

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 28, 2026

GRACE THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation)	001-35776 (Commission File Number)	98-1359336 (IRS Employer Identification No.)
103 Carnegie Center Suite 300 Princeton, New Jersey (Address of Principal Executive Offices)		08540 (Zip Code)
Registrant's telephone number, including area code: (609) 322-1602		
(Former Name or Former Address, if Changed Since Last Report)		

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	GRCE	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On July 28, 2026, Grace Therapeutics, Inc. (the “Company”) issued a press release announcing receipt of the U.S. Food and Drug Administration (“FDA”) meeting minutes from a Type A Meeting held with the FDA to discuss the Complete Response Letter issued on April 23, 2026 for the Company’s GTx-104 new drug application. In addition, the Company updated its corporate presentation on July 28, 2026 to reflect the path to NDA resubmission following the Type A Meeting.

A copy of the press release and updated corporate presentation are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release, dated July 28, 2026.
99.2	Corporate Presentation – Late Summer 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GRACE THERAPEUTICS, INC.

Date: July 28, 2026

By: /s/ Prashant Kohli
Prashant Kohli
Chief Executive Officer



**Grace Therapeutics Announces Receipt of Type A Meeting Minutes
from U.S. Food and Drug Administration**

FDA Did Not Identify Any Clinical Safety or Efficacy Deficiencies and Did Not Request Additional Clinical Data

Company Advancing a Dual-Source Manufacturing Strategy, Adding a U.S.-Based Site, Toward NDA Resubmission

Princeton, NJ, July 28, 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 receipt of the U.S. Food and Drug Administration (FDA) meeting minutes from a Type A Meeting held with the FDA to discuss the Complete Response Letter (CRL) issued on April 23, 2026. The minutes constitute the official record of the Type A meeting.

As previously disclosed, the CRL did not identify any clinical safety or efficacy deficiencies and did not request additional clinical data. The items cited by the FDA relate to the current good manufacturing practice (cGMP) compliance status of the Company's contract manufacturing organization — a facility-level matter, and not a GTx-104 product-specific quality finding — together with additional leachables data time points and excipient toxicology risk assessments. The Company intends to address each of the CRL items in its planned resubmission, including completing the required non-clinical studies.

As part of that plan, the Company is pursuing a dual-source manufacturing strategy. Its current contract manufacturer is responsible for remediating the cGMP matters identified at its facility and demonstrating inspection readiness, which would ultimately need to be verified through an FDA reinspection. In parallel, the Company is advancing technology transfer to a second-source contract manufacturer located in the United States. This approach gives GTx-104 more than one route to a compliant registration site and reduces reliance on any single manufacturing source. The Company has not designated a single path to resubmission; a resubmission may be supported by either contract manufacturer, or both.

“Following receipt of the FDA’s minutes, we have a clear view of what is required and are executing against it, including advancing a second manufacturing source in the United States so that we are not dependent on a single path to resubmission,” said Prashant Kohli, Chief Executive Officer of Grace Therapeutics. “We will report progress as key milestones are achieved. If approved, GTx-104 would represent a meaningful innovation in the care for aSAH, and we are committed to improving outcomes for aSAH patients.”

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 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 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 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 future prospects of the Company’s GTx-104 drug candidate; the Company’s belief that the issues identified by the FDA in the CRL can be successfully addressed in the Company’s resubmission of the NDA for GTx-104; the Company’s planned approach to addressing the items cited in the CRL following its Type A meeting with the FDA and receipt of the official meeting minutes; the Company’s dual source manufacturing strategy, including remediation at its current contract manufacturer and technology transfer to a second, U.S.-based contract manufacturer; the timing and outcome of any FDA reinspection of the current contract manufacturer; the Company’s plans to complete the required non-clinical studies; and the Company’s plans to report progress against key milestones; 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 timing and success of any regulatory resubmission of the NDA for GTx-104; (ii) the timing of any FDA reinspection of the Company’s current contract manufacturer, and that facility’s compliance status, which are determined by the FDA and outside the Company’s control, and the FDA’s position that it will not approve the NDA while the facility remains in an unacceptable compliance status; (iii) the ability of a second, U.S.-based contract manufacturer to generate the required stability and analytical data and to complete a product-specific pre-approval inspection; (iv) the need to complete additional non-clinical studies; (v) the requirement that any resubmission comprehensively address all items cited in the CRL and the risk of review delay; (vi) the Company’s potential need for additional capital, which may not be available on acceptable terms; (vii) changes to regulatory pathways; (viii) the Company’s ability to protect its intellectual property for GTx-104; and (ix) 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 and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, 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:

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Mike Moyer
Managing Director
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Email: mmoyer@lifesciadvisors.com



Corporate Presentation

| Late Summer 2026

Forward Looking Statements

Statements in this presentation 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, Inc. (the "Company") 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 presentation. The forward-looking statements in this presentation, including, but not limited to, statements regarding the Company's belief that it can address the items cited in the U.S. Food and Drug Administration's ("FDA") Complete Response Letter ("CRL") in a resubmission of its New Drug Application ("NDA") for GTx-104; the Company's planned approach to addressing the items cited in the CRL following its Type A meeting with the FDA and receipt of the official meeting minutes; the Company's second-source manufacturing strategy, including remediation at its current contract manufacturer and technology transfer to a second, U.S.-based contract manufacturer; the timing and outcome of any FDA reinspection of the current contract manufacturer; the Company's plans to complete the required non-clinical studies; and the Company's plans to report progress against key milestones; expected cash runway; the potential exercise of outstanding warrants; the future prospects of the Company's GTx-104 drug candidate; GTx-104's potential to bring enhanced treatment options to patients suffering from aneurysmal subarachnoid hemorrhage ("aSAH"); GTx-104's potential to be administered to improve the management of hypotension in patients with aSAH; gastrointestinal intolerance and dosing consistency compared with oral administration; the ability of GTx-104 to achieve a pharmacokinetic and safety profile similar to oral formulations of nimodipine; GTx-104's potential to provide improved bioavailability and the potential for reduced use of rescue therapies; GTx-104's potential to achieve medical and pharmacoeconomic benefit over oral formulations of nimodipine; GTx-104's commercial prospects; the Company's pre-commercial launch strategy for GTx-104; the future prospects of the Company's GTx-102 drug candidate; GTx-102's potential to provide clinical benefits to decrease symptoms associated with Ataxia Telangiectasia; 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 Postherpetic Neuralgia ("PHN") patients to treat severe nerve pain associated with the disease; the timing and outcomes of a Phase 3 efficacy and safety trial for GTx-101; the size of the addressable market for GTx-104 and GTx-102, and any future patent and other intellectual property filings made by the Company for new developments, are based upon Grace Therapeutics, Inc.'s 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 of any FDA reinspection of the Company's current contract manufacturer, and that facility's compliance status, which are determined by the FDA and outside the Company's control, and the FDA's position that it will not approve the NDA while the facility remains in an unacceptable compliance status; (iii) the ability of a second, U.S.-based contract manufacturer to generate the required stability and analytical data and to complete a product-specific pre-approval inspection; (iv) the need to complete additional non-clinical studies; (v) the requirement that any resubmission comprehensively address all items cited in the CRL and the risk of review delay; (vi) the Company's potential need for additional capital, which may not be available on acceptable terms; (vii) the timing and success of any regulatory resubmission of the NDA for GTx-104; (viii) changes to regulatory requirements or regulatory pathways; (ix) the Company's ability to protect its intellectual property rights for its product candidates; and (x) 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, and other documents that have been and will be filed by Grace Therapeutics, Inc. from time to time with the Securities and Exchange Commission and Canadian securities regulators. All forward-looking statements contained in this presentation speak only as of the date on which they were made. 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GTx-104 | aSAH



Nimodipine is the **SoC** and **clinically de-risked**; however, significant unmet needs remain with available oral formulations



GTx-104 – novel intravenous nimodipine – well positioned to **solve oral challenges** and potentially displace oral as SoC



Pivotal **Phase 3 STRIVE-ON** safety trial **met primary** endpoint; clinical **evidence of GTx-104 benefit vs oral capsules**



Potential to address a **severe rare disease** with **efficient commercial organization**; concentrated patient care



Orphan Drug Status with the potential for seven-year market exclusivity and **additional multi-layered IP protection**



Regulatory Update July 2026
FDA Type A meeting minutes received; advancing a targeted resubmission via dual-source manufacturing strategy

aSAH: aneurysmal Subarachnoid Hemorrhage.
All dates based on calendar year in the presentation.

Path to NDA Resubmission Following FDA Type A Meeting

A CMC and manufacturing matter — CRL did not identify any clinical safety or efficacy deficiencies and did not request additional clinical data

The CRL in context

What it is NOT

- Not an efficacy or safety deficiency
- Not a request for additional clinical trials or clinical data

What it IS

- cGMP compliance status of the current contract manufacturer — a facility-level matter, not a GTx-104 product-specific quality finding
- Additional leachables data time points and excipient toxicology risk assessments

Defined path to resubmission

Current CDMO

- Remediating facility cGMP matters and demonstrating inspection readiness; requires an FDA reinspection to verify remediation

Second source — in parallel

- Advancing technology transfer to a second-source CDMO in the United States — more than one route to a compliant registration site, reducing single-source dependence

Non-clinical

- Completing the required non-clinical studies

Resubmission: We intend to resubmit once all items cited in the CRL are fully addressed; a resubmission may be supported by either contract manufacturer, or both.

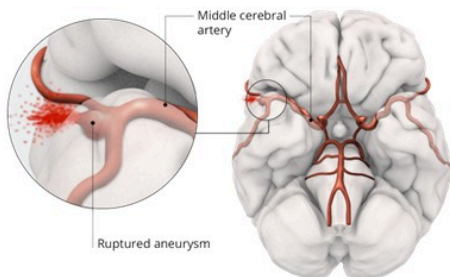
Updates: We will report progress as key milestones are achieved.

aSAH is a Rare and Severe Acute Brain Injury



- aSAH results in bleeding over the surface of the brain in the space between the brain and skull
- Primary cause is rupture of an aneurysm
- Condition can occur quickly, immediate intervention is key to survival
- Patients require surgical intervention and oral nimodipine therapy

Subarachnoid Hemorrhage



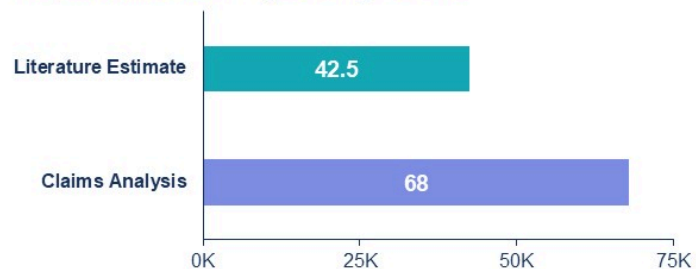
Occurs in Relatively Young Patients (~50% <60 yrs)



Significant Mortality (~10-15% before reaching hospital)

Est. Annual U.S. Hospital-Treated Patients (2023)

Hospital-treated aSAH may be as high as ~70k



Sources: ClearView Analysis (2025). Forian Claims Data. Fletcher Spaght market research; Becske T. (2018). Steven (2020).

Oral Nimodipine – The aSAH Standard of Care for >3 Decades

2023 AHA/ASA Guidelines For the management of patients with aSAH

Recommended Use of Nimodipine for Management of Cerebral Vasospasm and DCI

"Early initiation of **enteral** nimodipine is beneficial in preventing DCI and improving functional outcomes"

Consistent Administration is Beneficial in Improving Functional Outcomes

"**Consistent administration** is suggested even in the setting of nimodipine-induced hypotension... However, if nimodipine causes significant BP variability, temporary stoppage may be necessary."

Recognition of the **Potential** for Differentiation of IV Nimodipine, with Additional Data

"Although studies of **intravenous** and intra-arterial nimodipine have been reported there are limited data to make any recommendation for these routes of nimodipine administration"

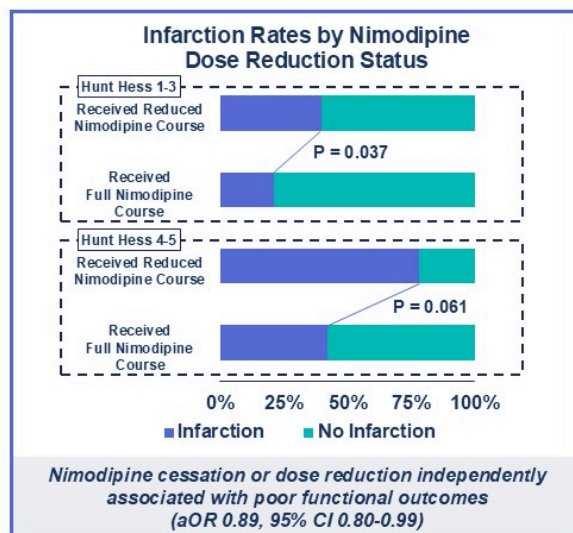
Nimodipine is the only approved therapy to improve neurological outcomes

Limited use of off-label therapies due to The Joint Commission monitoring adherence to care guidelines

Sources: Hoh (2023). Hernandez-Duran (2019). Sandow (2016).
DCI: Delayed Cerebral Infarction
The Joint Commission is a hospital accreditation agency



Nimodipine – Consistent Drug Administration Drives Positive Patient Outcomes



Nimodipine is administered six times per day for up to 21 days

Limited use of off-label therapies due to Joint Commission monitoring adherence to care guidelines

Sources: Hoh (2023), Hernandez-Duran (2019), Sandow (2016).
aOR: adjusted odds ratio; CI: Confidence Interval



Substantial Shortcomings of Oral Nimodipine



Administration Challenges

- High dosing burden of 60mg (2 x 30mg capsules), 6 times per day
- 45% of patients receive nimodipine through nasogastric tube (NGT) – often via capsule extraction
- Capsule extraction and administration is labor intensive



Fatal Medication Errors

- Inadvertent parenteral injection can result in death or serious life-threatening AEs
- Highest risk with capsule extraction
- NYMALIZE (oral liquid) tempers the risk of error, but has tolerability challenges (e.g., severe diarrhea) due to solubility limitations of nimodipine

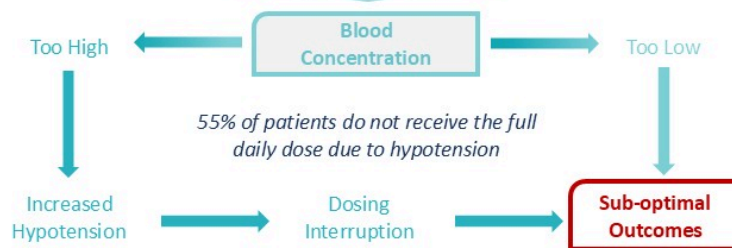


Sub-optimal Therapeutic Benefit with Oral Administration

High Pharmacokinetic Variability

- Inconsistent plasma concentration in both inter and intra subject
- High first-pass metabolism, leads to low bioavailability and frequent dosing
- Gastric motility issues and presence of food delay rate of absorption
- Potentially negligible concentration with NGT administration

Hypotension drives missed doses and diminished efficacy



Sources: Nimodipine Prescribing Label, Sandow et al., Mahmoud et al., Abboud et al., Soppi et al., Rabaut et al., Ho et al., Fletcher Spaght market research.

GTx-104 is a Novel IV Nimodipine Designed to Overcome Oral Delivery Challenges Supported by Strong IP, Ph. III Trial Success

GTx-104

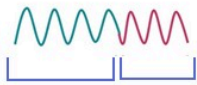
A novel intravenous nimodipine that is well positioned to **solve oral challenges** and potentially displace oral as SoC

Orphan Drug Status with the potential for seven-year market exclusivity and **additional multi-layered IP protection**

Pivotal **Phase 3 STRIVE-ON** safety trial **met primary** endpoint; clinical **evidence of GTx-104 benefit vs. oral capsules**

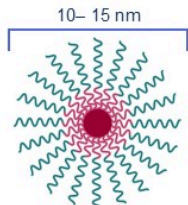
GTx-104 drug delivery technology

Surfactant Monomers



Hydrophilic Part Hydrophobic Part

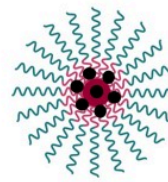
$\xrightarrow{> \text{CMC}}$
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Blank micelles



Nimodipine



Drug loaded micelles

- Overcomes **solubility limitations** of nimodipine in current formulations
- Patented formulation uses non-ionic surfactant **micelles** as the drug carrier to **solubilize nimodipine**
- **Simple to prepare** in pharmacy, stable at room temperature

CMC: Critical micelle concentration.

Phase 1 Trial Established Scientific Bridge between GTx-104 and Oral Nimodipine

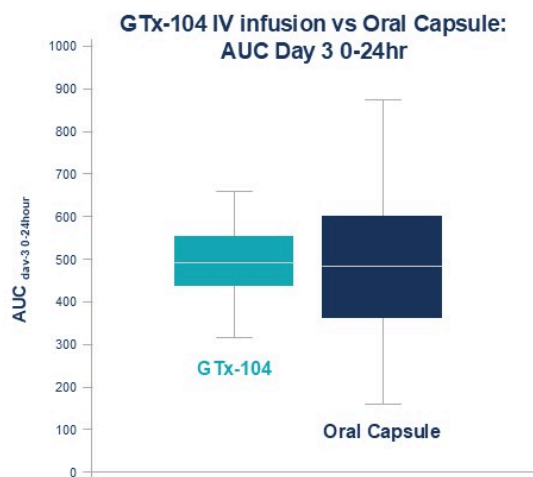
Trial met all primary and secondary endpoints; enabling the 505(b)2 regulatory pathway



GTx-104

Consistent and *predictable*
plasma concentrations

Observed *lower dose* variability
relative to oral capsule



STRIVE-ON Phase 3 Trial



Trial complete and reported topline data in January 2025

STRIVE-ON (NCT05995405) is a ~100-patient prospective, open-label, randomized (1:1 ratio), parallel group trial of GTx-104 compared with nimodipine oral capsules in patients hospitalized for aSAH



Primary Endpoint
Incidence of subjects with at least one episode of clinically significant hypotension

STRIVE-ON Trial Data Support Potential Clinical, Pharmacoeconomic, and Dosing / Administration Benefits over Current SoC, Nimodipine Oral Capsules



CLINICAL

90-DAY OUTCOMES (MRS*)

+29% relative increase in patients with good recovery at 90 days vs. oral capsules

HYPOTENSION EVENTS

-19% reduction from oral capsules

DOSE INTENSITY

54% vs. 8% with oral capsules receive >95% prescribed dose



PHARMACOECONOMIC

ICU DAYS

-1.5 days reduction from oral capsules

TIME ON VENTILATION

-5 days reduction from oral capsules

ICU READMISSION RATES

-48% reduction from oral capsules



DOSING & ADMIN.

PATIENT REST

No need to disrupt patient sleep every 4 hours

ADMINISTRATION

No feeding tube or swallowing of large pills required

TREATMENT PREP

No nimodipine capsule extraction and administration (laborious for staff)

* mRS: modified Rankin Score

Trial not statistically powered for hypothesis testing and comparisons between treatment arms

Demographics & Baseline Characteristics

Demographics well-balanced, except higher proportion of most severe with worst prognosis (Grade V) in GTx-104

	GTx-104 (N = 50)	Nimodipine Oral Capsules (N = 52)
Age (mean)	55	56
Sex, n (%)		
Female	33 (66.0%)	33 (63.5%)
Male	17 (34.0%)	19 (36.5%)
Hunt & Hess Grade, n (%)		
I	10 (20%)	8 (15%)
II	15 (30%)	15 (29%)
III	15 (30%)	16 (31%)
IV	6 (12%)	12 (23%)
V	4 (8%)	1 (2%)

Primary Endpoint – Clinically Significant Hypotension

~19% relatively fewer patients with clinically significant hypotension in GTx-104

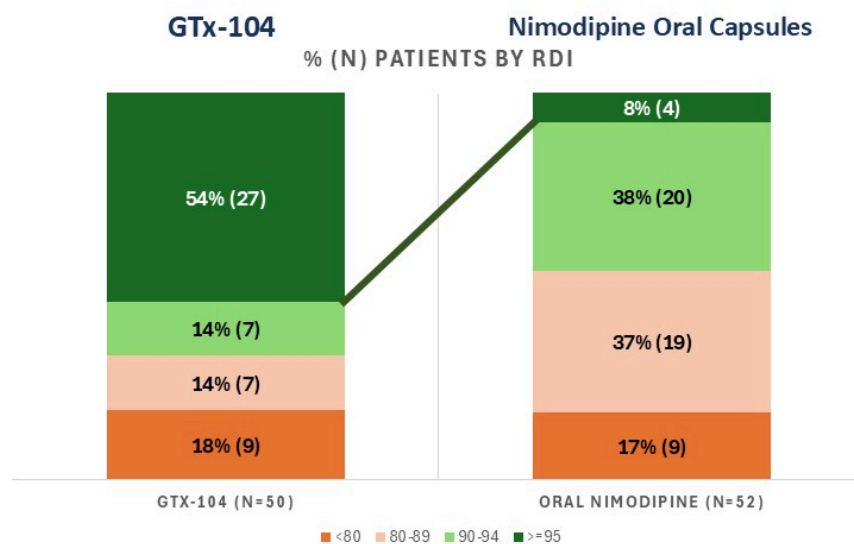
	GTx-104 (N = 50) n (%)	Nimodipine Oral Capsules (N = 52) n (%)
Clinically Significant Hypotension*	14 (28%)	18 (35%)

* Clinically significant hypotension: decrease in systolic BP > 20 mm Hg or diastolic BP > 10 mm Hg or systolic BP $\leq$ 100 confirmed by two consecutive readings within five minutes AND requiring medical intervention.

Trial not statistically powered for hypothesis testing and comparisons between treatment arms

Relative Dose Intensity (RDI)

54% of patients on GTx-104 had RDI of 95% or higher versus 8% on Nimodipine Oral Capsules



RDI: (total dose administered / total amount of expected dose) * 100

Trial not statistically powered for hypothesis testing and comparisons between treatment arms

Clinical Outcomes – mRS (day 90)

~29% relative increase in patients with good recovery in GTx-104



* 3 patients did not complete physician-conducted mRS at day-90. However, all 3 were confirmed alive at day-90

** 6 patients did not complete physician-conducted mRS at day-90. 5 were confirmed alive at day-90, and 1 survival status was unknown

Trial not statistically powered for hypothesis testing and comparisons between treatment arms

Patient-reported health scores favor GTx-104

QoL	GTx-104 (N = 38 ¹)	Nimodipine Oral Capsules (N = 40 ²)
Your Health Today Score mean (0 = being worst -> 100 = great)	75	70
Mobility, n (%) I have no or some problems I am confined to bed	38 (100%) 0	35 (88%) 5 (12%)
Self-Care, n (%) I have no or some problems I am unable to wash/dress	37 (97%) 1 (2.6%)	35 (88%) 5 (12%)
Usual Activities, n (%) I have no or some problems I am unable to perform	35 (92%) 3 (8%)	33 (84%) 7 (16%)
Pain/Discomfort, n (%) I have no or moderate pain I have extreme pain	36 (95%) 2 (5%)	38 (95%) 1 (2%)
Anxiety/Depression, n (%) I am not or moderately I am extremely	36 (95%) 2 (5%)	36 (90%) 3 (7%)

¹GTx-104: patient did not complete survey (4), dead (8 – all due to underlying disease, none were GTx-104 related).

²Nimodipine Oral Capsules: patient did not complete survey (8), dead (4 – all due to underlying disease, none were related to oral capsules). Oral also had 2 incomplete (pain, anxiety).

Trial not statistically powered for hypothesis testing and comparisons between treatment arms

Overall safety was comparable between the two groups

Summary of Adverse Events (AEs) (entire study duration of 90 days)	GTx-104 (N = 50)	Nimodipine Oral Capsules (N = 52)
All AEs, n (%) # of events	44 (88%) 157	43 (83%) 193
All AEs, events per n	3.6	4.5
All SAEs ¹ , n (%) # of events	18 (36%) 34	25 (48%) 48
All SAEs, events per n	1.9	1.9
Treatment-Related SAEs, n (%) # of events ²	0	2 (4%) 2
Mortality ³ , n (%)	8 (16%)	4 (8%)
Cause of death ⁴ (n) All deaths were due to severity of underlying disease	No deaths due to GTx-104 — aSAH (5), ICH (1), rebleed (1), cardiac arrest (1)	No deaths due to Nimodipine Oral Capsules — aSAH (2), rebleed (1), cardiac arrest (1)

¹ A few include sepsis, deep vein thrombosis, ICH, hydrocephalus, cerebral infarction, urinary tract infection, C. difficile, systemic inflammatory response, acute kidney injury, as well as death

² Nimodipine Oral Capsules: bradycardia, vasospasm

³ Mortality rate is equivalent or lower than previous well-controlled clinical trials (Oral NIMOTOP NDA)

⁴ Based on investigator assessment

SAEs: Serious Adverse Events; ICH: Intracerebral Hemorrhage; DCI: Delayed Cerebral Hemorrhage

1.5 fewer ICU days, 5 fewer ventilator days, and 48% relatively fewer ICU readmissions in GTx-104

	GTx-104 (N = 50)	Nimodipine Oral Capsules (N = 52)
ICU los, days Mean (SD)	16.4 (6.7)	17.9 (10.4)
Mechanical Ventilation days Mean (SD)	5.6 (5.7)	10.6 (13.9)
Hospital Readmissions*		
One readmission, n (%)	6 (12%)	7 (14%)
Two readmissions, n (%)	0	0
Three readmissions, n (%)	0	1 (2%)
ICU Readmissions		
One readmission, n (%)	2 (4%)	3 (6%)
Two readmissions, n (%)	0	1 (2%)

* Hospital Readmissions includes ICU readmissions. Readmissions were due to sequelae of aSAH e.g., UTI (urinary tract infection), DVT (deep vein thrombosis), Pneumonia, Seizures, Hydrocephalus, Cranioplasty.
SD: standard deviation

Trial not statistically powered for hypothesis testing and comparisons between treatment arms

Major patient resource utilization drivers in aSAH favor GTx-104

	GTx-104 (N = 50) n*			Nimodipine Oral Capsules (N = 52) n*		
	Day 1	Day 14	% change	Day 1	Day 14	% change
Mechanical Ventilation	14	1	-93%	12	7	-42%
External Ventricular Drain	32	10	-69%	35	17	-51%
Deep Sedation	5	1	-80%	8	5	-38%
Comatose	4	0	-100%	5	2	-60%

* Excludes patients that died before Day 14 for this analysis.

Trial not statistically powered for hypothesis testing and comparisons between treatment arms

Commercial Preparation



aSAH Market Opportunity

Addressable Patients

- **Literature**, typically limited to basal cistern aSAH (~80% of aSAH), suggests **~42.5K U.S. hospital-treated patients**
- **Claims analysis** suggests incidence of hospital-treated aSAH may be as high as **~70K**

Most Critical Unmet Needs

- **~45%** of treated patients are **unconscious or dysphagic (nasogastric tube)**
- **>25%** of treated patients have **poor dose compliance / blood pressure control**

70% of aSAH Cases Result in Death or Permanent Disability

- **~50% of patients** who survive the initial month **remain permanently dependent** on a caregiver to maintain daily living
- **Hospitalization charges** can be up to **~\$530k** for an aSAH patient
- aSAH is among the **most highly reimbursed Diagnosis-Related Groups (DRGs)** in neuro ICU

Sources: ClearView Analysis (2025). Forian Claims Data. Becske T. (2018). Steven (2020). Hoh (2023). Etminan. JAMA Neurol. 2019; Fegin. The Lancet Neurology. 2009; Labovitz. Neuroepidemiology. 2006; Shea. Neurosurgery. 2007; Linn. Stroke. 1996; Anderson. Stroke. 2000; Daniere. J de Radiologie Diagnostique. 2015; Ingall. Stroke. 1989; Giordan et al. J Neurosurg. 2021; Rinkel et al. Lancet Neurol. 2011; Intl Study of Unruptured Intracranial Aneurysms Investigators. NEJM. 1998.



GTx-104 target product profile is seen as valuable for its improved tolerability, cost savings, and easy IV use – with broad formulary inclusion by P&T committee

Primary Market Research Insights (2Q 2025)



EFFICACY

Respondents emphasized that reduction in hypotension is meaningful, as it allows more patients to remain on therapy and **avoid dose-limiting side effects**

"... The pro of Product X is certainly the efficacy endpoint. The fact that there is a **reduction in hypotensive events**. That is a pretty significant, 19% reduction ..."

- Neurointensivist, Stanford University

"... The reduction in hypotensive events is meaningful. I could use it for patients who **can not take nimodipine due to hypotensive episodes** ..."

- Neurointensivist, Mount Sinai

"... I would prefer to **use Product X in every patient** because one of the biggest reasons to not continue nimodipine is because of hypotension ..."

- Neurointensivist, Atlantic Health System



PHARMACOECONOMIC

HCPs highlighted that even **modest reductions** in ICU or ventilator time can have a significant impact on hospital costs, suggesting potential to deliver **value beyond drug price**—particularly given the high-cost aSAH care settings

"... From an economic standpoint, fewer days in the ICU or on a ventilator certainly could justify the cost of the drug. **Even a reduction of a single day is relevant**. When it gets to be 2 or 3 days, then it's very impressive ..."

- Neurosurgeon, USC

"... A reduction in ventilator days is great for the patient in reducing their risk of infections and **benefitting their financial bottom line**. It's also good for hospital costs ..."

- Critical Care Specialist, Intermountain Health

"... Most hospitals are over capacity right now. Any reduction in ICU or ventilator days typically translates to shorter hospital days, which will **benefit hospitals overall in terms of costs and resources** ..."

- Neurointensivist, Boston Medical Center



ROA (route of admin)

Immediate usability without NG tube placement was seen as an advantage, **enabling earlier intervention**, especially in unstable or intubated patients where time sensitive dosing is key

"... I **definitely prefer IVs for critically ill patients than oral**. You don't have to worry about placing down an NG tube ..."

- Neurosurgeon, Westchester Medical Center

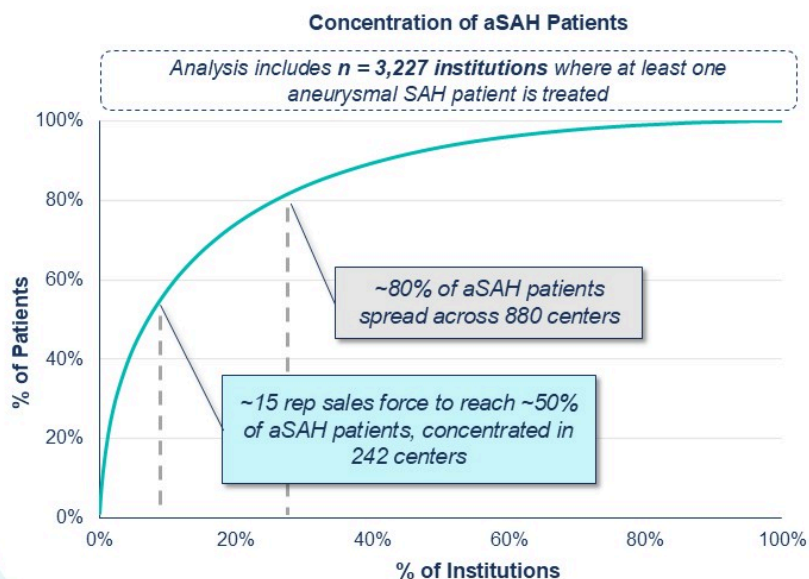
"... Blood levels are more consistent from one dose to the other, which makes a whole lot of sense since it's IV. It's mostly maintaining a therapeutic level and being at the peak of concentration that is a major advantage of IV ..."

- Neurosurgeon, UCSF

"... IV would be great because then **you don't have the NG tube anymore** or you don't need to rush for the NG tube because it's such a pain every time ..."

- Neurosurgeon, UCSF

Concentration of aSAH Care – Efficient Commercialization



aSAH-Treating Institutions Concentration

% aSAH Patients	% of Institutions	# of Institutions	Est. Sales Reps ¹
40%	~4%	146	~10
50%	~7%	242	~15
60%	~11%	380	~25



¹ Assumes each sales rep manages ~15 accounts.
Sources: ClearView Analysis (2025). Forian Claims Data.

Intellectual Property Portfolio

Multi-layered intellectual property protection strategy



GTx-104 received orphan drug status designation from the FDA

- Potential 7 years of marketing exclusivity in US upon NDA approval



US and international patent estate

- Consists primarily of formulation and method-of-use patents to extend exclusivity beyond what is granted through the orphan drug designation.
- Multiple patents granted worldwide, including six patents in the US
- Long patent shelf-life
 - First patent expiry 2037
 - Newest patent expiry 2043
- Continue building our patent portfolio by filing for patent protection on new developments

Capitalization

Grace Therapeutics, Inc. (GRCE) Cap Table (as of March 31, 2026)

Cash & Cash Equivalents Balance	USD \$17.0 M
Outstanding Common Stock	16,024,026
Debt	NONE
Stock options granted and outstanding	1,345,453
Total Fully Diluted Shares Outstanding ¹	23,033,731

Potential Gross Proceeds from Exercise of Outstanding Warrants

Feb-25 Private Placement ² : Potential Warrant Exercise Gross Proceeds	\$15.0 M
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¹Includes Pre-Funded Warrants, Common Warrants, Outstanding Stock Options

²Represents warrants exercisable for 4,418,292 shares of common stock (or pre-funded warrants in lieu thereof) issued on February 11, 2025, with an aggregate exercise price of approximately \$15.0 million. The warrants are immediately exercisable at an exercise price of \$3.395 per share and will expire on the earlier of (i) the 60th day after the date the FDA approves the New Drug Application for GTX-104 and (ii) September 25, 2028.

Experienced Leadership Team

Management Team



Prashant Kohli
Chief Executive Officer



Loch Macdonald, MD, PhD
Chief Medical Officer



Amresh Kumar, PhD
VP Program Management



Robert J. DeAversano
Principal Financial Officer and
Principal Accounting Officer



Scientific Advisory Board

Andrew Ducruet, MD 	Alex Choi, MD 	W. Taylor Kimberly, MD, PhD 	Alejandro A. Rabinstein, MD 	Sherry H-Y Chou, MD
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Deep aSAH Expertise in Research, Commercial, Drug & AHA Care Guidelines Development



Appendix (Deprioritized Programs)



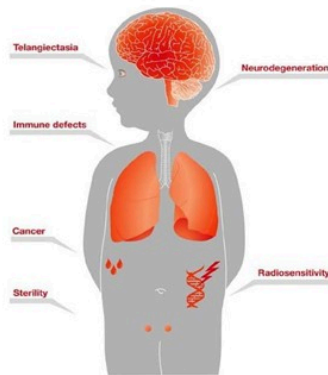
GTx-102 Program Overview & Regulatory Update

Ataxia-Telangiectasia

- Complex genetic neurodegenerative disorder diagnosed during infancy
- Inherited as an autosomal recessive trait, often affects more than one child in a family
- Average lifespan ~25 years
- Potential addressable market ~\$150 million

Unmet Need (No drugs approved)

- Treatment primarily directed toward control of symptoms
- Limited to speech, occupational and physical therapy
- Less than 20% of patients on any type of drug therapy for A-T symptoms



GTx-102

- Novel oral spray formulation of betamethasone intended to improve neurological symptoms of A-T patients
- Proof of concept supported by well-controlled Phase 1 trial with A-T patients
- PK bridging study topline results announced on 12/18/22 met all outcome measures

Regulatory

- FDA's written responses to EoP1 provides feedback on design of a single pivotal efficacy trial to support NDA
- Guidance includes primary endpoint scale and appropriate confirmatory evidence
- Plan to discuss with SAB potential trial design

Sources: Fletcher Spaght market research; National Organization for Rare Disorders (NORD); Lefton-Greif (2000); U.S. National Cancer Institute, A-T (2015).



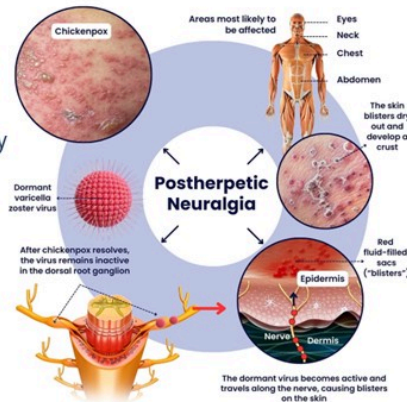
GTx-101 Program Overview

Postherpetic Neuralgia (rare disease)

- Caused by nerve damage from the herpes zoster virus which causes shingles
- Burning, painful, itchy, loss of feeling, sensitivity to touch or temperature, feeling worn out
- Symptoms can last for several years or may be permanent

Unmet Need

- Oral therapies (gabapentin, anticonvulsants, opioids) can have side effects and insufficient to manage pain in many cases
- Can be prone to abuse
- Lidocaine patches are hard to place, can cause skin irritation, are 12-hour on / off
- ~40% experience insufficient pain relief



GTx-101

- Non-narcotic, topical, bio-adhesive, transparent film-forming bupivacaine spray
- Biphasic drug release expected to provide immediate and continuous relief
- Potential Addressable market ~\$200m (PHN) to ~\$2.5b (lidocaine patch replacement)

Regulatory

- Completed Phase 1 (single dose) in 2022
- Met all primary outcome measures
- Clinical roadmap includes Phase 1 (multiple ascending dose) and Phase 2 (POC)