February 12, 2026

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

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 Society of Vascular and Interventional Neurology Annual Meeting

Company Continues Pre-Commercial Planning in Anticipation of Potential FDA Approval of NDA Submission for GTx-104 for the Treatment of Patients with aSAH

PRINCETON, N.J., Feb. 12, 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 quarter ended December 31, 2025.

“During our third quarter of fiscal 2026 we continued to execute on our clinical and corporate goals, led by our pre-commercial planning in anticipation of potential FDA approval of our New Drug Application (NDA) for GTx-104 for the treatment of aSAH,” said Prashant Kohli, CEO of Grace Therapeutics. “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 late breaking presentation at the Society of Vascular and Interventional Neurology annual meeting in November 2025. Our STRIVE-ON trial results continue to be well received by researchers, practitioners and industry leaders. 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.”

Third Quarter 2026 and Recent Corporate Highlights

- During our third fiscal quarter we provided grant support for the development of a Continuing Medical Education (CME) program for healthcare professionals in medical

specialties related to the care of aSAH patients. Content for the CME program was independently developed by leading providers of CME content and is intended to educate Health Care Professionals on the current challenges in treating aSAH patients.

- On November 21, 2025, the Company presented data from its pivotal Phase 3 STRIVE-ON Safety Trial of GTx-104 in aSAH as a late breaking trial at the Society of Vascular and Interventional Neurology annual meeting. The presentation titled *Safety and Tolerability of GTX-104 (Nimodipine Injection for IV Infusion) Compared with Oral Nimodipine in Patients with Aneurysmal Subarachnoid Hemorrhage: a Prospective, Randomized Trial,* was presented by Thomas P. Bleck, MD, Professor, Neurology (Neurocritical Care and Epilepsy/Clinical Neurophysiology) at Northwestern University Feinberg School of Medicine.
- On October 23, 2025, the Company announced that it had 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 on October 21, 2025.

Third Quarter 2026 Financial Results

The Company reported a net loss of approximately $2.3 million, or $0.14 per share, for the three months ended December 31, 2025, a decrease of approximately $1.8 million from the net loss of $4.2 million, or $0.36 per share, for the three months ended December 31, 2024. The decrease in net loss was primarily due to a $1.7 million decrease in research and development expenses and a $1.1 million decrease in the change of fair value of derivative warrant liabilities, partially offset by increases in general administrative expenses of $0.5 million and a decrease in income tax benefit of $0.6 million.

Total research and development expenses for the three months ended December 31, 2025, were $0.5 million, compared to $2.2 million for the three months ended December 31, 2024. The decrease of $1.7 million was primarily due to a $1.8 million decrease in research activities mainly due to completion of our GTx-104 pivotal Phase 3 STRIVE-ON safety clinical trial, partially offset by a $0.1 million increase in salaries and benefits due to merit increases.

General and administrative expenses were $2.0 million for the three months ended December 31, 2025, an increase of $0.5 million from $1.5 million for the three months ended December 31, 2024. The increase was primarily a result of an increase in professional fees and other general and administrative expenses primarily due to costs for GTx-104 pre-commercial planning.

Cash Runway

As of December 31, 2025, cash and cash equivalents were $18.7 million, a net decrease of $3.4 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 Company plans to use its current cash and cash equivalents to further the regulatory review process for GTx-104, pre-commercial planning, commercial team buildout, and product launch if GTx-104 is approved, working capital and other general corporate purposes. The Company believes its existing cash and cash equivalents will be sufficient to sustain planned operations through at least 12 months from the date of this press release.

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 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 if certain conditions are met at 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.

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 submission 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, 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, 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.

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

(Expressed in thousands except share data)	December 31, 2025 $	March 31, 2025 $
Assets		
Current assets:		
Cash and cash equivalents	18,672	22,133
Receivables	20	126
Prepaid expenses	519	453
Total current assets	19,211	22,712
Equipment, net	11	15
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	68,488	71,993
Liabilities and Stockholders' equity		
Current liabilities:		
Trade and other payables	1,284	1,930
Total current liabilities	1,284	1,930
Derivative warrant liabilities	-	1,141

Deferred tax liability	2,312	2,312
Total liabilities	3,596	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 December 31, 2025 and March 31, 2025	—	—
Common stock, $0.0001 par value per share; 100,000,000 authorized; 15,474,026 and 13,718,106 shares issued and outstanding as of December 31, 2025 and March 31, 2025, respectively	1	1
Additional paid-in capital	298,231	293,334
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(227,302)	(220,687)
Total stockholders' equity	64,892	66,610
Total liabilities and stockholders' equity	68,488	71,993

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

	Three months ended		Nine months ended	
	December 31, 2025	December 31, 2024	December 31, 2025	December 31, 2024
(Expressed in thousands, except share and per share data)				
	$	**$**	**$**	**$**
Operating expenses				
Research and development expenses, net of government assistance	(462)	(2,194)	(1,985)	(7,877)
General and administrative expenses	(1,987)	(1,510)	(6,082)	(5,619)
Loss from operating activities	(2,449)	(3,704)	(8,067)	(13,496)
Foreign exchange gain (loss)	4	(16)	5	(11)

Change in fair value of derivative warrant liabilities	(40)	(1,178)	900	578
Interest and other income, net	170	138	547	544
Total other income (loss), net	134	(1,056)	1,452	1,111
Loss before income tax recovery	(2,315)	(4,760)	(6,615)	(12,385)
Income tax benefit	—	605	—	2,181
Net loss and total comprehensive loss	(2,315)	(4,155)	(6,615)	(10,204)
Basic and diluted loss per share	(0.14)	(0.36)	(0.41)	(0.89)
Weighted-average number of shares outstanding	16,933,620	11,506,234	16,262,111	11,506,234

Source: Grace Therapeutics, Inc.