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): February 13, 2025

GRACE THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

State of Delaware	**001-35776**	**98-1359336**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
103 Carnegie Center **Suite 300** **Princeton, New Jersey**		**08540**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 609-322-1602

(Former Name or Former Address, if Changed Since Last Report)

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	GRCE	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 2.02 Results of Operations and Financial Condition.

The following information is furnished pursuant to Item 2.02 "Results of Operations and Financial Condition."

On February 13, 2025, Grace Therapeutics, Inc. (formerly Acasti Pharma Inc.) issued a press release announcing its financial results for the fiscal quarter ended December 31, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing or document.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release, dated February 13, 2025.
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 thereunto duly authorized.

GRACE THERAPEUTICS, INC.

Date: February 13, 2025

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

Exhibit 99.1

Grace Therapeutics Announces Third Fiscal Quarter 2025 Financial Results, Provides Business Update

Announced Phase 3 STRIVE-ON Safety Trial Met Primary Endpoint and Provided Clinical Benefit Compared to Orally Administered Nimodipine; New Drug Application (NDA) Submission Anticipated First Half of Calendar 2025

Secured Private Placement Financing of $15 Million in Upfront Gross Proceeds with the Potential to Receive up to an Additional $15 Million in Potential Warrant Exercise Proceeds for an Aggregate of Up to Approximately $30 Million in Potential Total Gross Proceeds

Princeton, NJ, February 13, 2025 (GLOBE NEWSWIRE)—Grace Therapeutics, Inc. (Nasdaq: GRCE) formerly Acasti Pharma Inc. (Grace Therapeutics or the Company), a late-stage, biopharma company advancing GTx-104, a clinical-stage, novel, injectable formulation of nimodipine being developed for IV infusion to address significant unmet medical needs in aneurysmal subarachnoid hemorrhage (aSAH) patients, today announced financial results and business highlights for the quarter ended December 31, 2024.

"During our third quarter and in subsequent weeks we continued to make significant progress in both clinical and corporate goals, announcing positive topline data from our Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial–NCT05995405), and securing up to $30 million in gross proceeds from a private placement financing with leading healthcare investors," said Prashant Kohli, CEO of Grace Therapeutics. "Data from our STRIVE-ON trial exceeded our expectations, demonstrating that GTx-104 was associated with improved clinical outcomes for patients when compared to patients treated with orally administered nimodipine. Importantly, the data also provides both medical and pharmacoeconomic evidence of the potential benefit of GTx-104 in aSAH patients, which could help drive adoption of GTx-104 by neurocritical care physicians and hospital pharmacies."

"We secured up to $30 million in a private placement led by Nantahala Capital and ADAR1 Partners, along with other leading healthcare-focused investors. This investment will support pre-commercial planning, commercial team build out and product launch if GTx-104 is approved. Our focus now is to finalize NDA submission for GTx-104 by the end of June 2025. The standard of care for aSAH has not seen meaningful innovation in nearly 40 years, and we believe the STRIVE-ON trial results point to a very promising role for GTx-104 as a potential breakthrough for the care of aSAH patients should it be approved by the FDA," concluded Mr. Kohli.

Highlights for Third Quarter Fiscal Quarter 2025 and Recent Weeks

- Announced Phase 3 STRIVE-ON safety trial met primary endpoint.
- NDA submission to the FDA is anticipated in the first half of calendar year 2025.
- Announced private placement financing of up to approximately $30.0 million in potential total gross proceeds, consisting of initial upfront funding of approximately $15.0 million and the potential to receive up to an additional approximately $15.0 million upon cash exercise of accompanying warrants at the election of the investors; the financing was led by Nantahala Capital and ADAR1 Partners, LP, and includes participation from new and existing healthcare-focused institutional investors, including Stonepine Capital Management, among others.The net proceeds of the initial upfront funding were approximately $13.8 million, after deducting fees and expenses.
- Hosted a virtual key opinion leader (KOL) event on November 20, 2024 featuring Abhishek Ray, MD (University Hospitals) and Andrew Webb, PharmD, BCCCP (Massachusetts General Hospital), who discussed the high unmet medical need and current treatment landscape for patients suffering from aSAH. For the replay, click here.
- Received written responses to its End of Phase 1 meeting in GTx-102 where the FDA made recommendations on the path toward an NDA. The FDA provided guidance on the design of a single pivotal efficacy and safety trial, including the neurological assessment scale for the primary endpoint, that could, with appropriate confirmatory evidence, support an NDA.

Third Fiscal Quarter 2025 Financial Results

For the three months ended December 31, 2024, the Company reported a net loss of $4.2 million, or $0.36 per share, an increase of $1.8 million from the net loss of $2.4 million, or $0.21 per share, for the three months ended December 31, 2023. The increase in net loss was primarily due to a $1.3 million difference in the change in fair value of derivative warrant liabilities, an increase in research and development expenses of $0.8 million, and a decrease in our interest income of $0.2 million, offset in part by a $0.4 million increase in income tax benefit.

Total research and development expenses for the three months ended December 31, 2024 were $2.2 million, compared to $1.4 million for the three months ended December 31, 2023. The increase of $0.8 million was primarily due to the increase in research activities for the GTx-104 pivotal Phase 3 safety clinical trial.

General and administrative expenses were $1.5 million for the three months ended December 31, 2024, compared to $1.6 million for the three months ended December 31, 2023. The decrease of $0.1 million was primarily a result of a decrease in professional fees of $0.2 million and stock-based compensation of $0.2 million, offset in part by higher salaries and benefits.

As of December 31, 2024, cash and cash equivalents were $11.1 million, a net decrease of $11.9 million compared to cash and cash equivalents of $23.0 million at March 31, 2024.

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 in the brain.. The result is a relatively uncommon type of stroke (aSAH) that accounts for about 5% of all strokes and an estimated 42,500 U.S. hospital treated patients.

About the Grace Therapeutics Asset Portfolio

GTx-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for 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.

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.

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 Company received written responses to its End of Phase 1 meeting in GTx-102 where the FDA made recommendations on the path toward an NDA. The FDA provided guidance on the design of a single pivotal efficacy and safety trial, including the neurological assessment scale for the primary endpoint, that could, with appropriate confirmatory evidence, support an NDA.

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, the Company believes 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 focusing on development of GTx-104. It is also possible that the Company may license or sell GTx-101.

About Grace Therapeutics

Grace Therapeutics, Inc. (formerly Acasti, Grace Therapeutics or the Company) is a late-stage biopharma company with drug candidates addressing rare and orphan diseases. Grace Therapeutics' 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. Grace Therapeutic'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. Grace Therapeutics' 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. In February 2025, Grace Therapeutics announced that its Phase 3 STRIVE-ON safety trial for GTx-104 met its primary endpoint and provided evidence of clinical benefit over orally administered nimodipine.

For more information, please visit: www.gracetx.com

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 Grace Therapeutics 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 future prospects of the Company's GTx-104 drug candidate, the timing of the Company's anticipated NDA submission for GTx-104, GTx-104's potential to bring enhanced treatment options to patients suffering from aSAH, GTx-104's potential to be administered to improve the management of hypotension in patients with aSAH, the ability of GTx-104 to achieve a pharmacokinetic and safety profile similar to the oral form of nimodipine, GTx-104's potential to achieve pharmacoeconomic benefit over the oral form of nimodipine, GTx-104's commercial prospects, the future prospects of the Company's GTx-102 drug candidate, GTx-102's potential to provide clinical benefits to decrease symptoms associated with Ataxia Telangiectasia, GTx-102's potential ease of drug administration, the timing and outcomes of a Phase 3 efficacy and safety study for GTx-102, the timing of an NDA filing for GTx-102, the size of the addressable market for GTx-104 and GTx 102, and any future patent and other intellectual property filings made by the Company for new developments are based upon Grace Therapeutics' 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 Grace Therapeutics' 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 the "Special Note Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2024, Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024, the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024 and other documents that have been and will be filed by Grace Therapeutics 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. Grace Therapeutics 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:

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---tables to follow---

GRACE THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)

(Expressed in thousands except share data)	December 31, 2024 $	March 31, 2024 $
Assets		
Current assets:		
Cash and cash equivalents	11,055	23,005
Receivables	301	722
Prepaid expenses	583	283
Total current assets	11,939	24,010
Equipment, net	19	24
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	61,224	73,300
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	1,971	1,684
Total current liabilities	1,971	1,684
Derivative warrant liabilities	3,781	4,359
Deferred tax liability	3,333	5,514
Total liabilities	9,085	11,557
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value per share; 10,000,000 authorized; none issued and outstanding	—	—
Common stock, $0.0001 par value per share; 100,000,000 authorized; 10,139,861 and 9,399,404 shares issued and outstanding as of December 31, 2024 and March 31, 2024, respectively	1	1
Additional paid-in capital	279,499	278,899
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(221,323)	(211,119)
Total stockholders' equity	52,139	61,743
Total liabilities and stockholders' equity	61,224	73,300

GRACE THERAPEUTICS, INC.
Condensed Consolidated Statements of Loss and Comprehensive Loss
(Unaudited)

	Three months ended		Nine months ended	
(Expressed in thousands, except share and per share data)	December 31, 2024 $	December 31, 2023 $	December 31, 2024 $	December 31, 2023 $
Operating expenses				
Research and development expenses, net of government assistance	(2,194)	(1,443)	(7,877)	(2,998)
General and administrative expenses	(1,510)	(1,600)	(5,619)	(5,106)
Restructuring cost	—	—	—	(1,485)
Loss from operating activities	(3,704)	(3,043)	(13,496)	(9,589)
Foreign exchange (loss) gain	(16)	3	(11)	(2)
Change in fair value of derivative warrant liabilities	(1,178)	125	578	(1,701)
Interest and other income, net	138	316	544	662
Total other income (expenses), net	(1,056)	444	1,111	(1,041)
Loss before income tax benefit	(4,760)	(2,599)	(12,385)	(10,630)
Income tax benefit	605	208	2,181	943
Net loss and total comprehensive loss	(4,155)	(2,391)	(10,204)	(9,687)
Basic and diluted loss per share	(0.36)	(0.21)	(0.89)	(1.09)
Weighted-average number of shares outstanding	11,506,234	11,506,257	11,506,234	8,874,872