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, 2023**

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: **(619) 949-3681**

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 November 13, 2023, Gyre Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its presentation of a poster on its lead product candidate, Hydronidone, at the American Association for the Study of Liver Diseases' Annual Liver Meeting from November 10, 2023 to November 14, 2023 in Boston, Massachusetts.

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.

Forward Looking Statements

This report and the press release attached as an exhibit contain forward-looking statements that pertain to future operating performance and that are not historic facts. Forward-looking statements may include, but are not limited to, words such as "believe," "plan," "strategy," "expect," "forecast," "possibility" and similar words that describe future operating activities, business performance, events or conditions. Forward-looking statements, whether spoken or written, are based on judgments made by the management of the Company, based on information that is currently available to it. As such, these forward-looking statements are subject to various risks and uncertainties, and actual business results may vary substantially from the forecasts expressed or implied in forward-looking statements. Consequently, investors are cautioned not to place undue reliance on forward-looking statements.

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, 2023
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, 2023**

By: /s/ Charles C. Wu, Ph.D.
Name: Charles C. Wu, Ph.D.
Title: Chief Executive Officer

Exhibit 99.1

Gyre Therapeutics Presents Poster at the American Association for the Study of Liver Diseases (AASLD) Annual Liver Meeting

SAN DIEGO, Calif., Nov. 13, 2023 – Gyre Therapeutics ("Gyre") (NASDAQ: GYRE), a clinical-stage biotechnology company developing anti-fibrotic therapeutics for a variety of chronic liver diseases, today announced the presentation of a poster at the American Association for the Study of Liver Diseases' (AASLD) Annual Liver Meeting, November 10-14, 2023, in Boston, Massachusetts.

Gyre's lead asset, Hydronidone, is currently being investigated for the treatment of Metabolic Dysfunction Associated Steatohepatitis (MASH)-associated liver fibrosis in the United States. Gyre's poster presented the potential antifibrotic effects of Hydronidone and its expected mode of action in mouse hepatic fibrosis models.

"We are encouraged by these preclinical results that support Hydronidone's candidacy as a potential treatment for liver fibrosis," said Charles Wu, Ph.D., Chief Executive Officer of Gyre Therapeutics. "Our team and collaborators showed Hydronidone's ability to ameliorate liver fibrosis by inhibiting the activation of hepatic stellate cells (HSCs) via Smad7-mediated Tumor Growth Transforming (TGF)-β degradation. Activation of the HSCs is recognized as a central event in the process of liver fibrogenesis with the TGF as one of the key mediators. The obtained mechanistic data support the potential of Hydronidone for the treatment of liver fibrosis associated with a spectrum of chronic liver diseases. We look forward to initiating the clinical program of Hydronidone in the United States in 2024."

Key highlights from the poster presentation are below:

- Hydronidone significantly improved liver damage in carbon tetrachloride (CCL4) and 3,5-diethoxycarbonyl-1,4-dihydropyridine (DDC) mouse hepatic fibrosis models and reduced the accumulation of collagen
- Hydronidone inhibited the activation of hepatic stellate cells via Smad7-mediated TGF-β degradation and decreased the expression of fibrosis genes in hepatic stellate cells
- In a ubiquitin-proteasome dependent pathway, Hydronidone promoted the Caveolin-1 mediated TGFβRI degradation via Smad7
- Specific knockdown of Smad7 in vivo blocked the antifibrosis effect of Hydronidone

Full details for the poster presentations are below:

Title: Hydronidone ameliorates liver fibrosis by inhibiting activation of hepatic stellate cells via Smad7-mediated degradation of TGFβRI
Presenting Authors: Xianjun Xu, Department of Gastroenterology, Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China
Poster Number: 3417-A
Date and Time: Sunday, November 12, 2023 from 1:00 p.m. to 2:00 p.m. ET
Location: Poster Hall A

A copy of the poster will be made available on the Gyre website at www.gyretx.com following the conclusion of the meeting.

About Gyre Therapeutics

Gyre Therapeutics ("Gyre") is a biopharmaceutical company headquartered in San Diego, CA, with a primary focus on the development and commercialization of Hydronidone (F351) for the treatment of Metabolic Dysfunction Associated Steatohepatitis (MASH)-associated fibrosis, formerly known as Nonalcoholic Steatohepatitis (NASH) in the United States. Hydronidone's development strategy in MASH is based on results obtained in mechanistic studies in MASH rodent model and results of a chronic Hepatitis-B induced liver fibrosis Phase 2 clinical study in China which met the primary endpoints of safety and efficacy and led recently to the designation of a breakthrough therapy by the New Medicines Product Administration of China (NMPA). Gyre is also advancing a diverse pipeline China through its indirect controlling interest in Beijing Continent Pharmaceuticals Ltd., Co., including pirfenidone, 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, including statements concerning the progress and future expectations and goals of Gyre's research and development efforts, including the timing of the clinical program of Hydronidone, 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 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: risks associated with the possible failure to realize certain anticipated benefits of the business combination with Catalyst Biosciences, Inc., including with respect to future financial and operating results; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; 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 filed on March 30, 2023 and subsequent reports filed with the SEC, and identified under "Risk Factors" in the Proxy Statement.
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
stephen@gilmartinir.com