November 13, 2023

Acasti Announces Second Quarter 2024 Financial Results and Business Highlights

- *Announced Dosing of First Patient in Pivotal STRIVE-ON Phase 3 Randomized Trial for GTX-104*
- *Completed $7.5 Million Private Placement Equity Financing led by ADAR1 Partners, LP, Providing Funding Well Beyond Anticipated Submission of GTX-104 New Drug Application (NDA)*
- *Highlighted the Potential of GTX-104 as New Treatment Standard for Aneurysmal Subarachnoid Hemorrhage (aSAH) in Key Opinion Leader Virtual Webinar*
- *Presented Poster on Pharmacokinetic Comparison of GTX-104 with Oral Nimodipine at 2023 Neurocritical Care Society Annual Meeting*

PRINCETON, N.J., Nov. 13, 2023 (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 the high unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH), today announced financial results and business highlights for the quarter ended September 30, 2023.

"During our second quarter we achieved significant strategic milestones, including initiating our pivotal Phase 3 STRIVE-ON randomized trial (the STRIVE-ON trial–NCT05995405) and securing $7.5 million, before expenses, in private placement financing with fundamental investors to provide funding well beyond the anticipated submission of GTX-104 NDA to the U.S. Food and Drug Administration (FDA) in the first half of 2025," said Prashant Kohli, CEO of Acasti. "This financing, led by ADAR1 with participation from other investors including existing shareholders and Acasti's Board Chairman, represents an important vote of confidence from the investment community. The potential of GTX-104 as an improvement over the current standard of care in aSAH was further reinforced in the virtual webinar we hosted in October with W. Taylor Kimberly, MD, PhD (Massachusetts General Hospital), which highlighted the key potential advantages of our novel injectable formulation over oral nimodipine. With our STRIVE-ON trial actively enrolling patients and a stronger balance sheet, we are well positioned to advance GTX-104 and realize its clinical and commercial prospects as a potential new treatment standard for aSAH."

Recent Corporate Highlights

- Announced Dosing of First Patient in GTX-104 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 SAH.
    - The prestigious UTHealth Houston is the first site to enroll an aSAH patient in the STRIVE-ON trial.
    - STRIVE-ON trial on track for potential NDA submission with the FDA anticipated

to occur in the first half of calendar 2025.

- Acasti previously announced alignment with FDA on GTX-104 pivotal Phase 3 trial protocol and obtained guidance on potential NDA submission package.

- Hosted a Key Opinion Leader Event GTX-104: A Potential New Treatment Standard for Rare and Life-Threatening aneurysmal Subarachnoid Hemorrhage (aSAH)
  - W. Taylor Kimberly, MD, PhD (Massachusetts General Hospital) joined Acasti leadership to discuss the high unmet medical need and current treatment landscape for patients suffering from aSAH.

  - The event highlighted the potential of GTX-104, a novel formulation of nimodipine as an intravenous infusion and an alternative to the current standard of care. Acasti leadership also provided insight into trial design, market dynamics, and future directions.

- Announced $7.5 Million private placement equity financing with fundamental investors.
  - Acasti currently intends to use the net proceeds from the private placement for clinical trial expenses to complete the Phase 3 clinical trial for GTX-104, prepare and submit an NDA filing for GTX-104 with FDA, pre-commercial planning, working capital and other general corporate purposes.

- Results of a pharmacokinetic comparison of GTX-104 with oral nimodipine presented as a poster at the *2023 Neurocritical Care Society* annual meeting.

Second Quarter 2024 Financial Results

The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America and are presented in U.S. dollars. 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.

- **Net loss** $3.3 million or $0.43 per share for the three months ended September 30, 2023 decreased by $1.7 million from the net loss of $5.0 million or $0.66 per share for the three months ended September 30, 2022. Our net loss of $3.3 million for the three months ended September 30, 2023, included $2.1 million loss from our operating activities and $1.8 million in expenses from the change in fair value of our warrant liabilities. These expenses were partially offset from interest income of $200 thousand from our investments and $446 thousand in income tax recovery.
- **Research and development expenses** before depreciation, amortization and stock-based compensation, expenses for the three months ended September 30, 2023 totaled $0.4 million compared to $3.1 million for the three months ended September 30, 2022. The net decrease was mainly attributable to the restructuring to align our organizational and management cost structure to prioritize resources to GTX-104 and reduce losses to improve cash flow and extend available cash resources.

- **General and administrative expenses** totaled $1.4 million before stock-based compensation and depreciation expense for the three months ended September 30, 2023, an increase of $0.1 million from $1.3 million for the three months ended September 30, 2022. The increase was primarily a result of an increase in legal, tax, accounting and other professional fees, partially offset by decreased salaries and benefits due to a reduction in general and administrative headcount due to our restructuring and reorganization of our management structure.
- **Cash and cash equivalents** as of September 30, 2023, totaled $27.0 million, a decrease of $0.9 million compared to cash and cash equivalents totaling $27.9 million at March 31, 2023 primarily due to ongoing research and development activities and funding the restructuring expense, offset by the net proceeds of $7.3 million from our September 2023 private placement offering. Our average monthly spend of $1 million for the six months ended September 30, 2023 decreased by $0.6 million from our average monthly spend of $1.6 million for the six months ended September 30, 2022.
- As of September 30, 2023, the Company had 9,399,404 common shares issued and outstanding.

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.

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.

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

(Expressed in thousands of U.S. dollars except share data)	September 30, 2023 $	March 31, 2023 $
Assets		
Current assets:		
Cash and cash equivalents	26,991	27,875
Short-term investments	15	15
Receivables	837	802
Prepaid expenses	1,044	598
Total current assets	28,887	29,290
Operating lease right of use asset	47	463
Equipment	10	104
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	78,210	79,123
Liabilities and Shareholders' equity		
Current liabilities:		
Trade and other payables	1,351	3,336
Operating lease liability	46	75
Total current liabilities	1,397	3,411
Derivative warrant liabilities	3,457	—
Operating lease liability	—	410

Deferred tax liability	6,611	7,347
Total liabilities	11,465	11,168
Shareholders' equity:		
Class A common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 9,399,404 and 7,435,533 shares issued and outstanding as of September 30, 2023 and March 31, 2023	261,038	258,294
Class B common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 0 shares issued and outstanding as of September 30, 2023 and March 31, 2023	—	—
Class C common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 0 shares issued and outstanding as of September 30, 2023 and March 31, 2023	—	—
Class D common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 0 shares issued and outstanding as of September 30, 2023 and March 31, 2023	—	—
Class E common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 0 shares issued and outstanding as of September 30, 2023 and March 31, 2023	—	—
Additional paid-in capital	17,307	13,965
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(205,562)	(198,266)
Total shareholders' equity	66,745	67,955
Commitments and contingencies		
Total liabilities and shareholders' equity	78,210	79,123

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

	Three months ended		Six months ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
(Expressed in thousands of U.S dollars, except share and per share data)	$	$	$	$
Operating expenses				

Research and development expenses, net of government assistance	(460)	(3,292)	(1,555)	(5,882)
General and administrative expenses	(1,589)	(1,680)	(3,352)	(3,599)
Sales and marketing	(43)	(136)	(154)	(357)
Restructuring cost	—	—	(1,485)	—
Loss from operating activities	(2,092)	(5,108)	(6,546)	(9,838)
Foreign exchange gain (loss)	(13)	(12)	(5)	(90)
Change in fair value of warrant liabilities	(1,826)	—	(1,826)	10
Interest income and other expense	212	36	346	68
Total other income (expense), net	(1,627)	24	(1,485)	(12)
Loss before income tax recovery	(3,719)	(5,084)	(8,031)	(9,850)
Income tax recovery	446	155	735	397
Net loss and total comprehensive loss	(3,273)	(4,929)	(7,296)	(9,453)
Basic and diluted loss per share	(0.43)	(0.66)	(0.97)	(1.28)
Weighted average number of shares outstanding	7,552,677	7,425,166	7,494,425	7,406,689

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Source: Acasti Pharma, Inc.