

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 23, 2025

GRACE THERAPEUTICS, 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

(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 October 23, 2025, Grace Therapeutics, Inc. (the “Company”) issued a press release announcing that the Company has secured approximately \$4.0 million in additional funding through exercises of common warrants that were previously issued in a private placement that the Company closed in September 2023. The remaining 1,190,927 common warrants issued in the 2023 private placement have expired as the 60th day after the U.S. Food and Drug Administration’s acceptance for review of the Company’s New Drug Application for GTx-104 has passed. GTx-104 is a clinical-stage, novel, injectable formulation of nimodipine being developed for I.V. 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 October 23, 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: October 23, 2025

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



Grace Therapeutics Secures Approximately \$4.0 Million through Common Warrant Exercises Following Acceptance of New Drug Application for GTx-104 for formal FDA Review

Princeton, NJ, October 23, 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 I.V. infusion to address significant unmet medical needs in aneurysmal subarachnoid hemorrhage (aSAH) patients, today announced it has secured approximately \$4.0 million in additional funding through exercises of common warrants that were previously issued in a private placement that the Company closed in September 2023. The Company issued 1,345,464 new shares of common stock at an exercise price of \$3.003 per share. The remaining 1,190,927 common warrants issued in the 2023 private placement have expired as the 60th day after the U.S. Food and Drug Administration's (FDA) acceptance for review of the Company's New Drug Application for GTx-104 has passed.

The FDA established a Prescription Drug User Fee Act (PDUFA) target date of April 23, 2026 for its review of the Company's NDA submission for GTx-104. The application seeks approval for GTx-104 for the treatment of patients with aSAH, and is supported by a comprehensive data package including positive data obtained from the Company's Phase 3 STRIVE-ON safety trial of GTx-104.

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 I.V. 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 I.V. infusion.

GTx-104 provides a convenient I.V. 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 healthy 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 I.V. 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 and the outcome of the FDA's 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, 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 outcome of the Company's NDA for GTx-104; (ii) changes to regulatory pathways; (iii) the Company's ability to maintain effective patent rights and other intellectual property protection for its product candidates and (iv) 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, the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025 filed with the Securities and Exchange Commission (SEC) and other documents that have been and will be filed by Grace Therapeutics from time to time with the SEC 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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