



Gyre Therapeutics Reports First Quarter 2025 Financial Results and Provides Business Update

May 9, 2025

Net Income of \$3.7 million; reaffirms Full-Year Revenue Guidance of \$118–\$128 million

- Q1 2025 revenue of \$22.1 million; GAAP basic EPS: \$0.03
- Completed data collection and achieved database lock for the pivotal Phase 3 trial of Hydronidone in Chronic Hepatitis B (“CHB”)-associated liver fibrosis; currently reviewing data and on track to report topline results in Q2 2025
- Received IND approval from China’s National Medical Products Administration (“NMPA”) for a new indication of pirfenidone to treat radiation-induced lung injury (“RILI”), with or without immune-related pneumonitis (“CIP”), marking Gyre’s first entry into oncology supportive care space
- Initiated commercialization of avatrombopag in China in March 2025, building a strategic presence with liver disease specialists
- Nintedanib remains on track for commercialization in May 2025, expanding IPF treatment options across our physician network
- \$51.3 million in cash, cash equivalents, and short and long-term deposits as of March 31, 2025

SAN DIEGO, May 09, 2025 (GLOBE NEWSWIRE) -- Gyre Therapeutics (“Gyre”) (Nasdaq: GYRE), an innovative, commercial-stage biotechnology company focused on organ fibrosis, today announced financial results for the first quarter ended March 31, 2025 and provided a business update.

“This quarter marked a meaningful step forward in expanding our market presence, particularly in the liver space,” said Han Ying, Ph.D., CEO of Gyre Therapeutics. “The successful launch of avatrombopag and our growing commercial footprint with hepatology and hematology specialists provide a strong foundation for our future growth. In addition, the recent NMPA approval to initiate a clinical trial of pirfenidone in radiation-induced lung injury, including with or without immune-related pneumonitis, supports our ability to enter the oncology supportive care space with a novel, lung-protective therapy. We plan to initiate an adaptive Phase 2/3 trial in the second half of 2025 to advance this program through development.”

First Quarter 2025 Business Highlights and Upcoming Milestones

Commercial Portfolio Expansion

ETUARY® (pirfenidone): Delivered \$21.7 million in Q1 sales. While sales declined year-over-year due to relatively high sales in the first quarter of 2024, ETUARY remains the market leader for idiopathic pulmonary fibrosis (IPF) in the PRC.

Nintedanib: Gyre remains on track to commercially launch nintedanib in May 2025, targeting multiple forms of fibrosing interstitial lung disease (“ILD”), including IPF, systemic sclerosis-associated ILD, and progressive fibrosing ILD. This is expected to expand Gyre’s share of the pulmonary fibrosis treatment landscape and support second-half 2025 revenue growth.

Avatrombopag: Commercialization of avatrombopag was initiated in March 2025, expanding Gyre’s footprint in hepatology and hematology. Approved for thrombocytopenia in adults with chronic liver disease and immune thrombocytopenic purpura, the launch aligns with Gyre’s strategy to deepen clinical engagement with liver disease specialists and diversify the market of available products.

Indication Expansion: Oncology Supportive Care

Pirfenidone New Indication: In March 2025, Gyre received NMPA approval to initiate a clinical trial of pirfenidone for RILI, including cases complicated by CIP. This development positions pirfenidone for potential entry into oncology supportive care, with plans to begin an adaptive Phase 2/3 trial in the second half of 2025 across top oncology centers in China.

Pipeline Development Updates

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:

- F230, a selective endothelin receptor agonist for the treatment of pulmonary arterial hypertension (“PAH”), is expected to begin a Phase 1 trial in Q2 2025.

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 Pharmaceuticals plans to submit an IND application in 2026.

Corporate Updates

- In March 2025, Gyre appointed Ping Zhang as Executive Chairman of the Company's Board of Directors; he remains a member of the Nominating and Corporate Governance Committee.

Financial Results

Cash Position

As of March 31, 2025, Gyre Therapeutics held \$15.0 million in cash and cash equivalents, \$14.8 million in short-term bank deposits, and \$21.4 million in long-term certificates of deposit, totaling \$51.3 million.

Gyre believes that its existing cash resources, combined with anticipated cash flow from commercial operations, will be sufficient to fund its operating and capital requirements for the next 12 months.

Financial Results for the Three Months Ended March 31, 2025

- **Revenues:** Revenues for the three months ended March 31, 2025, were \$22.1 million, compared to \$27.2 million in the same period last year. The \$5.1 million decrease was primarily due to a \$5.2 million decline in ETUARY[®] sales. This was anticipated, as early 2024 revenues were elevated by a one-time marketing campaign focused on rural expansion, which we did not repeat in 2025. The shift in marketing resources was deliberate, with funds reallocated to support the upcoming launches of Nintedanib and avatrombopag. Additionally, weaker economic conditions in China and increased competition in the IPF treatment market also contributed to the decline. Revenues from generic products decreased by \$0.2 million, partially offset by \$0.3 million in initial revenue from the March 2025 launch of avatrombopag.

Gyre anticipates revenue growth over the remainder of the year, driven by the planned commercial launch of Nintedanib in May 2025 and the continued expansion of avatrombopag. Based on current performance and market outlook, the company is reaffirming its full-year 2025 revenue guidance of \$118 to \$128 million¹, compared to \$105.8 million in 2024.

- **Cost of Revenues:** For the three months ended March 31, 2025, cost of revenues was \$0.9 million, compared to \$1.0 million for the same period in 2024. The \$0.1 million decrease was in line with the corresponding decline in sales.
- **Selling & Marketing Expense:** For the three months ended March 31, 2025, selling and marketing expense was \$10.8 million, compared to \$12.5 million for the same period in 2024. The \$1.7 million decrease was primarily driven by a reduction in commission costs due to the decrease of sales.
- **Research & Development Expense:** For the three months ended March 31, 2025, research and development expense was \$3.1 million, compared to \$2.2 million for the same period in 2024. The increase was primarily attributable to Gyre Pharmaceuticals and was driven by a \$1.3 million increase in clinical research expenses, primarily related to data analysis costs for F351. This increase was partially offset by a \$0.2 million decrease in materials and utilities and a \$0.1 million reduction in staff costs, primarily due to reduction of headcounts. The overall increase was further offset by a \$0.1 million decrease from Gyre Therapeutics, due to the reduction in contract services.

[1] 2025 revenue guidance assumes a constant foreign currency exchange rate and no significant economic disruption or downturn.

- **General & Administrative Expense:** For the three months ended March 31, 2025, general and administrative expense

was \$5.0 million, compared to \$3.4 million for the same period in 2024. The increase was primarily driven by a \$0.6 million increase in functional and administrative department's personnel and stock compensation costs, a \$0.8 million increase in miscellaneous expense, mainly due to the increase in the annual meeting expense.

- **Income from operations:** For the three months ended March 31, 2025, income from operations was \$2.3 million, compared to \$8.1 million for the same period in 2024. The decrease was primarily due to a reduction in revenue.
- **Net Income:** For the three months ended March 31, 2025, net income was \$3.7 million, compared to \$9.9 million in net income for the same period in 2024. The decrease was primarily attributable to lower income from operations and unfavorable change in fair value of warrant liabilities.
- **Non-GAAP Adjusted Net Income:** For the three months ended March 31, 2025, non-GAAP adjusted net income was \$2.9 million, compared to \$8.2 million non-GAAP adjusted net income for the same period in 2024. The decrease was primarily driven by the decline in revenue of \$5.1 million and increase in operating expenses of \$0.2 million.

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 F351 (Hydronidone)

F351 is a structural analogue of the approved anti-fibrotic IPF drug pirfenidone and has been shown to inhibit in vitro both p38γ kinase activity and TGF-β1-induced excessive collagen synthesis in hepatic stellate cells ("HSCs"), which are recognized as critical event in the development and progression of fibrosis in the liver. This is further supported by its anti-proliferative effects on the HSCs in the liver. In vitro anti-fibrotic effects of F351 were also confirmed in several established in vivo models of liver fibrosis such as CCl4-induced liver fibrosis mouse model, DMN-induced liver fibrosis rat model, and HSA-induced liver rat model, as well as mouse model of MASH fibrosis (CCl4+Western High Fat Diet).

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 is evaluating F351 in a Phase 3 clinical trial in CHB-associated liver fibrosis in the PRC, which is expected to report topline data by Q2 2025. F351 received Breakthrough Therapy designation by the NMPA Center for Drug Evaluation in March 2021. 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 in Gyre Pharmaceuticals (also known as Beijing Continent Pharmaceuticals Co., Ltd.).

About Gyre Therapeutics

Gyre Therapeutics is a biopharmaceutical company headquartered in San Diego, CA, with a primary focus on the development and commercialization of F351 (Hydronidone) for the treatment of MASH-associated fibrosis in the U.S. Gyre's development strategy for F351 in MASH is based on the company's experience in MASH rodent model mechanistic studies and CHB-induced liver fibrosis clinical studies. Gyre is also advancing a diverse pipeline in the PRC through its indirect controlling interest in Gyre Pharmaceuticals, including ETUARY therapeutic expansions, 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 topline results of the Phase 3 trial of Hydronidone in CHB-associated liver fibrosis, timing of initiation of Gyre's Phase 2 trial in the U.S. for F351 for the treatment of MASH-associated liver fibrosis, initiation of Gyre

Pharmaceuticals' clinical trial evaluating pirfenidone capsules in oncology-related pulmonary complications, timing of completion of Gyre's Phase 2 clinical trial in the PRC of F573 for ALF/ACLF, initiation of Phase 1 trial of F230 for the treatment of PAH and IND submission of F528 in COPD, the expectations regarding commercial launch of nintedanib, 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:

Stephen Jasper

stephen@gilmartinir.com

Gyre Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2025	2024
Revenues	\$ 22,058	\$ 27,172
Operating expenses:		
Cost of revenues	894	979
Selling and marketing	10,841	12,542
Research and development	3,095	2,182
General and administrative	4,955	3,398
Total operating expenses	19,785	19,101
Income from operations	2,273	8,071
Other income, net:		
Other income, net	107	122
Change in fair value of warrant liability	2,255	4,288
Income before income taxes	4,635	12,481
Provision for income taxes	(901)	(2,546)
Net income	3,734	9,935
Net income attributable to noncontrolling interest	1,036	2,403
Net income attributable to common stockholders	\$ 2,698	\$ 7,532
Net income per share attributable to common stockholders:		
Basic	\$ 0.03	\$ 0.09
Diluted	\$ 0.00	\$ 0.03

Weighted average shares used in calculating net income per share attributable to common stockholders:

Basic	86,420,530	83,265,879
Diluted	101,970,672	102,594,197

Gyre Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,045	\$ 11,813
Short-term bank deposits	14,846	14,858
Notes receivable	2,138	4,373
Accounts receivables, net	20,150	19,589
Other receivables from GNI	230	230
Inventories, net	7,878	6,337
Receivable from GCBP	—	4,961
Prepaid assets and other current assets	8,161	2,625
Total current assets	68,448	64,786
Property and equipment, net	23,518	23,880
Intangible assets, net	5,083	273
Deferred tax assets	5,818	5,619
Long-term certificates of deposit	21,367	24,568
Other assets, noncurrent	5,556	6,280
Total assets	\$ 129,790	\$ 125,406
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 122	\$ 108
Contract liabilities	28	61
Due to related parties	228	227
Accrued expenses and other current liabilities	17,239	10,615
Income tax payable	569	2,831
Operating lease liabilities, current	805	713
CVR derivative liability	—	4,961
Total current liabilities	18,991	19,516
Operating lease liabilities, noncurrent	780	885
Deferred government grants	905	928
Warrant liability, noncurrent	3,413	5,668
Other noncurrent liabilities	1,399	7
Total liabilities	25,488	27,004
Stockholders' equity:		
Common stock, \$0.001 par value, 400,000,000 shares authorized; 87,636,209 shares and 86,307,544 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	87	86
Additional paid-in capital	138,179	136,185

Statutory reserve	3,098	3,098
Accumulated deficit	(70,755)	(73,453)
Accumulated other comprehensive loss	(2,486)	(2,597)
Total Gyre stockholders' equity	68,123	63,319
Noncontrolling interest	36,179	35,083
Total equity	104,302	98,402
Total liabilities and stockholders' equity	\$ 129,790	\$ 125,406

Gyre Therapeutics, Inc.

Reconciliation of GAAP to Non-GAAP Financial Measures

(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2025	2024
Net income	\$ 3,734	\$ 9,935
Gain from change in fair value of warrant liability ⁽¹⁾	(2,255)	(4,288)
Stock-based compensation	507	11
Provision for income taxes	901	2,546
Non-GAAP adjusted net income	\$ 2,887	\$ 8,204

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