



Gyre Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

March 12, 2026

Full-year 2025 revenue increased 10% year-over-year to \$116.6 million, within revised guidance range

Full year 2026 revenue guidance of \$100.5 to \$111.0 million

Entered into agreement to acquire Cullgen to gain targeted protein degradation platform and pipeline; transaction anticipated to close in the second quarter of 2026

Alignment with China's Center for Drug Evaluation (CDE) on conditional approval filing and priority review eligibility for Hydronidone, subject to formal approval; New Drug Application (NDA) submission for conditional approval expected in the first half of 2026

Completed patient enrollment in the 52-week Phase 3 pirfenidone pneumoconiosis (PD) trial (272 patients across 18 sites)

Hydronidone U.S. Investigational New Drug (IND) application for MASH-associated liver fibrosis anticipated in 2026

SAN DIEGO, March 12, 2026 (GLOBE NEWSWIRE) -- Gyre Therapeutics (Gyre or the Company) (Nasdaq: GYRE), an innovative, commercial-stage biopharmaceutical company dedicated to advancing fibrosis-first therapies across organ systems affected by chronic disease, today announced financial results for the fourth quarter and full year ended December 31, 2025 and provided a business update.

"2026 is expected to be a pivotal regulatory year for Gyre as we advance Hydronidone toward conditional approval in China following our alignment with China's CDE," said Ping Zhang, Executive Chairman and Interim Chief Executive Officer of Gyre Therapeutics. "Our planned NDA submission in the first half of 2026 underscores the strength of our Phase 3 data and the constructive progress achieved through regulatory engagement. In addition, we have completed enrollment in our 52-week Phase 3 pirfenidone trial in pneumoconiosis, further strengthening our late-stage respiratory portfolio. We have also incorporated the complete Phase 2 and Phase 3 clinical data from our CHB-associated liver fibrosis program into our U.S. development strategy and expect to submit an IND application in 2026 for MASH-associated liver fibrosis. Finally, we recently announced an agreement to acquire Cullgen, a company with a robust pipeline of degraders, targeting inflammatory diseases and cancers, as well as U.S.-based drug discovery and development capabilities. Collectively, these achievements support the continued advancement of our differentiated pipeline across both China and the United States."

Fourth Quarter 2025 Business Highlights and Upcoming Milestones

Commercial Portfolio

- ETUARY® (pirfenidone): Generated \$106.1 million in sales of ETUARY® for the full year ended December 31, 2025, compared to \$105.0 million for the same period in 2024.
- Etores® (nintedanib ethanesulfonate soft capsules): Launched in June 2025 and generated \$4.6 million in sales for the full year ended December 31, 2025.
- Contiva® (avatrombopag maleate tablets): Launched in March 2025 and generated \$5.5 million in sales for the full year ended December 31, 2025.

Pipeline Development Updates

Hydronidone:

- In November 2025, Gyre Pharmaceuticals Co., Ltd. (Gyre Pharmaceuticals) presented positive Phase 3 trial results evaluating Hydronidone for the treatment of liver fibrosis in chronic hepatitis B (CHB)-associated liver fibrosis at The Liver Meeting® 2025, the annual meeting of the American Association of the Study of Liver Diseases. The abstract was selected as a *Poster of Distinction*.

- Following the Phase 3 trial results, Gyre Pharmaceuticals completed a Pre-NDA meeting with China's CDE. Based on the discussions, the CDE indicated that the existing Phase 3 clinical data support a conditional approval filing and potential priority review eligibility, subject to formal acceptance and approval. The Company plans to submit an NDA for conditional approval in the first half of 2026.
- In the United States, Gyre Therapeutics plans to conduct a hepatic impairment study under its active U.S. IND application to inform dose selection and enrollment criteria in patients with reduced hepatic function, supporting the Company's broader U.S. development strategy.
- Gyre Therapeutics remains on track to submit an IND application in 2026 with the U.S. Food & Drug Administration for Hydronidone in MASH-associated liver fibrosis, and, subject to IND clearance, initiate a Phase 2 clinical trial.

Pirfenidone:

- In the third quarter of 2025, Gyre Pharmaceuticals completed patient enrollment in its 52-week Phase 3 clinical trial evaluating pirfenidone for the treatment of PD. The multicenter, randomized, double-blind, placebo-controlled trial enrolled 272 patients across 18 clinical research centers in China and is designed to assess the efficacy and safety of 52 weeks of pirfenidone treatment in patients with this chronic occupational lung disease characterized by progressive pulmonary fibrosis. The final patient is expected to complete the trial in the third quarter of 2026.
- Following approval in March 2025 from China's National Medical Products Association's (NMPA) for a clinical trial evaluating pirfenidone in oncology-related pulmonary complications, Gyre Pharmaceuticals plans to initiate an adaptive Phase 2/3 trial in the first half of 2026 in China. This trial will evaluate pirfenidone for radiation-induced lung injury (RILI), including cases complicated by immune-related pneumonitis, at leading oncology centers.

Corporate Updates:

- In March 2026, Gyre announced an agreement to acquire Cullgen Inc. (Cullgen), a privately-held, clinical-stage biopharmaceutical company focused on the discovery and development of targeted protein degrader and degrader antibody conjugate therapies, in an all-stock transaction valued at approximately \$300 million. Following the closing of the acquisition, expected in the second quarter of 2026, the new combined entity is expected to be a fully integrated biopharmaceutical company with U.S.- and China-based capabilities spanning from discovery to manufacturing and commercialization and covering multiple therapeutic areas, including inflammatory diseases, cancers, and pain.

Financial Results

Cash Position

As of December 31, 2025, Gyre had cash, cash equivalents, short-term and long-term bank deposits of \$75.9 million.

Financial Results for the Three Months Ended December 31, 2025

- **Revenues:** Revenues for the three months ended December 31, 2025 were \$37.2 million, compared to \$27.9 million for the same period in 2024, representing an increase of \$9.3 million, or 33.3% year-over-year. The growth was driven by \$1.5 million in Etorel[®] sales and \$2.5 million in Contiva[®] sales, as well as a \$5.5 million increase in ETUARY[®] sales, partially offset by a \$0.2 million decrease in generic drug revenue. The increase in ETUARY[®] sales reflects strengthened commercial execution and the reallocation of marketing resources during the second half of 2025.
- **Cost of Revenues:** For the three months ended December 31, 2025, cost of revenues was \$1.7 million, compared to \$1.2 million for the same period in 2024. The \$0.5 million increase was primarily driven by a \$0.4 million increase in stock-based compensation expense, and a \$0.1 million increase in cost of sales of Etorel[®] and Contiva[®].
- **Selling and Marketing Expense:** Selling and marketing expense for the three months ended December 31, 2025 was \$23.8 million, compared to \$16.9 million for the same period in 2024, representing an increase of \$6.9 million, or 40.8% year-over-year. The increase was primarily attributable to expanded commercial activities, including a \$2.9 million increase in personnel costs driven by higher sales headcount and commissions, a \$2.2 million increase in stock-based compensation expense, a \$1.7 million increase in conference and promotional activities, and a \$0.1 million increase in travel and other expenses.
- **Research and Development Expense:** For the three months ended December 31, 2025, research and development expense was \$4.8 million, compared to \$3.7 million for the same period in 2024. The \$1.1 million increase was primarily driven by a \$0.6 million increase in facilities, depreciation and other expenses, attributable mainly to professional and consulting fees incurred in connection with research and development operations, a \$0.3 million increase in pre-clinical research costs, a \$0.2 million increase in clinical trial costs and a \$0.3 million increase in staff costs which included \$0.2

million in stock-based compensation expenses, partially offset by a \$0.3 million decrease in materials and utilities expenses.

- **General and Administrative Expense:** For the three months ended December 31, 2025, general and administrative expense was \$6.7 million, compared to \$5.5 million for the same period in 2024. The \$1.2 million increase was primarily driven by a \$1.2 million increase in stock-based compensation expense and a \$0.8 million increase in functional and administrative department's personnel expense, partially offset by a \$0.6 million decrease in professional service expense, a \$0.1 million decrease in depreciation and amortization expense and a \$0.1 million decrease in miscellaneous expense.
- **Income from Operations:** For the three months ended December 31, 2025, income from operations was \$0.1 million, compared to \$0.7 million income from operations for the same period in 2024. The \$0.6 million decrease in income from operations was driven primarily by a \$9.9 million increase in total operating expenses, partially offset by a \$9.3 million increase in revenue.
- **Net (Loss) Income:** For the three months ended December 31, 2025, net loss was \$1.4 million, compared to \$0.6 million net income for the same period in 2024. The \$2.0 million decrease was driven primarily by an increase in income tax expense of \$1.1 million, an increase in operating expenses of \$9.9 million and a decrease in other income of \$0.3 million, partially offset by an increase in revenue of \$9.3 million.
- **Non-GAAP Adjusted Net Income:** For the three months ended December 31, 2025, non-GAAP adjusted net income was \$4.3 million, compared to \$1.1 million for the same period in 2024. The \$3.2 million increase was primarily driven by an increase in revenue of \$9.3 million partially offset by the increase in operating expenses of \$5.8 million and an decrease in other income of \$0.3 million.

Financial Results for the Full Year Ended December 31, 2025

- **Revenues:** Revenues for the full year ended December 31, 2025 were \$116.6 million, compared to \$105.8 million for the same period in 2024, representing an increase of \$10.8 million, or 10.2% year-over-year. The growth was driven by \$5.5 million in Contiva[®] sales and \$4.6 million in Etorel[®] sales, along with a \$1.1 million increase in ETUARY[®] sales, partially offset by a \$0.4 million decline in generic drug revenue.

Sales of Contiva[®] and Etorel[®], which commenced commercialization in March 2025 and June 2025, respectively, were primarily driven by the targeted allocation of commercial and marketing resources to support their respective launches during the first half of 2025. The increase in ETUARY[®] sales reflects a strategic realignment of marketing efforts in the third quarter of 2025 to optimize product mix and address evolving market dynamics.

- **Cost of Revenues:** For the full year ended December 31, 2025, cost of revenues was \$5.4 million, compared to \$3.9 million for the same period in 2024. The \$1.5 million increase was primarily driven by a \$0.8 million increase in ETUARY[®]'s cost, due to higher plant, property and equipment depreciation from a plant renovation completed in the second half of 2024, a \$0.6 million increase in the cost of Contiva[®] and Etorel[®], in line with the corresponding increase in their sales, and a \$0.5 million increase in stock-based compensation expense. These factors were partially offset by a \$0.4 million decrease in costs related to generic drugs due to the decrease in sales.
- **Selling and Marketing Expense:** For the full year ended December 31, 2025, selling and marketing expense was \$65.2 million, compared to \$57.5 million for the same period in 2024. This \$7.7 million increase was primarily driven by a \$2.5 million increase in conference expenses and promotional expenses, attributable to the launch of additional promotional campaigns in the current year—particularly for the Company's new products, a \$2.6 million increase in staff costs, which was driven by expanded headcount and higher sales commissions, consistent with the corresponding growth in revenue, a \$2.3 million increase in stock-based compensation expense and a \$0.3 million increase in traveling and other expense.
- **Research and Development Expense:** For the full year ended December 31, 2025, research and development expense was \$13.7 million, compared to \$12.0 million for the same period in 2024. The \$1.7 million increase was attributable to a \$1.0 million increase in clinical trial costs, primarily as a result of data analysis costs for Hydronidone, PD and RILI, a \$0.4 million increase in staff costs, which included \$0.2 million in stock-based compensation expense, a \$0.5 million increase in facilities, depreciation and other expenses, attributable mainly to professional and consulting fees incurred in connection with research and development operations, and a \$0.4 million increase in pre-clinical research expenses. These expense increases were partially offset by a \$0.6 million decrease in materials and utilities expenses.
- **General and Administrative Expense:** For the full year ended December 31, 2025, general and administrative expense was \$20.8 million, compared to \$16.1 million for the same period in 2024. This \$4.7 million increase was primarily driven by a \$3.3 million increase in stock-based compensation expense, a \$1.3 million increase in functional and administrative department's personnel expense, and a \$0.9 million increase in miscellaneous expense. These cost increases were partially offset by a \$0.8 million decrease in professional service expenses.

- **Income from Operations:** For the full year ended December 31, 2025, income from operations was \$11.5 million, compared to \$16.2 million in income for the same period in 2024. The \$4.7 million decrease in income from operations was driven primarily by a \$15.5 million increase in total operating expenses, partially offset by a \$10.8 million increase in revenue.
- **Net Income:** For the full year ended December 31, 2025, net income was \$9.9 million, compared to \$17.9 million net income for the same period in 2024. This \$8.0 million decrease was driven primarily by the increase in operating expenses of \$15.5 million and decrease in change in fair value of warrant liability of \$4.5 million, partially offset by an increase in revenue of \$10.8 million, an increase in other income of \$0.4 million, and a decrease in income tax expense of \$0.8 million.
- **Non-GAAP Adjusted Net Income:** For the full year ended December 31, 2025, non-GAAP adjusted net income was \$18.9 million, compared to \$16.9 million for the same period in 2024. The increase was primarily driven by an increase in revenue of \$10.8 million and an increase in other income of \$0.4 million partially offset by an increase in operating expenses of \$9.2 million.

Full Year 2026 Financial Guidance

For the full year 2026, the Company expects to generate revenues of \$100.5 million to \$111.0 million, representing a decline of approximately 13.8% to 4.8% compared to 2025.

The Company anticipates that 2026 will be a transition period, during which it plans to prioritize regulatory activities, including preparation for the planned NDA submission of Hydronidone.

In addition, given uncertainties associated with the National Centralized Drug Procurement program and evolving market dynamics, the Company expects to moderate promotional activities for Contiva[®] and Etorel[®].

Please note the following regarding the total revenue guidance:

- *Guidance assumes a constant foreign currency exchange rate.*
- *Guidance assumes no significant economic disruption or downturn.*

Use of Non-GAAP Financial Measures by Gyre Therapeutics, Inc.

Gyre reports financial results in accordance with accounting principles generally accepted in the United States ("GAAP"). This release presents the financial measure "adjusted net income," which is not calculated in accordance with GAAP. The most directly comparable GAAP measure for this non-GAAP financial measure is "net income." Adjusted net income presents Gyre's results of operations after excluding gain from change in fair value of warrants, stock-based compensation, and provision for income taxes. This is meant to supplement, and not substitute, Gyre's financial information presented in accordance with GAAP. Adjusted net income as defined by Gyre may not be comparable to similar non-GAAP measures presented by other companies. Management believes that presenting adjusted net income provides investors with additional useful information in evaluating Gyre's performance and valuation. See the reconciliation of adjusted net income to net income in the section titled "Reconciliation of GAAP to Non-GAAP Financial Measures" below.

About Hydronidone

Hydronidone is a novel, orally administered anti-fibrotic agent designed to target key liver fibrosis pathways. It attenuates hepatic stellate cell activation and fibrogenesis, at least in part, by suppressing Tumor Growth Transforming (TGF)- β 1-induced signal transduction, including reduced p38 γ phosphorylation and upregulated Smad7 expression. This upregulation of Smad7 subsequently leads to downregulation of TGF- β RI and inhibition of Smad2/3 activation, thereby disrupting canonical TGF- β /Smad signaling and reducing fibrotic gene expression in hepatic stellate cells.

The drug has completed Phase 3 clinical evaluation in China for chronic hepatitis B (CHB)-associated liver fibrosis, including early (compensated) cirrhosis, and is being evaluated for its potential applicability across additional fibrotic diseases in region-specific development programs.

About Gyre Pharmaceuticals

Gyre Pharmaceuticals is a commercial-stage biopharmaceutical company committed to the research, development, manufacturing and commercialization of innovative drugs for organ fibrosis. Its flagship product, ETUARY[®] (pirfenidone capsule), was the first approved treatment for IPF in China in 2011 and has maintained a prominent market share (2024 net sales of \$105.8 million). In addition, Gyre Pharmaceuticals' pipeline includes Hydronidone, a structural analogue of pirfenidone, which demonstrated statistically significant fibrosis regression after 52 weeks of treatment in a pivotal Phase 3 clinical trial in CHB-associated liver fibrosis in China. Hydronidone received Breakthrough Therapy designation by the NMPA CDE in March 2021. Gyre

Revenues	\$	37,195	\$	27,872	\$	116,588	\$	105,757
Operating expenses:								
Cost of revenues		1,743		1,177		5,416		3,884
Selling and marketing		23,816		16,856		65,179		57,511
Research and development		4,815		3,712		13,698		12,024
General and administrative		6,701		5,464		20,804		16,109
Loss (Gain) on disposal of assets, net		2		(2)		4		66
Total operating expenses		<u>37,077</u>		<u>27,207</u>		<u>105,101</u>		<u>89,594</u>
Income from operations		118		665		11,487		16,163
Other income (expenses):								
Interest income, net		509		346		1,747		1,547
Other expense, net		(956)		(433)		(1,505)		(1,659)
Change in fair value of warrant liability		263		194		2,707		7,167
(Loss) Income before income taxes		<u>(66)</u>		<u>772</u>		<u>14,436</u>		<u>23,218</u>
Provision for income taxes		(1,300)		(203)		(4,556)		(5,320)
Net (loss) income		<u>(1,366)</u>		<u>569</u>		<u>9,880</u>		<u>17,898</u>
Net income attributable to noncontrolling interest		<u>357</u>		<u>668</u>		<u>4,853</u>		<u>5,813</u>
Net (loss) income attributable to common stockholders	\$	<u>(1,723)</u>	\$	<u>(99)</u>	\$	<u>5,027</u>	\$	<u>12,085</u>
Net (loss) income per share attributable to common stockholders:								
Basic	\$	<u>(0.02)</u>	\$	<u>(0.00)</u>	\$	<u>0.06</u>	\$	<u>0.14</u>
Diluted	\$	<u>(0.02)</u>	\$	<u>(0.00)</u>	\$	<u>0.02</u>	\$	<u>0.05</u>
Weighted average shares used in calculating net income per share attributable to common stockholders:								
Basic		<u>91,156,159</u>		<u>85,952,413</u>		<u>89,344,622</u>		<u>85,094,948</u>
Diluted		<u>91,156,159</u>		<u>85,952,413</u>		<u>103,180,037</u>		<u>102,293,526</u>

Gyre Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	<u>December 31,</u>	<u>December 31,</u>
	<u>2025</u>	<u>2024</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,070	\$ 11,813
Short-term bank deposits	15,355	14,858
Notes receivable	5,638	4,373
Accounts receivable, net	31,078	19,589
Other receivables from GNI	230	230
Inventories	10,171	6,337
Prepaid assets	1,338	1,189
Receivable from GCBP	—	4,961
Other current assets	<u>1,489</u>	<u>1,436</u>
Total current assets:	102,369	64,786
Property and equipment, net	23,599	23,880
Intangible assets, net	4,727	273
Right-of-use assets	1,131	1,818

Land use rights, net	1,425	1,432
Deferred tax assets	6,873	5,619
Long-term certificates of deposit	23,516	24,568
Other assets, noncurrent	2,492	3,030
Total assets	<u>\$ 166,132</u>	<u>\$ 125,406</u>
Liabilities, convertible preferred stock, and equity		
Current liabilities:		
Accounts payable	\$ 124	\$ 108
Contract liabilities	14	61
Due to related parties	227	227
Accrued expenses and other current liabilities	14,345	10,615
Income tax payable	2,940	2,831
Operating lease liabilities, current	636	713
CVR derivative liability	—	4,961
Total current liabilities:	<u>18,286</u>	<u>19,516</u>
Operating lease liabilities, noncurrent	303	885
Deferred government grants	852	928
Warrant liability, noncurrent	2,961	5,668
Other noncurrent liabilities	1,448	7
Total liabilities	<u>\$ 23,850</u>	<u>\$ 27,004</u>
Commitments and Contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value, 400,000,000 shares authorized; 91,314,007 shares and 86,307,544 shares issued and outstanding at December 31, 2025 and 2024, respectively	91	86
Additional paid-in capital	172,047	136,185
Statutory reserve	3,098	3,098
Accumulated deficit	(68,426)	(73,453)
Accumulated other comprehensive loss	(779)	(2,597)
Total Gyre stockholders' equity	<u>106,031</u>	<u>63,319</u>
Noncontrolling interest	36,251	35,083
Total equity	<u>142,282</u>	<u>98,402</u>
Total liabilities and stockholders' equity	<u>\$ 166,132</u>	<u>\$ 125,406</u>

Gyre Therapeutics, Inc.
Reconciliation of GAAP to Non-GAAP Financial Measures
(in thousands)
(unaudited)

	Three Months Ended		Years Ended December 31,	
	December 31,			
	2025	2024	2025	2024
Net (loss) income	\$ (1,366)	\$ 569	\$ 9,880	\$ 17,898
Gain from change in fair value of warrants ⁽¹⁾	(263)	(194)	(2,707)	(7,167)
Stock-based compensation	4,597	567	7,157	831
Provision for income taxes	1,300	203	4,556	5,320
Non-GAAP adjusted net income	<u>\$ 4,268</u>	<u>\$ 1,145</u>	<u>\$ 18,886</u>	<u>\$ 16,882</u>

(1) Reflects adjustments for fair value of warrants based on the Black-Scholes option pricing model.

