June 23, 2025

Grace Therapeutics Announces 2025 Fiscal Year-End Results, Provides Business Update

Held Type C meeting with FDA on Planned New Drug Application (NDA) Submission, Including Clinical, Non-clinical, and Chemistry, Manufacturing, and Control (CMC) Requirements

NDA On Track for Submission to FDA in First Half of Calendar 2025

NDA to be 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

Secured Private Placement Financing of $15 Million in Upfront Gross Proceeds with the Potential to Receive up to an Additional $15 Million in Potential Warrant Exercise Proceeds for an Aggregate of Up to Approximately $30 Million in Potential Total Gross Proceeds

PRINCETON, N.J., June 23, 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 aneurysmal subarachnoid hemorrhage (aSAH) patients, today announced the financial results and business highlights for the fiscal year ended March 31, 2025.

“During our 2025 fiscal year we made significant progress in both clinical and corporate goals, led by our announcement of positive topline data from our Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial–NCT05995405) and alignment with the U.S. Food and Drug Administration (FDA) on our planned submission of an NDA for GTx-104 for the treatment of aSAH,” said Prashant Kohli, CEO of Grace Therapeutics. “We also secured financing of $15 million up front with the potential to receive up to an additional $15 million upon cash exercise of accompanying warrants issued in a private placement led by Nantahala Capital and ADAR1 Partners, LP along with other leading healthcare-focused investors. This investment will support pre-commercial planning, commercial team build out and product launch, if GTx-104 is approved.”

“Our focus now is to finalize our NDA submission for GTx-104, which we expect to complete by the end of June 2025. The standard of care for aSAH has not seen meaningful innovation in nearly 40 years. Data from our STRIVE-ON trial exceeded our expectations, and although STRIVE-ON was not designed or powered to demonstrate efficacy, the data provide support for improved clinical outcomes for patients treated with GTx-104 when compared to patients treated with orally administered nimodipine. Importantly, the data also provides both medical and pharmacoeconomic evidence of the potential benefit of GTx-104 in aSAH patients,

which could help drive adoption of GTx-104 by neurocritical care physicians and hospital pharmacies. 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 should it be approved by the FDA," concluded Mr. Kohli.

2025 Corporate Highlights

- Held Type C meeting with the FDA to obtain feedback on the completed the STRIVE-ON trial and the planned NDA submission for GTx-104, including CMC requirements. Based on feedback from the FDA, the Company believes that the data and regulatory packages as currently structured will be sufficient for submission of an NDA.
- Successfully concluded the STRIVE-ON trial, with GTx-104 meeting its primary endpoint; other measures also favored or were comparable to GTx-104.
- NDA for GTx-104 is on track for submission to the FDA by the end of the first half of calendar year 2025.
- Completed private placement financing of up to approximately $30.0 million in potential total gross proceeds, consisting of initial upfront funding of approximately $15.0 million and the potential to receive up to an additional approximately $15.0 million upon cash exercise of accompanying warrants at the election of the investors; the financing was led by Nantahala Capital and ADAR1 Partners, LP, and included participation from new and existing healthcare-focused institutional investors, including Stonepine Capital Management, among others. The net proceeds of the initial upfront funding were approximately $13.7 million, after deducting fees and expenses.
- 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.

Fiscal Year 2025 Financial Results

The Company reported a net loss of $9.6 million, or $0.79 loss per share, for the fiscal year ended March 31, 2025, a decrease of $3.3 million from the net loss of $12.9 million, or $1.35 per share, for the fiscal year ended March 31, 2024. The decrease in net loss was primarily due to an approximately $6.0 million difference in change in fair value of derivative warrant liabilities, a $1.5 million decrease in restructuring costs, and a $1.4 million increase in income tax benefits, partially offset by a $4.8 million increase in research and development expenses, net of government assistance, a $0.5 million increase in general and administrative expenses, and a $0.2 million decrease in interest and other income, net.

Total research and development expenses for the fiscal year ended March 31, 2025 were $9.5 million, compared to $4.7 million for the fiscal year ended March 31, 2024. The increase of $4.8 million was primarily due to the increase in research activities for the GTx-04 pivotal Phase 3 safety clinical trial.

General and administrative expenses were $7.2 million for the fiscal year ended March 31, 2025, an increase of $0.5 million from $6.7 million for the fiscal year ended March 31, 2024. The increase was primarily a result of increased legal, tax, accounting and other professional fees primarily related to the continuance and domestication completed in October 2024, increased salaries and benefits due to merit increases and hiring of a new

employee, partially offset by a decrease in other expenses due primarily to adjustments for Canadian goods and services tax and a decrease in miscellaneous expenses as a result of restructuring in the prior year period. Stock-based compensation of $0.5 million the fiscal year ended March 31, 2025, decreased by $0.2 million compared to $0.7 million for the fiscal year ended March 31, 2024. The decrease was primarily due to fewer stock option awards granted during the fiscal year ended March 31, 2025.

At March 31, 2025, the Company had cash and cash equivalents of $22.1 million, a net decrease of $0.9 million compared to cash and cash equivalents of $23.0 million at March 31, 2024.

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 is $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 is $7.6 million.

While the Company believes that current cash and cash equivalents provide cash runway into the third quarter of calendar 2026, 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 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 a relatively uncommon type of stroke (aSAH) 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.

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 of the Company's anticipated 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 and timing of the proposed 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 and other documents that have been and will be filed by Grace Therapeutics from time to time with the Securities and Exchange Commission 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

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GRACE THERAPEUTICS, INC.
Consolidated Balance Sheets

(Expressed in thousands except share data)	March 31, 2025 $	March 31, 2024 $
Assets		
Current assets:		
Cash and cash equivalents	22,133	23,005
Receivables	126	722

Prepaid expenses	453	283
Total current assets	22,712	24,010
Equipment, net	15	24
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	71,993	73,300
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	1,930	1,684
Total current liabilities	1,930	1,684
Derivative warrant liabilities	1,141	4,359
Deferred tax liability	2,312	5,514
Total liabilities	5,383	11,557
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, 2025 and 2024	—	—
Common stock, $0.0001 par value per share; 100,000,000 authorized; 13,718,106 and 9,399,404 shares issued and outstanding as of March 31, 2025 and 2024, respectively	1	1
Additional paid-in capital	293,334	278,899
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(220,687)	(211,119)
Total stockholders' equity	66,610	61,743
Total liabilities and stockholders' equity	71,993	73,300

GRACE THERAPEUTICS, INC.

Consolidated Statements of Loss and Comprehensive Loss

(Expressed in thousands, except share and per share data)	Year Ended March 31, 2025	Year Ended March 31, 2024
	$	$
Operating expenses		

Research and development expenses, net of government assistance	(9,511)	(4,683)
General and administrative expenses	(7,168)	(6,684)
Restructuring cost	—	(1,485)
Loss from operating activities	(16,679)	(12,852)
Foreign exchange (loss) gain	(17)	(16)
Change in fair value of derivative warrant liabilities	3,218	(2,728)
Interest and other income, net	711	911
Total other income, net	3,912	(1,833)
Loss before income tax benefit	(12,767)	(14,685)
Income tax benefit	3,199	1,832
Net loss and total comprehensive loss	(9,568)	(12,853)
Basic and diluted loss per share	(0.79)	(1.35)
Weighted-average number of shares outstanding	12,087,270	9,529,123

Source: Grace Therapeutics, Inc.