August 11, 2023

Acasti Announces First Quarter 2024 Financial Results and Business Highlights

- *New leadership team singularly focused on executing GTX-104 strategy*
- *Announced alignment with the U.S. Food and Drug Administration (FDA) for Pivotal STRIVE-ON Phase 3 Safety Trial for GTX-104 with first patient expected to be dosed prior to the end of 2023*
- *Cash and cash equivalents as of quarter end were $21.6 million; company reiterates projected cash runway to Q2 2025, beyond potential submission of GTX-104 New Drug Application (NDA)*
- *Abstract of pharmacokinetic comparison of GTX-104 with oral nimodipine accepted for presentation at 2023 Neurocritical Care Society (NCS) annual meeting*

PRINCETON, N.J, Aug. 11, 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 June 30, 2023.

"During our first quarter we made substantial progress executing on the strategic vision we laid out in April, moving with full speed to prioritize development of GTX-104, streamline our operations, extend our cash runway to fully fund the clinical development of GTX-104, and strengthen our leadership team with industry leaders in our sector," said Prashant Kohli, CEO of Acasti. "With FDA alignment of our proposed protocol and dosing regimen for our pivotal Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial) now in hand, we are completing our advanced preparations for the trial, and plan to initiate it in the coming weeks. We expect to dose the first patient in this trial in the fourth quarter of this calendar year and, if successful, potentially submit an NDA for GTX-104 in the first half of calendar 2025. With the efficiencies gained through our operational realignment, we reiterate that our projected cash runway now extends to the second quarter of 2025, inclusive of the potential NDA submission. We are excited about the progress we have made and look forward to presenting the data highlighting the potential of GTX-104 at the NCS conference later next week."

Recent Corporate Highlights

- Implemented strategic realignment plan that extends projected cash runway through calendar Q2 2025
  - Prioritized resources to biggest value driver – GTX-104.
  - Significant extension of the Company's cash runway facilitates the achievement of critical value inflection milestones, including a potential NDA filing for GTX-104.
  - Evaluation of strategic alternatives to maximize value of de-prioritized pipeline assets (GTX-102 and GTX-101) including out-licensing or sale.

- Announced alignment with FDA on the STRIVE-ON trial protocol.
    - The STRIVE-ON trial will be a prospective, open-label, randomized (1:1 ratio), parallel group trial of GTX-104 compared with oral nimodipine, in patients hospitalized for aSAH. Key trial design features include:
        - Approximately 100 patients will be enrolled at an estimated 25 hospitals in the U.S.
        - The primary endpoint is safety and will be measured as comparative adverse events, including hypotension, between the two groups.
        - GTX-104 will be administered as a continuous IV infusion of 0.15 mg/hour, and a 30-minute IV bolus of 4 mg every 4 hours. Oral nimodipine will be administered as 60 mg (two 30 mg capsules) every 4 hours.
        - Both groups will receive their assigned GTX-104 or oral nimodipine for up to 21 consecutive days and will be evaluated from commencement of patient treatment through a 90-day follow-up period.

    - The FDA also provided guidance for a potential GTX-104 NDA submission.
    - GTX-104 has been administered to over 150 healthy subjects to date and has a well- established safety profile.
- Announced selection of WuXi as CRO to conduct the STRIVE-ON trial of GTX-104 in aSAH patients; Acasti and WuXi continue preparatory work in advance of Acasti's recent alignment with the FDA on the protocol for the STRIVE-ON trial.
- Abstract of pharmacokinetic comparison of GTX-104 with oral nimodipine accepted for presentation as a poster at the *2023 Neurocritical Care Society (NCS)* annual meeting.
    - The poster is titled *GTX-104, Novel IV Formulation of Nimodipine to Treat Subarachnoid Hemorrhage: A Pharmacokinetic Comparison with Oral Nimodipine.*

- Enhanced senior leadership team with the appointments of Dr. R. Loch Macdonald, MD, PhD, (Chief Medical Officer), Carrie D'Andrea (VP Clinical Operations), and Amresh Kumar, PhD (VP Program Management).
- Announced expansion of Scientific Advisory Board (SAB) to include:
    - Distinguished physicians and key opinion leaders W. Taylor Kimberly, MD, PhD, Alejandro A. Rabinstein, MD and Sherry H-Y. Chou, MD
    - Acasti’s SAB now possesses clinical expertise in neurosurgery and neurocritical care from leading academic medical centers across the country.

First 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** for the three months ended June 30, 2023, was $4.0 million, or $0.54 per share compared to $4.5 million, or $0.61 per share, for the three months ended June 30, 2022.

- **Research and development expenses** before depreciation, amortization and stock-based compensation expenses for the three months ended June 30, 2023 totaled $1.1 million compared to $2.3 million for the three months ended June 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 $1.7 million before stock-based compensation and depreciation expense for the three months ended June 30, 2023, an increase of $0.1 million from $1.6 million for the three months ended June 30, 2022. The increase was primarily a result of an increase in legal, tax, accounting and other professional fees.
- **Restructuring cost** for the three months ended June 30, 2023, totaled $1.5 million primarily consisting of employee severance costs. On May 8, 2023, the Company communicated its decision to terminate a substantial amount of its workforce as part of a plan that intended to align the Company's organizational and management cost structure to prioritize resources to GTX-104 and reduce losses to improve cash flow and extend available cash resources.
- **Cash and cash equivalents** as of June 30, 2023, totaled $21.6 million, a decrease of $6.2 million compared to cash and cash equivalents totaling $27.8 million at March 31, 2023, primarily due to ongoing research and development activities, and funding the restructuring expense.
- As of June 30, 2023, the Company had 7,435,533 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 anticipated benefits of the Company’s operational restructuring, the timing of the planned initiation of the Company's STRIVE-ON trial, anticipated NDA submission with the FDA, GTX-104's potential to bring enhanced treatment options to patients suffering from aSAH, and the anticipated trial design of STRIVE-ON 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; (ii) regulatory requirements or developments and the outcome and timing of the proposed IND 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. NASDAQ does not accept responsibility for the adequacy or accuracy of this release.

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---tables to follow---

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

		Three months ended	
		June 30, 2023	June 30, 2022
(Expressed in thousands of U.S dollars, except share and per share data)	Notes	$	$
Operating expenses			
Research and development expenses, net of government assistance	6	(1,095)	(2,590)
General and administrative expenses		(1,763)	(1,919)
Sales and marketing		(111)	(221)
Restructuring cost	15	(1,485)	—
Loss from operating activities		(4,454)	(4,730)

Foreign exchange gain (loss)		8	(78)
Change in fair value of warrant liabilities		—	10
Interest income and other expense		134	32
Total other income (loss), net		142	(36)
Loss before income tax recovery		(4,312)	(4,766)
Income tax recovery		289	242
Net loss and total comprehensive loss		(4,023)	(4,524)
Basic and diluted loss per share	11	(0.54)	(0.61)
Weighted average number of shares outstanding		7,435,533	7,388,065

See accompanying notes to unaudited interim financial statements

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

(Expressed in thousands of U.S. dollars except share data)	Notes	June 30, 2023 $	March 31, 2023 $
Assets			
Current assets:			
Cash and cash equivalents		21,633	27,875
Short-term investments	5	15	15
Receivables	4	837	802
Prepaid expenses		1,127	598
Total current assets		23,612	29,290
Operating lease right of use asset		71	463
Equipment		84	104
Intangible assets		41,128	41,128
Goodwill		8,138	8,138
Total assets		73,033	79,123
Liabilities and Shareholders' equity			
Current liabilities:			
Trade and other payables	7	1,886	3,336

Operating lease liability	8	80	75
Total current liabilities		1,966	3,411
Operating lease liability		—	410
Deferred tax liability		7,057	7,347
Total liabilities		9,023	11,168
Shareholders' equity:			
Common shares, no par value per share; unlimited shares authorized as of June 30, 2023 and March 31, 2023; 7,435,533 shares issued and outstanding as of June 30, 2023 and March 31, 2023	9(a)	258,294	258,294
Additional paid-in capital		14,043	13,965
Accumulated other comprehensive loss		(6,038)	(6,038)
Accumulated deficit		(202,289)	(198,266)
Total shareholders' equity		64,010	67,955
Commitments and contingencies	14		
Total liabilities and shareholders' equity		73,033	79,123

See accompanying notes to unaudited interim financial statements.

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Source: Acasti Pharma, Inc.