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): **May 9, 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 offices)	(Zip Code)

Registrant's telephone number, including area code: **(858) 567-7770**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	GYRE	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2024, Gyre Therapeutics, Inc. issued a press release announcing its financial results for the three months ended March 31, 2024. 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 May 9, 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: **May 9, 2024**

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

Exhibit 99.1

Gyre Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Update

Phase 3 clinical trial evaluating F351 for the treatment of CHB-associated liver fibrosis in the PRC remains on track with data anticipated by early 2025

U.S. IND submission to evaluate F351 for the treatment of NASH-associated liver fibrosis expected in late 2024; Phase 2a trial expected to initiate in 2025

Acquired the rights to complementary assets relating to nintedanib through Gyre Pharmaceuticals to improve competitiveness in the PRC

Cash and cash equivalents totaled $29.8 million as of March 31, 2024

SAN DIEGO, May 9, 2024 (GLOBE NEWSWIRE) – Gyre Therapeutics ("Gyre") (Nasdaq: GYRE), a clinical-stage, self-sustainable biotechnology company developing anti-fibrotic therapeutics for a variety of chronic organ diseases, today announced financial results for the first quarter ended March 31, 2024, and provided a business update.

"Supported by sales of our market-leading IPF drug, ETUARY, Gyre is well-positioned to advance multiple pipeline programs addressing organ fibrosis, including our Phase 3 clinical trial of F351 in CHB-associated liver fibrosis in the PRC that is on track to report data by early 2025," said Han Ying, Ph.D., Chief Executive Officer of Gyre Therapeutics. "Pending these results, we plan to initiate a Phase 2a trial in the U.S. for F351 in patients with NASH-associated liver fibrosis with the goal of obtaining early proof-of-concept as a basis of expansion into a more comprehensive Phase 2/3 clinical program. We look forward to continuing to grow the company, accelerate our clinical development programs, and strengthen our research and development efforts to bring medicines for fibrotic and inflammatory conditions to patients in need."

First Quarter 2024 Business Highlights and Upcoming Milestones

ETUARY (Pirfenidone capsules) Sales Update

- **Generated sales of $26.9 million in Q1 of 2024.** For the quarter ended March 31, 2024, Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals), Gyre's majority indirectly owned subsidiary in the People's Republic of China ("PRC"), generated $26.9 million in sales of ETUARY, representing an increase of 10% from the same period in 2023, driven by enhanced marketing and sales initiatives in regions of the PRC where sales were previously lower in the first quarter of fiscal year 2023.

Clinical Development Updates

F351 (Hydronidone):

- **Phase 3 trial evaluating F351 for the treatment of Chronic Hepatitis B ("CHB")-associated liver fibrosis remains on track with topline data expected by early 2025.** In October 2023, Gyre Pharmaceuticals completed enrollment of its Phase 3 trial in patients with CHB-associated liver fibrosis in the PRC. The trial is evaluating 248 patients with a primary endpoint of the reduction of the liver fibrosis score (Ishak Scoring System) by at least one grade after taking F351 in combination with entecavir. Gyre Pharmaceuticals expects to report topline data by early 2025.
- **Plans to initiate a Phase 2a clinical trial in Non-Alcoholic Steatohepatitis ("NASH")-associated liver fibrosis in 2025.** Gyre expects to file an investigational new drug ("IND") application with the U.S. Food and Drug Administration ("FDA") by the end of 2024. Pending FDA review and the results from the PRC Phase 3 trial in CHB-associated liver fibrosis, Gyre intends to initiate a Phase 2a proof-of-concept clinical trial to evaluate F351 for the treatment of NASH-associated liver fibrosis 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 the treatment of acute/acute on-chronic liver failure ("ALF/ACLF").

Preclinical Development Updates

- **F230:** F230 is a selective endothelin receptor agonist. Gyre Pharmaceuticals is evaluating F230 in the PRC for the treatment of pulmonary arterial hypertension ("PAH") in preclinical studies. In March 2024, Gyre Pharmaceuticals submitted an IND application for F230 in the PRC.
- **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 in the PRC.

Corporate Updates

- In May 2024, Gyre Pharmaceuticals executed a comprehensive agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. to acquire the rights to complementary assets and know-how relating to nintedanib, a kinase inhibitor for the treatment of idiopathic pulmonary fibrosis. The agreement is intended to enable Gyre Pharmaceuticals to provide patients more choices and benefits, improve patient access to nintedanib through its PRC nationwide sales network, and further enhance Gyre Pharmaceuticals' competitiveness with respect to treatments for pulmonary fibrosis.

Financial Results

Cash Position

As of March 31, 2024, Gyre had cash and cash equivalents of $29.8 million, compared to $33.5 million as of December 31, 2023. The $3.7 million change was primarily due to a $2.9 million increase from net cash provided by operating activities, a $7.2 million decrease from net cash used in investing activities and a $0.7 million increase from net cash provided by financing activities. Based on current plans, Gyre anticipates that its cash resources as of March 31, 2024 will enable it to fund operations through at least 12 months following the issuance of the condensed consolidated financial statements.

Financial Results for the Quarter Ended March 31, 2024

- **Revenues:** For the three months ended March 31, 2024, revenues were $27.2 million as a result of Gyre's indirect controlling interest in Gyre Pharmaceuticals. For the three months ended March 31, 2023, revenues were $24.9 million. The increase was driven by a $2.2 million increase in sales of pharmaceuticals products as a result of enhanced marketing and sales initiatives in regions of the PRC where sales were previously lower in the first quarter of 2023.

- **Cost of Revenues:** For the three months ended March 31, 2024, cost of revenues was $1.0 million as a result of Gyre's indirect controlling interest in Gyre Pharmaceuticals. For the three months ended March 31, 2023, cost of revenues was $1.1 million. The decrease was primarily driven by a $0.1 million decrease in raw materials mainly due to the stoppage loss that occurred at the Cangzhou factory in 2023.

- **Selling & Marketing Expense:** For the three months ended March 31, 2024, selling and marketing expense was $12.5 million, compared to $12.8 million for the same period in 2023. The decrease was primarily driven by a $1.8 million decrease in conference costs due to a decrease in conference activity, offset by a $1.5 million increase in staff costs due to an increase in staff headcount.

- **R&D Expense:** For the three months ended March 31, 2024, research and development expense was $2.2 million, compared to $2.6 million for the same period in 2023. The decrease was primarily attributable to a $0.5 million decrease in clinical trial expenses and a $0.1 million decrease in pre-clinical research expenses. The latter is a result of several research and development projects advancing to the clinical trials stage or reaching the application phase in 2023. This overall decrease was partially offset by a $0.2 million increase in research and development payroll costs due to increased headcount.

- **G&A Expense:** For the three months ended March 31, 2024, general and administrative expense was $3.4 million, compared to $1.7 million for the same period in 2023. The increase was primarily attributable to a $1.2 million increase in payroll expenses and a $0.6 million increase in miscellaneous expenses mainly related to IT and computer as well as office consumables expenses.

- **Income from Operations:** For the three months ended March 31, 2024, income from operations was $8.1 million, compared to $6.7 million in income from operations for the same period in 2023.

- **Net Income:** For the three months ended March 31, 2024, net income was $9.9 million, compared to $4.2 million in net income for the same period in 2023.
- **Net Income Attributable to Common Stockholders:** For the three months ended March 31, 2024, net income attributable to common stockholders was $7.5 million, compared to $2.2 million in net income attributable to common stockholders 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 CCl_4-induced liver fibrosis mouse model, DMN-induced liver fibrosis rat model, and HSA-induced liver rat model, as well as mouse model of NASH fibrosis (CCl_4+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 National Medical Products Administration's ("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 NASH-associated

fibrosis in the U.S. Gyre's development strategy for F351 in NASH is based on the company's experience in NASH 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, the U.S. IND submission of F351, initiation of Gyre's Phase 2a trial and comprehensive Phase 2/3 clinical program in the U.S. for F351, the expectations regarding generic drug 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, 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
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	2023
Revenues	$ 27,172	$ 24,931
Operating expenses:		
Cost of revenues	979	1,125
Selling and marketing	12,542	12,768
Research and development	2,182	2,635
General and administrative	3,398	1,739
Total operating expenses	19,101	18,267
Income from operations	8,071	6,664
Other income (expense), net:		
Interest income, net	328	184
Other income	109	66
Change in fair value of warrant liability	4,288	—
Other expenses	(315)	(643)
Income before income taxes	12,481	6,271
Provision for income taxes	(2,546)	(2,054)
Net income	9,935	4,217
Net income attributable to noncontrolling interest	2,403	1,973
Net income attributable to common stockholders	$ 7,532	$ 2,244
Net income per share attributable to common stockholders:		
Basic	$ 0.09	$ 0.04
Diluted	$ 0.03	$ 0.03
Weighted average shares used in calculating net income per share attributable to common stockholders:		
Basic	83,265,879	63,588,119
Diluted	102,594,197	78,921,366

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

	March 31, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 29,785	$ 33,509
Short-term bank deposits	7,567	$ —
Accounts and note receivables, net	15,458	15,552
Other receivables from GNI	1,287	1,287
Inventories, net	4,939	4,281
Prepaid assets	1,790	1,547
Other current assets	1,897	1,045
Total current assets	62,723	57,221
Property and equipment, net	23,564	23,288
Long-term receivable from GCBP	4,780	4,722
Intangible assets, net	196	205
Right-of-use assets	359	489
Land use rights, net	1,480	1,493
Deferred tax assets	5,000	4,695
Long-term certificates of deposit	23,106	23,431
Other assets, noncurrent	802	995
Total assets	$ 122,010	$ 116,539
Liabilities, convertible preferred stock, and equity		
Current liabilities:		
Accounts payable	$ 330	$ 355
Deferred revenue	35	39
Due to related parties	1,362	1,369
CVR excess closing cash payable	422	1,085
Accrued expenses and other current liabilities	10,767	11,935
Income tax payable	6,470	5,054
Operating lease liabilities, current	100	210
Total current liabilities	19,486	20,047
Operating lease liabilities, noncurrent	175	199
Deferred government grants	203	213
CVR derivative liability, noncurrent	4,780	4,722
Warrant liability, noncurrent	8,547	12,835
Other noncurrent liabilities	48	49
Total liabilities	33,239	38,065
Convertible Preferred Stock, $0.001 par value, 5,000,000 shares authorized; nil shares and 13,151 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	64,525
Stockholders' equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized; 85,423,246 shares and 76,595,616 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	85	77
Additional paid-in capital	133,199	68,179
Statutory reserve	3,098	3,098
Accumulated deficit	(78,006)	(85,538)
Accumulated other comprehensive loss	(1,736)	(1,644)
Total Gyre stockholders' equity (deficit)	56,640	(15,828)
Noncontrolling interest	32,131	29,777
Total equity	88,771	13,949
Total liabilities, convertible preferred stock, and equity	$ 122,010	$ 116,539

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

	Three Months Ended March 31,	
	2024	2023
Net income	$ 9,935	$ 4,217
Gain from change in fair value of warrants [1]	(4,288)	—
Stock-based compensation	11	—
Provision for income taxes	2,546	2,054
Non-GAAP adjusted net income	$ 8,204	$ 6,271

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