Zacks Small-Cap Research

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Grace Therapeutics, Inc. (GRCE: NASDAQ)

GRCE: FY:25 Second Quarter Results

Grace's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates. Additionally, we apply an 85% probability of commercial success to the GTX-104 program. The adjustment recognizes regulatory and commercialization risks. The model includes contributions from the United States and the developed world.

Current Price (11/14/2024)	$3.11
Valuation	**$12.50**

OUTLOOK

Grace is a clinical-stage, biotechnology company focused on rare disease. Its lead program, GTX-104, is a novel injectable formulation of nimodipine for the treatment of aneurysmal subarachnoid hemorrhage (aSAH). Other programs include GTX-102 for Ataxia Telangiectasia & GTX-101 for postherpetic neuralgia. GTX-104 is formulated from a previously approved product and a patented technology that employs non-ionic surfactant micelles to overcome delivery shortcomings.

Nimodipine is a lipophilic calcium channel blocker that has been shown to be effective in improving outcomes following aSAH surgery. Its FDA approved oral formulation presents several drawbacks especially for patients that have difficulty swallowing. An IV formulation using safe excipients can address many of these challenges and is represented by GTX-104.

GTX-104 has completed enrollment in its pivotal Phase III safety trial and is expected to report data in early 2025. Results will contribute to an NDA submission to the FDA later in 1H:25. Other candidates are ready for Phase III (GTX-102) & Phase II (GTX-101) and are available for partnering or further development if additional capital becomes available.

SUMMARY DATA

52-Week High	**3.60**
52-Week Low	**1.98**
One-Year Return (%)	**42.7**
Beta	**1.5**
Average Daily Volume (sh)	**33,053**
Shares Outstanding (mil)	**11.5**
Market Capitalization ($mil)	**31.5**
Short Interest Ratio (days)	**3.3**
Institutional Ownership (%)	**21.4**
Insider Ownership (%)	**38.4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2024	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2025	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2026					$0.0 E
2027					$1.4 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2024	-$0.54 A	-$0.43 A	-$0.21 A	-$0.34 A	-$1.35 A
2025	-$0.24 A	-$0.30 A	-$0.24 E	-$0.20 E	-$0.98 E
2026					-$0.67 E
2027					-$0.48 E

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What's New?

Grace Therapeutics, Inc (NASDAQ: GRCE) reported financial results and achievements for its fiscal second quarter ending September 30th, 2024 on November 13th. Activity since the beginning of its fiscal year in March includes completion of enrollment in the STRIVE-ON trial, a corporate name change to Grace Therapeutics and attendance at various investor and industry events. Looking ahead, the company will host a key opinion leader (KOL) event to discuss the use of GTx-104 in aneurysmal subarachnoid hemorrhage (aSAH) on November 20th.

Grace reported second quarter 2024 earnings along with the filing of its Form 10-Q on November 12th. Grace generated no revenues in 2Q:24 and incurred operating expense of $4.8 million, producing a net loss of ($3.4) million or ($0.30) per share.

For the quarter ending September 30th, 2024 and versus the same comparable prior year period:

- Research & development expenses totaled $3.0 million, rising 5.5x from $0.5 million due to the recognition of expenses for the GTx-104 pivotal Phase 3 STRIVE-ON safety clinical trial;
- General & administrative expenses were $1.9 million, expanding 17% from $1.6 million. The increase resulted from increased legal, tax, accounting, audit and other professional fees primarily related to the company's re-domicile to Delaware, increased salaries and benefits due to merit increases and hiring of a new employee, offset by a decrease in other expenses due primarily to adjustments for claims for Canadian goods and service tax and decrease in miscellaneous expenses as a result of restructuring;
- Total other income was $0.5 million vs. ($1.6) million of expense with differences in the change in fair value of warrants the primary contributor;
- Income tax benefit was $0.9 million vs. $0.4 million;
- Net loss was ($3.4) million, or ($0.30) per share, compared to ($3.3) million, or ($0.43) per share.

At the end of 2Q:24, cash and marketable securities totaled $15.2 million, compared to year end 2023 cash balance of $23.0 million. Cash burn for the first six months of 2024 was ($7.8) million versus ($8.2) million in the comparable prior year period. Following the end of the quarter, the company conducted a private placement that raised a net $11.6 million. Management anticipates that the cash balance is sufficient to support company operations until 2Q:26.

Milestones

- Robert J. DelAversano appointed as CFO – January 2024
- Enrollment completion for STRIVE-ON – Fall 2024
- Name change to Grace Therapeutics – October 2024
- Key opinion leader (KOL) event -
- Report of STRIVE-ON trial topline data – 1Q:25
- Submission of NDA for GTX-104 – 2Q:25

Recent Accomplishments

Since the launch of the STRIVE-ON trial in 2H:23, Grace continued efforts to delist from the TSX Venture exchange, obtain a relisting on the NASDAQ and redomicile in the United States. Robert DelAversano was appointed as CEO in January 2024. The STRIVE-ON trial made steady progress in 2024, with company representatives sharing posters and clinical trial details at scientific and investor conferences. By September, only 11 months after the first patient was enrolled, the company announced that it had completed patient enrollment. Future milestones were identified including a data readout of the trial in 1Q:25 and submission of a new drug application (NDA) via the 505(b)(2) pathway to the FDA in 1H:25. Following the move back to the US and in an effort to return to its roots and reflect the origin of its pipeline programs, Acasti changed its name to Grace Therapeutics, effective at the end of October 2024.

Recent Initiation

We recently initiated on Grace Therapeutics in our report entitled From Confusion to Infusion. The initiation highlights the problematic and complex methods that are now required to administer nimodipine to aSAH patients who cannot swallow and how GTx-104 can address these shortcomings.

GTX-104 is an intravenous (IV) formulation of nimodipine that is a better alternative to the oral version for treating patients that are unconscious or unable to swallow, which is common for those suffering from an aSAH. Nimodipine is approved for subarachnoid hemorrhage due to its ability to prevent vasoconstriction following an aneurysm. In several studies, the drug has demonstrated that it can improve neurological outcomes and boost recovery in aSAH patients. Despite its benefits, the drug presents several shortcomings due to its oral formulation which makes it difficult to deliver to unconscious patients. Low bioavailability and other drug characteristics contribute to highly variable levels of blood plasma levels. The variability can lead to hypotension.

Grace has completed two Phase I pharmacokinetic (PK) and PK bridging studies and has completed enrollment in its Phase III STRIVE-ON trial. The Phase I demonstrated that GTX-104 is 100% bioavailable compared to 7.2% of the drug reaching the drug plasma in the oral formulation. Grace's version produces lower dose variability, which has been associated with hypotension, and it has an improved safety profile with no serious adverse events.

STRIVE-ON is a 100-patient trial evaluating hospitalized aSAH patients in a randomized, open label comparison between oral nimodipine and GTX-104. The primary endpoint is safety and is measured as comparative adverse events, including hypotension, between the two groups. The Phase III STRIVE-ON trial is now complete and we expect to see topline results in early 2025. GTX-104 will subsequently be submitted in a new drug application (NDA) via the 505(b)(2) pathway. Assuming normal FDA review times suggests that approval could come by early 2026 with commercialization to follow shortly after.

aSAH affects up to 40,000 individuals in the United States every year and has a global incidence ranging from 9 to 11 per 100,000 persons. Women are more likely than men to suffer the rupture and the highest incidence occurs around a person's sixth decade. Symptoms of the condition include a sudden, severe headache, neck stiffness, nausea and vomiting among others. The patient should immediately go to the emergency room where he or she will be triaged to determine if they have suffered an aSAH and to transport them to a specialized center such as a neurointensive care unit (Neuro-ICU) staffed by neurosurgeons and neurointensivists. After diagnosis treatment includes surgical clipping or endovascular coiling. After the patient is stabilized with an emphasis on strict blood pressure control, he or she is administered oral nimodipine to prevent vasospasm over the next two or three weeks. This allows sufficient blood flow in the brain to protect brain tissue and allow for effective healing.

While oral nimodipine is associated with better outcomes for aSAH patients compared to placebo, it has a number of shortcomings. The primary weakness is that the oral formulation is difficult to administer to patients that are unconscious or have a hard time swallowing. Due to the neurological damage arising from a ruptured aneurysm, many aSAH patients are semi-conscious or unconscious. Oral nimodipine should be administered every four hours due to its short half-life and it should not be taken with food as this impacts its bioavailability. Blood plasma levels can vary widely as over 85% of the drug is lost due to breakdown in the stomach and extensive first pass metabolism in the liver. Higher blood plasma levels can cause hypotension which is associated with neurological impairment, organ damage, reduced kidney function and other risks. In Europe there is an IV formulation of nimodipine branded Nimotop; however, the product solubilizes the drug with high levels of ethanol and propylene glycol. These excipients have numerous negative effects and prevented the product from being approved by the FDA. Grace's IV formulation uses excipients generally recognized as safe (GRAS), and provides a product which is able to improve upon the ethanol-based European version and the oral formulation's primary weaknesses.

Key reasons to own Grace's shares:

- **Aneurysmal Subarachnoid Hemorrhage (aSAH) represents an unmet medical need**
  - **Annual incidence of ~40,000 in the United States**
- **Approved oral treatment has numerous shortcomings addressed by GTX-104**
  - **Oral version does not work for patients unable to swallow**
  - **Existing work-around requires pill crushing and feeding tube administration**
  - **High first pass metabolism makes accurate dosing difficult**
  - **Narrow therapeutic index for oral nimodipine requires precise dosing**
- **Lead candidate GTX-104 provides improvements over oral administration**
  - **Predictable drug concentration**
  - **Effective hypotension management**
  - **Reduced drug intake**
  - **No food effects and fewer drug-drug interactions**
- **Delivery platform based on non-ionic surfactant micelles overcomes solubility limitations**
- **Pipeline offers other clinical assets**
  - **GTX-102 for Ataxia-Telangiectasia**
  - **GTX-101 for Postherpetic Neuralgia**
- **Robust intellectual property**
  - **Patent for proprietary hydrophobic drug delivery platform**
  - **All pipeline candidates granted orphan drug designation by FDA**

Summary

Grace Therapeutics is on track with its STRIVE-ON trial and is expected to report topline in 1Q:25 and submit an NDA to the FDA in the months after. To educate stakeholders the company will hold a KOL event later this week to discuss aSAH and further explain the unmet need in this condition. We recently initiated on Grace, highlighting the ability of GTx-104's IV formulation to address many of the shortcomings of the oral version of nimodipine. The relative benefits of GTx-104 are so significant, we think it could be standard of care within a few years. With a late-stage product months away from an NDA and a relatively high approval rate for the 505(b)(2) pathway, we maintain our valuation of $12.50 per share.

PROJECTED FINANCIALS

Grace Therapeutics, Inc. - Income Statement

Grace Therapeutics, Inc.	2024 A	Q1 A	Q2 A	Q3 E	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($USD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$1,363**
Research & Development	$4,683	$2,708	$2,976	$1,700	$1,200	$8,584	$2,800	$1,000
General & Administrative	$6,432	$2,255	$1,855	$1,500	$1,500	$7,110	$7,200	$8,000
Sales & Marketing	$252	$0	$0	$0	$0	$0	$0	$0
Income from Operations	($11,367)	($4,963)	($4,831)	($3,200)	($2,700)	($15,694)	($10,000)	($7,637)
Restructuring & Impairments	$1,485	$0	$0	$0	$0	$0	$0	$0
Other Items	($2,744)	$1,387	$375	$0	$0	$1,762	$0	$0
Net Interest Expense	$911	$235	$172	$0	$0	$407	$0	$0
Pre-Tax Income	($14,685)	($3,341)	($4,284)	($3,200)	($2,700)	($13,525)	($10,000)	($7,637)
Provision for Income Tax	$1,832	$724	$852	$448	$378	$2,402	$1,400	$1,069
Tax Rate	*-12.5%*	*-21.7%*	*-14.0%*	*-14.0%*	*-14.0%*	*-17.8%*	*-14.0%*	*-14.0%*
Net Income	**($12,853)**	**($2,617)**	**($3,432)**	**($2,752)**	**($2,322)**	**($11,123)**	**($8,600)**	**($6,568)**
Net Margin								
Reported EPS	**($1.35)**	**($0.24)**	**($0.30)**	**($0.24)**	**($0.20)**	**($0.98)**	**($0.67)**	**($0.48)**
YOY Growth								
Basic Shares Outstanding	9,529	10,929	11,506	11,550	11,600	11,396	12,800	13,650

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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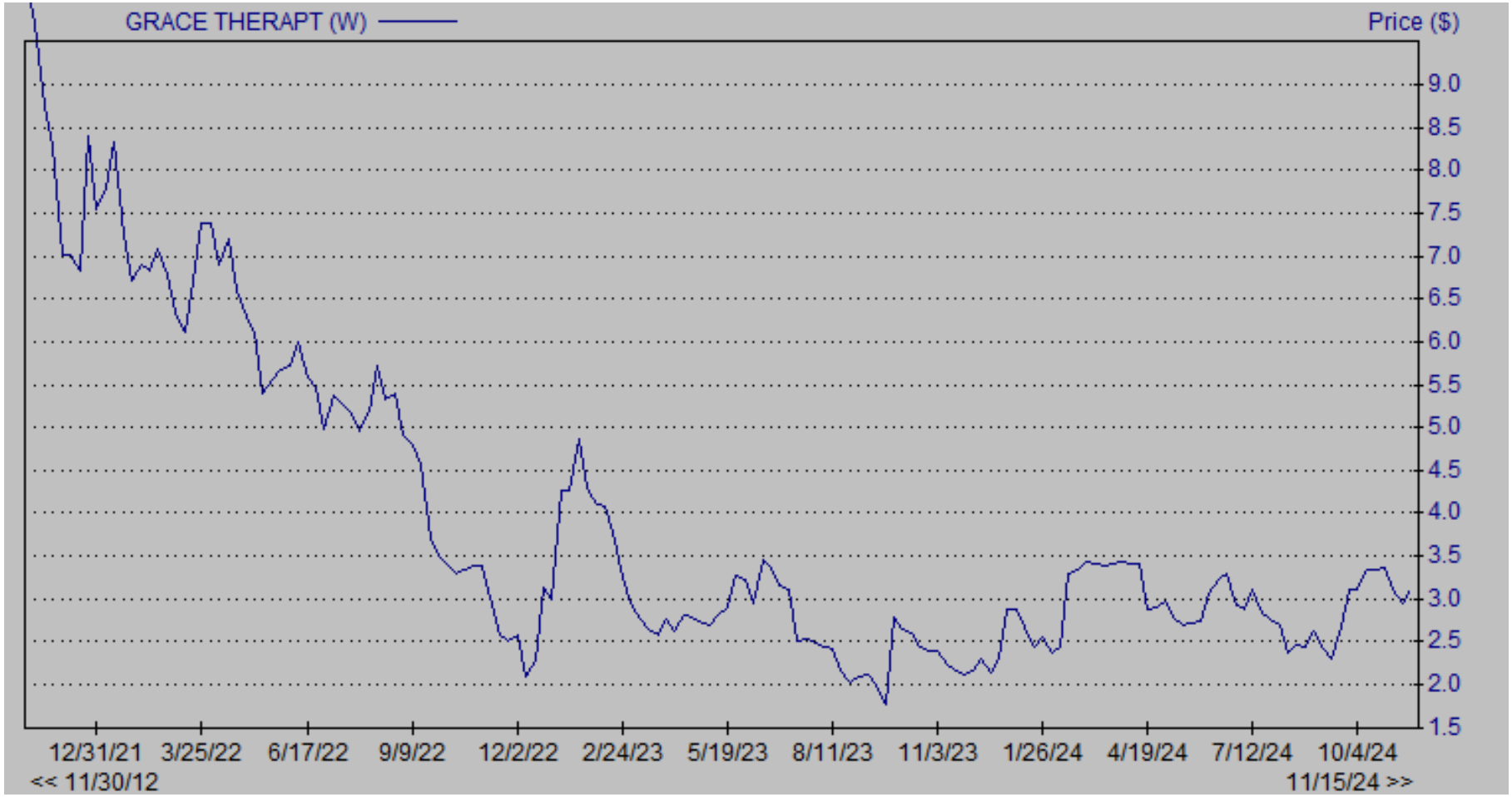
HISTORICAL STOCK PRICE

Grace Therapeutics, Inc. – Share Price Chart[1]



[1] Source: Zacks Research System

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