November 13, 2024

Grace Therapeutics Announces Second Fiscal Quarter 2025 Financial Results, Provides Business Update

STRIVE-ON Data Readout Expected First Calendar Quarter 2025; NDA Submission on Track for 1H Calendar 2025

Completed Corporate Re-Branding, Connecting Company to Rich Scientific Legacy of Grace Therapeutics

Announced Completion of Patient Enrollment in Pivotal Phase 3 STRIVE-ON Safety Trial of GTx-104

Hosting Virtual KOL Event on GTx-104 in aneurysmal Subarachnoid Hemorrhage November 20, 2024

Projected Cash Runway into Second Calendar Quarter 2026

PRINCETON, N.J., Nov. 13, 2024 (GLOBE NEWSWIRE) -- Grace Therapeutics, Inc. (Nasdaq: GRCE) formerly Acasti Pharma Inc. (Grace Therapeutics or the Company), a late-stage, biopharma company advancing GTx-104, a clinical-stage, novel, injectable formulation of nimodipine being developed for intravenous (IV) infusion in aneurysmal subarachnoid hemorrhage (aSAH) patients to address significant unmet medical needs, today announced financial results and business highlights for the quarter ended September 30, 2024.

“During our second quarter we continued to make significant progress in both clinical and corporate goals, completing enrollment of our Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial–NCT05995405) ahead of schedule and rebranding the Company to Grace Therapeutics,” said Prashant Kohli, CEO of Grace Therapeutics. “With enrollment in the STRIVE-ON trial now complete, we anticipate a data readout in first calendar quarter of 2025, and remain on track to submit a New Drug Application (NDA) to the U.S. Food Drug Administration in the first half of calendar 2025. The potential benefits of GTx-104 in the treatment of aSAH will be highlighted in our Key Opinion Leader Webinar featuring Drs. Abhishek Ray and Andrew Webb on November 20th.

“Our rebranding to Grace Therapeutics reconnects our company to its rich scientific legacy established under the Grace name over more than a decade. The breakthroughs in nimodipine formulation that led to the development of GTx-104 were made by years of scientific research by our exceptional team while Grace Therapeutics was located in the pharma industry research corridor of New Jersey, and we are very pleased to return to those roots. In conjunction with the rebranding, we also redomiciled to the United States as a Delaware corporation effective October 7, 2024. We believe these steps offer several

potential benefits, including a U.S. corporate structure that should increase the company's attractiveness and marketability to potential strategic partners and global institutional investors," concluded Mr. Kohli.

Highlights for Second Fiscal Quarter 2025 and Recent Weeks

- Announced completion of patient enrollment in the Phase 3 STRIVE-ON safety trial.
- We anticipate a data readout from the STRIVE-ON trial in the first calendar quarter of 2025.
- NDA submission to the FDA is anticipated in the first half of calendar year 2025.
- Completion of the Company's redomicile to the State of Delaware, which was approved by the Company's shareholders at the Company's Annual and Special Meeting of Shareholders held on September 30, 2024.
- Change of the Company's corporate name to Grace Therapeutics, Inc. The Company's common stock commenced trading under the trading symbol "GRCE" on Nasdaq effective October 28, 2024.

Second Fiscal Quarter 2025 Financial Results

For the three months ended September 30, 2024, the Company reported a net loss of $3.4 million, or $0.30 per share, an increase by $0.1 million from the net loss of $3.3 million, or $0.43 per share, for the three months ended September 30, 2023. The increase in net loss was primarily due to an increase in research and development expenses of $2.5 million and general and administrative expenses of $0.2 million, offset in part by a $2.2 million difference in the change in fair value of derivative warrant liabilities and $0.4 million increase in income tax benefit.

Total research and development expenses for the three months ended September 30, 2024 were $3.0 million, compared to $0.5 million for the three months ended September 30, 2023. This increase of $2.5 million was primarily due to the increase in research activities for the GTx-104 pivotal Phase 3 STRIVE-ON safety clinical trial.

General and administrative expenses were $1.9 million for the three months ended September 30, 2024, an increase of $0.3 million from $1.6 million for the three months ended September 30, 2023. The increases were primarily a result of increased legal, tax, accounting, audit and other professional fees primarily related to the Company's re-domicile to Delaware, increased salaries and benefits due to merit increases and hiring of new employee, offset by a decrease in other expenses due primarily to adjustments for claims for Canadian goods and service tax and decrease in miscellaneous expenses as a result of restructuring.

At September 30, 2024, the Company had cash and cash equivalents of $15.1 million, a net decrease of $7.9 million compared to cash and cash equivalents of $23.0 million as of March 31, 2024. The Company believes its existing cash and cash equivalents will be sufficient to fund operations into the second calendar quarter of 2026.

KOL Event on aneurysmal Subarachnoid Hemorrhage (aSAH)

Grace Therapeutics is hosting a virtual key opinion leader (KOL) event on Wednesday, November 20, 2024 at 2:00 PM ET.

The event will feature Abhishek Ray, MD (University Hospitals) and Andrew Webb, PharmD, BCCCP (Massachusetts General Hospital), who will discuss the high unmet medical need and current treatment landscape for patients suffering from aneurysmal Subarachnoid Hemorrhage (aSAH), a rare and life-threatening medical emergency.

A live question and answer session will follow the formal presentations.

To register, click here.

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. the brain. A primary cause of such bleeding is rupture of an aneurysm. The result is a relatively uncommon type of stroke (aSAH) that accounts for about 5% of all strokes and has an incidence of six per 100,000 person years.

About the Grace Therapeutics Asset Portfolio

GTx-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous (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 150 healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine. The addressable market in the United States for GTx-104 is estimated to be about $300 million, based on market research.

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 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, 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. (formerly Acasti, 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 intravenous 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 anticipated cash runway, the timing of the Company's planned NDA submission with the FDA in connection with the Company's Phase 3 STRIVE-ON safety trial and the timing of data readouts from the STRIVE-ON trial, GTx-104's commercial prospects; the size of the addressable market for GTx-104, the Company's beliefs regarding the potential benefits of GTx-104, including GTx-104's potential to bring enhanced treatment options to patients suffering from aSAH, and the anticipated benefits and future development, license or sale of the Company's other drug candidates 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 clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; and (v) actual costs associated with Grace Therapeutics' clinical trials as compared to management's current expectations. 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, 2024, Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024, the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024 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.

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---tables to follow---

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

	September 30, 2024	March 31, 2024

(Expressed in thousands except share data)	$	$
Assets		
Current assets:		
Cash and cash equivalents	15,155	23,005
Short-term investments	15	—
Receivables	415	722
Prepaid expenses	477	283
Total current assets	16,062	24,010
Equipment, net	21	24
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	65,349	73,300
Liabilities and shareholders' equity		
Current liabilities:		
Trade and other payables	2,674	1,684
Total current liabilities	2,674	1,684
Derivative warrant liabilities	2,603	4,359
Deferred tax liability	3,938	5,514
Total liabilities	9,215	11,557
Commitments and contingencies		
Shareholders' equity:		
Class A common shares, no par value per share; unlimited shares authorized; 10,139,861 and 9,399,404 shares issued and outstanding as of September 30, 2024 and March 31, 2024, respectively	261,038	261,038
Class B, C, D and E common shares, no par value per share; unlimited shares authorized; none issued and outstanding	—	—
Additional paid-in capital	18,302	17,862
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(217,168)	(211,119)
Total shareholders' equity	56,134	61,743
Total liabilities and shareholders' equity	65,349	73,300

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

	Three months ended		Six months ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
(Expressed in thousands, except share and per share data)	$	$	$	$
Operating expenses				
Research and development expenses, net of government assistance	(2,976)	(460)	(5,684)	(1,555)
General and administrative	(1,855)	(1,632)	(4,109)	(3,506)
Restructuring cost	—	—	—	(1,485)
Loss from operating activities	(4,831)	(2,092)	(9,793)	(6,546)
Foreign exchange gain (loss)	13	(13)	5	(5)
Change in fair value of derivative warrant liabilities	362	(1,826)	1,756	(1,826)
Interest and other income, net	172	212	407	346
Total other income (expenses), net	547	(1,627)	2,168	(1,485)
Loss before income tax benefit	(4,284)	(3,719)	(7,625)	(8,031)
Income tax benefit	852	446	1,576	735
Net loss and total comprehensive loss	(3,432)	(3,273)	(6,049)	(7,296)
Basic and diluted loss per share	(0.30)	(0.43)	(0.53)	(0.97)
Weighted average number of shares outstanding	11,506,234	7,552,677	11,506,234	7,494,425

Source: Grace Therapeutics, Inc.