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): February 12, 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: 609 649-9272

(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 February 12, 2024, Acasti Pharma Inc. issued a press release announcing its financial results for the fiscal quarter ended December 31, 2023. 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 February 12, 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: February 12, 2024

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

Exhibit 99.1

Acasti Announces Third Fiscal Quarter 2024 Financial Results and Business Highlights

- *Projected Cash Runway Extends into Second Calendar Quarter 2026, Well Beyond Potential 1H 2025 Submission of GTX-104 New Drug Application (NDA)*
- *Patient Enrollment in Pivotal STRIVE-ON Phase 3 Trial Continues, On Track for NDA Submission Timeline*
- *Poster Highlighting the STRIVE-ON Trial Presented at 2024 International Stroke Conference*

Princeton, NJ, February 12, 2024 (GLOBE NEWSWIRE)-- Acasti Pharma Inc. (Nasdaq: ACST) (Acasti or the Company), a late-stage, biopharma company advancing GTX-104, its novel 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 December 31, 2023.

"During the third quarter 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). Having dosed the first patient in October, we've continued to enroll more patients and sites since that time," said Prashant Kohli, CEO of Acasti. "With our balance sheet enhanced by the $7.5 million private placement secured last quarter and prudent use of resources announced in our strategic realignment plan in May 2023, our cash runway is now expected to extend into the second calendar quarter of 2026, well beyond our potential submission of GTX-104 NDA in the first half of 2025."

Recent Corporate Highlights

- Announced dosing of first patient in 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.
- STRIVE-ON trial on track for potential NDA submission with the FDA anticipated to occur in the first half of calendar 2025.
- Hosted a Key Opinion Leader Event GTX-104: A Potential New Treatment Standard for Rare and Life-Threatening aneurysmal Subarachnoid Hemorrhage (aSAH)
- Overview of STRIVE-ON trial presented as a poster at the *2024 International Stroke Conference*.

Third Quarter 2024 Financial Results

On June 29, 2023, the Board of Directors of the Company approved a reverse stock split of the Company's Class A common shares, no par value per share, at a ratio of 1-for-6, which was effective on July 10, 2023. All references below to the number of common shares, price per share and weighted average number of shares outstanding have been adjusted to reflect such reverse stock split.

The Company reported a net loss of $2.4 million, or $0.21 per share, for the three months ended December 31, 2023, a decrease of $1.5 million from the net loss of $3.9 million, or $0.52 per share, for the three

months ended December 31, 2022. The Company's net loss of $2.4 million for the three months ended December 31, 2023, included $3.0 million of operating expenses, that were offset in part by interest income of $0.3 million from our investments, $0.1 million gain on change in fair of derivative warrant liabilities and $0.2 million in income tax recovery.

- **Research and development expenses** for the three months ended December 31, 2023 totaled $1.4 million compared to $2.5 million for the three months ended December 31, 2022. The decrease from the prior year period was mainly attributable to the Company's strategic realignment plan to align the organizational and management cost structure to prioritize resources to GTX-104, thereby reducing losses to improve cash flow and extend available cash resources.
- **General and administrative expenses** were $1.6 million for the three months ended December 31, 2023, unchanged from $1.6 million for the three months ended December 31, 2022.

The Company's cash, cash equivalents and short-term investments as of December 31, 2023, were $25.1 million. The Company believes its cash, cash equivalents and short-term investments are sufficient to fund its 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.

About GTX-104

GTX-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous infusion (IV) 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. 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 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: 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 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, and GTX-104's potential to bring enhanced treatment options to patients suffering from aSAH 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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ACASTI PHARMA INC.
Condensed Consolidated Interim Balance Sheets
(Unaudited)

(Expressed in thousands except share data)	December 31, 2023 $	March 31, 2023 $
Assets		
Current assets:		
Cash and cash equivalents	18,545	27,875
Short-term investments	6,569	15
Receivables	959	802
Prepaid expenses	811	598
Total current assets	26,884	29,290
Operating lease right of use asset	23	463
Equipment	12	104
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	76,185	79,123
Liabilities and Shareholders' equity		
Current liabilities:		
Trade and other payables	1,746	3,336
Operating lease liability	24	75
Total current liabilities	1,770	3,411
Derivative warrant liabilities	3,332	—
Operating lease liability	—	410
Deferred tax liability	6,403	7,347
Total liabilities	11,505	11,168
Commitments and contingencies		
Shareholders' equity:		
Class A common shares, no par value per share; unlimited shares authorized as of December 31, 2023 and March 31, 2023; 9,399,404 and 7,435,533 shares issued and outstanding as of December 31, 2023 and March 31, 2023, respectively	261,038	258,294
Class B, C, D and E common shares, no par value per share; unlimited shares authorized as of December 31, 2023 and March 31, 2023; none issued and outstanding	—	—
Additional paid-in capital	17,633	13,965
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(207,953)	(198,266)
Total shareholders' equity	64,680	67,955
Total liabilities and shareholders' equity	76,185	79,123

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

	Three months ended		Nine months ended	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
(Expressed in thousands, except share and per share data)	$	$	$	$
Operating expenses				
Research and development expenses, net of government assistance	(1,443)	(2,450)	(2,998)	(8,332)
General and administrative expenses	(1,570)	(1,589)	(4,922)	(5,187)
Sales and marketing	(30)	(206)	(184)	(563)
Restructuring cost	—	—	(1,485)	—
Loss from operating activities	(3,043)	(4,245)	(9,589)	(14,082)
Foreign exchange gain (loss)	3	15	(2)	(75)
Change in fair value of derivative warrant liabilities	125	—	(1,701)	10
Interest income and other expense, net	316	67	662	134
Total other income (expense), net	444	82	(1,041)	69
Loss before income tax recovery	(2,599)	(4,163)	(10,630)	(14,013)
Income tax recovery	208	274	943	671
Net loss and total comprehensive loss	(2,391)	(3,889)	(9,687)	(13,342)
Basic and diluted loss per share	(0.21)	(0.52)	(1.09)	(1.80)
Weighted-average number of shares outstanding	11,506,257	7,435,472	8,874,872	7,416,318