UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 13, 2024

Gyre Therapeutics, Inc. (Exact name of registrant as specified in its charter)

Delaware	000-51173	56-2020050
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
12770 High Bluff Drive Suite 150		
San Diego, CA		92130
(Address of principal executive office	res)	(Zip Code)
Registrant	s telephone number, including area code: (858)	567-7770
(Forme	N/A r name or former address, if changed since last i	eport)
Check the appropriate box below if the Form 8-K filing following provisions (see General Instruction A.2. below in the following provisions (see General Instruction A.2.)		obligation of the registrant under any of the
☐ Written communications pursuant to Rule 425	under the Securities Act (17 CFR 230.425)	
☐ Soliciting material pursuant to Rule 14a-12 un	der the Exchange Act (17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant	to Rule 14d-2(b) under the Exchange Act (17 C	FR 240.14d-2(b))
☐ Pre-commencement communications pursuant	to Rule 13e-4(c) under the Exchange Act (17 C	FR 240.13e-4(c))
Securities registered pursuant to Section 12(b) of the A	ct:	
		Name of each exchange on which
Title of each class	Trading Symbol(s)	registered
Common Stock	GYRE	The Nasdaq Capital Market
ndicate by check mark whether the registrant is an emchapter) or Rule 12b-2 of the Securities Exchange Act		of the Securities Act of 1933 (§230.405 of this
Emerging growth company □		
f an emerging growth company, indicate by check ma or revised financial accounting standards provided pur		nded transition period for complying with any new

Item 2.02. Results of Operations and Financial Condition.

On November 13 ,2024, Gyre Therapeutics, Inc. issued a press release announcing its financial results for the three and nine months ended September 30, 2024 and other matters described. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

As provided in General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 incorporated herein shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall such information or Exhibit 99.1 be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits. The following exhibits are being furnished herewith:

Exhibit Number	Exhibit Title or Description	
99.1	Press Release, dated November 13, 2024	
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GYRE THERAPEUTICS, INC.

Date: **November 13, 2024** By: /s/ Han Ying, Ph.D.

Name: Han Ying, Ph.D.
Title: Chief Executive Officer



Gyre Therapeutics Reports Third Quarter 2024 and Year-To-Date Financial Results and Provides Business Update

Last patient completed pivotal Phase 3 trial in CHB-associated liver fibrosis in the PRC with data expected in Q1 2025

On track to initiate U.S. Phase 2 trial of F351 in MASH-associated liver fibrosis in 2025

Commercial launch of avatrombopag maleate tablets expected by the first half of 2025

Commercial launch of nintedanib expected in 2025

Cash and cash equivalents totaled \$15.9 million as of September 30, 2024

SAN DIEGO, Nov. 13, 2024 (GLOBE NEWSWIRE) -- Gyre Therapeutics ("Gyre") (Nasdaq: GYRE), a self-sustainable, commercial-stage biotechnology company with clinical development programs focusing on a variety of chronic organ diseases, today announced financial results for the third quarter and nine months ended September 30, 2024, and provided a business update.

"Our team has made great progress over the last several months and recently achieved a significant milestone with the final patient completing 52 weeks of study in our pivotal Phase 3 trial for F351 in CHB-associated liver fibrosis. We are encouraged by F351's potential as a novel treatment for this fibrotic disease and are excited to share topline results in the first quarter 2025," said Han Ying, Ph.D., Chief Executive Officer of Gyre Therapeutics. "With several upcoming milestones in 2025, including the commercial launch of two new products in the PRC as well as the anticipated initiation of U.S. Phase 2 trial of F351 in MASH-associated liver fibrosis, we remain confident in Gyre's ability to deliver in the clinic and the commercial market for patients in need."

Third Quarter 2024 Business Highlights and Upcoming Milestones

Commercial-Stage Updates

- **ETUARY (Pirfenidone) sales update:** For the quarter ended September 30, 2024, Gyre Pharmaceuticals, Gyre's majority indirectly owned subsidiary in the People's Republic of China ("PRC"), generated \$25.3 million in sales of ETUARY.
- 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") in adult patients undergoing elective diagnostics procedures or therapy. This approval expands Gyre's rare disease product lines and provides a treatment option for a common and potentially life-threatening hematologic complication in patients with CLD. Gyre anticipates launching avatrombopag in the PRC in the first half of 2025 and plans to leverage its existing extensive sales and marketing platform.

• **Nintedanib:** Gyre Pharmaceuticals is planning to start commercializing nintedanib, a small-molecule drug for the treatment of idiopathic pulmonary fibrosis ("IPF"), which was acquired from Jiangsu Wangao Pharmaceuticals Co., Ltd., in the PRC in 2025. Nintedanib is the other product approved for the treatment of IPF, which is currently approved globally for the treatment of IPF. Nintedanib is expected to provide patients more choices and benefits, and further enhance Gyre Pharmaceuticals' leading position in the pulmonary fibrosis market.

Clinical Development Updates

F351 (Hydronidone):

- All patients completed 52-week Phase 3 trial evaluating F351 for the treatment of Chronic Hepatitis B ("CHB")-associated liver fibrosis. In October 2024, Gyre Pharmaceuticals announced the final patient had completed the 52-week pivotal Phase 3 trial in patients with CHB-associated liver fibrosis in the PRC. The trial evaluated 248 patients 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 Pharmaceuticals remains on track to report topline data in the first 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 PRC Phase 3 trial in CHB-associated liver fibrosis, Gyre intends to initiate a Phase 2 proof-of-concept clinical trial to evaluate F351 for the treatment of MASH-associated liver fibrosis associated in 2025.

F573:

• Ongoing Phase 2 trial in the PRC. Gyre Pharmaceuticals is conducting a randomized, double-blind, placebo-controlled Phase 2 clinical trial in the PRC to assess the safety and efficacy of F573, a caspase inhibitor for injection in the treatment of acute/acute on-chronic liver failure.

Preclinical Development Updates

- **F230:** F230 is a selective endothelin receptor agonist for the treatment of pulmonary arterial hypertension ("PAH"). In May 2024, Gyre Pharmaceuticals received NMPA approval for its Investigational New Drug ("IND") application to evaluate for F230 tablets for the treatment of PAH and expects to initiate a Phase 1 trial in 2025.
- **F528:** F528 is a novel anti-inflammation agent that targets the inhibition of multiple inflammatory cytokines and has the potential to modify the progression of chronic obstructive pulmonary disease ("COPD") with low toxicity in vivo. Gyre Pharmaceuticals is evaluating F528 in preclinical studies as a potential first-line therapy for the treatment of COPD.

Corporate Updates

• In August 2024, Gyre announced the appointment of David M. Epstein, Ph.D., to its Board of Directors. Dr. Epstein has extensive global experience in biotech companies across the United States and Asia. Dr. Epstein is a co-founder of PairX Bio Pte. Ltd., where he currently serves as director, President and Chief Executive Officer. Dr. Epstein co-founded and served as President and Chief Executive Officer of Black Diamond Therapeutics, leading the company through its

January 2020 IPO. Prior to Black Diamond, Dr. Epstein was Vice Dean, Innovation & Entrepreneurship and Associate Professor at Duke-NUS Medical School in Singapore.

Financial Results

Cash Position

As of September 30, 2024, Gyre had cash and cash equivalents of \$15.9 million. Based on current plans, Gyre anticipates that its cash resources as of September 30, 2024 will enable it to fund operations through at least 12 months following the issuance of the condensed financial statements.

Financial Results for the Three Months Ended September 30, 2024

- Revenues: Revenues for the three months ended September 30, 2024 were \$25.5 million, compared to \$32.0 million for the same period in 2023. The \$6.5 million decrease was primarily driven by a \$6.4 million decrease in anti-fibrosis drug sales and a \$0.1 million decrease in generic drug sales due to fluctuations in the Chinese economy significantly affecting demand for anti-fibrosis drugs and decreasing healthcare spending generally. To support future revenue growth, we plan to commercially launch new products, such as nintedanib and avatrombopag, in early 2025, which will be supported by our extensive sales and marketing platform across the PRC.
- Cost of Revenues: For the three months ended September 30, 2024, cost of revenues was \$1.0 million, compared to \$1.2 million for the same period in 2023. The decrease was primarily driven by a \$0.1 million factory stoppage loss due to factory renovation in 2023 and a \$0.1 million decrease in sales quantity.
- Selling & Marketing Expense: For the three months ended September 30, 2024, selling and marketing expense was \$13.7 million, compared to \$13.9 million for the same period in 2023. The decrease was primarily driven by a \$0.9 million decrease in conference costs due to a decrease in conference activity, a \$0.9 million decrease in staff cost as well as a \$0.1 million decrease in other expenses, partially offset by a \$1.5 million increase in promotional expenses and a \$0.2 million increase in travel expense.
- **R&D Expense:** For the three months ended September 30, 2024, research and development expense was \$2.8 million, compared to \$3.0 million for the same period in 2023. The decrease was primarily from Gyre Pharmaceuticals, and was driven by a \$0.5 million decrease in pre-clinical research expense and a \$0.2 million decrease in staff cost due to the decrease in headcount in the research and development department, partially offset by a \$0.5 million increase in our clinical trial expense and clinical trial expense from Gyre Pharmaceuticals.
- **G&A Expense:** For the three months ended September 30, 2024, general and administrative expense was \$3.8 million, compared to \$1.2 million for the same period in 2023. The increase was primarily driven by costs associated with being a public company, including a \$0.9 million increase in functional and administrative department's personnel and stock compensation costs, a \$0.6 million increase in miscellaneous expenses, and a \$1.2 million increase in professional expense.
- **Income from operations:** For the three months ended September 30, 2024, income from operations was \$4.2 million, compared to \$12.8 million for the same period in 2023.

• **Net Income:** For the three months ended September 30, 2024, net income was \$2.9 million, compared to \$7.5 million in net income for the same period in 2023.

Financial Results for the Nine Months Ended September 30, 2024

- **Revenues:** For the nine months ended September 30, 2024, revenue was \$77.9 million, compared to \$86.3 million for the same period in 2023. The \$8.4 million decrease was primarily driven by a \$8.0 million decrease in anti-fibrosis drug sales and a \$0.4 million decrease in generic drugs due to the same factors mentioned above. If approved by the NMPA for commercial use, we expect that F351 for the treatment of CHB-associated liver fibrosis in the PRC will support revenue growth in the future, which will be supported by our extensive sales and marketing platform across the PRC.
- Cost of Revenues: For the nine months ended September 30, 2024, cost of revenues was \$2.7 million, compared to \$3.4 million for the same period in 2023. The decrease was primarily driven by a \$0.4 million factory stoppage loss due to factory renovation in 2023, and a \$0.4 million decrease in generic drug cost due to the decrease of sales, offset by a \$0.1 million increase of the staff cost and new equipment depreciation.
- Selling & Marketing Expense: For the nine months ended September 30, 2024, selling and marketing expense was \$40.7 million, compared to \$44.7 million for the same period in 2023. The decrease was primarily driven by a \$5.3 million decrease in conference costs due to a decrease in conference activity, partially offset by a \$1.0 million increase in promotional expenses, a \$0.2 million increase in staff costs due to an increase in staff headcount, and a \$0.1 million increase in other expenses.
- **R&D Expense:** For the nine months ended September 30, 2024, research and development expense was \$8.3 million, compared to \$9.2 million for the same period in 2023. The \$1.5 million decrease from Gyre Pharmaceuticals was primarily driven by a \$1.0 million decrease in pre-clinical research expenses, a \$0.3 million decrease in materials and utilities, and a \$0.2 million decrease in staff cost due to the decrease in headcount in the research and development department. These decreases were offset by a \$0.6 million increase in our clinical trial costs and research and development consulting costs.
- **G&A Expense:** For the nine months ended September 30, 2024, general and administrative expense was \$10.6 million, compared to \$4.6 million for the same period in 2023. The increase was primarily driven by costs associated with being a public company, including a \$2.9 million increase in functional and administrative department's personnel and stock compensation costs, a \$1.8 million increase in miscellaneous expenses, and a \$1.3 million increase in professional expense.
- **Income from operations:** For the nine months ended September 30, 2024, income from operations was \$15.6 million, compared to \$24.4 million for the same period in 2023.
- **Net Income:** For the nine months ended September 30, 2024, net income was \$17.3 million, compared to \$15.5 million for the same period in 2023.

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 CCI4-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 (CCI4+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 (2023 net sales of \$112.1 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 early 2025. F351 received Breakthrough Therapy designation by the NMPA Center for Drug Evaluation in March 2021. Gyre Pharmaceuticals is also developing treatments for 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 CHBassociated liver fibrosis in the PRC, the U.S. IND submission of F351 in MASH-associated liver fibrosis, initiation of Gyre's Phase 2 trial and comprehensive Phase 2/3 clinical program in the U.S. for F351, timing of topline results from Phase 2 clinical trial in the PRC of F573 for acute/acute on-chronic liver failure and initiation of Phase 1 trial of F230 for the treatment of PAH, the expectations regarding generic drug nintedanib, the anticipated commercial launch of 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.

For Investors:

Stephen Jasper

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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,				
		2024		2023		2024		2023
Revenues	\$	25,488	\$	32,042	\$	77,885	\$	86,302
Operating expenses:								
Cost of revenues		958		1,184		2,707		3,386
Selling and marketing		13,699		13,928		40,655		44,695
Research and development		2,775		3,009		8,312		9,212
General and administrative		3,823		1,157		10,645		4,607
Total operating expenses		21,255		19,278		62,319		61,900
Income from operations		4,233		12,764		15,566		24,402
Other income (expense), net:								
Interest income, net		523		283		1,201		718
Other expense, net		(598)		(1,333)		(1,226)		(1,281)
Change in fair value of warrant liability		(228)		_		6,973		_
Loss on disposal of assets, net		_		(526)		(68)		(526)
Income before income taxes		3,930		11,188		22,446		23,313
Provision for income taxes		(1,074)		(3,678)		(5,117)		(7,816)
Net income		2,856		7,510		17,329		15,497
Net income attributable to noncontrolling interest		1,732		3,534		5,145		7,424
Net income attributable to common stockholders	\$	1,124	\$	3,976	\$	12,184	\$	8,073
Net income per share attributable to common stockholders:			_		_		_	
Basic	\$	0.01	\$	0.06	\$	0.14	\$	0.13
Diluted	\$	0.01	\$	0.05	\$	0.05	\$	0.10
Weighted average shares used in calculating net income per share attributable to common stockholders:								
Basic		85,643,646		63,588,119		84,807,041		63,588,119
Diluted	1	02,640,373		78,904,324		102,505,585		78,907,695

Gyre Therapeutics, Inc. Condensed Consolidated Balance Sheets

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

	September 30, 2024		December 31, 2023		
	(L	Jnaudited)			
Assets					
Current assets:					
Cash and cash equivalents	\$	15,866	\$	33,509	
Short-term bank deposits		9,226		_	
Accounts and note receivables, net		19,487		15,552	
Other receivables from GNI		1,287		1,287	
Inventories, net		6,379		4,281	
Prepaid assets		1,051		1,547	
Other current assets		1,513		1,045	
Total current assets		54,809		57,221	
Property and equipment, net		24,442		23,288	
Long-term receivable from GCBP		4,900		4,722	
Intangible assets, net		184		205	
Right-of-use assets		1,984		489	
Land use rights, net		1,479		1,493	
Deferred tax assets		5,161		4,695	
Long-term certificates of deposit		29,515		23,431	
Other assets, noncurrent		2,766		995	
Total assets	\$	125,240	\$	116,539	
Liabilities, convertible preferred stock, and equity					
Current liabilities:					
Accounts payable	\$	303	\$	355	
Deferred revenue		36		39	
Due to related parties		1,288		1,369	
CVR excess closing cash payable		_		1,085	
Accrued expenses and other current liabilities		9,553		11,935	
Income tax payable		2,842		5,054	
Operating lease liabilities, current		694		210	
Total current liabilities		14,716		20,047	
Operating lease liabilities, noncurrent		1,101		199	
Deferred government grants		185		213	
CVR derivative liability, noncurrent		4,900		4,722	
Warrant liability, noncurrent		5,862		12,835	
Other noncurrent liabilities		2		49	
Total liabilities		26,766		38,065	
Convertible Preferred Stock, \$0.001 par value, 5,000,000 shares authorized;					
nil shares and 13,151 shares issued and outstanding at September 30, 2024 and December 31, 2023,					
respectively		_		64,525	
Stockholders' equity:					
Common stock, \$0.001 par value, 400,000,000 shares authorized; 85,769,526 shares and 76,595,616 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively		85		77	
Additional paid-in capital		134,296		68,179	
Statutory reserve Accumulated deficit		3,098 (73,354)		3,098	
		(73,354)		(85,538)	
Accumulated other comprehensive loss		(946)	_	(1,644)	
Total Gyre stockholders' equity (deficit)		63,179		(15,828)	
Noncontrolling interest		35,295		29,777	
Total equity		98,474	_	13,949	
Total liabilities, convertible preferred stock, and equity	\$	125,240	\$	116,539	

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

(In thousands) (Unaudited)

	Three Months Ended September 30,				Nine Months Ended September 30,				
		2024		2023		2024		2023	
Net income	\$	2,856	\$	7,510	\$	17,329	\$	15,497	
Loss (gain) from change in fair value of warrants (1)		228		_		(6,973)		_	
Stock-based compensation		237		_		264		_	
Provision for income taxes		1,074		3,678		5,117		7,816	
Non-GAAP adjusted net income	\$	4,395	\$	11,188	\$	15,737	\$	23,313	

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