

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 25, 2024

**ACASTI PHARMA INC.**  
(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of Incorporation)

**001-35776**  
(Commission File Number)

**98-1359336**  
(IRS Employer Identification No.)

**103 Carnegie Center  
Suite 300  
Princeton, New Jersey**  
(Address of Principal Executive Offices)

**08540**  
(Zip Code)

Registrant's telephone number, including area code: **(609) 322-1602**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	ACST	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01. Other Events.**

On October 25, 2024, Acasti Pharma Inc. (the “Company”) announced via press release that it will change its corporate name to “Grace Therapeutics, Inc.” effective on October 28, 2024 and its common stock will begin trading under the trading symbol “GRCE” beginning at the open of the market on October 28, 2024. The Company also announced its plans to hold a virtual Key Opinion Leader Event on November 20, 2024. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference in this Item 8.01.

**Item 9.01. Financial Statements and Exhibits.****(d) Exhibits**

<u>Exhibit</u>	<u>Description</u>
<a href="#">99.1</a>	Press Release, dated October 25, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**ACASTI PHARMA INC.**

Date: October 25, 2024

By: /s/ Prashant Kohli  
Prashant Kohli  
Chief Executive Officer

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**Acasti Announces Corporate Name Change  
to Grace Therapeutics, Inc.**

*Name Change Reflects Extensive Scientific and Corporate Brand Equity Previously Established under Grace Therapeutics*

*Grace Therapeutics will begin trading on Nasdaq under the trading symbol "GRCE" effective October 28, 2024*

*Virtual Key Opinion Leader Event to be held on November 20<sup>th</sup>*

Princeton, NJ, October 25, 2024 (GLOBE NEWSWIRE)-- Acasti Pharma Inc. (Nasdaq: ACST) (Acasti or the Company), a late-stage, biopharma company advancing GTx-104, its novel injectable formulation of nimodipine that addresses high unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH), today announced that it is changing its name to Grace Therapeutics, Inc. (Grace Therapeutics). Grace Therapeutics was the name of the company developing GTx-104 prior to its merger with Acasti in 2021. Grace Therapeutics will begin trading on Nasdaq under the trading symbol "GRCE" at the open of the market on October 28, 2024 and all company branding including corporate website will be updated accordingly.

"The Grace Therapeutics brand reconnects us to our roots that are steeped in scientific innovation and highlights our transformative journey," said Prashant Kohli, CEO of Acasti. "The breakthrough formulation of GTx-104 is the result of a decade of research by our exceptional scientific team while Grace Therapeutics was located in the pharma industry research corridor of New Jersey. We have continued to make significant progress in the clinical development plan of GTx-104, including full enrollment of the STRIVE-ON trial and anticipate a data readout in early calendar 2025 with an expected submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the first half of calendar 2025.

"In addition to advancing GTx-104 over the past 18 months, we successfully restructured to an agile biopharma model, rebuilt the management team, prioritized the pipeline, divested legacy assets, strengthened the balance sheet, and re-domiciled to the United States as a Delaware corporation. We believe these steps offer several potential benefits, including a U.S. corporate structure that should increase the company's attractiveness and marketability to potential strategic partners and global institutional investors. We are proud of the progress made within a relatively short timeframe and look forward to fully realizing the Company's value under the Grace Therapeutics brand."

The Company will host a Key Opinion Leader (KOL) event titled *Virtual KOL Event on GTx-104 in aneurysmal Subarachnoid Hemorrhage*, on November 20, 2024 at 2pm Eastern Time. To register for this debut event hosted by Grace Therapeutics, [click here](#). A replay of the event will be available and archived for at least 180 days after the webcast.

**About the Acasti Asset Portfolio**

GTx-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous (IV) infusion 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.

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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.

GTx-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve neurological symptoms of Ataxia-Telangiectasia (A-T), for which there are currently no FDA-approved therapies. GTx-102 is a stable, concentrated oral spray formulation comprised of the gluco-corticosteroid betamethasone that, together with other excipients can be sprayed conveniently over the tongue of the A-T patient and is rapidly absorbed. The further development of GTx-102 has been deprioritized in favor of our focus on development of GTx-104. It is also possible that we may license or sell our GTx-102 drug candidate.

GTx-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to ease the symptoms of patients suffering with postherpetic neuralgia (PHN). GTx-101 is administered via a metered-dose of bupivacaine spray and forms a thin bio-adhesive topical film on the surface of the patient's skin, which enables a touch-free, non-greasy application. It also comes in convenient, portable 30 ml plastic bottles. Unlike oral gabapentin and lidocaine patches, we believe that the biphasic delivery mechanism of GTx-101 has the potential for rapid onset of action and continuous pain relief for up to eight hours. No skin sensitivity was reported in a Phase 1 trial. The further development of GTx-101 has been deprioritized in favor of our focus on development of GTx-104. It is also possible that we may license or sell our GTx-101 drug candidate.

#### **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: [www.acasti.com](http://www.acasti.com) or [www.gracetx.com](http://www.gracetx.com).**

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## 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 timing of a data readout from the Company's Phase 3 STRIVE-ON safety trial of GTx-104, the timing of the Company's planned NDA submission with the FDA in connection with the Company's Phase 3 STRIVE-ON safety trial, GTx-104's commercial prospects; the size of the addressable market for GTx-104, the Company's beliefs regarding the potential benefits of GTx-104, including GTx-104's potential to bring enhanced treatment options to patients suffering from aSAH, and the anticipated benefits and future development, license or sale of the Company's other drug candidates 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 STRIVE-ON 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.

For more information, please contact:

### Acasti Contact:

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