Gyre Therapeutics Reports Third Quarter 2025 and Year-to-Date Financial Results and Provides Business Update

November 7, 2025

Net income of $5.9 million and $11.2 million for the three and nine months ended September 30, 2025, respectively

Full-year revenue guidance revised to $115-118 million (from $118 - $128 million previously) due to delayed Etorel® (Nintedanib) rollout and government procurement-related uncertainty

Q3 2025 vs Q3 2024 Highlights

- *Quarterly revenue of $30.6 million, up 20% year-over-year, driven by ETUARY® growth and contributions from sales of Etorel® and Contiva®.*
- *GAAP net income doubled to $5.9 million and adjusted net income rose to $8.8 million, reflecting commercial execution and disciplined cost control.*
- *Operating income increased 64% to $6.9 million, as operating expenses grew at a slower pace than revenue.*
- *Basic EPS improved to $0.04, compared to $0.01 year-over-year.*

Nine-Month 2025 Highlights

- *Revenue of $79.4 million, moderately above the prior-year period, supported by steady Q3 growth of Etorel® and Contiva®, after earlier supply chain and distribution delays related to new product launches.*
- *Basic EPS down from $0.14 to $0.08, reflecting higher operating expenses related to the dual product launches in the first half of 2025, partially offset by the strong Q3 profit recovery.*
- *$80.3 million in cash, cash equivalents, and short and long-term deposits, up 57% year-to-date, as of Sept 30, 2025.*

Business Update

- *Hydronidone New Drug Application (NDA) progressing in China, with Priority Review discussions ongoing and targeted submission following completion of regulatory interactions.*
- *Completed patient enrollment in the 52-week Phase 3 pirfenidone pneumoconiosis (PD) trial (272 patients, 18 sites).*
- *Plan to initiate an adaptive Phase 2/3 trial of pirfenidone in oncology-related pulmonary complications (RILI/immune-related pneumonitis) in Q4 2025.*
- *U.S. MASH IND anticipated timeline adjusted to 2026 to allow for (i) the incorporation of the complete Phase 2 and 3 CHB-associated liver fibrosis clinical data from China; and (ii) planning and expected initiation of a hepatic impairment study under the existing U.S. IND to further inform safety, dose optimization, and regulatory discussions.*

SAN DIEGO, Nov. 07, 2025 (GLOBE NEWSWIRE) -- Gyre Therapeutics (“Gyre”) (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 third quarter ended September 30, 2025 and provided a business update.

“Following the positive results from our pivotal Phase 3 trial in the PRC evaluating Hydronidone for the treatment of CHB-associated liver fibrosis, we are working diligently toward our NDA submission and are leveraging Hydronidone’s Breakthrough Therapy designation to bring this much-needed therapy to patients in China,” said Ping Zhang, Executive Chairman and Interim Chief Executive Officer of Gyre Therapeutics. “With enrollment now completed in our 52-week Phase 3 trial of pirfenidone for the treatment of pneumoconiosis, we continue to advance our pipeline in China. We are also preparing for U.S. clinical activities and expect to file the U.S. IND for Hydronidone for the treatment of MASH-associated liver fibrosis in 2026, supported by the translation and regulatory-quality review of our China Phase 2 and Phase 3 trial data and an upcoming hepatic impairment study.”

Third Quarter Business Highlights and Upcoming Milestones

Commercial Portfolio

ETUARY® (pirfenidone): Generated $27.7 million in sales of ETUARY® for the quarter ended September 30, 2025, compared to $25.3 million for the same period in 2024.

Etorel® (nintedanib ethanesulfonate soft capsules): Generated $1.5 million in sales of Etorel® for the quarter ended September 30, 2025, the first full quarter of launch.

Contiva® (avatrombopag maleate tablets): Generated $1.2 million in sales of Contiva® for the quarter ended September 30, 2025.

Pipeline Development Updates

Hydronidone:

New Drug Application (NDA) in China:

- Building on the positive Phase 3 trial results, Gyre Pharmaceuticals is actively engaging with China's National Medical Products Administration (NMPA) to confirm Priority Review eligibility for Hydronidone's New Drug Application (NDA).
- The Company remains on track to advance regulatory filing activities and intends to proceed with the NDA submission for Hydronidone in China upon completion of ongoing regulatory interactions and resolution of any outstanding requirements.

Hydronidone U.S. IND Timing Update:

- The anticipated timeline for submitting the U.S. IND for Hydronidone for the treatment of MASH-associated liver fibrosis has been adjusted due to the delayed availability of the full Phase 3 trial data set from the completed trial of Hydronidone for the treatment of CHB-associated liver fibrosis in China. The Phase 2 and Phase 3 trial data form the core clinical safety package supporting the U.S. program, and the translation and regulatory-quality review of the Clinical Study Reports are currently in progress.
- In parallel, Gyre plans to conduct a hepatic impairment study in U.S. subjects under its active U.S. IND. In light of the shifting market dynamics in the MASH landscape, this study is expected to help determine dose selection and appropriate enrollment criteria in populations with reduced hepatic function, thereby supporting a more robust Phase 2 development strategy.
- With these activities underway, Gyre expects to file the U.S. IND for Hydronidone for the treatment of MASH-associated liver fibrosis in 2026, and, subject to U.S. IND clearance, initiate a Phase 2 trial.

Pirfenidone Development and Indication Expansion:

- In the third quarter of 2025, Gyre Pharmaceuticals completed patient enrollment in the 52-week Phase 3 clinical trial evaluating pirfenidone for the treatment of pneumoconiosis. The multicenter, randomized, double-blind, placebo-controlled trial enrolled 272 patients across 18 clinical research centers in China. The trial is designed to evaluate the efficacy and safety of 52 weeks of pirfenidone treatment in patients with pneumoconiosis, a chronic occupational lung disease characterized by progressive pulmonary fibrosis.
- Following the NMPA's approval in March 2025 of Gyre Pharmaceuticals' clinical trial application for pirfenidone in oncology-related pulmonary complications, Gyre Pharmaceuticals plans to initiate an adaptive Phase 2/3 trial in the fourth quarter of 2025 in the PRC, targeting radiation-induced lung injury (RILI) including cases complicated by immune-related pneumonitis across leading oncology centers.

Financial Results

Cash Position

As of September 30, 2025, Gyre held $40.4 million in cash and cash equivalents, $19.6 million in short-term bank deposits, and $20.3 million in long-term certificates of deposit, totaling $80.3 million.

Financial Results for the Three Months Ended September 30, 2025

- **Revenues**: Revenues for the three months ended September 30, 2025 were $30.6 million, compared to $25.5 million for the same period in 2024. The $5.1 million increase was primarily due to $1.5 million from Etorel® sales, $1.2 million from Contiva® sales and a $2.4 million increase in revenue from ETUARY® sales. The increase in ETUARY® sales was mainly

driven by a shift in marketing focus in the third quarter. We continue to anticipate revenue growth over the remainder of the year, driven by the growth of ETUARY® sales and supplemented by the commercialization of Etorel® and Contiva® in 2025.

- **Cost of Revenues**: For the three months ended September 30, 2025, cost of revenues was $1.6 million, compared to $1.0 million for the same period in 2024. The $0.6 million increase was primarily attributable to a $0.2 million increase in the costs associated with Contiva® and Etorel®, in line with the corresponding increase in their sales, and a $0.5 million increase in costs associated with ETUARY® due to the higher sales and increased production costs for the product batch related to such sales, partially offset by a $0.1 million decrease in costs associated with generic drugs due to the decrease of sales.

- **Selling and Marketing Expense**: For the three months ended September 30, 2025, selling and marketing expense was $15.3 million, compared to $13.7 million for the same period in 2024. The $1.6 million increase was primarily attributable to a $0.5 million increase in payroll costs, driven by higher headcount and an increase of sales in the three months ended September 30, 2025 and a $1.1 million increase in promotion and conference expenses.

- **Research and Development Expense**: For the three months ended September 30, 2025, research and development expense was $2.4 million, compared to $2.8 million for the same period in 2024. The decrease was primarily attributable to a $0.4 million decrease in clinical trial costs resulting from the completion of the Phase 3 trial of Hydronidone in the second quarter of 2025, and a $0.2 million decrease in pre-clinical research expenses, partially offset by $0.2 million increase in staff costs.

- **General and Administrative Expense**: For the three months ended September 30, 2025, general and administrative expense was $4.3 million, compared to $3.8 million for the same period in 2024. The $0.5 million increase was primarily driven by a $1.1 million increase in functional and administrative department's personnel and stock compensation costs and a $0.2 million increase in miscellaneous expenses, partially offset by a $0.8 million decrease in professional fees.

- **Income from Operations**: For the three months ended September 30, 2025, income from operations was $6.9 million, compared to $4.2 million for the same period in 2024. The $2.7 million increase was primarily driven by a $5.1 million increase in revenue, partially offset by a $2.4 million increase in total operating expenses.

- **Net Income**: For the three months ended September 30, 2025, net income was $5.9 million, compared to $2.9 million for the same period in 2024. The increase was primarily driven by an increase in revenue of $5.1 million and an increase in other income of $0.8 million, partially offset by an increase in operating expenses of $2.4 million and an increase in income tax expense of $0.6 million.

- **Non-GAAP Adjusted Net Income**: For the three months ended September 30, 2025, non-GAAP adjusted net income was $8.8 million, compared to $4.4 million for the same period in 2024. The increase was primarily driven by an increase in revenue of $5.1 million and an increase in other income of $0.8 million, partially offset by an increase in operating expenses of $1.5 million.

Financial Results for the Nine Months Ended September 30, 2025

- **Revenues**: Revenues for the nine months ended September 30, 2025 were $79.4 million, compared to $77.9 million for the same period in 2024. The $1.5 million increase was primarily driven by the increase in new product sales of Contiva® by $3.0 million and Etorel® by $3.1 million, partially offset by a $4.4 million decline in ETUARY® sales and a $0.2 million decrease in generic drug revenue. The decrease in ETUARY® sales was primarily due to the allocation of marketing resources towards the launches of two new products during the first half of the year. In the third quarter, Gyre refocused marketing efforts on ETUARY® in response to market uncertainties related to Etorel® and Contiva®, both of which were included in the latest national volume-based procurement catalog. For the three months ended September 30, 2025, Gyre recorded an increase in ETUARY® sales compared to the same period in 2024, and Gyre expects ETUARY® sales will continue to grow in the three months ended December 31, 2025 compared to the same period in 2024.

  We revised our full-year revenue guidance (see “Revised Full Year 2025 Financial Guidance” section below) primarily due to lower-than-expected sales of Contiva® and Etorel® relative to internal budget expectations. While both products continue to expand their commercial presence, initial rollout challenges and external market dynamics have resulted in lower than-expected sales.

  For Etorel®, early-year supply chain and distribution delays moderated launch uptake, and uncertainty related to government volume-based procurement led customers to cautious purchasing behavior. While the underlying demand has started to improve, current performance remains below our original expectations for the year.

- **Cost of Revenues**: For the nine months ended September 30, 2025, cost of revenues was $3.7 million, compared to $2.7

million for the same period in 2024. The $1.0 million increase was primarily driven by a $0.1 million increase in stock-based compensation and a $0.4 million increase in the costs of Etorel® and Contiva®, in line with the corresponding increase in their sales, as well as a $0.8 million increase in ETUARY®'s cost due to the higher plant, property and equipment depreciation from a plant renovation in 2025, partially offset by a $0.3 million decrease in costs related to generic drugs due to the decrease of sales.

- **Selling and Marketing Expense**: For the nine months ended September 30, 2025, selling and marketing expense was $41.4 million, compared to $40.7 million for the same period in 2024. The $0.7 million increase was primarily driven by a $0.9 million increase in conference expenses and a $0.1 million increase in stock compensation costs, partially offset by a $0.3 million reduction in staff costs.
- **Research and Development Expense**: For the nine months ended September 30, 2025, research and development expense was $8.9 million, compared to $8.3 million for the same period in 2024. The $0.6 million increase was primarily attributable to a $1.0 million increase in clinical trial costs, primarily as a result of data analysis costs for Hydronidone in the first half of 2025. This increase was offset by a $0.2 million decrease in materials and utilities expenses and a $0.2 million decrease in pre-clinical research expenses.
- **General and Administrative Expense**: For the nine months ended September 30, 2025, general and administrative expense was $14.1 million, compared to $10.6 million for the same period in 2024. The $3.5 million increase was primarily driven by a $2.8 million increase in functional and administrative department's personnel and stock compensation costs and a $0.9 million increase in miscellaneous expense, mainly due to the increase in expenses related to Gyre Pharmaceuticals' annual employee appreciation event, partially offset by a $0.2 million decrease in professional fees.
- **Income from Operations**: For the nine months ended September 30, 2025, income from operations was $11.4 million, compared to $15.5 million for the same period in 2024. The $4.1 million decrease was primarily driven by a $5.6 million increase in total operating expenses, partially offset by a $1.5 million increase in revenue.
- **Net Income**: For the nine months ended September 30, 2025, net income was $11.2 million, compared to $17.3 million for the same period in 2024. The decrease was primarily driven by the increase in operating expenses of $5.6 million and decrease in change in fair value of warrant liability of $4.5 million, partially offset by an increase in revenue of $1.5 million, an increase in other income of $0.7 million, and a decrease of income tax expense of $1.9 million.
- **Non-GAAP Adjusted Net Income**: For the nine months ended September 30, 2025, non-GAAP adjusted net income was $14.6 million, compared to $15.7 million for the same period in 2024. The decrease was primarily driven by the increase in operating expenses of $3.3 million, partially offset by an increase in revenue of $1.5 million and an increase in other income of $0.7 million.

Revised Full Year 2025 Financial Guidance

Full-year revenue guidance revised from $118–128 million to $115–118 million, reflecting slower-than-expected commercialization of Etorel® (nintedanib) due to early supply chain and distribution challenges, as well as increased market uncertainty related to China's centralized procurement policy leading to more cautious purchasing behavior in the second half of the year, partially offset by stronger-than-expected ETUARY® sales.

Please note that the revenue guidance assumes a constant foreign currency rate and 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 the 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 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 the PRC 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 the PRC. Hydronidone received Breakthrough Therapy designation by the NMPA Center for Drug Evaluation in March 2021. Gyre Pharmaceuticals is also developing treatments for PD, RILI with or without immune-related pneumonitis, COPD, PAH and ALF/ACLF. In October 2023, Gyre Therapeutics acquired an indirect majority interest of 65.2% in Gyre Pharmaceuticals. In the third quarter of 2025, this indirect interest was increased from 65.2% to 69.7% through the increased capital contribution from BJContinent Pharmaceuticals Limited to Gyre Pharmaceuticals.

About Gyre Therapeutics

Gyre Therapeutics is a biopharmaceutical company headquartered in San Diego, CA, primarily focused on the development and commercialization of Hydronidone for liver fibrosis, including MASH, in the United States Gyre's strategy builds on its experience in mechanistic studies using MASH rodent models and clinical studies in CHB-induced liver fibrosis. In the People's Republic of China, Gyre is advancing a broad pipeline through its indirect controlling interest in Gyre Pharmaceuticals, including therapeutic expansions of ETUARY®, and development programs for F573, F528, and F230.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, are forward-looking statements, including statements concerning: the expectations regarding Gyre's research and development efforts, timing of expected clinical readouts, including the anticipated timing of the submission of Gyre's U.S. IND for Hydronidone for the treatment of MASH-associated liver fibrosis, a hepatic impairment study of Hydronidone in U.S. subjects under Gyre's active IND, the initiation of Gyre's Phase 2/3 trial in the PRC for pirfenidone capsules for the treatment of RILI, including cases complicated by immune-related pneumonitis, the filing of an NDA with the NMPA and timing for potential commercial approval for Hydronidone for the treatment of CHB-associated liver fibrosis and trial design of Gyre's Phase 3 clinical trial evaluating pirfenidone for the treatment of pneumoconiosis, the expectations regarding commercial revenues from the sales of Etorel® and Contiva® maleate tablets, interactions with regulators, expectations regarding future product sales, Gyre's ability to meet its expected revenue guidance and Gyre's financial position and cash resources. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: Gyre's ability to execute on its clinical development strategies; positive results from a clinical trial may not necessarily be predictive of the results of future or ongoing clinical trials; the timing or likelihood of regulatory filings and approvals; competition from competing products; the impact of general economic, health, industrial or political conditions in the United States or internationally; the sufficiency of Gyre's capital resources and its ability to raise additional capital; supply chain and distribution delays and challenges. Additional risks and factors are identified under "Risk Factors" in Gyre's Annual Report on Form 10-K for the year ended December 31, 2024 filed on March 17, 2025 and in other filings with the Securities and Exchange Commission.

Gyre expressly disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

For Investors:
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Gyre Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,	Nine Months Ended September 30,

	2025	2024	2025	2024
Revenues	$ 30,564	$ 25,488	$ 79,393	$ 77,885
Operating expenses:				
Cost of revenues	1,628	958	3,673	2,707
Selling and marketing	15,328	13,699	41,363	40,655
Research and development	2,363	2,775	8,883	8,312
General and administrative	4,319	3,823	14,103	10,645
Loss on disposal of assets, net	1	—	2	68
Total operating expenses	23,639	21,255	68,024	62,387
Income from operations	6,925	4,233	11,369	15,498
Other income, net:				
Change in fair value of warrant liability	(23)	(228)	2,444	6,973
Other income (expense), net	727	(75)	689	(25)
Income before income taxes	7,629	3,930	14,502	22,446
Provision for income taxes	(1,693)	(1,074)	(3,256)	(5,117)
Net income	5,936	2,856	11,246	17,329
Net income attributable to noncontrolling interest	2,326	1,732	4,496	5,145
Net income attributable to common stockholders	$ 3,610	$ 1,124	$ 6,750	$ 12,184
Net income per share attributable to common stockholders:				
Basic	$ 0.04	$ 0.01	$ 0.08	$ 0.14
Diluted	$ 0.03	$ 0.01	$ 0.04	$ 0.05
Weighted average shares used in calculating net income per share attributable to common stockholders:				
Basic	90,850,040	85,643,646	88,707,709	84,807,041
Diluted	103,971,546	102,640,373	102,813,522	102,505,585

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

	September 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 40,402	$ 11,813
Short-term bank deposits	19,647	14,858
Notes receivable	693	4,373
Accounts receivable, net	25,877	19,589
Other receivables from GNI	230	230
Inventories	8,854	6,337
Receivable from GCBP	—	4,961
Prepaid assets and other current assets	2,873	2,625

Total current assets	98,576	64,786
Property and equipment, net	23,608	23,880
Intangible assets, net	4,847	273
Deferred tax assets	6,714	5,619
Long-term certificates of deposit	20,317	24,568
Other assets, noncurrent	5,322	6,280
Total assets	$ 159,384	$ 125,406
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 556	$ 108
Contract liabilities	58	61
Due to related parties	228	227
Accrued expenses and other current liabilities	11,799	10,615
Income tax payable	2,646	2,831
Operating lease liabilities, current	626	713
CVR derivative liability	—	4,961
Total current liabilities	15,913	19,516
Operating lease liabilities, noncurrent	539	885
Deferred government grants	866	928
Warrant liability, noncurrent	3,224	5,668
Other noncurrent liabilities	1,427	7
Total liabilities	21,969	27,004
Stockholders' equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized; 90,890,381 shares and 86,307,544 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	91	86
Additional paid-in capital	167,134	136,185
Statutory reserve	3,098	3,098
Accumulated deficit	(66,703)	(73,453)
Accumulated other comprehensive loss	(1,700)	(2,597)
Total Gyre stockholders' equity	101,920	63,319
Noncontrolling interest	35,495	35,083
Total equity	137,415	98,402
Total liabilities and stockholders' equity	$ 159,384	$ 125,406

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Net income	$ 5,936	$ 2,856	$ 11,246	$ 17,329
Loss (gain) from change in fair value of warrant liability [(1)]	23	228	(2,444)	(6,973)
Stock-based compensation	1,147	237	2,560	264
Provision for income taxes	1,693	1,074	3,256	5,117
Non-GAAP adjusted net income	$ 8,799	$ 4,395	$ 14,618	$ 15,737

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