



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

August 11, 2025

Net income of \$1.6 million and \$5.3 million for the three and six months ended June 30, 2025, respectively; reaffirms full-year revenue guidance of \$118-128 million

Ping Zhang, Executive Chairman, appointed interim CEO as Dr. Han Ying transitions to scientific leadership role

- Revenue of \$26.8 million and \$48.8 million for the three and six months ended June 30, 2025, respectively
- GAAP basic EPS: \$0.00 and \$0.04 for the three and six months ended June 30, 2025, respectively
- Pivotal Phase 3 trial of Hydronidone (F351) in CHB-associated liver fibrosis demonstrated statistically significant fibrosis regression after 52 weeks of treatment; Phase 2 trial in the United States evaluating Hydronidone for the treatment of MASH-associated liver fibrosis expected to initiate in 2H 2025, pending regulatory approval
- Successfully launched Etores (nintedanib ethanesulfonate soft capsules) in the PRC for the treatment of SSc-ILD and PF-ILD
- Announced NMPA approval for clinical trial evaluating pirfenidone capsules in oncology-related pulmonary complications with Phase 2/3 trial anticipated in 2H 2025
- First volunteer dosed in Phase 1 clinical trial of F230 for treatment of PAH

SAN DIEGO, Aug. 11, 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 second quarter ended June 30, 2025 and provided a business and leadership update.

Dr. Han Ying has stepped down as Chief Executive Officer and will transition into the role of Senior Vice President, Science and will oversee research and discovery activities to support Gyre's fibrosis focused pipeline. Ping Zhang, Executive Chairman, has been appointed Interim Chief Executive Officer, and will lead the company's day-to-day operations and strategic global expansion.

"I want to thank Dr. Ying for his contributions and dedication during his tenure as CEO. His deep background in research and discovery will be invaluable to advance our science and continued innovation," said Mr. Zhang. "As interim CEO, I am excited to work closely with our leadership team to strengthen Gyre's global footprint and accelerate our progress toward delivering transformative therapies to patients."

"Looking ahead, we are thrilled with the rapid progress we have made towards expanding our commercial footprint and advancing our pipeline of fibrosis-first therapies. Our lead compound, Hydronidone, demonstrated statistically significant fibrosis regression in patients with CHB-associated liver fibrosis in a pivotal Phase 3 trial in the PRC, a critical step that not only underscores the potential of Hydronidone, but also lays the foundation to expand into additional fibrotic indications," continued Mr. Zhang. "In the second half of 2025 we are well-positioned to grow our footprint in the United States with our planned Phase 2 trial evaluating Hydronidone in MASH-associated liver fibrosis, while continuing to advance our robust pipeline in the PRC, highlighted by a new Phase 2/3 trial of pirfenidone in oncology-related pulmonary complications expected to initiate later this year. In addition, Gyre Pharmaceuticals remains on track to file an NDA for Hydronidone with the NMPA in the third quarter of 2025 to potentially support our growing commercial portfolio."

Second Quarter Business Highlights and Upcoming Milestones

Commercial Portfolio Expansion

ETUARY® (pirfenidone): Generated \$23.5 million in sales of ETUARY® for the quarter ended June 30, 2025, compared to \$25.1 million for the same period in 2024.

Etores (nintedanib ethanesulfonate soft capsules): In June 2025, Gyre launched Etores in the PRC for the treatment of systemic sclerosis-associated ILD, and progressive fibrosing ILD, and generated sales of \$1.6 million in the first partial quarter of launch.

Contiva (avatrombopag maleate tablets): In March 2025, Gyre initiated commercialization of Contiva in the PRC for

thrombocytopenia in adults with chronic liver disease and immune thrombocytopenic purpura, and generated sales for \$1.5 million in the second quarter of 2025.

Pipeline Development Updates

Hydronidone:

- In May 2025, Gyre reported positive results from its pivotal Phase 3 trial of Hydronidone for chronic hepatitis B (“CHB”)-associated liver fibrosis in the PRC, which demonstrated statistically significant regression in liver fibrosis after 52 weeks compared to placebo. In addition, Hydronidone met a key secondary endpoint with statistically significant inflammation improvement without fibrosis progression at Week 52 versus the placebo arm. Hydronidone was well tolerated with a comparable incidence of serious adverse events (4.88% vs. 6.45% in the placebo group) and no discontinuations due to adverse events in either group. Gyre plans to submit primary results for publication in a peer-reviewed journal and present full trial results at a future medical conference. Based on these results, Gyre intends to file a New Drug Application (“NDA”) with the PRC’s National Medical Products Administration (“NMPA”) in the third quarter of 2025.
- Gyre previously submitted an investigational new drug application (“IND”) for the treatment of liver fibrosis associated with a broad spectrum of chronic liver diseases with the U.S. Food and Drug Administration and conducted a Phase 1 trial of Hydronidone in healthy volunteers for the treatment of metabolic dysfunction-associated steatohepatitis (“MASH”)-associated liver fibrosis. The Company is currently conducting an internal review to determine whether a new IND will be required for a Phase 2 trial in MASH-associated liver fibrosis. The Phase 2 trial is expected to start in the second half of 2025, subject to regulatory feedback.

ETUARY® (Pirfenidone):

- Gyre plans to initiate an adaptive Phase 2/3 trial of pirfenidone for radiation-induced lung injury (“RILI”), including cases complicated by immune-related pneumonitis across top oncology centers in the PRC in the second half of 2025.

F573:

- F573 is a caspase inhibitor and potential Category 1 new drug for the treatment of acute/acute on-chronic liver failure (“ALF/ACLF”). Completion of the Phase 2 clinical trial of F573 for ALF/ACLF is expected by the end of 2026.

F230:

- In June 2025, the first volunteer was successfully dosed in a Phase 1 clinical trial evaluating F230, a novel endothelin A receptor agonist, for the treatment of pulmonary arterial hypertension (“PAH”) in the PRC.

F528:

- F528, a novel anti-inflammation agent with the potential to modify the progression of chronic obstructive pulmonary disease (“COPD”), is undergoing preclinical studies as a potential first-line therapy for the treatment of COPD. Gyre plans to submit an IND application in 2026.

Corporate Updates

- In August 2025, Ping Zhang was appointed interim CEO as Dr. Han Ying transitions to a scientific leadership role. Mr. Zhang, who was appointed Executive Chairman in March 2025, has served on Gyre’s Board of Directors since January 2025.
- In May 2025, Gyre completed an underwritten public offering of 2,555,555 shares of its common stock at a public offering price of \$9.00 per share. The gross proceeds of the offering, before deducting underwriting discounts and commissions and other offering expenses, were approximately \$23.0 million.
- In the third quarter of 2025, BJContinent Pharmaceuticals Limited increased its capital contribution in Gyre Pharmaceuticals (also known as Beijing Continent Pharmaceuticals Co., Ltd.) by \$1.28 million in exchange for 9,184,910 additional shares. As a result, the Company’s indirect interest in Gyre Pharmaceuticals increased from 65.2% to 69.7%.

Financial Results

Cash Position

As of June 30, 2025, Gyre held \$36.5 million in cash and cash equivalents, \$17.9 million in short-term bank deposits, and \$21.5 million in long-term certificates of deposit, totaling \$75.9 million. The increase of cash and cash equivalents mainly includes net proceeds of approximately \$21.3 million received from the May 2025 underwritten public offering.

Financial Results for the Three Months Ended June 30, 2025

- **Revenues:** Revenues for the three months ended June 30, 2025 were \$26.8 million, compared to \$25.2 million for the same period in 2024. The \$1.6 million increase was primarily driven by a \$1.6 million increase in revenue as a result of EtoREL's commercial launch in June 2025 and a \$1.5 million increase in revenue from the sales of Contiva. These increases were offset by a \$1.5 million decline in ETUARY[®] sales.

Gyre anticipates revenue growth over the remainder of the year, driven by the commercial launch of EtoREL in June 2025 and the continued expansion of Contiva.

- **Cost of Revenues:** For the three months ended June 30, 2025, cost of revenues was \$1.2 million, compared to \$0.8 million for the same period in 2024. The \$0.4 million increase was primarily driven by a \$0.2 million increase in the costs associated with Contiva and EtoREL, in line with the corresponding increase in their sales, and a \$0.2 million increase in ETUARY[®]'s cost due to the higher plant, property and equipment depreciation from a plant renovation.
- **Selling and Marketing Expense:** For the three months ended June 30, 2025, selling and marketing expense was \$15.2 million, compared to \$14.4 million for the same period in 2024. The \$0.8 million increase was primarily attributable to a \$0.9 million increase in payroll costs, driven by higher headcount and increase of sales in the three months ended June 30, 2025, partially offset by \$0.1 million decrease in promotion and conference expenses.
- **Research and Development Expense:** For the three months ended June 30, 2025, research and development expense was \$3.4 million, compared to \$3.3 million for the same period in 2024. The \$0.1 million increase was primarily attributable to a \$0.1 million increase in clinical trial costs, primarily related to data analysis costs for Hydronidone, and a \$0.1 million increase in staff costs. These increases were partially offset by a \$0.1 million decrease in materials and utilities expenses.
- **General and Administrative Expense:** For the three months ended June 30, 2025, general and administrative expense was \$4.8 million, compared to \$3.4 million for the same period in 2024. The \$1.4 million increase was primarily driven a \$0.5 million increase in professional fees, and a \$0.9 million increase in functional and administrative department's personnel and stock compensation costs.
- **Income from Operations:** For the three months ended June 30, 2025, income from operations was \$2.2 million, compared to \$3.2 million income from operation for the same period in 2024. The \$1.0 million decrease was primarily driven by \$2.6 million increase in total operating expenses, partially offset by a \$1.6 million increase in revenue.
- **Net Income:** For the three months ended June 30, 2025, net income was \$1.6 million, compared to \$4.5 million net income for the same period in 2024.
- **Non-GAAP Adjusted Net Income:** For the three months ended June 30, 2025, non-GAAP adjusted net income was \$2.9 million, compared to \$3.1 million non-GAAP adjusted net income for the same period in 2024. The decrease was primarily driven by the increase in operating expenses of \$1.7 million, partially offset by an increase in revenue of \$1.6 million.

Financial Results for the Six Months Ended June 30, 2025

- **Revenues:** Revenues for the six months ended June 30, 2025 were \$48.8 million, compared to \$52.4 million for the same period in 2024. The \$3.6 million decrease was primarily driven by a \$6.8 million decline in ETUARY[®] sales, partially offset by the increase in new product sales of Contiva by \$1.8 million and EtoREL by \$1.6 million. The decrease in ETUARY[®] sales was mainly due to lower sales volume compared to the first half of 2024, when revenues were elevated by a one-time rural marketing campaign that was not repeated in 2025. Additionally, weaker economic conditions in China and increased competition in the IPF treatment market also contributed to the decline. During the first half of 2025, marketing funds were intentionally shifted to support the launches of EtoREL and Contiva.

Gyre anticipates revenue growth over the remainder of the year, driven by the continued expansion of Contiva in March 2025 and the commercial launch of EtoREL in June 2025.

- **Cost of Revenues:** For the six months ended June 30, 2025, cost of revenues was \$2.0 million, compared to \$1.7 million for the same period in 2024. The \$0.3 million increase was primarily driven by a \$0.1 million increase in stock-based compensation and a \$0.2 million increase in the costs of EtoREL and Contiva, in line with the corresponding increase in their sales.
- **Selling and Marketing Expense:** For the six months ended June 30, 2025, selling and marketing expense was \$26.0 million, compared to \$26.9 million for the same period in 2024. The \$0.9 million decrease was primarily driven by a reduction in commission costs due to the decrease of sales.

- **Research and Development Expense:** For the six months ended June 30, 2025, research and development expense was \$6.5 million, compared to \$5.5 million for the same period in 2024. The \$1.0 million increase was primarily attributable to a \$1.5 million increase in clinical trial costs, primarily as a result of data analysis costs for Hydronidone. This increase was offset by a \$0.3 million decrease in materials and utilities expenses and a \$0.1 million decrease in facilities, depreciation and other.
- **General and Administrative Expense:** For the six months ended June 30, 2025, general and administrative expense was \$9.8 million, compared to \$6.8 million for the same period in 2024. The \$3.0 million increase was primarily driven a \$0.6 million increase in professional fees, a \$1.6 million increase in functional and administrative department's personnel and stock compensation costs, and a \$0.8 million increase in miscellaneous expense, mainly due to the increase for the annual meeting expense.
- **Income from Operations:** For the six months ended June 30, 2025, income from operations was \$4.4 million, compared to \$11.3 million income from operation for the same period in 2024. The \$6.9 million decrease was primarily driven by a \$3.6 million decrease in revenue and \$3.3 million increase in total operating expenses.
- **Net Income:** For the six months ended June 30, 2025, net income was \$5.3 million, compared to \$14.5 million net income for the same period in 2024.
- **Non-GAAP Adjusted Net Income:** For the six months ended June 30, 2025, non-GAAP adjusted net income was \$5.8 million, compared to \$11.3 million non-GAAP adjusted net income for the same period in 2024. The decrease was primarily driven by the decline in revenue of \$3.6 million and increase in operating expenses of \$1.9 million.

Full Year 2025 Financial Guidance

For the full year 2025, the Company expects to generate revenues of \$118 to \$128 million, representing growth of 11.3% to 20.8% over 2024 revenue, primarily driven by the anticipated commercial launches of Etozel and Contiva and sales of ETUARY®.

Guidance Range

Total Revenue	\$118 to \$128 million
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Please note that total revenue guidance assumes a constant foreign currency exchange 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 \$105.0 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 and NDA filing is expected in the third quarter of 2025. Gyre Pharmaceuticals is also developing treatments for PD, DKD, 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 timing of the initiation of Gyre's Phase 2 trial in the U.S. for Hydronidone for the treatment of MASH-associated liver fibrosis, 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 for Hydronidone for the treatment of CHB-related liver fibrosis, timing of completion of Gyre's Phase 2 clinical trial in the PRC of F573 for ALF/ACLF, and IND submission of F528 in COPD, the expectations regarding commercial revenues from the sales of Etoel and Contiva maleate tablets, interactions with regulators, expectations regarding future product sales, 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. 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues	\$ 26,771	\$ 25,225	\$ 48,829	\$ 52,397
Operating expenses:				
Cost of revenues	1,151	770	2,045	1,749
Selling and marketing	15,194	14,414	26,035	26,956
Research and development	3,425	3,355	6,520	5,537
General and administrative	4,829	3,424	9,784	6,822
Loss on disposal of assets, net	1	68	1	68
Total operating expenses	24,600	22,031	44,385	41,132
Income from operations	2,171	3,194	4,444	11,265
Other income, net:				
Change in fair value of warrant liability	212	2,913	2,467	7,201

Other (expense) income, net	(145)	(72)	(38)	50
Income before income taxes	2,238	6,035	6,873	18,516
Provision for income taxes	(662)	(1,497)	(1,563)	(4,043)
Net income	1,576	4,538	5,310	14,473
Net income attributable to noncontrolling interest	1,134	1,010	2,170	3,413
Net income attributable to common stockholders	\$ 442	\$ 3,528	\$ 3,140	\$ 11,060
Net income per share attributable to common stockholders:				
Basic	\$ 0.00	\$ 0.04	\$ 0.04	\$ 0.13
Diluted	\$ 0.00	\$ 0.01	\$ 0.01	\$ 0.04
Weighted average shares used in calculating net income per share attributable to common stockholders:				
Basic	89,119,344	85,502,403	87,295,099	84,384,141
Diluted	102,701,707	102,205,888	101,868,781	102,421,084

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

	June 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,491	\$ 11,813
Short-term bank deposits	17,874	14,858
Notes receivable	499	4,373
Accounts receivables, net	24,629	19,589
Other receivables from GNI	230	230
Inventories, net	8,861	6,337
Receivable from GCBP	—	4,961
Prepaid assets and other current assets	2,701	2,625
Total current assets	91,285	64,786
Property and equipment, net	23,401	23,880
Intangible assets, net	4,962	273
Deferred tax assets	6,134	5,619
Long-term certificates of deposit	21,528	24,568
Other assets, noncurrent	5,336	6,280
Total assets	\$ 152,646	\$ 125,406
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 71	\$ 108
Contract liabilities	—	61
Due to related parties	219	227
Accrued expenses and other current liabilities	14,924	10,615
Income tax payable	1,084	2,831
Operating lease liabilities, current	622	713
CVR derivative liability	—	4,961
Total current liabilities	16,920	19,516

Operating lease liabilities, noncurrent	771	885
Deferred government grants	884	928
Warrant liability, noncurrent	3,201	5,668
Other noncurrent liabilities	1,427	7
Total liabilities	23,203	27,004
Stockholders' equity:		
Common stock, \$0.001 par value, 400,000,000 shares authorized; 90,822,828 shares and 86,307,544 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	91	86
Additional paid-in capital	161,437	136,185
Statutory reserve	3,098	3,098
Accumulated deficit	(70,313)	(73,453)
Accumulated other comprehensive loss	(2,287)	(2,597)
Total Gyre stockholders' equity	92,026	63,319
Noncontrolling interest	37,417	35,083
Total equity	129,443	98,402
Total liabilities and stockholders' equity	\$ 152,646	\$ 125,406

Gyre Therapeutics, Inc.
Reconciliation of GAAP to Non-GAAP Financial Measures

(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Net income	\$ 1,576	\$ 4,538	\$ 5,310	\$ 14,473
Gain from change in fair value of warrant liability ⁽¹⁾	(212)	(2,913)	(2,467)	(7,201)
Stock-based compensation	906	16	1,413	27
Provision for income taxes	662	1,497	1,563	4,043
Non-GAAP adjusted net income	\$ 2,932	\$ 3,138	\$ 5,819	\$ 11,342

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