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): August 13, 2026

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 August 13, 2026, Grace Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended June 30, 2026. 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 August 13, 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 thereunto duly authorized.

GRACE THERAPEUTICS, INC.

Date: August 13, 2026

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

Grace Therapeutics Announces First Quarter 2027 Financial Results,
Provides Business Update

Princeton, NJ, August 13, 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 IV infusion to address significant unmet medical needs in aSAH patients, today announced the financial results and business highlights for the three months ended June 30, 2026.

"We continue to make progress on the requirements for resubmission of our New Drug Application (NDA) for GTx-104," said Prashant Kohli, Chief Executive Officer of Grace Therapeutics. "As previously disclosed, the U.S. Food and Drug Administration's (FDA) Complete Response Letter (CRL) identified no clinical safety or efficacy deficiencies—the remaining items relate to chemistry, manufacturing and controls (CMC) and non-clinical data. We continue to address those items while advancing two manufacturing sites toward NDA resubmission. Our current contract manufacturer is remediating the FDA's facility-level findings, while our second, U.S.-based contract manufacturer is advancing the technology transfer needed to begin the required 12-month stability program. NDA resubmission timing will reflect whichever manufacturing site reaches readiness first. The recent financing extends our expected cash runway through the end of calendar 2028, positioning us to execute on both manufacturing sites as we work toward NDA resubmission. We look forward to reporting our progress as we achieve these important milestones."

First Quarter 2027 and Recent Corporate Highlights

- Announced a $10 million private placement financing with new and existing institutional and accredited investors. The Company intends to use the net proceeds from the financing to support the manufacturing and regulatory work needed to advance GTx-104.

- Announced receipt of the FDA meeting minutes from a Type A Meeting held with the FDA to discuss the CRL issued on April 23, 2026. The minutes constitute the official record of the Type A meeting. As previously disclosed, the CRL did not identify any clinical safety or efficacy deficiencies and did not request additional clinical data. The items cited by the FDA relate to the current good manufacturing practice (cGMP) compliance status of the Company's contract manufacturing organization — a facility-level matter, and not a GTx-104 product-specific quality finding — together with additional leachables data time points and excipient toxicology risk assessments. The Company intends to address each of the CRL items in its planned resubmission, including completing the required non-clinical studies.

- As part of its resubmission plan, the Company has initiated a dual-source manufacturing strategy for GTx-104 to mitigate potential remediation issues from the Company's current contract manufacturer and provide flexibility, while continuing to address the remaining CMC and non-clinical items identified in the CRL. As such, a technology transfer to a second, U.S.-based contract manufacturer is already underway. The timing of NDA resubmission will reflect the manufacturing pathway that reaches readiness first: either (i) the U.S.-based facility, which would require completion of a full CMC package supported by 12 months of stability data following the technology transfer; or (ii) the Company's current contract manufacturer, if it successfully remediates its FDA compliance issues and is able to support the NDA sooner.

First Quarter 2027 Financial Results

The Company reported a net loss of $15.8 million, or $0.91 loss per share for the three months ended June 30, 2026, compared to $3.4 million, or $0.21 loss per share, for the quarter ended June 30, 2025. The increase in net loss was primarily due to a $13.5 million impairment of IPR&D related to GTx-101 and GTx-102 as further described below. This increase was partially offset by a favorable $0.5 million difference in the change in fair value of derivative warrant liabilities and a $0.4 million decrease in general and administrative expenses. Cash used in operations was approximately $3.2 million.

Consistent with the Company's previously announced 2023 decision to deprioritize GTx-101 and GTx-102 in favor of GTx-104, and following reevaluation of strategic priorities during the first quarter of 2027, the Company recorded a full impairment of the remaining IPR&D carrying value associated with GTx-101 and GTx-102. The Company also evaluated the carrying value of its IPR&D related to GTx-104 following the receipt of the CRL. Based on the assessment, the Company determined that the fair value exceeds the carrying amount, and no impairment charge was required for the quarter ended June 30, 2026.

Total research and development expenses for the three months ended June 30, 2026, were $0.7 million, compared to $1.0 million three months ended June 30, 2025. The decrease was primarily due to a $0.3 million decrease in research activities mainly due to the completion of our GTx-104 pivotal Phase 3 STRIVE-ON safety clinical trial and submission of our NDA to the FDA during the prior period, whereas the current period research activities were only focused on addressing certain items identified in the CRL from the FDA.

General and administrative expenses were $1.7 million for the three months ended June 30, 2026, a decrease of $0.4 million from $2.1 million for the three months ended June 30, 2025. The decrease was primarily a result of a decrease in pre-commercial planning activities for GTx-104 offset in part by increased legal costs related to the Type A meeting with the FDA, and a decrease in stock-based compensation due to the issuance of new stock option awards for the three months ended June 30, 2025, with no such issuance occurring for the three months ended June 30, 2026.

Cash Runway

As of August 11, 2026, cash and cash equivalents were $22.2 million, The Company plans to use its current cash towards resolving the items cited in the CRL, working capital and other general corporate purposes. The Company believes its existing cash and cash equivalents will be sufficient to sustain planned operations, including the activities to address the items cited in the CRL, through the end of calendar 2028.

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 aSAH, a relatively uncommon type of stroke 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 healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to nimodipine oral capsules.

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 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. GTx-104 has been granted Orphan Drug Designation by the FDA, which provides seven years of marketing exclusivity post-launch in the United States if certain conditions are met at NDA approval, and additional intellectual property protection with 52 granted and pending patents.

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 Company's cash runway; future prospects of the Company's GTx-104 drug candidate; the Company's belief that the issues identified by the FDA in the CRL can be successfully addressed in the Company's resubmission of the NDA for GTx-104; the Company's planned approach to addressing the items cited in the CRL following its Type A meeting with the FDA and receipt of the official meeting minutes; the Company's dual source manufacturing strategy, including remediation at its current contract manufacturer and technology transfer to a second, U.S.-based contract manufacturer; the timing and outcome of any FDA reinspection of the current contract manufacturer; the Company's plans to complete the required non-clinical studies; and the Company's plans to report progress against key milestones; GTx-104's potential to bring enhanced treatment options to patients suffering from aSAH; the ability of GTx-104 to potentially eliminate the need for nasogastric tube administration in unconscious or dysphagic patients; the potential of GTx-104 to lower food effects, drug-to-drug interactions, and to eliminate potential dosing errors; the potential of GTx-104 to better manage hypotension in aSAH patients; and the Company's intellectual property estate for 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 timing and success of any regulatory resubmission of the NDA for GTx-104; (ii) the timing of any FDA reinspection of the Company's current contract manufacturer, and that facility's compliance status, which are determined by the FDA and outside the Company's control, and the FDA's position that it will not approve the NDA while the facility remains in an unacceptable compliance status; (iii) the ability of a second, U.S.-based contract manufacturer to generate the required stability and analytical data and to complete a product-specific pre-approval inspection; (iv) the need to complete additional non-clinical studies; (v) the requirement that any resubmission comprehensively address all items cited in the CRL and the risk of review delay; (vi) the Company's potential need for additional capital, which may not be available on acceptable terms; (vii) changes to regulatory pathways; (viii) the Company's ability to protect its intellectual property for GTx-104; and (ix) 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, 2026 filed with the Securities and Exchange Commission (SEC) and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, to be filed with the 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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---tables to follow---

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

(Expressed in thousands except share data)	June 30, 2026 $	March 31, 2026 $
Assets		
Current assets:		
Cash and cash equivalents	13,756	16,977
Receivables	20	20
Prepaid expenses	557	383
Total current assets	14,333	17,380
Equipment, net	7	8
Intangible assets	27,595	41,128
Goodwill	8,138	8,138
Total assets	50,073	66,654
Liabilities and Stockholders' equity		
Current liabilities:		
Trade and other payables	1,250	2,146
Total current liabilities	1,250	2,146
Deferred tax liability	612	612
Total liabilities	1,862	2,758
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value per share; 10,000,000 authorized; none issued and outstanding as of June 30, 2026 and March 31, 2026	—	—
Common stock, $0.0001 par value per share; 100,000,000 authorized; 16,274,026 and 16,024,026 shares issued and outstanding as of June 30, 2026 and March 31, 2026, respectively	1	1
Additional paid-in capital	298,518	298,413
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(244,270)	(228,480)
Total stockholders' equity	48,211	63,896
Total liabilities and stockholders' equity	50,073	66,654

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

	Three months ended	
	June 30, 2026	June 30, 2025
(Expressed in thousands, except share and per share data)	$	$
Operating expenses		
Research and development expenses	(697)	(955)
General and administrative expenses	(1,687)	(2,135)
Impairment of intangible assets	(13,533)	—
Loss from operating activities	(15,917)	(3,090)
Foreign exchange (loss) gain	(14)	10
Change in fair value of derivative warrant liabilities	—	(487)
Interest and other income, net	141	205
Total other income (expense) , net	127	(272)
Loss before income tax benefit	(15,790)	(3,362)
Income tax benefit	—	—
Net loss and total comprehensive loss	(15,790)	(3,362)
Basic and diluted loss per share	(0.91)	(0.21)
Weighted-average number of shares outstanding	17,269,986	15,924,522