November 14, 2022

Acasti Pharma Reports Second Quarter 2023 Operational Results

Company to Host Conference Call Today at 1:00pm ET

LAVAL, Québec, Nov. 14, 2022 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST and TSX-V: ACST), a late-stage, specialty pharma company advancing three clinical stage drug candidates addressing rare and orphan diseases, today announced financial and operational results for the second quarter ended September 30, 2022.

Recent Highlights

- The Company expects to receive guidance from the Food and Drug Administration (FDA) on its proposed phase 3 study design for GTX-104 in the form of a Type C meeting by the end of 2022 or early in the first calendar quarter of 2023. This FDA guidance should allow the Company to initiate the Phase 3 safety study and begin enrolling the first patients as planned in the first half of 2023. The study is expected to take about 18 months to complete and is expected to be the final clinical step required to seek approval under the 505(b)(2) regulatory pathway.
- The pharmacokinetic (PK) bridging study for GTX-102 was initiated on September 13, 2022. The Company expects to report topline results on schedule before the end of calendar 2022. Assuming the PK bridging study meets its primary endpoint, the next development step is to conduct a Phase 3 safety and efficacy trial in Ataxia-Telangiectasia (A-T) patients. The Company plans to request a Type B meeting with the FDA following the completion of the PK study to confirm the Phase 3 study design, and assuming the PK bridging study meets its primary endpoint, the Phase 3 safety study is expected to be initiated in the second half of 2023. If both studies meet their primary endpoints, a new drug application (NDA) filing for GTX-102 under Section 505(b)(2) is expected to follow.
- The single dose PK study of GTX-101, was initiated on July 26, 2022, in healthy human volunteers. This PK study is the next step in the Company’s proposed 505(b)(2) regulatory pathway for GTX-101. The PK study is expected to be completed by the end of calendar 2022 as planned and will provide important information on the dosing strength and frequency which will be used for additional clinical studies of GTX-101.
- The Company finished the second fiscal quarter ended September 30, 2022, with $34.9 million in cash, cash equivalents and short-term investments. Management continues to believe that based on current projections, the Company has sufficient capital to fund operations through at least March 2024, allowing for the advancement of GTX-104 well into Phase 3 and advancing GTX-102 and GTX-101 to key value inflection points.

Management Discussion

Jan D'Alvise, Chief Executive Officer of Acasti said, "We remain focused on advancing our three clinical programs, and I'm pleased to report that significant progress was made during the second fiscal quarter. Importantly, we remain on track to initiate and enroll the first patients in our Phase 3 safety study for GTX-104 in the first half of calendar 2023. GTX-104, our most advanced clinical candidate, is a novel aqueous formulation of nimodipine intended to be administered via continuous IV infusion for the treatment of hospitalized and critically ill patients suffering from Subarachnoid Hemorrhage (SAH). The study is expected to be the final clinical step required to seek market approval under the 505(b)(2) regulatory pathway."

"During the last quarter, we initiated two PK bridging studies as planned, one for GTX-102, our novel, concentrated oral-mucosal spray of betamethasone intended to improve the symptoms of A-T, a neurodegenerative genetic disorder that effects young children; and one for GTX-101, our novel non-narcotic, topical bio-adhesive, film-forming bupivacaine spray designed to treat Postherpetic Neuralgia (PHN), the severe and often debilitating nerve pain that can persist following a shingles infection. The GTX-102 PK study is the next step in the proposed 505(b)(2) regulatory pathway and is expected to be completed with top line results reported before year end. The GTX-101 single dose PK study is expected to also be completed with topline results reported by the end of calendar 2022 and will provide important information on the dose and dosing frequency for additional clinical studies of GTX-101."

"We are excited about the excellent progress we are making to deliver innovative new treatments to thousands of patients who currently lack effective therapies, and we look forward to reporting on the near-term milestones expected to be reached in the next couple months for each of our programs."

Program Updates

GTX-104: GTX-104 is a clinical stage, novel formulation of nimodipine for continuous IV infusion in SAH patients. In May 2022, the Company announced that the top line results from its PK bridging study for GTX-104 had met all its planned study endpoints. The primary objective of the study was to evaluate the relative bioavailability of GTX-104 compared to oral nimodipine in healthy adult male and female subjects, while the secondary objective was to assess its safety and tolerability. The results showed statistically no difference in maximum and total exposure between GTX-104 and the oral formulation of nimodipine, and no serious adverse events were observed. This result means that GTX-104 can be considered essentially bioequivalent to oral nimodipine. Importantly, the inter- and intra-subject variability was also much lower for GTX-104 as compared with oral nimodipine.

The Company believes that because of its better absorption profile and more consistent blood levels, GTX-104 may provide physicians with a more reliable and effective treatment for patients with SAH. This feature could be a key competitive advantage, as GTX-104 could help to reduce the incidence of hypotensive events and vasospasm, which require immediate and costly intervention and can lead to worse outcomes for the patient.

The Company has submitted the PK bridging study data and a proposed phase 3 safety study design to the FDA and requested a Type C meeting to get the agency's feedback and guidance. The Company expects to receive that guidance by the end of 2022 or early in the

first calendar quarter of 2023. This FDA guidance should allow the Company to initiate the Phase 3 safety study and enroll the first patient in the first half of 2023. The Phase 3 safety study is expected to be the final step required to seek regulatory approval under the 505(b)(2) regulatory pathway before submitting an NDA to the FDA for GTX-104 for the treatment of SAH patients.

GTX-102: GTX-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve the neurological symptoms of A-T, for which there are currently no FDA-approved therapies. GTX-102 is comprised of a proprietary formulation of the gluco-corticosteroid betamethasone that can be sprayed conveniently over the tongue of the A-T patient.

The Company initiated its planned PK bridging study as planned in fiscal Q2 to evaluate the comparative bioavailability, pharmacokinetics, and safety of its oral betamethasone spray, GTX-102, compared to an intramuscular injection of betamethasone and to an oral solution of betamethasone, in 48 healthy subjects. The First Subject, First Dose was administered on September 13, 2022. This PK study is the next step in the proposed 505(b)(2) regulatory pathway for GTX-102 and is expected to be completed with top line results reported before the end of calendar year 2022.

GTX-101: GTX-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to treat PHN, the severe and often debilitating nerve pain that can persist following a shingles infection. The data from a single dose Phase 1 clinical trial for GTX-101 along with regulatory guidance from the FDA's Division of Anesthesiology has informed the design of additional preclinical toxicology studies, and a proposed clinical and regulatory pathway for approval.

On July 26, 2022, the Company initiated its PK bridging study to evaluate the relative bioavailability of GTX-101 compared to the reference listed drug bupivacaine in 48 healthy subjects. The PK study is the next step in the Company's proposed 505(b)(2) regulatory pathway for GTX-101. The PK study is expected to be completed with topline results reported by the end of calendar 2022 as planned. These results will provide important information on the dosing strength and frequency for additional planned clinical studies of GTX-101.

Q2 2023 Financial Results (U.S. Dollars)

The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America.

Research and development expenses, net of government assistance for the three months ended September 30, 2022, totaled $3.3 million compared to $0.6 million for the three months ended September 30, 2021. Our research and development during the quarter ended September 30, 2022, was focused primarily on our clinical development programs for GTX-104, GTX-102, and GTX-101 drug candidates.

General and administrative expenses for the three months ended September 30, 2022, were $1.6 million compared to $2.9 million for the three months ended September 30, 2021. This decrease was a result of decreased legal, tax, accounting and other professional fees that had been incurred in connection with the Grace acquisition. The decrease in professional fees was partly offset by an increase in salaries and benefits due to the reinstated accruals

for our employee incentive bonus program.

Loss from operating activities for the three months ended September 30, 2022, was $5.1 million compared to a loss of $3.6 million for the three months ended September 30, 2021. For the three months ended September 30, 2021, a financial gain of $4.5 million resulted mostly due to the decrease in the fair value of the derivative warrant liabilities.

Net loss and total comprehensive loss for the three months ended September 30, 2022, was $4.9 million, or $0.11 loss per share, compared to a net income of $1.0 million, or $0.03 income per share, for the three months ended September 30, 2021.

Cash, cash equivalents and short-term investments totaled $34.9 million as of September 30, 2022, 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 is expected to fund our lead asset GTX-104 well into phase 3, and GTX-102 and GTX-101 to additional important milestones.

Acasti is also pleased to announce that Vimal Kavuru, an independent Director, was appointed as Chairman of the Company.

Financing Activities

As previously disclosed, Acasti entered into an amended and restated ATM sales agreement on June 29, 2020 (the "Sales Agreement") with B. Riley FBR Inc., Oppenheimer & Co. Inc. and H.C. Wainwright & Co., LLC (collectively, the "Agents"), to implement an "at-the market" equity offering program under which Acasti may issue and sell from time to time its common shares having an aggregate offering price of up to $75 million through the Agents (the "ATM Program"). Pursuant to the ATM Program, as required pursuant to the policies of the TSX Venture Exchange ("TSXV"), since the last distributions reported on August 11, 2022, Acasti issued an aggregate of 118,638 common shares (the "ATM Shares") over the NASDAQ Stock Market for aggregate gross proceeds to the Company of US $112,705. The ATM Shares were sold at prevailing market prices averaging US $0.93 per share. No securities were sold through the facilities of the TSXV or, to the knowledge of the Company, in Canada. The ATM Shares were sold pursuant to a U.S. registration statement on Form S-3 (No. 333-239538) as made effective on July 7, 2020, as well as the Sales Agreement. Pursuant to the Sales Agreement, a cash commission of 3.0% on the aggregate gross proceeds raised was paid to the Agents in connection with their services. The recent ATM sales have been made in the month of August 2022. As a result of the recent ATM sales since June 2022, Acasti has a total of 44,612,831 common shares issued and outstanding as of November 11, 2022.

Conference Call Details

Acasti will host a conference call on Monday, November 14, 2022, at 1:00 PM Eastern Time to discuss the Company's corporate progress and other developments, as well as financial results for its quarter ended September 30, 2022.

The conference call will be available via telephone by dialing toll free 844-836-8745 for U.S. callers or +1 412-317-6797 for international callers. A webcast of the call may be accessed at https://app.webinar.net/KP8QXdZzj5R or on the Company's Investor Relations section of

its website: https://www.acastipharma.com/investors/.

A webcast replay will be available on the Investors News/Events section of the Company's website (https://www.acastipharma.com/investors/). A telephone replay of the call will be available approximately one hour following the call, through November 21, 2022, and can be accessed by dialing 877-344-7529 for U.S. callers or +1 412-317-0088 for international callers and entering replay access code: 8826640.

About Acasti

Acasti is a specialty pharma company advancing three clinical stage drug candidates addressing rare and orphan diseases. Acasti's novel drug candidates 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—all which could help to increase treatment compliance and improve patient outcomes.

Acasti's three lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provides the assets with seven years of marketing exclusivity post-launch in the United States, and have additional intellectual property protection with over 40 granted and pending patents. Acasti's lead clinical assets target underserved orphan diseases: (i) GTX-104, an intravenous infusion targeting Subarachnoid Hemorrhage (SAH), 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; (ii) GTX-102, an oral mucosal spray targeting Ataxia-telangiectasia (A-T), a progressive, neurodegenerative genetic disease that primarily affects children, causing severe disability, and for which no treatment currently exists; and (iii) GTX-101, a topical spray targeting Postherpetic Neuralgia (PHN), a persistent and often debilitating neuropathic pain caused by nerve damage from the varicella zoster virus (shingles), which may persist for months and even years. 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 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 and Acasti's other pre-clinical and clinical trials for GTX-102 and GTX-101; (ii) regulatory requirements or developments and the outcome of meetings with the FDA; (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. Neither NASDAQ, the TSXV nor its Regulation Services Provider (as that term is defined in the policies of the TSXV) accepts responsibility for the adequacy or accuracy of this release.

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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, 2022 $	March 31, 2022 $
Assets		
Current assets:		
Cash and cash equivalents	34,926	30,339
Short-term investments	14	13,322
Receivables	859	548

Assets held for sale	352	352
Prepaid expenses	1,354	720
Total current assets	37,505	45,281
Right of use asset	510	315
Equipment	122	250
Intangible assets	69,810	69,810
Goodwill	12,964	12,964
Total assets	120,911	128,620
Liabilities and shareholders' equity		
Current liabilities:		
Trade and other payables	3,735	3,156
Lease liability	70	104
Total current liabilities	3,805	3,260
Derivative warrant liabilities	-	10
Lease liability	450	191
Deferred tax liability	16,492	16,889
Total liabilities	20,747	20,350
Shareholders' equity:		
Common shares	258,294	257,990
Additional paid-in capital	13,200	12,154
Accumulated other comprehensive loss	(6,040)	(6,037)
Accumulated deficit	(165,290)	(155,837)
Total shareholder's equity	100,164	108,270
Commitments and contingencies		
Total liabilities and shareholders' equity	120,911	128,620

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

	Three months ended		Six Months ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
(Expressed in thousands of U.S dollars, except per share data)	$	$	$	$

Operating expenses				
Research and development expenses, net of government assistance	(3,292)	(585)	(5,882)	(1,054)
General and administrative expenses	(1,680)	(2,957)	(3,598)	(5,633)
Sales and marketing expenses	(136)	(25)	(357)	(25)
Loss from operating activities	(5,108)	(3,567)	(9,837)	(6,712)
Financial income (expenses)	24	4,548	(13)	4,575
Income (loss) before income tax recovery	(5,084)	981	(9,850)	(2,137)
Income tax recovery	155	-	397	-
Net income (loss) and total comprehensive income (loss)	(4,929)	981	(9,453)	(2,137)
Basic and diluted loss per share	(0.11)	0.03	(0.21)	(0.07)
Weighted average number of shares outstanding	44,550,996	32,788,275	44,440,132	29,436,032

Source: Acasti Pharma, Inc.