June 18, 2026

Grace Therapeutics Announces 2026 Fiscal Year-End Financial Results, Provides Business Update

Type A Meeting Scheduled with FDA to Potentially Clarify Path to GTx-104 NDA Resubmission

Phase 3 STRIVE-ON Safety Trial Data Presented at Multiple Medical Conferences

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

PRINCETON, N.J., June 18, 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 fiscal year ended March 31, 2026.

“Since receipt of the U.S. Food and Drug Administration’s (FDA) Complete Response Letter (CRL) in April 2026, we have been working diligently on addressing the cited items, and we look forward to a constructive discussion with the FDA as we continue to prepare our resubmission,” said Prashant Kohli, CEO of Grace Therapeutics. “FDA approval of our New Drug Application (NDA) for GTx-104 for the treatment of aSAH would represent the first meaningful innovation in the standard of care for these patients in more than 40 years. As evidenced by the response among researchers, practitioners and industry leaders to the presentation of our Phase 3 STRIVE-ON trial results at major medical conferences throughout the fiscal year, we believe there is a significant desire in the marketplace for an intravenously administered nimodipine. We are confident in the robust data package supporting our NDA, and that the issues identified by the FDA can be successfully addressed in our resubmission.”

Fiscal 2026 and Recent Corporate Highlights

- On April 23, 2026, the FDA issued a CRL for the Company’s NDA for GTx-104 for the treatment of patients with aSAH. In the CRL, the FDA referenced certain items in the Chemistry, Manufacturing, and Controls (CMC) and Non-Clinical sections of the application, which Grace believes it can address in a resubmission of its NDA. The cited items are related to additional leachable data time points for commercial product, non-clinical product toxicology risk assessments, and current Good Manufacturing Practices (cGMP) deficiencies with our contract manufacturing organization. No clinical deficiencies were identified. A Type A meeting with the FDA has been scheduled to

potentially clarify the path forward and determine the appropriate next steps. The Company expects to provide a regulatory update after the receipt of official meeting minutes.

- Phase 3 STRIVE-ON trial results were presented at multiple major medical conferences over the last twelve months:
  - *2026 American Academy of Neurology*, (April 18-22, 2026, Chicago, IL)
  - *Society of Critical Care Medicine's Critical Care Congress* (March 22-24, 2026, Chicago, IL)
  - *American Association of Neuroscience Nurses* (March 21-24, 2026, Dallas, TX)
  - *Society of Vascular and Interventional Neurology* (November 19-22, 2025, Orlando, FL)
  - *2025 Neurocritical Care Society* (September 18-21, 2025, Montreal, Quebec)
- The U.S. Patent and Trademark Office issued a U.S. Patent No. 12,414,943, titled "Nimodipine Parenteral Administration". The method of use patent, published on September 16, 2025, 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. GTx-104 has also been granted Orphan Drug Designation from the FDA, which provides seven years of marketing exclusivity in United States if certain conditions are met upon FDA approval of the NDA.

Fiscal Year 2026 Financial Results

The Company reported a net loss of $7.8 million, or $0.47 loss per share for the fiscal year ended March 31, 2026, representing a $1.8 million decrease in net loss from $9.6 million, or $0.79 loss per share, for the fiscal year ended March 31, 2025.

Total research and development expenses were $2.4 million for the fiscal year ended March 31, 2026, compared with $9.5 million, for the fiscal year ended March 31, 2025. The decrease of $7.1 million was primarily due to the decrease in research activities of $7.5 million driven by the close-out of the GTx-104 pivotal Phase 3 safety clinical trial during the first calendar quarter of 2026, offset by a $0.4 million increase in external consulting and data management costs incurred in support of the NDA of GTx-104, which was submitted to the FDA in June 2025.

General and administrative expenses were $8.7 million for the fiscal year ended March 31, 2026, compared to $7.2 million for the fiscal year ended March 31, 2025. The increase of $1.5 million was primarily driven by $0.8 million in non-recurring legal and due diligence costs incurred in connection with strategic initiatives evaluated during the period, as well as increased professional fees and other general and administrative costs of $0.9 million primarily related to pre-commercial planning for GTx-104, offset in part by a decrease in salaries and benefits of $0.2 million primarily a result of decreased headcount.

Cash Runway

At March 31, 2026, the Company had cash and cash equivalents of $17.0 million, a net decrease of $5.1 million compared to cash and cash equivalents of $22.1 million at March 31, 2025. The Company plans to use its current cash towards resolving the items cited in the FDA's Complete Response Letter, 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 nimodipine oral capsules (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 the GTx-104 arm and the oral nimodipine arm, 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 in the GTx-104 arm compared to four deaths in the oral nimodipine arm. The survival status of one patient in 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 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 and cash position; the future prospects of the Company's GTx-104 drug candidate; the Company's belief that there is a significant desire in the marketplace for an alternative to orally administered nimodipine; the Company's belief that the issues identified by the FDA in the CRL can be successfully addressed in the Company's resubmission of an NDA for GTx-104; the expected timing and outcome of the Type A meeting with the FDA; the Company's expectations that the Type A meeting with the FDA will clarify the path forward and determine next steps; the Company's plans to provide a regulatory update after the receipt of official meeting minutes from such Type A meeting; 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 outcome of any Type A meeting with the FDA related to GTx-104; (ii) the timing and success of any regulatory resubmission of the NDA for GTx-104; (iii) changes to regulatory pathways; (iv) the Company's ability to protect its intellectual property for GTx-104; 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, 2026, 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.
Consolidated Balance Sheets

	March 31, 2026	March 31, 2025

(Expressed in thousands except share data)	$	$
Assets		
Current assets:		
Cash and cash equivalents	16,977	22,133
Receivables	20	126
Prepaid expenses	383	453
Total current assets	17,380	22,712
Equipment, net	8	15
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	66,654	71,993
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	2,146	1,930
Total current liabilities	2,146	1,930
Derivative warrant liabilities	—	1,141
Deferred tax liability	612	2,312
Total liabilities	2,758	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 March 31, 2026 and 2025	—	—
Common stock, $0.0001 par value per share; 100,000,000 authorized; 16,024,026 and 13,718,106 shares issued and outstanding as of March 31, 2026 and 2025, respectively	1	1
Additional paid-in capital	298,413	293,334
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(228,480)	(220,687)
Total stockholders' equity	63,896	66,610
Total liabilities and stockholders' equity	66,654	71,993

Consolidated Statements of Loss and Comprehensive Loss

(Expressed in thousands, except share and per share data)	Year Ended March 31, 2026 $	Year Ended March 31, 2025 $
Operating expenses		
Research and development expenses	2,405	9,511
General and administrative expenses	8,672	7,168
Loss from operating activities	(11,077)	(16,679)
Foreign exchange loss	(1)	(17)
Change in fair value of derivative warrant liabilities	900	3,218
Interest and other income, net	685	711
Total other income, net	1,584	3,912
Loss before income tax benefit	(9,493)	(12,767)
Income tax benefit	1,700	3,199
Net loss and total comprehensive loss	(7,793)	(9,568)
Basic and diluted loss per share	(0.47)	(0.79)
Weighted-average number of shares outstanding	16,510,632	12,087,270

Source: Grace Therapeutics, Inc.