

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): March 3, 2025

GRACE THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

State of 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 March 3, 2025, Grace Therapeutics, Inc. updated its corporate presentation, including cash position and runway guidance. A copy of the updated corporate presentation is attached hereto as Exhibit 99.1 to this Form 8-K and is incorporated by reference into this Item 8.01.

Item 9.01 Exhibits.**(d) Exhibits**

<u>Exhibit</u>	<u>Description</u>
99.1	Corporate Presentation, dated March 3, 2025.
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 thereunto duly authorized.

GRACE THERAPEUTICS, INC.

Date: March 3, 2025

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



Corporate Presentation

| March 2025

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. 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 expected cash runway, preliminary estimates of the Company's cash and cash equivalents, the future prospects of the Company's GTx-104 drug candidate, the timing of the Company's anticipated NDA submission for GTx-104 with the FDA, 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, the ability of GTx-104 to achieve a pharmacokinetic and safety profile similar to the oral form 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 pharmacoeconomic benefit over the oral form of nimodipine, GTx-104's commercial prospects, the Company's pre-commercial launch strategy for GTx104, 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, GTx-102's potential ease of drug administration, the timing and outcomes of a Phase 3 efficacy and safety study for GTx-102, the timing of an NDA filing for GTx-102, 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 success and timing of regulatory submissions of the STRIVE-ON Phase 3 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, the Quarterly Reports on Form 10-Q and Form 10-Q/A for the quarterly period ended December 31, 2024 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. 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.

GTx-104 | aSAH



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



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**



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



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



Anticipate **NDA** submission in **1H:25**

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

Experienced Leadership Team

Management Team



Prashant Kohli
Chief Executive Officer



Loch Macdonald, MD, PhD
Chief Medical Officer



Carrie D'Andrea
VP Clinical Operations



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



Deep aSAH Expertise in Research, Commercial, Drug & AHA Care Guidelines Development

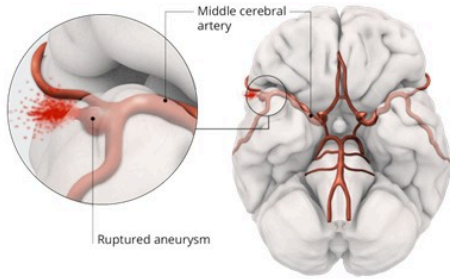


aSAH is a Rare and Severe Acute Brain Injury



- 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



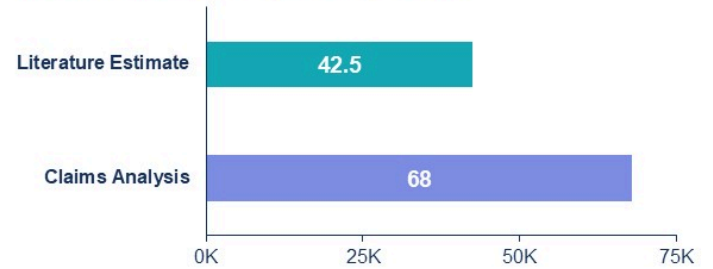
Occurs in Relatively Young Patients (~50% <60 yrs)



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"

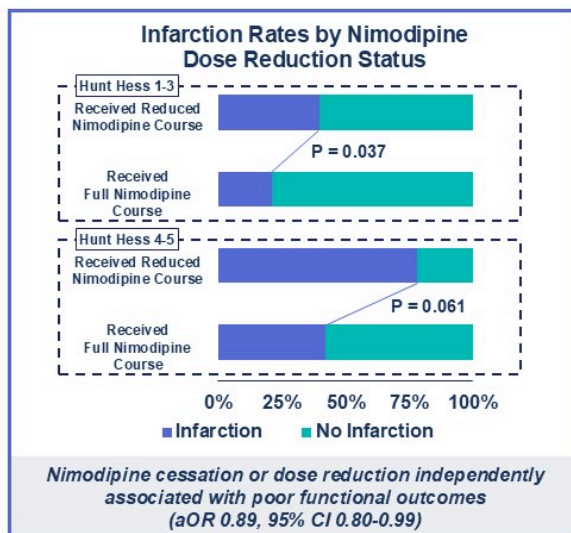
Nimodipine is the only approved therapy to improve neurological outcomes

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

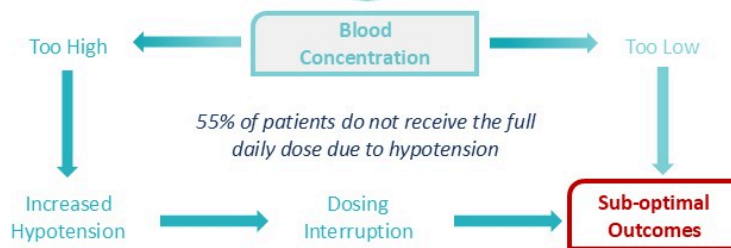


Sub-optimal Therapeutic Benefit with Oral Administration

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 Technology Overview

Breakthrough formulation of GTx-104 is the result of a decade of research by Grace scientific team

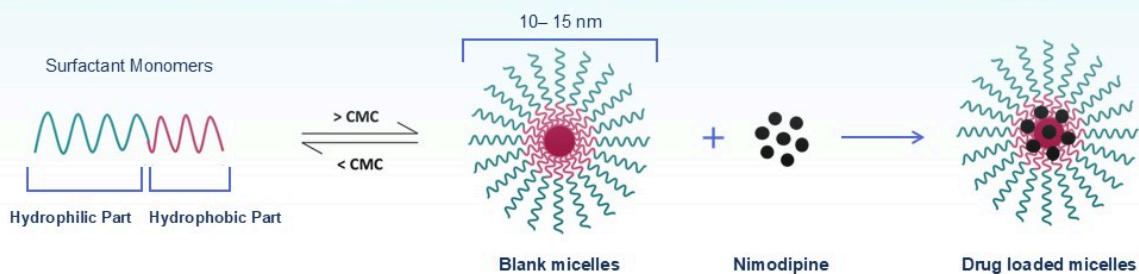
GTx-104 is a *novel formulation* of nimodipine for IV infusion in aSAH patients

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

GTx-104 Drug Delivery Technology



CMC: Critical micelle concentration.

GTx-104 Value Proposition

Clinical Value

- ✓ Predictable drug concentration & dose compliance
- ✓ Reduced drug intake, reduced DDIs & no food effects
- ✓ More effective hypotension management

Hospital Value

- ✓ Reduced hospital resources
- ✓ The Joint Commission compliance to aSAH care guidelines
- ✓ Reduced medication errors & nursing burden

Patient Value

- ✓ Lower disease burden & faster recovery
- ✓ Safer & more convenient treatment
- ✓ Improved functional outcomes

	Risk of Fatal Parenteral Use	Requires Feeding Tube	Excipient Intolerance	Hemodynamic Control	Dose Compliance	Markets
Nimodipine Capsules	Yes	Yes	No	Poor	Poor	U.S. / WW
NYMALIZE (Oral Liquid)	Yes (Reduced)	Yes	Yes	Poor	Poor	U.S. / Select WW
NIMOTOP (Injectable)	No	No	Yes *	Unknown	Rescue Only	EU / China
GTx-104	No	No	No	Optimal	Optimal	Global Rights NDA Submission 1H:25

Sources: Nimodipine capsule packaging insert. Fletcher Spaght market research. Soppi V. (2007).

* High alcohol content (~24% volume/volume) also requires central catheter for administration

WW: Worldwide

DDI: drug-drug interaction



GTx-104 Phase 1: Results

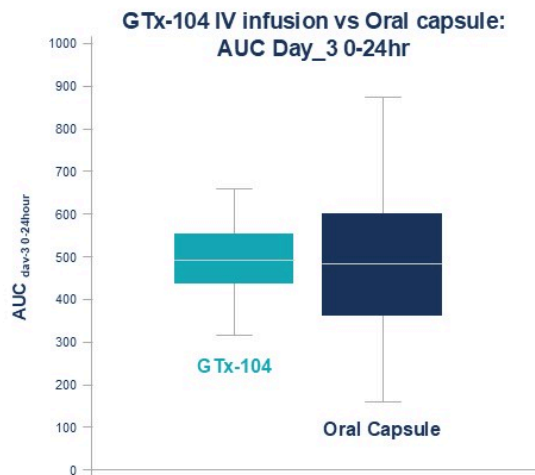
Trial met all primary and secondary endpoints; established scientific bridge between GTx-104 and oral nimodipine



GTx-104

Consistent and *predictable*
plasma concentrations

Significantly *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 oral nimodipine in patients hospitalized for aSAH



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

mRS: modified Rankin Scale

Demographics & Baseline Characteristics



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

	GTX-104 (N = 50)	Oral Nimodipine (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

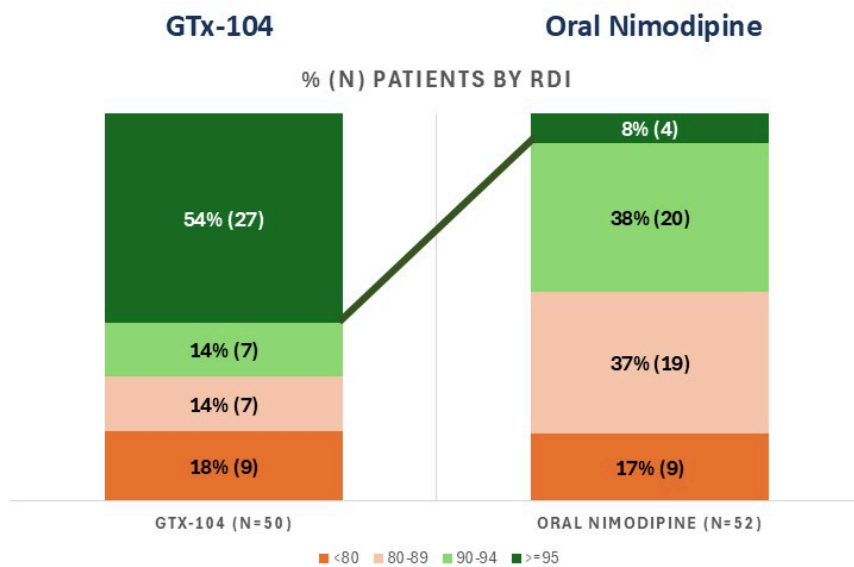


~19% relatively fewer patients with clinically significant hypotension in GTX-104

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

Relative Dose Intensity (RDI)

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



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

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



Patient-reported health scores favor GTx-104

QoL	GTx-104 (N = 38 ¹)	Oral Nimodipine (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%)

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

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

Overall safety was comparable between the two groups

Summary of Adverse Events (AEs) (entire study duration of 90 days)	GTx-104 (N = 50)	Oral Nimodipine (N = 52)
All AEs, n (%) # of events	44 (88%) 158	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 Oral Nimodipine 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 Oral Nimodipine: 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)	Oral Nimodipine (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

Major patient resource utilization drivers in aSAH favor GTx-104

	GTx-104 (N = 50) n*			Oral Nimodipine (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.

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, Becks 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 Market Research Survey

Insights from hospital Pharmacy & Therapeutics (P&T) committee decision makers



Survey Design

- 31 hospital administrators, critical and neuro intensive care physicians at Comprehensive or Advanced Stroke Centers involved in purchasing decisions
- 20 respondents are current or former members of P&T committees
- No GTx-104 investigators currently participating in STRIVE-ON trial included



Market Opportunity

Respondents report **80% likelihood** of adopting GTx-104 assuming 100% bioavailability, better safety, no food effects, effective hypotension management, and potential hospital & patient value

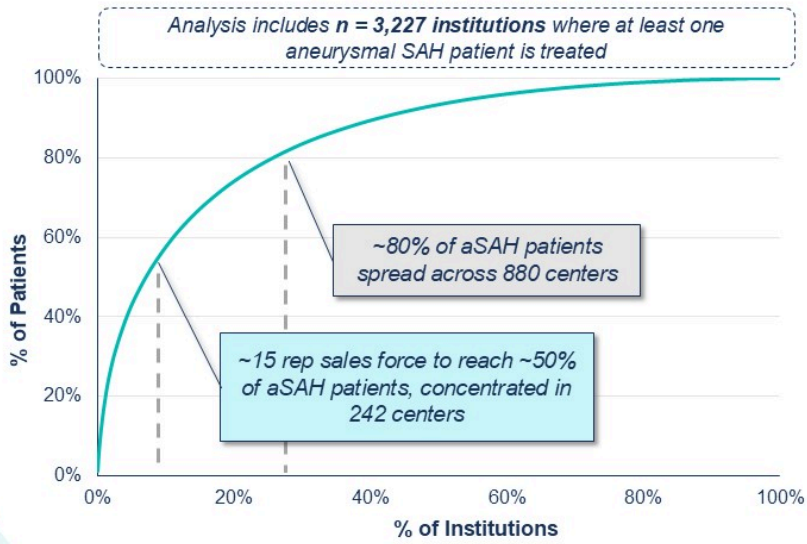


Challenges with Current Standard of Care

Respondents ranked **risk of hypotension** as the most problematic issue that may arise when administering oral formulations of nimodipine

Concentration of aSAH Care

Concentration of aSAH Patients



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 five patents in the US
- Long patent shelf-life
 - First patent expiry 2037
 - Newest patent expiry 2042
- Continue building our patent portfolio by filing for patent protection on new developments

Recent Financing Provides Expected Cash Runway to Calendar Q2 2027

Grace Therapeutics, Inc. (GRCE) Cap Table (as of February 26, 2025)

Cash & Cash Equivalents Balance	USD \$25.1 M
Outstanding Common Stock	13,718,106
Debt	NONE
Stock options granted and outstanding	934,923
Total Fully Diluted Shares Outstanding ¹	23,814,132

Potential Gross Proceeds from Exercise of Outstanding Warrants

Feb-25 Private Placement ² : Potential Warrant Exercise Gross Proceeds	\$15.0 M
Sep-23 Private Placement ³ : Potential Warrant Exercise Gross Proceeds	\$7.6 M
Total Potential Gross Proceeds from Exercise of Outstanding Warrants	\$22.6 M

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.

³Represents warrants exercisable for 2,536,391 shares of common stock issued on September 25, 2023, with an aggregate exercise price of approximately \$7.6 million. The warrants are immediately exercisable at an exercise price of \$3.003 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.

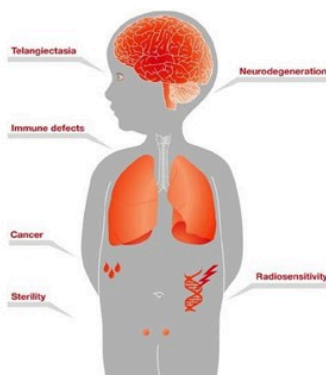
Appendix (Deprioritized Programs)



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).



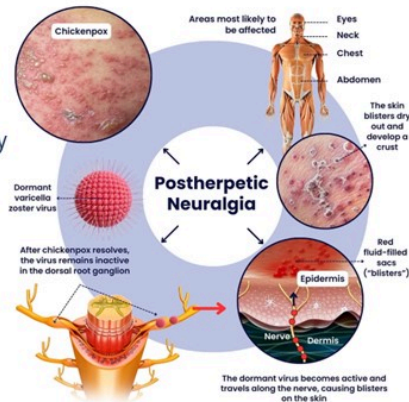
GTx-101 Program Overview

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)