Gyre Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

March 17, 2025

Data from pivotal Phase 3 trial in CHB-associated liver fibrosis expected in Q2 2025

Commercial launch in the PRC of generic nintedanib for the treatment of IPF and avatrombopag maleate tablets for the treatment of CLD-associated thrombocytopenia expected in 2025

Initiation of U.S. Phase 2 trial of F351 in MASH-associated liver fibrosis expected in 2025

Full year 2025 total revenue guidance of $118 to $128 million

SAN DIEGO, March 17, 2025 (GLOBE NEWSWIRE) -- Gyre Therapeutics ("Gyre") (Nasdaq: GYRE), a self-sustainable, commercial-stage biotechnology company with clinical development programs focusing on organ fibrosis, today announced financial results for the fourth quarter and full year ended December 31, 2024 and provided a business update.

"2025 is shaping up to be a pivotal year for Gyre across both our commercial-stage and clinical-stage portfolios. We plan to expand and enhance our commercial product offerings through the additions of nintedanib for IPF, SSc-ILD and PF-ILD, as well as avatrombopag for CLD-associated thrombocytopenia and chronic idiopathic thrombocytopenia ("ITP"). Given our proven track record and extensive sales and marketing platform, we are confident in our ability to successfully launch and expand these two products in the PRC," said Han Ying, Ph.D., Chief Executive Officer of Gyre Therapeutics. "In parallel, we expect to share topline data from our pivotal Phase 3 trial in CHB-associated liver fibrosis in the second quarter of 2025, which will help inform our U.S. Phase 2 proof-of-concept trial of F351 in MASH-associated liver fibrosis."

Full Year 2024 Business Highlights and Upcoming Milestones

Commercial-Stage Updates

- ETUARY (Pirfenidone) sales update: For the year ended December 31, 2024, Gyre Pharmaceuticals generated $105.0 million primarily in sales of ETUARY.
- Nintedanib: In May 2024, Gyre Pharmaceuticals executed a comprehensive agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. to obtain the drug registration certificate for and became the marketing authorization holder of nintedanib, the other product approved for the treatment of treatment of idiopathic pulmonary fibrosis ("IPF"). In addition, it has also been approved for the treatment of SSc-ILD and PF-ILD. Gyre Pharmaceuticals plans to initiate commercialization of the nintedanib product in the PRC in 2025.
- Avatrombopag: In June 2024, Gyre Pharmaceuticals received approval from China's National Medical Products Administration ("NMPA") for avatrombopag maleate tablets for the treatment of thrombocytopenia associated with chronic liver disease ("CLD") and chronic idiopathic thrombocytopenia ("ITP") in adult patients undergoing elective diagnostics procedures or therapy. Gyre Pharmaceuticals plans to begin commercialization of avatrombopag in 2025.

Pipeline Development Updates

F351 (Hydronidone):

- All patients completed 52-week pivotal Phase 3 trial in chronic hepatitis B ("CHB")-associated liver fibrosis in the PRC. In October 2024, Gyre Pharmaceuticals announced the last patient completed the 52-week pivotal Phase 3 trial. The trial is evaluating 248 patients with CHB-associated liver fibrosis in the PRC with a primary endpoint of the reduction of the liver fibrosis score (Ishak Scoring System) by at least one stage after taking F351 in combination with entecavir. Gyre expects to report topline data in the second quarter of 2025.
- Plans to initiate a Phase 2 clinical trial in metabolic dysfunction-associated steatohepatitis ("MASH")-associated liver fibrosis in 2025. Pending the results from the pivotal Phase 3 trial in CHB-associated liver fibrosis, Gyre intends to initiate a Phase 2 proof-of-concept trial in the U.S. to evaluate F351 for the treatment of MASH-associated liver fibrosis in 2025.

F573:

- F573 is a caspase inhibitor and a 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 as a treatment 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 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 plans to submit an IND application in 2026.

Corporate Updates

- In January 2025, appointed Ping Zhang to the Company's Board of Directors as the lead independent director and member of the Nominating Committee. In addition, Ying Luo, Ph.D., resigned as Chairman and member of the Board of Directors of Gyre and Gyre Pharmaceuticals, Gyre's majority indirectly owned subsidiary in the People's Republic of China ("PRC"), to focus on other responsibilities at GNI Group Ltd. Songjiang Ma has been appointed Chairman of the Board of Directors of Gyre Pharmaceuticals.

Financial Results

Cash Position

As of December 31, 2024, Gyre had cash, cash equivalents, short-term and long-term bank deposits of $51.2 million.

Financial Results for the Three Months Ended December 31, 2024

- Revenues: Revenues for the three months ended December 31, 2024 were $27.9 million, compared to $27.1 million for the same period in 2023. The $0.8 million increase was primarily driven by a $1.0 million increase in ETUARY's revenue and a $0.2 million decrease in generic drug revenue. The growth in ETUARY sales was attributed to the active expansion of the IPF treatment market, increased market penetration, and a stronger focus on ETUARY sales. To support future revenue growth, Gyre Pharmaceuticals plans to commercially launch two new products, nintedanib and avatrombopag, in 2025, which will be supported by its extensive sales and marketing platform in the PRC.
- Cost of Revenues: For the three months ended December 31, 2024, cost of revenues was $1.2 million, compared to $1.3 million for the same period in 2023. The $0.1 million decrease was primarily driven by a $0.2 million decrease in generic drug cost due to the decrease in sales and a $0.1 million decrease in factory stoppage loss due to factory renovation in 2023, offset by a $0.2 million increase due to the increase of ETUARY's cost due to the increase in sales.
- Selling and Marketing Expense: For the three months ended December 31, 2024, selling and marketing expense was $16.9 million, compared to $16.5 million for the same period in 2023. The increase was primarily driven by a $2.1 million increase in promotion expense and conference expenses, offset by a $1.1 million decrease in selling and marketing payroll costs, a $0.3 million decrease in stock-based compensation expense and a $0.3 million decrease in travel and miscellaneous expenses.
- Research and Development Expense: For the three months ended December 31, 2024, research and development expense was $3.7 million, compared to $4.6 million for the same period in 2023. The decrease was primarily driven by a $0.5 million decrease in pre-clinical and clinical research expenses and a $0.5 million decrease in stock-based compensation expense, offset by a $0.1 million increase in miscellaneous expense.
- General and Administrative Expense: For the three months ended December 31, 2024, general and administrative expense was $5.5 million, compared to $10.1 million for the same period in 2023. The decrease was primarily driven by a $5.8 million decrease in stock-based compensation cost, offset by a $0.8 million increase in the functional and administrative department's personnel cost and a $0.4 million increase in professional expense, including legal and consulting fees.
- Income (Loss) from Operations: For the three months ended December 31, 2024, income from operations was $0.7 million, compared to $91.1 million loss from operation for the same period in 2023. The increase in income from operations was driven primarily by acquired in-process research and development expense recognized in the fourth quarter of 2023 and there was no such expense in the same period in 2024.

- Net Income (Loss): For the three months ended December 31, 2024, net income was $0.6 million, compared to $101.0 million net loss for the same period in 2023.
- Non-GAAP Adjusted Net Income: For the three months ended December 31, 2024, non-GAAP adjusted net income was $1.1 million, compared to $2.1 million for the same period in 2023. The decrease was primarily driven by the costs of being a public company for three months in 2024, as compared to two months in 2023.

Financial Results for the Full Year Ended December 31, 2024

- Revenues: Revenues for the full year ended December 31, 2024 were $ 105.8 million, compared to $113.5 million for the same period in 2023. The $7.7 million decrease was primarily driven by a $7.1 million decrease in ETUARY's revenue and a $0.6 million decrease in generic drug revenue as a result of decreased sales volumes. The decrease in ETUARY and generic drug sales volumes was due to fluctuations in the Chinese economy that significantly affected demand for anti-fibrosis drugs and decreasing healthcare spending generally. To support future revenue growth, Gyre plans to commercially launch two new products, nintedanib and avatrombopag, in 2025, which will be supported by Gyre Pharmaceuticals' extensive sales and marketing platform across the PRC.
- Cost of Revenues: For the full year ended December 31, 2024, cost of revenues was $3.9 million, compared to $4.6 million for the same period in 2023. The $0.7 million decrease was primarily driven by a $0.5 million factory stoppage loss due to factory renovation in 2023, which did not occur in 2024, and a $0.2 million decrease due to decreased sales volumes.
- Selling and Marketing Expense: For the full year ended December 31, 2024, selling and marketing expense was $57.5 million, compared to $61.2 million for the same period in 2023. The decrease was primarily driven by a $2.4 million decrease in conference costs and promotion expense due to decreased sales activities, a $0.9 million decrease in selling and marketing payroll costs due to the decrease of sales of ETUARY in 2024, a $0.3 million decrease in share base compensation expense, and a $0.1 million decrease in miscellaneous expenses.
- Research and Development Expense: For the full year ended December 31, 2024, research and development expense was $12.0 million, compared to $13.8 million for the same period in 2023. The decrease was primarily from Gyre Pharmaceuticals, and was driven by a $0.3 million decrease in materials and utilities, a $1.3 million decrease in pre-clinical research expense due to several research and development projects advancing to the clinical trials stage or reaching the application phase in 2024, and a $0.4 million decrease in staff cost due to reduced headcount, and a $0.5 million decrease in stock-based compensation, related to options being fully vested in 2023, which did not occur in 2024, This overall decrease was partially offset by a 0.7 million increase in general research and development expense from Gyre Therapeutics due to increased consulting fees.
- General and Administrative Expense: For the full year ended December 31, 2024, general and administrative expense was $16.1 million, compared to $14.7 million for the same period in 2023. The increase was primarily driven by costs associated with being a public company, including a $1.9 million increase in professional expense, a $2.1 million increase in miscellaneous expenses and a $3.0 million increase in the functional and administrative department's personnel cost, offset by a $5.6 million decrease in stock-based compensation cost.
- Income (loss) from Operations: For the full year ended December 31, 2024, income from operations was $16.2 million, compared to $67.2 million loss for the same period in 2023. The increase in income from operations was driven primarily by acquired in-process research and development expense recognized in 2023 and there was no such expense in the same period in 2024.
- Net Income (loss): For the full year ended December 31, 2024, net income was $17.9 million, compared to $85.5 million net loss for the same period in 2023.
- Non-GAAP Adjusted Net Income: For the full year ended December 31, 2024, non-GAAP adjusted net income was $16.9 million, compared to $25.4 million for the same period in 2023. The decrease was primarily driven by a $7.7 million decline in revenue and a $1.1 million increase in operating expenses. Despite these changes, the gross profit margin remained consistent.

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 nintedanib and avatrombopag and sales of ETUARY.

Guidance Range

Total Revenue	$118 to $128 million

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 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 Hydronidone (F351)

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 $105.0 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 readout 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, 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 timing of topline data from Gyre Pharmaceuticals' Phase 3 clinical trial evaluating F351 for the treatment of CHB-associated liver fibrosis in the PRC, initiation of Gyre's Phase 2 trial in the U.S. for F351 for the treatment of MASH-associated liver fibrosis, 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 and avatrombopag 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, 2023 filed on March 27, 2024 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.

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Gyre Therapeutics, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Three Months Ended December 31, (Unaudited)		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Revenues	$ 27,872	$ 27,148	$ 105,757	$ 113,450
Operating expenses:				
Cost of revenues	1,177	1,250	3,884	4,636
Selling and marketing	16,856	16,464	57,511	61,159
Research and development	3,712	4,568	12,024	13,780
General and administrative	5,464	10,055	16,109	14,662
Acquired in-process research and development	—	83,104	—	83,104
Divestiture losses	—	2,711	—	2,711
Loss on disposal of property and equipment	(2)	102	66	628
Total operating expenses	27,207	118,254	89,594	180,680
Income (loss) from operations	665	(91,106)	16,163	(67,230)
Other income (expense), net:				
Interest income, net	346	326	1,547	1,044
Other expense, net	(433)	(237)	(1,659)	(1,518)
Change in fair value of warrant liability	194	(9,261)	7,167	(9,261)
Income (loss) before income taxes	772	(100,278)	23,218	(76,965)
Provision for income taxes	(203)	(699)	(5,320)	(8,515)
Net income (loss)	569	(100,977)	17,898	(85,480)
Net income attributable to noncontrolling interest	668	29	5,813	7,453
Net income (loss) attributable to common stockholders	$ (99)	$ (101,006)	$ 12,085	$ (92,933)
Net income (loss) per share attributable to common stockholders:				
Basic	$ (0.00)	$ (1.39)	$ 0.14	$ (1.41)
Diluted	$ (0.00)	$ (1.39)	$ 0.05	$ (1.41)
Weighted average shares used in calculating net income (loss) per share attributable to common stockholders:				
Basic	85,952,413	72,489,183	85,094,948	65,831,675

Diluted	85,952,413	72,489,183	102,293,526	65,831,675

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

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 11,813	$ 33,509
Short-term bank deposits	14,858	—
Notes receivable	4,373	389
Accounts receivable, net	19,589	15,163
Other receivables from GNI	230	1,287
Inventories, net	6,337	4,281
Prepaid assets	1,189	1,547
Receivable from GCBP	4,961	—
Other current assets	1,436	1,045
Total current assets:	64,786	57,221
Property and equipment, net	23,880	23,288
Long-term receivable from GCBP	—	4,722
Intangible assets, net	273	205
Right-of-use assets	1,818	489
Land use rights, net	1,432	1,493
Deferred tax assets	5,619	4,695
Long-term certificates of deposit	24,568	23,431
Other assets, noncurrent	3,030	995
Total assets	$ 125,406	$ 116,539
Liabilities, convertible preferred stock, and equity		
Current liabilities:		
Accounts payable	$ 108	$ 355
Contract liabilities	61	39
Due to related parties	227	1,369
CVR excess closing cash payable	—	1,085
Accrued expenses and other current liabilities	10,615	11,935
Income tax payable	2,831	5,054
Operating lease liabilities, current	713	210
CVR derivative liability	4,961	—
Total current liabilities:	19,516	20,047
Operating lease liabilities, noncurrent	885	199
Deferred government grants	928	213
CVR derivative liability, noncurrent	—	4,722
Warrant liability, noncurrent	5,668	12,835
Other noncurrent liabilities	7	49
Total liabilities	$ 27,004	$ 38,065
Commitments and Contingencies		
Convertible Preferred Stock, $0.001 par value, 5,000,000 shares authorized; nil shares and 13,151 shares issued and outstanding at December 31, 2024 and 2023, respectively	—	64,525
Equity:		

Common stock, $0.001 par value, 400,000,000 shares authorized; 86,307,544 shares and 76,595,616 shares issued and outstanding at December 31, 2024 and 2023, respectively	86	77
Additional paid-in capital	136,185	68,179
Statutory reserve	3,098	3,098
Accumulated deficit	(73,453)	(85,538)
Accumulated other comprehensive loss	(2,597)	(1,644)
Total Gyre stockholders' equity (deficit)	63,319	(15,828)
Noncontrolling interest	35,083	29,777
Total equity	98,402	13,949
Total liabilities, convertible preferred stock, and equity	$ 125,406	$ 116,539

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

	Three Months Ended December 31,		Years Ended December 31,	
	2024	2023	2024	2023
Net income (loss)	$ 569	$ (100,977)	$ 17,898	$ (85,480)
Acquired in-process research and development [1]	—	83,104	—	83,104
(Gain) loss from change in fair value of warrants [2]	(194)	9,261	(7,167)	9,261
Stock-based compensation	567	7,281	831	7,281
Divestiture losses [3]	—	2,711	—	2,711
Provision for income taxes	203	699	5,320	8,515
Non-GAAP adjusted net income	$ 1,145	$ 2,079	$ 16,882	$ 25,392

(1) Reflects adjustments for a reverse asset acquisition with CPI as the accounting acquirer and Catalyst as the legal acquirer.
(2) Reflects adjustments for fair value of warrants based on the Black-Sholes option pricing model.
(3) Reflects adjustments loss from the divestiture of all assets other than 56.0% indirect ownership interest in Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals).