November 10, 2021

Acasti Pharma Provides Business Update for the Second Quarter of Fiscal 2022

Conference call to be held on Wednesday, November 10th at 1:00 p.m. ET

LAVAL, Québec, Nov. 10, 2021 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST and TSX-V: ACST), today provided a business update and announced its operating and financial results for the second quarter of fiscal 2022 ended September 30, 2021.

Corporate Highlights:

- Successfully completed merger with Grace Therapeutics, Inc. (“Grace”) on August 27, 2021, that brought 3 clinical stage assets, all with Orphan Drug Designation, and several non-clinical stage assets to Acasti.
- Initiated pharmacokinetic (PK) bridging study for GTX-104, a novel aqueous formulation of water insoluble nimodipine being developed for the treatment of Subarachnoid Hemorrhage (SAH); Results expected in the first half of calendar 2022
- Awarded Composition-of-Matter Patents for GTX-101 in Europe, China, and Mexico
- Awarded Composition-of-Matter Patent for GTX-102 in Japan

“During the second quarter, we successfully completed a transformational merger with Grace Therapeutics, bringing to Acasti a range of new and exciting opportunities in sizable markets with substantial unmet medical needs. We have created an exciting specialty pharma company with a diverse portfolio of drug candidates focused on rare diseases,” commented, Jan D’Alvise, Chief Executive Officer of Acasti Pharma. “In the short time since completing the merger, we have made good progress regarding our clinical pipeline and business operations. We swiftly integrated the Grace team with Acasti, allowing the Company to immediately focus on advancing its clinical pipeline. Towards this end, we have commenced subject enrollment for a pivotal PK bridging study for GTX-104, which will assess its relative bioavailability compared to currently marketed oral nimodipine capsules. Based on encouraging results from an earlier safety and dose-escalation crossover study conducted by Grace, we believe that GTX-104 has the potential to provide improved bioavailability and lower intra-subject variability compared to oral capsules. This could result in better management of hypotension in patients with SAH, and potentially lead to better outcomes. We continue to anticipate reporting the results of this study during the first half of calendar 2022. If the PK study and the end of Phase 2 meeting with the FDA go as planned, we would plan to commence a Phase 3 safety study of GTX-104 in the second half of calendar 2022.

“I’m also pleased to report we have strengthened our patent portfolio with four composition of matter patents granted for GTX-101 and GTX-102. The European Patent Office, Chinese Patent Office and the Mexican Patent Office have issued composition of matter patents for

GTX-101, our novel bio-adhesive film forming topical spray formulation of bupivacaine being developed for the treatment of Postherpetic Neuralgia (PHN). Additionally, the Japanese Patent Office has granted a composition of matter patent for GTX-102, our novel, easy-to-use oral mucosal spray formulation of betamethasone, intended to improve neurological symptoms of Ataxia-Telangiectasia (A-T), a pediatric genetic disorder for which no treatment currently exists. These patents provide protection in important international markets beyond 2036 and are valuable additions to our intellectual property portfolio. We are very pleased to have been granted these patents and have already made meaningful progress advancing our pipeline within the short timeframe following the closing of the merger. We remain highly encouraged by the potential of our pipeline of assets and look forward achieving meaningful milestones in the months ahead," concluded Ms. D'Alvise.

As of September 30, 2021, Acasti had $50.8 million of cash, cash equivalents and short-term investments. The Company believes these funding resources provide at least two years of operating runway, based on management's current projections.

Second Quarter of Fiscal 2022 Financial Results (US Dollars)

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

- **Acquisition of Grace** - On August 27, 2021, we completed our acquisition of Grace via a merger and Grace became a wholly owned subsidiary of Acasti and was renamed Acasti Pharma U.S. Inc. In connection with the business combination, 18,241,233 common shares of Acasti were issued to the shareholders of Grace as consideration at a value of $60.8 million. Net liabilities of $4.3 million and intangible assets of in-process research and development of $65.2 million related to the therapeutic pipeline consisting of three unique clinical stage programs/assets supported by intellectual property were assumed. Acquisition-related expense of regulatory, financial advisory and legal fees totaled $3.2 million.
- **Loss from operating activities** for the three months ended September 30, 2021 was $3.6 million, compared to a loss of $8.0 million for the three months ended September 30, 2020. The reduction was due mainly to a reduction in R&D and sales and marketing expenses, offset by an increase in general and administrative expenses as a result of increased legal, tax, accounting and other professional fees related to the Grace transaction for the three months ended September 30, 2021. The Company also recognized $5.3 million of impairment charges, including $3.7 million related to intangible assets and $1.6 million related to production and lab equipment for the CaPre program.
- **Net income** for the three months ended September 30, 2021 was $1.0 million or $0.03 per share, compared to a net loss of $6.1 million or $0.52 per share for the three months ended September 30, 2020. The increase resulted primarily from a gain of $4.5 million due mostly to a decrease in the fair value of the derivative warrant liability, as well as a decrease in R&D expenses as the TRILOGY Phase 3 clinical program for CaPre was completed.
- **Research and development expenses** before depreciation, amortization and stock-based compensation expenses for the three months ended September 30, 2021, totaled $0.55 million compared to $0.81 million for the three months ended September 30, 2020. The net decrease was mainly attributable to the reduction in professional

fees within the research and development departments associated with the completed TRILOGY trials, as well as to the reversal of the prior period provision after assessments and correspondence from tax authorities. There were no significant R&D costs in Q2 related to the acquired assets from Grace, as these programs only began to ramp up as of September 2021.

- **General and administrative expenses** before stock-based compensation expenses for the three months ended September 30, 2021 were $2.9 million compared to $1.1 million for the three months ended September 30, 2020. This increase was a result of increased legal, tax, accounting and other professional fees related to the Grace acquisition.
- **Sales and marketing expenses** before stock-based compensation expenses were $0.03 for the three months ended September 30, 2021, compared to $0.02 million for the three months ended September 30, 2020, as marketing activities in support of the assets acquired from Grace were not yet initiated in the current period.
- **Cash, cash equivalents and short-term investments** totaled $50.8 million as of September 30, 2021, compared to $11.6 million in cash and cash equivalents as of September 30, 2020.

Senior Management and Board Committee Changes

George Kottayil has been named Chief Operating Officer, U.S. alongside Pierre Lemieux, who continues as Chief Operating Officer, Canada and Chief Scientific Officer of Acasti. Mr. Kottayil was a co-founder and previously served as Chief Executive Officer of Grace (which was renamed Acasti Pharma U.S. Inc. after the merger), prior to its acquisition by Acasti in August 2021.

On August 26, 2021, shareholders elected Dr. Roderick N. Carter, Jean Marie (John) Canan, Jan D'Alvise, William A. Haseltine, Vimal Kavuru, and Donald Olds to Acasti's Board of Directors. Dr. Carter will continue to serve as Chairman of the Board and as a member of the Audit and Governance & Human Resources Committees. Mr. Canan will continue to serve as Chair of the Audit Committee, and Mr. Olds will continue to serve as Chair of the Governance & Human Resources Committee, and as a member of the Audit Committee. Mr. Kavuru has replaced Mr. Canan as a member of the Governance & Human Resources Committee of the Board.

Conference Call

Acasti will host a conference call on Wednesday, November 10, 2021 at 1:00 PM Eastern Time to discuss the Company's corporate progress and other developments, as well as financial results for the fiscal 2022 second quarter ended September 30, 2021.

The conference call will be available via telephone by dialing toll free 877-545-0523 for U.S. callers or +1 973-528-0016 for international callers and using entry code 948112. A webcast of the call may be accessed at https://www.webcaster4.com/Webcast/Page/2210/43383 or on the Company's Investor Relations section of the website: https://www.acastipharma.com/investors/.

A webcast replay will be available on the Company's Investors News/Events section of the website (https://www.acastipharma.com/investors/) through November 10, 2022. A telephone replay of the call will be available approximately one hour following the call,

through November 17, 2021, and can be accessed by dialing 877-481-4010 for U.S. callers or +1 919-882-2331 for international callers and entering conference ID: 43383.

About Acasti

Acasti is a specialty pharma company with drug delivery technologies and 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—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 U.S. Food and Drug Administration, which provide the assets with 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 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 unknown 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," "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 PK bridging study for GTX-104 and Acasti's other pre-clinical and clinical trials; (ii) the potential of GTX-104 to provide improved bioavailability and lower intra-subject variability compared to oral capsules; (iii) regulatory requirements or developments and the outcome of meetings

with the Food and Drug Administration; (iv) changes to clinical trial designs and regulatory pathways; (v) legislative, regulatory, political and economic developments; and (vi) the effects of COVID-19 on clinical programs and business operations. 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 may be filed by Acasti from time to time with the Securities and Exchange Commission. 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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