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): June 25, 2025

GRACE THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

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 8.01. Other Events.

On June 25, 2025, Grace Therapeutics, Inc. issued a press release announcing its submission of a New Drug Application to the U.S. Food and Drug Administration for 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 patients. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release, dated June 25, 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 hereunto duly authorized.

GRACE THERAPEUTICS, INC.

Date: June 25, 2025

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

Exhibit 99.1

Grace Therapeutics Announces Submission of New Drug Application to U.S. Food and Drug Administration for GTx-104

Submission Seeks Approval of GTx-104 in the Treatment of Patients with aneurysmal Subarachnoid Hemorrhage (aSAH)

Comprehensive Data Package Includes Positive Results from Phase 3 STRIVE-ON Safety Trial of GTx-104

Submission Has the Potential to Trigger Exercise of up to $7.6 million in Gross Proceeds from 2023 Financing Warrants Tied to FDA Acceptance of NDA for Review

Princeton, NJ, June 25, 2025 (GLOBE NEWSWIRE)—Grace Therapeutics, Inc. (Nasdaq: GRCE) (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 the submission to the U.S. Food and Drug Administration (FDA) of the Company's New Drug Application (NDA) for GTx-104. The application includes a comprehensive data package, including positive data obtained from the Company's Phase 3 STRIVE-ON safety trial of GTx-104, whereby it met its primary endpoint and provided evidence of clinical benefit when compared to orally administered nimodipine.

"The submission of our NDA for GTx-104 for the treatment of aSAH is a significant milestone for Grace Therapeutics, built on more than a decade of painstaking research and innovation," said Prashant Kohli, Chief Executive Officer of Grace Therapeutics. "Our NDA is supported by a robust data package including positive results from our STRIVE-ON trial, which provide support for improved clinical outcomes in aSAH patients and both medical and pharmacoeconomic evidence of the potential benefit of GTx-104 in the treatment of aSAH. The standard of care for aSAH has not seen meaningful innovation in nearly 40 years, and we believe these results point to a very promising role for GTx-104 as a potential breakthrough for the care of aSAH patients. We look forward to engaging with the FDA during the review process."

Submission of the NDA has the potential to trigger the exercise of up to $7.6 million in warrants issued as part of a private placement the Company completed in September 2023. Under the terms of the September 2023 private placement, each warrant is exercisable for one share of common stock at an exercise price of $3.003 per share. These warrants will be immediately exercisable and will expire on the earlier of (i) the 60th day after the date of the acceptance by the FDA of a NDA for the Company's product candidate GTX-104 or (ii) September 25, 2028.

The FDA typically has a 60-day period to determine if the Company's NDA is complete and acceptable for filing. Grace has obtained Orphan Drug Designation from the FDA for GTx-104, which generally provides seven years of marketing exclusivity in United States upon FDA approval of the NDA. Additionally, the Company believes that its U.S. and international patent estate will protect the market value of GTx-104 beyond marketing exclusivity.

About the STRIVE-ON Safety Trial

The STRIVE-ON safety trial (NCT05995405) was a prospective, randomized open-label trial of GTx-104 compared with oral nimodipine in patients hospitalized with aSAH. 50 patients were administered GTx-104 and 52 patients received oral nimodipine. The primary endpoint was the number of patients with at least one episode of clinically significant hypotension reasonably considered to be caused by the drug, and additional endpoints included safety, clinical, and pharmacoeconomic outcomes. The trial met its primary endpoint, with patients receiving GTx-104 observed to have a 19% reduction in at least one incidence of clinically significant hypotension compared to oral nimodipine (28% versus 35%). Other measures also favored or were comparable to GTx-104, including: 54% patients had relative dose intensity (RDI) of 95% or higher compared to only 8% on oral nimodipine, and 29% more patients had favorable functional outcomes at 90 days. In addition, there were fewer intensive care unit (ICU) readmissions, ICU days, and ventilator days for patients receiving GTx-104 versus oral nimodipine. Adverse events were comparable between the two arms and no new safety issues were identified with patients receiving GTx-104. All deaths in both arms of the trial were due to severity of the patient's underlying disease. There were eight deaths on the GTx-104 arm compared to four deaths on the oral nimodipine arm. The survival status of one patient on the oral nimodipine arm was unknown. No deaths were determined to be related to GTx-104 or oral nimodipine.

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 GTx-104

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 200 patients and health volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine.

About Grace Therapeutics

Grace Therapeutics, Inc. (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 IV 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.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 FDA's acceptance for review of the Company's NDA submission for GTx-104, benefits of GTx-104's Orphan Drug Designation, 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, higher dose compliance and better functional recovery over the oral form of nimodipine, GTx-104's commercial prospects, and the Company's patent estate and its ability to extend exclusivity of GTx-104 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 NDA application for GTx-104; (iii) changes to regulatory pathways; (iv) the Company's ability to maintain effective patent rights and other intellectual property protection for its product candidates and (v) legislative, regulatory, political and economic developments. 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, 2025, 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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