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# GRACE THERAPEUTICS, INC.

## FORM 8-K
(Current report filing)

Filed 11/12/26 for the Period Ending 11/12/26

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|---|---|
| Address | 103 CARNEGIE CENTER<br>SUITE 300<br>PRINCETON, NJ, 08540 |
| Telephone | 609-322-1602 |
| CIK | 0001444192 |
| Symbol | GRCE |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Medical Research |
| Sector | Healthcare |
| Fiscal Year | 03/31 |

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**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): November 12, 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**<br>**Suite 300**<br>**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 November 12, 2026, Grace Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended September 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 November 12, 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: November 12, 2026

By: /s/ Prashant Kohli

Prashant Kohli
Chief Executive Officer

**Exhibit 99.1**

**Grace Therapeutics Announces Second Quarter 2027 Financial Results,**
**Provides Business Update**

Princeton, N.J., November 12, 2026 (GLOBE NEWSWIRE) — Grace Therapeutics, Inc. (Nasdaq: GRCE) (Grace Therapeutics or the Company), a late-stage biopharma company advancing GTx-104, a novel, injectable formulation of nimodipine that has completed a Phase 3 clinical trial and is 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 September 30, 2026.

"With no clinical safety or efficacy deficiencies identified in the U.S. Food and Drug Administration's (FDA) Complete Response Letter (CRL), we continue to execute our plan to address the chemistry, manufacturing and controls (CMC) and non-clinical data items, and are making progress toward resubmission of our New Drug Application (NDA) for GTx-104," said Prashant Kohli, Chief Executive Officer of Grace Therapeutics. "Our dual-source manufacturing strategy to address potential remediation issues at our current contract manufacturer is progressing, and the timing of our NDA resubmission will reflect whichever manufacturing site reaches readiness first. The financing concluded in August extends our expected cash runway through the end of calendar 2028, and positions us well as we work toward NDA resubmission. We look forward to reporting our progress as we work toward achieving these important milestones."

**Second Quarter 2027 and Recent Corporate Highlights**

- Completed a $10 million private placement financing with certain 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 FDA did not identify any clinical safety or efficacy deficiencies and did not request additional clinical data. The Company is working on its previously disclosed plan to address the identified issues and will report progress as key milestones are achieved.

- Initiated a dual-source manufacturing strategy for GTx-104 to address potential remediation issues from its current contract manufacturing organization (CMO). The Company's current CMO has responded to the FDA, submitted a corrective action plan, and, the Company believes, is executing that plan in direct communication with the FDA. Reinspection timing depends on the current CMO's readiness and FDA scheduling. In parallel, technology transfer was initiated during the quarter ended September 30, 2026 to a second, U.S.-based CMO, starting with analytical method transfer. The Company has also initiated the required non-clinical studies. The NDA resubmission may be supported by either CMO, or both, and its timing will reflect the pathway that reaches readiness first.

**Second Quarter 2027 Financial Results**

The Company reported a net loss of $2.1 million, or $0.11 per share, for the three months ended September 30, 2026, an increase of $1.2 million from the net loss of $0.9 million, or $0.06 per share, for the three months ended September 30, 2025. The increase in net loss was primarily due to a $1.4 million favorable change in the fair value of derivative warrant liabilities recorded during the three months ended September 30, 2025 with no such activity recorded in the three months ended September 30, 2026 as the applicable warrants have expired, as well as an increase in research and development expenses of $0.3 million, offset partially by a $0.6 million decrease in general and administrative expenses.

Total research and development expenses for the three months ended September 30, 2026 were $0.9 million, compared to $0.6 million for the three months ended September 30, 2025. The increase of $0.3 million primarily reflected higher third-party research activities related to the dual-source manufacturing strategy for GTx-104 and the required non-clinical studies identified in the CRL.

General and administrative expenses were $1.4 million for the three months ended September 30, 2026, a decrease of $0.6 million from $2.0 million for the three months ended September 30, 2025. The decrease was primarily the result of a $0.3 million decrease in professional fees primarily related to decreased legal fees, a $0.1 million decrease in pre-commercial planning activities for GTx-104, and a $0.1 million decrease in salaries and benefits.

**Cash Runway**

As of September 30, 2026, cash and cash equivalents were $21.3 million, a net increase of $4.3 million compared to cash and cash equivalents of $17.0 million at March 31, 2026. Cash used in operations for the six months ended September 30, 2026 was approximately $5.0 million. As announced in August 2026, the Company completed a private placement of its common stock with certain institutional and accredited investors. Net proceeds to the Company were $9.2 million. The Company plans to use its existing cash and cash equivalents towards resolving the items cited in the FDA's 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 per year.

**About GTx-104**

GTx-104 is a novel, injectable formulation of nimodipine that has completed a Phase 3 clinical trial and is 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, but not limited to, statements regarding the Company's cash runway and its planned uses of its existing cash and cash equivalents; the Company's intended uses of the net proceeds from the August 2026 financing; future prospects of GTx-104; 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; 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 belief that its current contract manufacturer is executing the corrective action plan in direct communication with the FDA; the Company's plans to complete the required non-clinical studies; 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 ability of the Company's current contract manufacturer to regain compliance and generate the required leachables data, the timing of any FDA reinspection of that 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 complete the technology transfer, manufacture three registration batches, generate the required 12 months of stability data, analytical data and leachables data, and 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, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 and the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, 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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---tables to follow---

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

| *(Expressed in thousands except share data)* | September 30, 2026 $ | March 31, 2026 $ |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | 21,311 | 16,977 |
| Receivables | 20 | 20 |
| Prepaid expenses | 629 | 383 |
| Total current assets | 21,960 | 17,380 |
| Equipment, net | 5 | 8 |
| Intangible assets | 27,595 | 41,128 |
| Goodwill | 8,138 | 8,138 |
| Total assets | 57,698 | 66,654 |
| | | |
| Liabilities and Stockholders' equity | | |
| Current liabilities: | | |
| Trade and other payables | 1,614 | 2,146 |
| Total current liabilities | 1,614 | 2,146 |
| | | |
| Deferred tax liability | 604 | 612 |
| Total liabilities | 2,218 | 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 September 30, 2026 and March 31, 2026 | — | — |
| Common stock, $0.0001 par value per share; 100,000,000 authorized; 21,035,930 and 16,024,026 shares issued and outstanding as of September 30, 2026 and March 31, 2026, respectively | 2 | 1 |
| Additional paid-in capital | 307,917 | 298,413 |
| Accumulated other comprehensive loss | (6,038) | (6,038) |
| Accumulated deficit | (246,401) | (228,480) |
| Total stockholders' equity | 55,480 | 63,896 |
| Total liabilities and stockholders' equity | 57,698 | 66,654 |

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

| *(Expressed in thousands, except share and per share data)* | Three months ended | | Six months ended | |
|---|---|---|---|---|
| | September 30, 2026 | September 30, 2025 | September 30, 2026 | September 30, 2025 |
| | $ | $ | $ | $ |
| **Operating expenses** | | | | |
| Research and development expenses | (885) | (568) | (1,582) | (1,523) |
| General and administrative expenses | (1,407) | (1,961) | (3,094) | (4,096) |
| Impairment of intangible assets | — | — | (13,533) | — |
| **Loss from operating activities** | (2,292) | (2,529) | (18,209) | (5,619) |
| Foreign exchange (loss) gain | (1) | (8) | (15) | 3 |
| Change in fair value of derivative warrant liabilities | — | 1,427 | — | 940 |
| Interest and other income, net | 154 | 172 | 295 | 375 |
| Total other income, net | 153 | 1,591 | 280 | 1,318 |
| Loss before income tax benefit | (2,139) | (938) | (17,929) | (4,301) |
| Income tax benefit | 8 | — | 8 | — |
| **Net loss and total comprehensive loss** | (2,131) | (938) | (17,921) | (4,301) |
| Basic and diluted loss per share | ($0.11) | ($0.06) | ($0.96) | ($0.27) |
| **Weighted-average number of shares outstanding** | 20,116,776 | 15,924,522 | 18,701,159 | 15,924,522 |