

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 12, 2025

GRACE THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

State of 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 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 12, 2025, Grace Therapeutics, Inc. issued a press release announcing its financial results for the three months ended June 30, 2025. 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 12, 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 thereunto duly authorized.

GRACE THERAPEUTICS, INC.

Date: August 12, 2025

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



**Grace Therapeutics Announces First Quarter 2026 Financial Results,
Provides Business Update**

Submission of New Drug Application (NDA) to U.S. Food and Drug Administration (FDA) for GTx-104 Seeking Approval of GTx-104 in the Treatment of Patients with aneurysmal Subarachnoid Hemorrhage (aSAH)

NDA Supported by Data from Phase 3 STRIVE-ON Safety Trial, which Met Primary Endpoint and Provided Evidence of Clinical Benefit Compared to Orally Administered Nimodipine

Princeton, NJ, August 12, 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 aSAH patients, today announced the financial results and business highlights for the quarter ended June 30, 2025.

“During our first quarter of 2026 we continued to execute on our clinical and corporate goals, led by the submission of our NDA to the FDA for GTx-104 for the treatment of aSAH,” said Prashant Kohli, CEO of Grace Therapeutics. “Our NDA for GTx-104 was a significant milestone for the Company and built on more than a decade of painstaking research and innovation. Our NDA is supported by a robust data package including positive results from our STRIVE-ON trial, which provided evidence of improved clinical outcomes in aSAH patients treated with GTx-104 as well as potential medical and pharmacoeconomic benefits 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 the STRIVE-ON trial results point to a very promising role for GTx-104 as a potential breakthrough for the care of aSAH patients. We are hopeful the FDA will accept our NDA for formal review, and look forward to continued engagement with the FDA during the review process.”

First Quarter 2026 Corporate Highlights

- Submission to the FDA of the Company’s NDA for GTx-104. The application included 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.
- 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 are immediately exercisable and will expire on the earlier of (i) the 60th day after the date of the acceptance by the FDA of an 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 provide additional marketing exclusivity for GTx-104.

First Quarter 2026 Financial Results

The Company reported a net loss of \$3.4 million, or \$0.21 per share, for the three months ended June 30, 2025, an increase of \$0.8 million from the net loss of \$2.6 million, or \$0.24 per share, for the three months ended June 30, 2024. The increase in net loss was primarily due to a \$1.9 million difference in the change in fair value of derivative warrant liabilities and a \$0.7 million decrease in income tax benefit, partially offset by a \$1.8 million decrease in research and development expenses and a \$0.1 million decrease in general and administrative expenses.



Total research and development expenses were approximately \$0.9 million for the three months ended June 30, 2025, compared to \$2.7 million for the three months ended June 30, 2024. The decrease of approximately \$1.8 million was primarily due to a \$1.9 million decrease in research activities mainly due to completion of our GTx-104 pivotal Phase 3 STRIVE-ON safety clinical trial, offset in part by a \$0.1 million increase in professional fees in connection with the preparation and submission of our NDA to the FDA.

General and administrative expenses were approximately \$2.1 million for the three months ended June 30, 2025, a decrease of \$0.1 million from \$2.2 million for the three months ended June 30, 2024. The decrease was primarily a result of decreased legal, accounting, tax, audit and other professional fees related to the continuance and domestication completed in October 2024, offset in part by an increase in salaries and benefits due to merit increases, increases in other general and administrative expenses primarily due to costs for GTx-104 commercial assessment, and an increase in stock-based compensation due to the issuance of new stock option awards.

Cash Runway

As of June 30, 2025, cash and cash equivalents were \$20.0 million, a net decrease of approximately \$2.1 million compared to cash and cash equivalents of \$22.1 million at March 31, 2025.

The private placement the Company completed in February 2025 included common warrants exercisable for shares of common stock (or pre-funded warrants in lieu thereof) at an exercise price of \$3.395 per share. Each common warrant is immediately exercisable and will expire on the earlier of (i) the 60th day after the date the FDA approves the NDA for GTx-104 and (ii) September 25, 2028. Potential gross proceeds from the exercise of the February 2025 common warrants are \$15.0 million.

The private placement the Company completed in September 2023 included common warrants exercisable for shares of common stock at an exercise price of \$3.003 per share. Each common warrant is immediately exercisable and will expire on the earlier of (i) the 60th day after the date of the acceptance by the FDA of the NDA for GTX-104 or (ii) five years from the date of issuance. Potential gross proceeds from the exercise of the September 2023 common warrants are \$7.6 million.

While the Company believes that current cash and cash equivalents provide cash runway through at least the next twelve months, the runway could extend into the second quarter of calendar 2027 if all of the common warrants issued in connection with the Company's February 2025 and September 2023 private placements are exercised at the election of the investors.

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 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 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 the Grace Therapeutics Asset Portfolio

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.

GTx-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve neurological symptoms of Ataxia-Telangiectasia (A-T), for which there are currently no FDA-approved therapies. GTx-102 is a stable, concentrated oral spray formulation comprised of the gluco-corticosteroid betamethasone that, together with other excipients can be sprayed conveniently over the tongue of the A-T patient and is rapidly absorbed. The Company received written responses to its End of Phase 1 meeting in GTx-102 where the FDA made recommendations on the path toward an NDA. The FDA provided guidance on the design of a single pivotal efficacy and safety trial, including the neurological assessment scale for the primary endpoint, that could, with appropriate confirmatory evidence, support an NDA. The further development of GTx-102 has been deprioritized in favor of focusing on development of GTx-104. It is also possible that the Company may license or sell GTx-102.

GTx-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to ease the symptoms of patients suffering with postherpetic neuralgia (PHN). GTx-101 is administered via a metered-dose of bupivacaine spray and forms a thin bio-adhesive topical film on the surface of the patient's skin, which enables a touch-free, non-greasy application. It also comes in convenient, portable 30 ml plastic bottles. Unlike oral gabapentin and lidocaine patches, which are used for the treatment of PHN, the Company believes that the biphasic delivery mechanism of GTx-101 has the potential for rapid onset of action and continuous pain relief for up to eight hours. No skin sensitivity was reported in a Phase 1 trial. The further development of GTx-101 has been deprioritized in favor of focusing on development of GTx-104. It is also possible that the Company may license or sell GTx-101.

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 Company's cash runway, the future prospects of the Company's GTx-104 drug candidate, the timing and outcome of the Company's NDA submission for GTx-104, the Company's belief that the data and regulatory packages as currently structured will be sufficient for submission of such NDA, 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 medical and pharmacoeconomic benefit, GTx-104's commercial prospects, the future prospects of the Company's GTx-102 drug candidate, GTx-102's potential to provide clinical benefits to decrease symptoms associated with A-T, the timing and outcomes of a Phase 3 efficacy and safety trial for GTx-102, the timing of an NDA filing for GTx-102, the future prospects of the Company's GTX-101 drug candidate, GTX-101's potential to be administered to PHN patients to treat the severe nerve pain associated with the disease and any future patent and other intellectual property filings made by the Company for new developments 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 of the Company's NDA application for GTx-104; (iii) changes to regulatory pathways; 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 to be 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)

	June 30, 2025	March 31, 2025
<i>(Expressed in thousands except share data)</i>	\$	\$
Assets		
Current assets:		
Cash and cash equivalents	20,005	22,133
Receivables	20	126
Prepaid expenses	500	453
Total current assets	20,525	22,712
Equipment, net	14	15
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	69,805	71,993
Liabilities and Stockholders' equity		
Current liabilities:		
Trade and other payables	2,315	1,930
Total current liabilities	2,315	1,930
Derivative warrant liabilities	1,628	1,141
Deferred tax liability	2,312	2,312
Total liabilities	6,255	5,383
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, 2025 and March 31, 2025	—	—
Common stock, \$0.0001 par value per share; 100,000,000 authorized; 13,828,562 and 13,718,106 shares issued and outstanding as of June 30, 2025 and March 31, 2025, respectively	1	1
Additional paid-in capital	293,636	293,334
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(224,049)	(220,687)
Total stockholders' equity	63,550	66,610
Total liabilities and stockholders' equity	69,805	71,993



GRACE THERAPEUTICS, INC.

Condensed Consolidated Statements of Loss and Comprehensive Loss
(Unaudited)

	Three months ended	
	June 30, 2025	June 30, 2024
<i>(Expressed in thousands, except share and per share data)</i>	\$	\$
Operating expenses		
Research and development expenses	(955)	(2,708)
General and administrative expenses	(2,135)	(2,255)
Loss from operating activities	(3,090)	(4,963)
Foreign exchange gain (loss)	10	(8)
Change in fair value of derivative warrant liabilities	(487)	1,395
Interest and other income, net	205	235
Other (expense) income, net	(272)	1,622
Loss before income tax benefit	(3,362)	(3,341)
Income tax benefit	—	724
Net loss and total comprehensive loss	(3,362)	(2,617)
Basic and diluted loss per share	(0.21)	(0.24)
Weighted-average number of shares outstanding	15,924,522	10,928,543