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): November 13, 2025

GRACE THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

State of Delaware	**001-35776**	**98-1359336**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
103 Carnegie Center **Suite 300** **Princeton, New Jersey**		**08540**
(Address of Principal Executive Offices)		**(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 2.02 Results of Operations and Financial Condition.

The following information is furnished pursuant to Item 2.02 "Results of Operations and Financial Condition."

On November 13, 2025, Grace Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended September 30, 2025. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing or document.

Item 8.01 Other Events.

On November 13, 2025, the Company updated its corporate presentation, which includes its updated cash position as of October 31, 2025. A copy of the updated corporate presentation is attached hereto as Exhibit 99.2 to this Form 8-K and is incorporated by reference into this Item 8.01.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release, dated November 13, 2025.
99.2	Corporate Presentation, dated November 13, 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: November 13, 2025

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

Exhibit 99.1

Grace Therapeutics Announces Second Quarter 2026 Financial Results, Provides Business Update

Announced U.S. Food and Drug Administration (FDA) Acceptance for Review of New Drug Application (NDA) for GTx-104

FDA Established April 23, 2026 as PDUFA Target Date for Review of Submission Seeking Approval for GTx-104 in the Treatment of Patients with aneurysmal Subarachnoid Hemorrhage (aSAH)

Phase 3 STRIVE-ON Safety Trial Data Presented at 2025 Neurocritical Care Annual Meeting

Granted Sixth U.S. Patent Covering IV Dosing Regimen for GTx-104

Princeton, NJ, November 13, 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 aSAH patients, today announced the financial results and business highlights for the quarter ended September 30, 2025.

"During our second quarter of 2026 we continued to execute on our clinical and corporate goals, led by FDA acceptance for review of our NDA for GTx-104 for the treatment of aSAH," said Prashant Kohli, CEO of Grace Therapeutics. "Acceptance of our NDA for review is another significant milestone for the Company and further demonstrates our ability to execute as we continue to advance this important innovation for aSAH patients. Our NDA is supported by a robust data package including positive results from our STRIVE-ON trial, which provided evidence of improved clinical outcomes in aSAH patients treated with GTx-104 as well as potential medical and pharmacoeconomic benefits of GTx-104 in the treatment of aSAH. We were pleased to see these data highlighted in a presentation at the *Neurocritical Care* annual meeting, where the results were well received by the conference attendees. Also this quarter, the U.S. Patent and Trademark Office issued a new method of use patent covering the dosing regimen for IV administration of nimodipine used in our STRIVE-ON trial for GTx-104. This new patent coverage on the dosing regimen should be included in the label for GTx-104 if it is approved by the FDA, adding a new layer and extending the duration of our intellectual property protections. We believe that if our NDA for GTx-104 is approved by the FDA, our strong U.S. and international patent estate will help to maximize the long-term market value of GTx-104 and correspondingly deliver value for our shareholders." The standard of care for aSAH has not seen meaningful innovation in nearly 40 years, and we believe that if GTx-104 is approved, our STRIVE-ON trial results point to a very promising role for GTx-104 in the treatment of these patients. We look forward to continuing to engage with the FDA during their review as they work toward the PDUFA target date of April 23, 2026."

Second Quarter 2026 Corporate Highlights

- On August 22, 2025, the FDA accepted the Company's NDA for GTx-104 for formal review, establishing April 23, 2026 as its PDUFA target date. The application is supported by a comprehensive data package, including positive data obtained from the Company's Phase 3 STRIVE-ON safety trial of GTx-104, whereby it met its primary endpoint and provided evidence of clinical benefit when compared to orally administered nimodipine. These data were presented at the *Neurocritical Care* annual meeting, held in Montreal, Quebec, Canada in September 2025.

- On September 16, 2025, U.S. Patent and Trademark Office issued a U.S. Patent No. 12,414,943, titled "Nimodipine Parenteral Administration". The new method of use patent covers the dosing regimen for IV administration of nimodipine used in the Phase 3 STRIVE-ON safety trial for GTx-104. Grace Therapeutics has established a multi-layered intellectual property estate for GTx-104, including five patents on the composition of the Company's formulation of nimodipine, which provide patent protection to 2037. The new patent on the IV dosing regimen for GTx-104 strengthens the Company's intellectual property position and extends protection to 2043. Grace has also been granted Orphan Drug Designation from the FDA, which provides GTx-104 with seven years of marketing exclusivity in United States upon FDA approval of the Company's NDA.

- On October 23, 2025, the Company announced that it has secured approximately $4.0 million in additional funding through exercises of common warrants that were previously issued in a private placement that the Company closed in September 2023. The Company issued 1,345,464 new shares of common stock at an exercise price of $3.003 per share. The remaining 1,190,927 common warrants issued in the 2023 private placement expired as the 60th day after the FDA's acceptance for review of the Company's NDA for GTx-104 has passed. The Company estimates that its cash and cash equivalents were approximately $20.0 million as of October 31, 2025.

Second Quarter 2026 Financial Results

The Company reported a net loss of $0.9 million, or $0.06 per share, for the three months ended September 30, 2025, a decrease of $2.5 million from a net loss of $3.4 million, or $0.30 per share, for the three months ended September 30, 2024. The decrease in net loss was primarily due to a $2.4 million decrease in research and development expenses and a $1.1 million difference in the change in fair value of derivative warrant liabilities, partially offset by a $0.9 million decrease in income tax benefit and a $0.1 million increase in general and administrative expenses.

Total research and development expenses for the three months ended September 30, 2025, were $0.6 million, compared to $3.0 million for the three months ended September 30, 2024. The decrease of $2.4 million was primarily due to a $2.5 million decrease in research activities mainly due to completion of our GTx-104 pivotal Phase 3 STRIVE-ON safety trial, partially offset by an increase in salaries and benefits due to merit increases.

General and administrative expenses were $2.0 million for the three months ended September 30, 2025, an increase of $0.1 million from $1.9 million for the three months ended September 30, 2024. The increase was primarily a result of an increase in other general and administrative expenses primarily due to costs for GTx-104 pre-commercial planning.

Cash Runway

As of September 30, 2025, cash and cash equivalents were $16.9 million, a net decrease of $5.2 million compared to cash and cash equivalents of $22.1 million at March 31, 2025.

In October 2025, the Company received $4.0 million in gross proceeds from exercises of common warrants that were previously issued in a private placement in September 2023. 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 are $15.0 million.

While the Company believes that current cash and cash equivalents provide cash runway through at least the next twelve months, 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 private placement 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 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 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 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 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. 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, 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 and cash position, the future prospects of the Company's GTx-104 drug candidate, the outcome of the Company's NDA submission for GTx-104, 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 of the Company's NDA application for GTx-104; (iii) changes to regulatory pathways; (iv) our ability to protect our intellectual property for our drug candidates; and (v) legislative, regulatory, political and economic developments. The foregoing list of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in the "Special Note Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2025, the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025 and the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025 to be filed with the Securities and Exchange Commission ("SEC") and other documents that have been and will be filed by Grace Therapeutics from time to time with the SEC and Canadian securities regulators. All forward-looking statements contained in this press release speak only as of the date on which they were made. Grace Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by applicable securities laws.

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

---tables to follow---

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

(Expressed in thousands except share data)	September 30,2025 $	March 31,2025 $
Assets		
Current assets:		
Cash and cash equivalents	16,862	22,133
Receivables	20	126
Prepaid expenses	416	453
Total current assets	17,298	22,712
Equipment, net	12	15
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	66,576	71,993
Liabilities and Stockholders' equity		
Current liabilities:		
Trade and other payables	1,245	1,930
Total current liabilities	1,245	1,930
Derivative warrant liabilities	201	1,141
Deferred tax liability	2,312	2,312
Total liabilities	3,758	5,383
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value per share; 10,000,000 authorized; none issued and outstanding as of September 30, 2025 and March 31, 2025	—	—
Common stock, $0.0001 par value per share; 100,000,000 authorized; 14,128,562 and 13,718,106 shares issued and outstanding as of September 30, 2025 and March 31, 2025, respectively	1	1
Additional paid-in capital	293,842	293,334
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(224,987)	(220,687)
Total stockholders' equity	62,818	66,610
Total liabilities and stockholders' equity	66,576	71,993

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

	Three months ended		Six months ended	
(Expressed in thousands, except share and per share data)	September 30, 2025 $	September 30, 2024 $	September 30, 2025 $	September 30, 2024 $
Operating expenses				
Research and development expenses, net of government assistance	(568)	(2,976)	(1,523)	(5,684)
General and administrative expenses	(1,961)	(1,855)	(4,096)	(4,109)
Loss from operating activities	(2,529)	(4,831)	(5,619)	(9,793)
Foreign exchange (loss) gain	(8)	13	3	5
Change in fair value of derivative warrant liabilities	1,427	362	940	1,756
Interest and other income, net	172	172	375	407
Total other income, net	1,591	547	1,318	2,168
Loss before income tax recovery	(938)	(4,284)	(4,301)	(7,625)
Income tax benefit	—	852	—	1,576
Net loss and total comprehensive loss	(938)	(3,432)	(4,301)	(6,049)
Basic and diluted loss per share	(0.06)	(0.30)	(0.27)	(0.53)
Weighted-average number of shares outstanding	15,924,522	11,506,234	15,924,522	11,506,234

Exhibit 99.2

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 expected cash runway, the potential exercise of outstanding warrants, the future prospects of the Company's GTx-104 drug candidate, the outcome of the Company's 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, 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 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 of the NDA submission for GTx-104; (iii) changes to clinical trial designs and regulatory pathways; (iv) the Company's ability to protect its intellectual property rights for its product candidates; and (v) legislative, regulatory, political and economic developments. The foregoing list of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in the "Special Note Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2025, Quarterly Reports on Forms 10-Q for the quarterly periods ended June 30, 2025 and September 30, 2025 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.

Executive Summary

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***

NDA filed June 2025; accepted for review August 22, 2025
Target ***PDUFA April 23, 2026***

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

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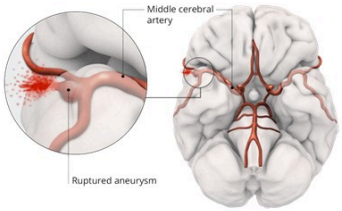
aSAH is a Rare and Severe Acute Brain Injury

- 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

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

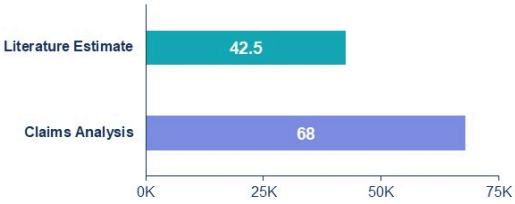
Significant Mortality (~10-15% before reaching hospital)

Subarachnoid Hemorrhage



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 Commision is a hospital accredation agency

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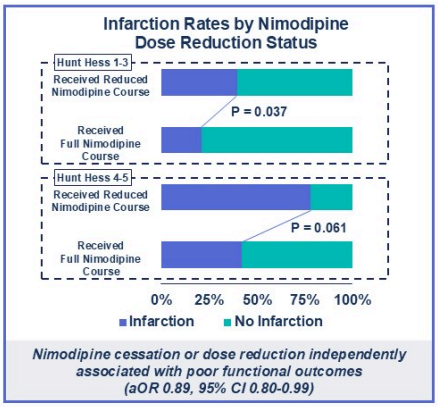
Nimodipine – Consistent Drug Administration Drives Positive Patient Outcomes



Nimodipine cessation or dose reduction independently associated with poor functional outcomes (aOR 0.89, 95% CI 0.80-0.99)

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

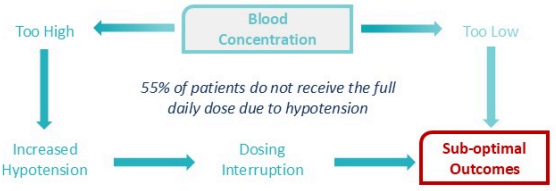
- Inadvertent parenteral injection can result in death or serious life-threatening AEs
- Highest risk with capsule extraction
- NYMALIZE (oral liquid) tempers the risk of error, but has tolerability challenges (e.g., severe diarrhea) due to solubility limitations of nimodipine

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.

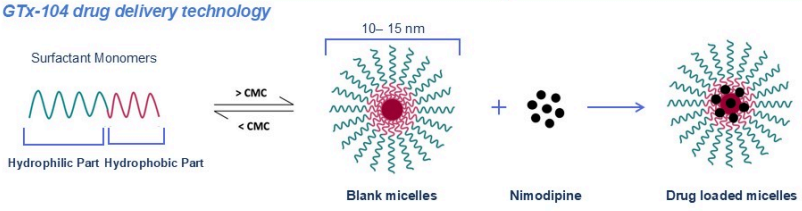
GTx-104 is a Novel IV Nimodipine Designed to Overcome Oral Delivery Challenges Supported by Strong IP, Ph. III Trial Success, and a filed NDA

GTx-104

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

- ***Orphan Drug Status*** with 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***
- Target ***PDUFA April 23, 2026***

GTx-104 drug delivery technology



- 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.

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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 internation

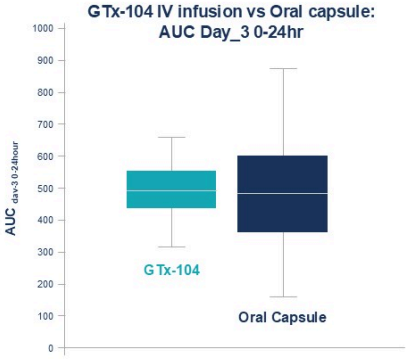
Phase 1 Trial Established Scientific Bridge between GTx-104 and Oral Nimodipine

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

GTx-104

Consistent and ***predictable*** plasma concentrations

Significantly ***lower dose*** variability relative to oral capsule



Source: GTx-104-002 CSR; results announced May 2022


STRIVE-ON Phase 3 Trial
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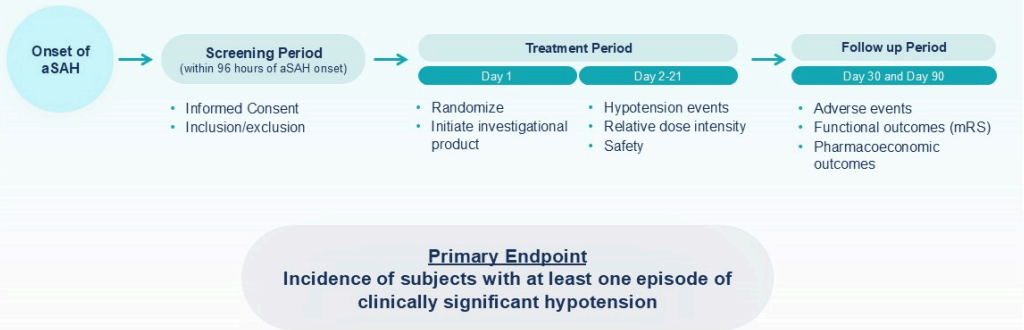
GTx-104 STRIVE-ON Phase 3 Pivotal Safety Trial Design

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

STRIVE-ON Trial Data Demonstrates Key Clinical, Pharmacoeconomic, and Dosing / Administration Benefits over Current SoC, Oral Nimodipine

CLINICAL

IMPROVED 90-DAY OUTCOMES (MRS*)	FEWER HYPOTENSION EVENTS	BETTER RELATIVE DOSE INTENSITY
+29% relative increase in patients with good recovery at 90 days vs. oral nimodipine	**-19%** **reduction** from oral nimodipine	**54%** vs. 8% with oral nimodipine receive >95% prescribed dose

PHARMACOECONOMIC

FEWER ICU DAYS	LESS TIME ON VENTILATION	REDUCED ICU READMISSION RATES
-1.5 days **reduction** from oral nimodipine	**-5 days** **reduction** from oral nimodipine	**-48%** **reduction** from oral nimodipine

DOSING & ADMIN.

IMPROVED PATIENT REST	EASIER ADMINISTRATION	LESS LABOR-INTENSIVE TREATMENT PREP
No need to disrupt patient sleep every 4 hours	No feeding tube or swallowing of large pills required	No nimodipine capsule extraction and administration (laborious for staff)

* mRS – modified Rankin Score

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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

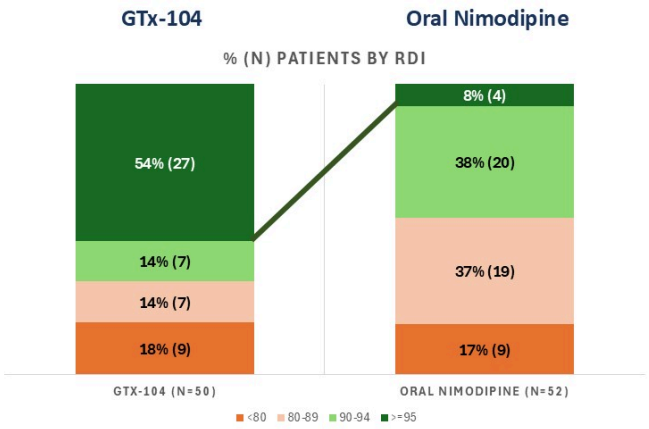
~19% relatively fewer patients with clinically significant hypotension in GTx-104

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

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

Relative Dose Intensity (RDI)

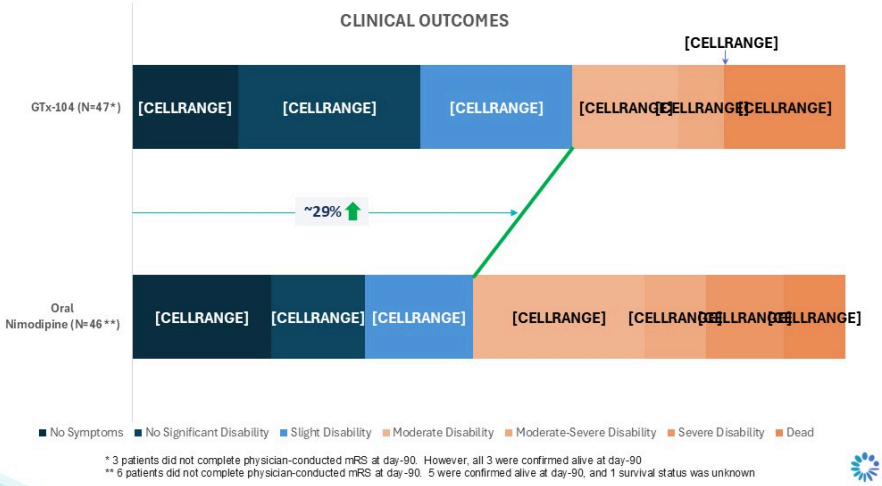
54% of patients on GTx-104 had RDI of 95% or higher versus 8% on Oral Nimodipine



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

Clinical Outcomes – QoL (Quality of Life; day 90)

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	38 (100%)	35 (88%)
I am confined to bed	0	5 (12%)
Self-Care, n (%)		
I have no or some problems	37 (97%)	35 (88%)
I am unable to wash/dress	1 (2.6%)	5 (12%)
Usual Activities, n (%)		
I have no or some problems	35 (92%)	33 (84%)
I am unable to perform	3 (8%)	7 (16%)
Pain/Discomfort, n (%)		
I have no or moderate pain	36 (95%)	38 (95%)
I have extreme pain	2 (5%)	1 (2%)
Anxiety/Depression, n (%)		
I am not or moderately	36 (95%)	36 (90%)
I am extremely	2 (5%)	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).

Safety

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%) 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 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

ICU Length of Stay (los), Mechanical Ventilator & Readmissions

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 (%) Two readmissions, n (%) Three readmissions, n (%)	 6 (12%) 0 0	 7 (14%) 0 1 (2%)
ICU Readmissions One readmission, n (%) Two readmissions, n (%)	 2 (4%) 0	 3 (6%) 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

Pharmacoeconomics

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.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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.

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GTx-104 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 the reduction in hypotension with GTx-104 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 GTx-104's 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)

GTx-104's **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

Sources: Third party conducted interviews, research, and analysis

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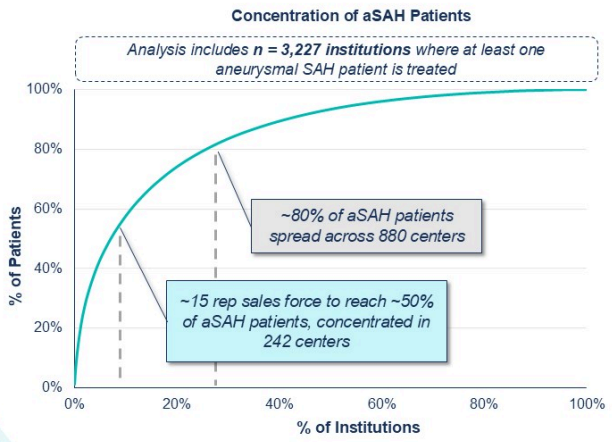
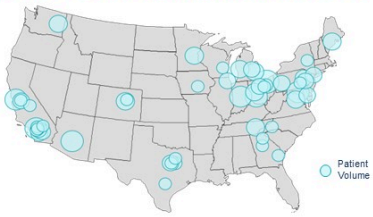
Concentration of aSAH Care – Efficient Commercialization



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 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

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Recent Financing and Warrant Exercise with Potential Exercise of Outstanding Warrants Provides Expected Cash Runway to Calendar Q2 2027

Grace Therapeutics, Inc. (GRCE) Cap Table (as of October 31, 2025)	
Cash & Cash Equivalents Balance	**USD $20.0 M**[3]
Outstanding Common Stock	**15,474,026**
Debt	**NONE**
Stock options granted and outstanding	**1,309,703**
Total Fully Diluted Shares Outstanding[1]	**22,997,981**

Potential Gross Proceeds from Exercise of Outstanding Warrants	
Feb-25 Private Placement[2]: Potential Warrant Exercise Gross Proceeds	**$15.0 M**

[1] Includes Pre-Funded Warrants, Common Warrants, Outstanding Stock Options

[2] Represents 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.

[3] The preliminary unaudited financial information presented is an estimate based on information available to management as of October 31, 2025, has not been reviewed or audited by the Company's independent registered accounting firm, and is subject to change.

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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. DelAversano
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


Appendix (Deprioritized Programs)
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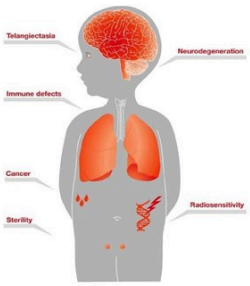
GTx-102 Program Overview & Regulatory Update

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).

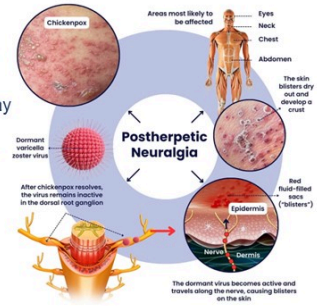
GTx-101 Program Overview

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)

PHN: Postherpetic Neuralgia
Sources: Fletcher Spaght, Inc. analysis (2022); CDC MMWR June 6, 2008. UK and several US states have reclassified gabapentin as a scheduled drug