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 30, 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 7.01. Regulation FD Disclosure.

On May 30, 2024, Gyre Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing that Gyre Pharmaceuticals Co., Ltd., a company organized under the laws of the People's Republic of China ("Gyre Pharmaceuticals"), which is the Company's majority indirectly owned subsidiary, has received approval from the Center for Drug Evaluation ("CDE") of the People's Republic of China's National Medical Products Administration ("NMPA") for its Investigational New Drug ("IND") application for F230 tablets, a selective endothelin receptor antagonist, for the treatment of pulmonary arterial hypertension ("PAH").

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On May 30, 2024, the CDE of the NMPA approved Gyre Pharmaceuticals' IND application for F230 tablets, a selective endothelin receptor antagonist, for the treatment of PAH. In addition to PAH, the Company is also exploring other disease indications for F230.

Forward-Looking Statements

This Current Report on Form 8-K and the press release furnished as Exhibit 99.1 contain "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 Current Report on Form 8-K and the press release furnished as Exhibit 99.1, including statements concerning expectations regarding Gyre Pharmaceuticals' research and development efforts, including the clinical development of F230 for the treatment of PAH and other disease indications, and statements regarding the therapeutic potential and utility, efficacy and clinical benefits of F230, are forward-looking statements. 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 Current Report on Form 8-K. 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 Current Report on Form 8-K. 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. Additional risks and factors are identified under "Risk Factors" in the Company's Annual Report on Form 10-K filed on March 27, 2024 and subsequent reports filed with the Securities and Exchange Commission.

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 30, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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 30, 2024**

By: /s/ Ruoyu Chen
Name: Ruoyu Chen
Title: Chief Financial Officer

Exhibit 99.1

Gyre Pharmaceuticals Receives IND Approval from China's NMPA to Evaluate F230 for the Treatment of Pulmonary Arterial Hypertension

SAN DIEGO, May 30, 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 that the Center for Drug Evaluation ("CDE") of China's National Medical Products Administration ("NMPA") has approved Gyre Pharmaceuticals' (Gyre's indirectly controlled subsidiary) Investigational New Drug ("IND") application for F230 tablets, a selective endothelin receptor antagonist, for the treatment of pulmonary arterial hypertension ("PAH"). F230 was originally licensed from Eisai through Gyre's indirect majority stockholder, GNI Group Ltd.

"PAH is a rare disease and a progressive, life-threatening disorder that represents a significant unmet need with no known cure," said Han Ying, Ph.D., Chief Executive Officer of Gyre. "Through Gyre Pharmaceuticals, we are committed to advancing F230 through clinical development with the ultimate goal of improving patient outcomes and enhancing the quality of life for those affected by this devastating condition."

In preclinical animal studies, F230 resulted in significant decreases of, or exhibited a decrease trend based on different dose groups in, mean pulmonary arterial pressure, right ventricular systolic pressure, right ventricular/left ventricular plus septum and pulmonary artery wall thickness. Even at the minimum effective dosage, the differences of those indexes between the treatment group and the PAH model group were statistically significant. In addition to PAH, Gyre is also exploring other disease indications for F230.

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, including the clinical development of F230 for the treatment of PAH and other disease indications, and statements regarding the therapeutic potential and utility, efficacy and clinical benefits of F230. 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:
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