
Commitments and contingencies		
Shareholders' equity:		
Class A common shares, no par value per share; unlimited shares authorized; 10,139,861 and 9,399,404 shares issued and outstanding as of June 30, 2024 and March 31, 2024, respectively	261,038	261,038
Class B, C, D and E common shares, no par value per share; unlimited shares authorized; none issued and outstanding	—	—
Additional paid-in capital	18,100	17,862
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(213,736)	(211,119)
Total shareholders' equity	59,364	61,743
Total liabilities and shareholders' equity	69,718	73,300

**Exhibit 99.1****ACASTI PHARMA INC.**
Condensed Consolidated Statements of Loss and Comprehensive Loss
(Unaudited)

	Three months ended	
	June 30, 2024	June 30, 2023
	\$	\$
<i>(Expressed in thousands, except share and per share data)</i>		
Operating expenses		
Research and development expenses, net of government assistance	(2,708)	(1,095)
General and administrative expenses	(2,255)	(1,874)
Restructuring cost	—	(1,485)
Loss from operating activities	(4,963)	(4,454)
Foreign exchange (loss) gain	(8)	8
Change in fair value of derivative warrant liabilities	1,395	—
Interest income and other expense, net	235	134
Total other income, net	1,622	142
Loss before income tax recovery	(3,341)	(4,312)
Income tax benefit	724	289
Net loss and total comprehensive loss	(2,617)	(4,023)
Basic and diluted loss per share	(0.24)	(0.54)
Weighted-average number of shares outstanding	10,928,543	7,435,533