June 23, 2023

Acasti Pharma Reports Fiscal Year 2023 Operational Results

LAVAL, Québec, June 23, 2023 /PRNewswire/ -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST), 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 and operational results for the fiscal year ended March 31, 2023.

Recent Highlights

- United States Food and Drug Administration (FDA) has confirmed the 505(b)(2) regulatory pathway for GTX-104 and that the GTX-104-002 PK study may have met the criteria for a scientific bridge.
- Successfully submitted GTX-104 Pivotal Phase 3 Safety Study protocol Investigational New Drug (IND) amendment to the FDA with the expectation that a first patient will be dosed in the second half of calendar 2023.
- Implemented strategic transformation of operating model to an agile biopharma reflecting its operational focus on GTX-104. In alignment with the new operating model, Acasti has brought on a small and highly experienced new management team with deep subject matter knowledge and direct, hands-on clinical trial experience in aSAH.
- Significant extension of the Company's cash runway which is expected to be sufficient to fund the Company through calendar Q2 2025 and the achievement of critical value inflection milestones, including a potential New Drug Application (NDA) filing for GTX-104.
- Evaluation of strategic alternatives to maximize value of de-prioritized pipeline assets (GTX-102 and GTX-101).
- The Company finished the fiscal year ended March 31, 2023, with $27.9 million in cash, cash equivalents and short-term investments.

Management Discussion

Prashant Kohli, Chief Executive Officer of Acasti, said, "After receiving positive clarifying feedback from the FDA on the proposed Phase 3 Safety Study for GTX-104 whereby they concurred with the suitability of the 505(b)(2) regulatory pathway and that Acasti's GTX-104-002 PK study may have met the criteria for a scientific bridge, we moved swiftly to submit the full protocol for our pivotal Phase 3 Safety Study in May 2023. Further, we implemented a strategic realignment plan to maximize shareholder value, including a strategic transformation of Acasti's operating model to that of an agile biopharma company which we believe allows our cash runway to be sufficient to achieve a potential NDA filing for GTX-104 in 2025. Our new, highly motivated, and energized organization is entirely focused on achieving critical value inflection milestones in the quarters and years to come."

FY 2023 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.

Research and development expenses, net of government assistance for the twelve months ended March 31, 2023, totaled $9.9 million compared to $5.6 million for the twelve months ended March 31, 2022. Our research and development during the year ended March 31, 2023 was focused primarily on three clinical development programs GTX-104, GTX-102, and GTX-101 drug candidates. Due to the strategic realignment announced on April 4, 2023, the Company will focus its future research and development expenses exclusively on GTX-104. Future development of GTX-102 and GTX-101 will depend on additional dedicated funding or the signing of a strategic partnership. Research and development expenses during the year ended March 31, 2022, related to the completion of our TRILOGY Phase 3 clinical program for our former drug candidate CaPre, as well as the initiation and progression of development work related to GTX-104, GTX-102 and GTX-101.

General and administrative expenses for the twelve months ended March 31, 2023 were $7.6 million compared to $9.3 million for the twelve months ended March 31, 2022. The decrease was primarily a result of decreased legal, tax, accounting and other professional fees related to the Grace merger for the year ended March 31, 2022. Due to the strategic realignment announced on April 4, 2023, the Company is over time discontinuing its operations in Canada and has proceeded to lay off substantially all its workforce, allowing Acasti's new management team to rebuild a leaner organization in the United States.

As a result of the strategic realignment plan announced on April 4, 2023 to prioritize resources to GTX-104, and away from GTX-101 and GTX-102, the company incurred an impairment of intangible assets of $28.7 million, and an impairment of goodwill of $4.8 million, for the period ended March 31, 2023.

Loss from operating activities for the twelve months ended March 31, 2023 was $52.1 million compared to a loss of $15.6 million for the twelve months ended March 31, 2022. The change is primarily a result of the combined $33.5 million impairments to intangible assets and goodwill mentioned.

For the twelve months ended March 31, 2022, a financial gain of $5.1 million resulted mostly due to the decrease in the fair value of the derivative warrant liabilities.

Net loss and total comprehensive loss for the twelve months ended March 31, 2023 was $(42.4) million, or $(0.95) loss per share, compared to a net loss of $(9.8) million, or $(0.27) income per share, for the twelve months ended March 31, 2022. The change is primarily a result of the combined $33.5 million impairments to intangible assets and goodwill mentioned.

Cash, cash equivalents and short-term investments totaled $27.9 million as of March 31, 2023, compared to $43.7 million in cash, cash equivalents and short-term investments as of March 31, 2022. Based on management's current projections, current cash, cash equivalents and short-term investments are expected to be sufficient to fund the Company through calendar Q2 2025, facilitating achievement of critical value inflection milestones, including a potential New Drug Application (NDA) filing for GTX-104.

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 on the Company's anticipated cash runway, 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; (v) actual costs associated with Acasti's clinical trials as compared to management's current expectations; and (vi) the projected extension of the Company's cash runway to calendar Q2 2025. 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. The NASDAQ does not accept responsibility for the adequacy or accuracy of this release.

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ACASTI PHARMA INC.

Condensed Consolidated Balance Sheet

(Unaudited)

	As of	
	March 31, 2023	March 31, 2022
(Expressed in thousands of U.S. dollars except share data)	$	$
Assets		
Current assets:		
Cash and cash equivalents	27,875	30,339
Short-term investments	15	13,322
Receivables	802	548
Assets held for sale	—	352

Prepaid expenses	598	720
Total current assets	29,290	45,281
Operating lease right of use asset	463	315
Equipment	104	250
Intangible assets	41,128	69,810
Goodwill	8,138	12,964
Total assets	79,123	128,620
Liabilities and Shareholders' equity		
Current liabilities:		
Trade and other payables	3,336	3,156
Operating lease liability	75	104
Total current liabilities	3,411	3,260
Derivative warrant liabilities	—	10
Operating lease liability	410	191
Deferred tax liability	7,347	16,889
Total liabilities	11,168	20,350
Shareholders' equity:		
Common shares, no par value per share; unlimited shares authorized as of March 31, 2023 and March 31, 2022; 44,612,831 and 44,288,183 shares issued and outstanding as of March 31, 2023 and March 31, 2022, respectively	258,294	257,990
Additional paid-in capital	13,965	12,154
Accumulated other comprehensive loss	(6,038)	(6,037)
Accumulated deficit	(198,266)	(155,837)
Total shareholder's equity	67,955	108,270
Commitments and contingencies		
Total liabilities and shareholders' equity	79,123	128,620

ACASTI PHARMA INC.

Condensed Consolidated Statements of Loss and Comprehensive Loss

(Unaudited)

	Year ended March 31, 2023	Year ended March 31, 2022
(Expressed in thousands of U.S. dollars except share and per data)	$	$

Operating Expenses		
Research and development expenses, net of government assistance	(9,972)	(5,559)
General and administrative expenses	(7,614)	(9,263)
Sales and marketing	(661)	(518)
Impairment of intangible assets	(28,682)	—
Impairment of goodwill	(4,826)	—
Impairment of assets held for sale	(400)	(249)
Loss from operating activities	(52,155)	(15,589)
Other income	184	5,122
Loss before income tax recovery	(51,971)	(10,467)
Income tax recovery	9,542	648
Net loss and total comprehensive loss	(42,429)	(9,819)
Basic and diluted loss per share	(0.95)	(0.27)
Weighted average number of shares outstanding	44,612,831	36,841,762

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