

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 7, 2024

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

**Delaware**  
(State or other jurisdiction of incorporation)

**000-51173**  
(Commission File Number)

**56-2020050**  
(IRS Employer Identification No.)

**12770 High Bluff Drive**  
**Suite 150**  
**San Diego, CA**  
(Address of principal executive offices)

**92130**  
(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 8, 2024, GNI Group Ltd., a company incorporated under the laws of Japan with limited liability which holds an indirect controlling interest in 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 entered into a comprehensive agreement with Jiangsu Wangao Pharmaceutical Co., Ltd. (“Jiangsu Wangao”) to acquire the rights to generic drug Nintedanib, a competing drug to ETUARY®.

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 7, 2024, Gyre Pharmaceuticals entered into a comprehensive agreement with Jiangsu Wangao to acquire rights to generic drug Nintedanib, a competing drug to ETUARY. With this acquisition, Gyre Pharmaceuticals is acquiring a new product approved for the treatment of idiopathic pulmonary fibrosis and expects to provide patients more choices and benefits, leverage its PRC nationwide sales network, and further enhance Gyre Pharmaceuticals’ leading position in the pulmonary fibrosis market.

### **Forward-Looking Statements**

This report 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 the press release furnished as Exhibit 99.1 and this Current Report on Form 8-K, including statements concerning expectations regarding Gyre Pharmaceuticals’ position in the pulmonary fibrosis market, expectations regarding annual sales revenue of Nintedanib and the expansion of Gyre Pharmaceuticals’ portfolio of therapeutic drugs for the treatment of idiopathic pulmonary fibrosis, 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 report. 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 report, including the timeline for centralized procurement of Nintedanib and the risk that expected revenues may not be realized. 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 8, 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 8, 2024**

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

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### Notification of Conclusion of License Agreement by Gyre Pharmaceuticals Co.

GNI Group (“the Company”) is pleased to announce that Gyre Pharmaceuticals Co. Ltd., aka Beijing Continent Pharmaceuticals Co., Ltd. (“BC”), a consolidated subsidiary of the Company, has executed a comprehensive agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. to acquire the rights to generic Nintedanib, a competing drug for ETUARY®.

ETUARY®, which is manufactured and marketed by BC, has been growing at a high rate in the past, with sales growing 15-20% annually. In addition, according to Frost & Sullivan data, the idiopathic pulmonary fibrosis (“IPF”) drug market in the PRC is expected to reach approximately \22.4 billion by 2022 and \127.4 billion by 2031. In the case of overall pulmonary fibrosis drug market, it is expected to be several times larger than the IPF drug market. Although we have been increasing production and expanding the sales network, we have not been able to fully respond to the rapid growth of the market. Currently, ETUARY® is approved only for the treatment of IPF among fibrosis, and its Phase 3 trial is ongoing for pulmonary fibrosis associated with other factors. With the conclusion of this agreement, we will acquire a new product lineup that acts on IPF and other similar diseases and will further enhance our leading position in fibrosis.

IPF is recognized as a rare disease. Therapeutic drugs for rare diseases have stable drug prices, and with this license purchase, if not incorporated into the centralized purchasing system, we expect annual sales of over \4 billion. ETUARY® is not included in the centralized purchasing system.

We will continue to enhance pipelines for rare disease treatments to offer more options and benefits to patients.

#### 1. Outline of the counterparty to this agreement

(1)	Name	Jiangsu Wangao Pharmaceutical Co., Ltd.
(2)	Adress	No. 688 Dinghai Road, Haimen Economic and Technological Development Zone, Nantong, Jiangsu Province
(3)	Title and name of the representative	Junhua Yao
(4)	Business	Research, development and manufacture of pharmaceutical products
(5)	Capital stock	Not available due to confidentiality agreement

(6)	Date of Establishment	2003	
(7)	Major Shareholders and Shareholding Ratio	Not available due to confidentiality agreement	
(8)	The relationship between the counterparty and the Company	Capital relationships	Not applicable.
		Human resource relationships	Not applicable.
		Business relationships	Not applicable.
		Related Party Status	Not applicable.
(9)	The operating results and financial positions of the counterparty in the last 3 years	Not available due to confidentiality agreement	

2. Date

(1)	Date of BOD resolution	May 7, 2024
(2)	Date of conclusion	May 7, 2024
(3)	Date of commencement of sales	To be determined upon consultation between the parties

3. Forecasts

We are currently examining the impact on this fiscal year's performance and will report the results as soon as they are known.

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