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): April 23, 2026

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 April 23, 2026, Grace Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has issued a Complete Response Letter for the Company's New Drug Application for GTx-104 in the treatment of patients with aneurysmal subarachnoid hemorrhage.

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 April 23, 2026.
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: April 23, 2026

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

Exhibit 99.1

Grace Therapeutics Provides Regulatory Update on New Drug Application for GTx-104

FDA Issued Complete Response Letter Citing Outstanding Items Related to Chemistry, Manufacturing, and Controls and Non-Clinical Information

FDA Does not Request Additional Clinical Data

Company Intends to Resubmit Application Following Resolution of Cited Items

Princeton, NJ, April 23, 2026 (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 intravenous infusion to address significant unmet medical needs in aneurysmal subarachnoid hemorrhage (aSAH) patients, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) for the Company's New Drug Application (NDA) for GTx-104 for the treatment of patients with aSAH.

In its CRL, the FDA referenced certain items in the Chemistry, Manufacturing, and Controls (CMC) and Non-Clinical sections of the application, which Grace believes it can address in a resubmission of its NDA. The cited items are related to leachables data for product packaging, non-clinical product toxicology risk assessments, and product manufacturing deficiencies at our contract manufacturing organization. The Company intends to request a Type A meeting with the FDA to clarify the path forward and determine the appropriate next steps.

"Potential FDA approval of our NDA for GTx-104 for the treatment of aSAH would represent the first meaningful innovation in the standard of care for these patients in more than 40 years," said Prashant Kohli, Chief Executive Officer of Grace Therapeutics. "We are confident in the robust data package supporting our NDA submission, and that the CMC issues identified by the FDA can be successfully addressed in our resubmission."

About the STRIVE-ON Trial

The STRIVE-ON 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 secondary 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 GTx-104 or were comparable between GTx-104 and oral nimodipine, including: 54% patients on GTx-104 had relative dose intensity (RDI) of 95% or higher compared to only 8% on oral nimodipine, and 29% more patients on GTx-104 than on oral nimodipine 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 in the U.S.

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 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 Food and Drug Administration (FDA), which provides seven years of marketing exclusivity post-launch in the United States if certain conditions are met at New Drug Application (NDA) approval, 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.

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 Company's belief that it can address the items related to CMC and non-clinical information cited in the FDA's Complete Response Letter in a resubmission of its NDA for GTx-104; the Company's intentions to request a Type A meeting with the FDA to clarify the path forward and determine the appropriate next steps 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, gastrointestinal intolerance and dosing consistency compared with oral administration, the ability of GTx-104 to achieve a pharmacokinetic and safety profile similar to the oral form of nimodipine, and GTx-104's potential to achieve medical and pharmacoeconomic benefit, 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 of any regulatory resubmission related to the Phase 3 STRIVE-ON safety trial for GTx-104; (ii) changes to regulatory requirements or pathways; (iii) our ability to protect our intellectual property for our drug 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, the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025 and the Company's Quarterly Report on Form 10-Q for the quarterly period ended December 31, 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 visit: www.gracetx.com

For more information, please contact:

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