

November 13, 2025



Grace Therapeutics Announces Second Quarter 2026 Financial Results, Provides Business Update

Announced U.S. Food and Drug Administration (FDA) Acceptance for Review of New Drug Application (NDA) for GTx-104

FDA Established April 23, 2026 as PDUFA Target Date for Review of Submission Seeking Approval for GTx-104 in the Treatment of Patients with aneurysmal Subarachnoid Hemorrhage (aSAH)

Phase 3 STRIVE-ON Safety Trial Data Presented at 2025 Neurocritical Care Annual Meeting

Granted Sixth U.S. Patent Covering IV Dosing Regimen for GTx-104

PRINCETON, N.J., Nov. 13, 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 September 30, 2025.

"During our second quarter of 2026 we continued to execute on our clinical and corporate goals, led by FDA acceptance for review of our NDA for GTx-104 for the treatment of aSAH," said Prashant Kohli, CEO of Grace Therapeutics. "Acceptance of our NDA for review is another significant milestone for the Company and further demonstrates our ability to execute as we continue to advance this important innovation for aSAH patients. 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. We were pleased to see these data highlighted in a presentation at the *Neurocritical Care* annual meeting, where the results were well received by the conference attendees. Also this quarter, the U.S. Patent and Trademark Office issued a new method of use patent covering the dosing regimen for IV administration of nimodipine used in our STRIVE-ON trial for GTx-104. This new patent coverage on the dosing regimen should be included in the label for GTx-104 if it is approved by the FDA, adding a new layer and extending the duration of our intellectual property protections. We believe that if our NDA for GTx-104 is approved by the FDA, our strong U.S. and international patent estate will help to maximize the long-term market value of GTx-104 and correspondingly deliver value for our shareholders." The standard of care for aSAH has not seen meaningful innovation in nearly 40 years, and we believe that if GTx-104 is approved, our STRIVE-ON trial results point to a very promising role for GTx-104 in the treatment of these patients. We look forward to continuing to engage with the FDA during their review as they work toward the PDUFA

target date of April 23, 2026.”

Second Quarter 2026 Corporate Highlights

- On August 22, 2025, the FDA accepted the Company's NDA for GTx-104 for formal review, establishing April 23, 2026 as its PDUFA target date. The application is supported by 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. These data were presented at the *Neurocritical Care* annual meeting, held in Montreal, Quebec, Canada in September 2025.
- On September 16, 2025, U.S. Patent and Trademark Office issued a U.S. Patent No. 12,414,943, titled “Nimodipine Parenteral Administration”. The new method of use patent covers the dosing regimen for IV administration of nimodipine used in the Phase 3 STRIVE-ON safety trial for GTx-104. Grace Therapeutics has established a multi-layered intellectual property estate for GTx-104, including five patents on the composition of the Company's formulation of nimodipine, which provide patent protection to 2037. The new patent on the IV dosing regimen for GTx-104 strengthens the Company's intellectual property position and extends protection to 2043. Grace has also been granted Orphan Drug Designation from the FDA, which provides GTx-104 with seven years of marketing exclusivity in United States upon FDA approval of the Company's NDA.
- On October 23, 2025, the Company announced that 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 expired as the 60th day after the FDA's acceptance for review of the Company's NDA for GTx-104 has passed. The Company estimates that its cash and cash equivalents were approximately \$20.0 million as of October 31, 2025.

Second Quarter 2026 Financial Results

The Company reported a net loss of \$0.9 million, or \$0.06 per share, for the three months ended September 30, 2025, a decrease of \$2.5 million from a net loss of \$3.4 million, or \$0.30 per share, for the three months ended September 30, 2024. The decrease in net loss was primarily due to a \$2.4 million decrease in research and development expenses and a \$1.1 million difference in the change in fair value of derivative warrant liabilities, partially offset by a \$0.9 million decrease in income tax benefit and a \$0.1 million increase in general and administrative expenses.

Total research and development expenses for the three months ended September 30, 2025, were \$0.6 million, compared to \$3.0 million for the three months ended September 30, 2024. The decrease of \$2.4 million was primarily due to a \$2.5 million decrease in research activities mainly due to completion of our GTx-104 pivotal Phase 3 STRIVE-ON safety trial, partially offset by an increase in salaries and benefits due to merit increases.

General and administrative expenses were \$2.0 million for the three months ended September 30, 2025, an increase of \$0.1 million from \$1.9 million for the three months ended September 30, 2024. The increase was primarily a result of an increase in other general and administrative expenses primarily due to costs for GTx-104 pre-commercial planning.

Cash Runway

As of September 30, 2025, cash and cash equivalents were \$16.9 million, a net decrease of \$5.2 million compared to cash and cash equivalents of \$22.1 million at March 31, 2025.

In October 2025, the Company received \$4.0 million in gross proceeds from exercises of common warrants that were previously issued in a private placement in September 2023. 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.

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 private placement 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 and cash position, the future prospects of the Company's GTx-104 drug candidate, the outcome of the Company's NDA submission 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, 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; (iv) our ability to protect our intellectual property for our drug candidates; and (v) 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 and the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 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:

Grace Therapeutics Contact:

Prashant Kohli
Chief Executive Officer
Tel: 609-322-1602
Email: info@gracetx.com
www.gracetx.com

Investor Relations:

LifeSci Advisors
Mike Moyer
Managing Director
Phone: 617-308-4306
Email: mmoyer@lifesciadvisors.com

GRACE THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2025	March 31, 2025
<i>(Expressed in thousands except share data)</i>	\$	\$
Assets		
Current assets:		
Cash and cash equivalents	16,862	22,133
Receivables	20	126
Prepaid expenses	416	453
Total current assets	17,298	22,712
Equipment, net	12	15
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	66,576	71,993

Liabilities and Stockholders' equity

Current liabilities:

Trade and other payables	1,245	1,930
Total current liabilities	1,245	1,930

Derivative warrant liabilities	201	1,141
Deferred tax liability	2,312	2,312
Total liabilities	3,758	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 September 30, 2025 and March 31, 2025

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Common stock, \$0.0001 par value per share; 100,000,000
authorized; 14,128,562 and 13,718,106

shares issued and outstanding as of September 30, 2025

and March 31, 2025, respectively

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Additional paid-in capital	293,842	293,334
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(224,987)	(220,687)
Total stockholders' equity	62,818	66,610
Total liabilities and stockholders' equity	66,576	71,993

GRACE THERAPEUTICS, INC.

Condensed Consolidated Statements of Loss and Comprehensive Loss

(Unaudited)

	Three months ended		Six months ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
<i>(Expressed in thousands, except share and per share data)</i>	\$	\$	\$	\$

Operating expenses

Research and development expenses, net of government assistance	(568)	(2,976)	(1,523)	(5,684)
General and administrative expenses	(1,961)	(1,855)	(4,096)	(4,109)
Loss from operating activities	(2,529)	(4,831)	(5,619)	(9,793)

Foreign exchange (loss) gain	(8)	13	3	5
Change in fair value of derivative warrant liabilities	1,427	362	940	1,756
Interest and other income, net	172	172	375	407
Total other income, net	1,591	547	1,318	2,168
Loss before income tax recovery	(938)	(4,284)	(4,301)	(7,625)
Income tax benefit	—	852	—	1,576
Net loss and total comprehensive loss	(938)	(3,432)	(4,301)	(6,049)
Basic and diluted loss per share	(0.06)	(0.30)	(0.27)	(0.53)
Weighted-average number of shares outstanding	15,924,522	11,506,234	15,924,522	11,506,234



Source: Grace Therapeutics, Inc.