



Gyre Therapeutics Reports First Quarter 2026 Results and Provides Business Update

May 7, 2026

Q1 2026 revenue of \$22.5 million; GAAP basic EPS: \$(0.10)

Full year 2026 revenue guidance of \$100.5 to \$111.0 million affirmed

NDA for F351 (hydrnidone) for CHB-associated liver fibrosis submitted to China's CDE in March 2026

Completed acquisition of Cullgen in an approximately \$300 million all-stock transaction, expanding pipeline into inflammatory diseases and cancers

First patient enrolled in Phase 2/3 trial evaluating ETUARY™ for radiation-induced lung injury, including immune-related pneumonitis

SAN DIEGO, May 07, 2026 (GLOBE NEWSWIRE) -- Gyre Therapeutics, Inc. (Gyre, the Company or Gyre Therapeutics) (Nasdaq: GYRE), an innovative, commercial stage biopharmaceutical company with operations in the United States and China, today announced financial results for the first quarter ended March 31, 2026, and provided a business update.

"Building on our successful pre-NDA meeting with China's CDE at the beginning of the year, we are particularly encouraged by the NMPA's priority review designation for F351, reinforcing both the strength of our clinical data and the significant unmet need in liver fibrosis," said Ying Luo, Chief Executive Officer of Gyre Therapeutics. "In parallel, our acquisition of Cullgen expands our capabilities into targeted protein degradation, positioning Gyre to drive long-term innovation beyond fibrosis. We believe these achievements strengthen our foundation as a fully integrated, multi-national biopharmaceutical company as we advance our mission to deliver transformative therapies to patients worldwide."

First Quarter Business Highlights and Upcoming Milestones

Commercial Products:

ETUARY™ (pirfenidone), the Company's primary product, generated \$21.0 million in sales for the quarter ended March 31, 2026, compared to \$21.7 million for the same period in 2025. Etoresol™ (nintedanib ethanesulfonate soft capsules), which was launched in June 2025, generated \$0.7 million in sales for the quarter ended March 31, 2026. Contiva™ (avatrombopag maleate tablets), launched in March 2025, generated \$0.8 million in sales for the quarter ended March 31, 2026, compared to \$0.3 million for the same period in 2025.

Pipeline Development Updates

Hydrnidone (F351):

In March 2026, Gyre announced that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) granted priority review designation to F351 for the treatment of chronic hepatitis B (CHB)-associated liver fibrosis. Subsequently, Gyre, through its majority-owned subsidiary Gyre Pharmaceuticals Co., Ltd., submitted a New Drug Application (NDA) to the CDE to seek conditional approval for this indication, which is currently under completeness review for acceptance.

Pirfenidone (ETUARY™):

A Phase 3 trial of pirfenidone for the treatment of pneumoconiosis (PD) in the People's Republic of China (PRC) completed enrollment in 2025. A total of 272 patients were enrolled evaluating the efficacy and safety of 52 weeks of pirfenidone capsule treatment in patients with PD versus placebo. The final patient is expected to complete the study in the third quarter of 2026.

In April 2026, Gyre initiated its adaptive Phase 2/3 clinical trial in oncology-related pulmonary complications, with the first patient enrolled. The trial is evaluating pirfenidone for radiation-induced lung injury (RILI), including cases complicated by immune-related pneumonitis, at leading oncology centers.

Corporate Updates:

- In March 2026, Gyre announced its acquisition of Cullgen Inc., a clinical-stage biopharmaceutical company, to create a fully integrated biopharmaceutical company with U.S.- and China-based capabilities. The transaction was completed in May 2026. The acquisition will supplement Gyre's fibrosis-focused pipeline with novel targeted protein degrader and degrader antibody conjugate product candidates designed to eliminate therapeutically relevant proteins in patients for the treatment of critical conditions including inflammatory diseases and cancers.
- Concurrent with the acquisition of Cullgen, Gyre is undertaking a comprehensive evaluation of its pipeline and clinical development strategy to prioritize programs across the combined organization. The Company intends to provide further updates regarding its strategic direction upon completion of this evaluation.

Financial Results

Cash Position

As of March 31, 2026, Gyre held \$37.5 million in cash and cash equivalents, \$12.3 million in short-term bank deposits, and \$29.4 million in long-term certificates of deposit, totaling \$79.2 million. Compared to \$75.9 million as of December 31, 2025, total cash increased by \$3.3 million, or 4%, primarily driven by higher customer collections and reduced tax payments.

Financial Results for the Three Months Ended March 31, 2026

- Revenues: Revenues for the three months ended March 31, 2026 were \$22.5 million, compared to \$22.1 million for the same period in 2025. The \$0.4 million, or 2%, increase was primarily due to the increase in Contiva™ and Etozel™ sales by approximately \$0.5 million and \$0.7 million, respectively, partially offset by the decrease in ETUARY™ sales and other products sales by approximately \$0.7 million and \$0.1 million, respectively. Contiva™ was launched in March 2025, and Etozel™ was not commercially launched until June 2025. ETUARY™ revenue declined by approximately 3% year-over-year, primarily attributable to the seasonal fluctuation in 2026 compared to 2025.
- Cost of Revenues: For the three months ended March 31, 2026, cost of revenues was \$1.2 million, compared to \$0.9 million for the same period in 2025. The \$0.3 million, or 37%, increase was primarily driven by a \$0.3 million rise in early production costs for Etozel™ cost of sales and a \$0.2 million increase in stock-based compensation expense, partially offset by a \$0.2 million decrease in ETUARY™ cost of sales.
- Selling and Marketing Expense: For the three months ended March 31, 2026, selling and marketing expense was \$14.1 million, compared to \$10.8 million for the same period in 2025. The \$3.3 million, or 30%, increase was primarily driven by a \$2.9 million increase in promotion expenses for Etozel™ and Contiva™, and early-stage preparation activities for F351 commercial launch, and a \$1.0 million increase in stock-based compensation expense, partially offset by a \$0.5 million decrease in staff cost due to a decrease in bonus and a \$0.1 million decrease in travel and other expenses.
- Research and Development Expense: For the three months ended March 31, 2026, research and development expense was \$6.7 million, compared to \$3.1 million for the same period in 2025. The \$3.6 million, or 118%, increase was primarily attributable to Gyre Pharmaceuticals and was driven by a \$2.0 million increase in clinical research expenses, primarily relating to the Phase 3c and other clinical trial for F351 in the PRC requested by NMPA. The increase also reflects a \$0.5 million increase in materials and utilities expenses, and a \$1.1 million increase attributable to Gyre Therapeutics' pre-clinical activities for future investigational new drug (IND) filings in the United States. These costs represent planned investments and are expected to continue in the near- to medium-term.
- General and Administrative Expense: For the three months ended March 31, 2026, general and administrative expense was \$7.3 million, compared to \$5.0 million for the same period in 2025. The \$2.3 million, or 46%, increase was primarily driven by a \$0.8 million increase in stock-based compensation costs, a \$0.9 million increase in staff costs due to the Company's internal realignment of responsibilities and compensation adjustments, and a \$0.6 million increase in miscellaneous expenses.
- Transaction Costs: For the three months ended March 31, 2026, \$2.5 million transaction costs were incurred in connection with the acquisition of Cullgen. As the merger transaction closed in early May 2026, we expect there will be additional non-recurring transaction costs incurred after the first quarter of 2026.
- (Loss) Income from Operations: For the three months ended March 31, 2026, loss from operations was \$9.4 million, compared to income from operations of \$2.3 million for the same period in 2025. The \$11.7 million decrease was primarily driven by \$12.1 million increase in total operating expense driven by transactions costs, increased stock based compensation, expanded marketing expenses for Etozel™ and Contiva™, early-stage preparation activities for ETUARY™ and Phase 3c and other clinical trial and pre-clinical activities, partially offset by a \$0.4 million increase in revenue.
- Net (Loss) Income: For the three months ended March 31, 2026, net loss was \$9.9 million, compared to net income of

\$3.7 million for the same period in 2025. The \$13.6 million decrease was primarily driven by an increase in operating expenses of \$12.1 million, a decrease in other income of \$2.2 million, partially offset by a decrease in income tax expense of \$0.3 million, and an increase in revenue of \$0.4 million.

- **Non-GAAP Adjusted Net (Loss) Income:** For the three months ended March 31, 2026, non-GAAP adjusted net loss was \$4.2 million, compared to non-GAAP adjusted net income of \$2.9 million for the same period in 2025. The \$7.1 million decrease was primarily driven by the increase in operating expenses of \$5.6 million and a decrease in other income of \$2.2 million, offset by an increase in revenue of \$0.4 million and a decrease in income tax expenses of \$0.3 million.

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 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 F351

F351 is Gyre’s lead development candidate for the treatment of liver fibrosis that is being developed for two different indications. It is a structurally modified derivative of pirfenidone designed to optimize metabolic properties while targeting the TGF-β1 signaling pathway, a key mediator of fibrogenesis. Gyre is developing F351 for two primary indications: Chronic hepatitis B (CHB)-associated liver fibrosis in the PRC and MASH-associated liver fibrosis initially in the United States.

In the United States, Gyre has completed a Phase 1 clinical trial in healthy volunteers evaluating F351’s safety, tolerability, and PK. Gyre plans to file an Investigational New Drug (IND) application in the U.S. by the end of 2026, and, if the IND becomes effective, initiate a Phase 2 clinical trial.

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™, was the first approved treatment for idiopathic pulmonary fibrosis in the PRC in 2011 and has maintained a prominent market share (2025 net sales of \$116.6 million). In addition, Gyre Pharmaceuticals’ pipeline includes F351, a structural analogue of pirfenidone, which demonstrated statistically significant fibrosis regression after 52 weeks of treatment in a pivotal Phase 3 clinical trial in CHB-associated liver fibrosis in the PRC. F351 received Breakthrough Therapy designation by the NMPA CDE in March 2021. CDE granted priority review status to the NDA for F351 in March 2026. In March 2026, Gyre Pharmaceuticals Co., Ltd., submitted its NDA to the CDE to seek conditional approval for F351. Gyre Pharmaceuticals is also developing treatments for pneumoconiosis, RILI with or without immune-related pneumonitis, chronic obstructive pulmonary disease, pulmonary arterial hypertension and acute/acute-on-chronic liver failure. As of the first quarter of 2026, Gyre Therapeutics owns a 69.7% equity interest in Gyre Pharmaceuticals.

About Gyre Therapeutics

Gyre Therapeutics is a commercial-stage biopharmaceutical company headquartered in San Diego, CA focused on the development and commercialization of small-molecule therapeutics with its most advanced programs addressing organ fibrosis and inflammatory diseases.

Gyre’s wholly-owned subsidiary, Cullgen Inc., is a clinical-stage biopharmaceutical company focused on the discovery and development of targeted protein degrader and degrader-antibody conjugate (DAC) therapies for critical conditions including cancer and inflammatory diseases. Cullgen has created a portfolio of highly selective targeted protein degrader and DAC product candidates designed to potently and efficiently eliminate therapeutically relevant proteins in patients.

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 and the timing of expected clinical readouts and regulatory filings, including the timing of the CDE’s review of Gyre Pharmaceuticals’

submission of formal NDA for F351 as a treatment for CHB-induced liver fibrosis and Gyre Pharmaceuticals' adaptive Phase 2/3 trial of pifrenidone for the treatment of RILI, the future operations of Gyre, the nature, strategy and focus of Gyre, the development and commercial potential and potential benefits of any product candidates of Gyre, the ability of Cullgen's degraders and DACs to strengthen Gyre's asset portfolio and the additional expected benefits of the acquisition, including Gyre's ability to successfully integrate the businesses and operations of Gyre and Cullgen. 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; supply chain and distribution delays and challenges. Additional risks and factors are identified under "Risk Factors" in Gyre's Annual Report on Form 10-K for the year ended December 31, 2025 filed on March 13, 2026 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.

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Gyre Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2026	2025
Revenues	\$ 22,519	\$ 22,058
Operating expenses:		
Cost of revenues	1,227	894
Selling and marketing	14,136	10,841
Research and development	6,738	3,095
General and administrative	7,220	4,955
Transaction costs	2,553	—
Total operating expenses	<u>31,874</u>	<u>19,785</u>
(Loss) income from operations	(9,355)	2,273
Other income, net:		
Change in fair value of warrant liability	89	2,255
Other income, net	29	107
(Loss) income before income taxes	<u>(9,237)</u>	4,635
Provision for income taxes	(621)	(901)
Net (loss) income	<u>(9,858)</u>	3,734
Net (loss) income attributable to noncontrolling interest	<u>(1,167)</u>	1,036
Net (loss) income available to common stockholders	<u>\$ (8,691)</u>	<u>\$ 2,698</u>
Net (loss) income per share attributable to common stockholders:		
Basic	<u>\$ (0.10)</u>	<u>\$ 0.03</u>
Diluted	<u>\$ (0.10)</u>	<u>\$ 0.00</u>

Weighted average shares used in calculating net income per share attributable to common stockholders:

Basic	91,317,142	86,420,530
Diluted	91,344,584	101,970,672

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

	March 31, 2026	December 31, 2025
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,501	\$ 37,070
Short-term bank deposits	12,307	15,355
Notes receivable	3,817	5,638
Accounts receivables, net	22,763	31,078
Other receivables from GNI	230	230
Inventories	11,352	10,171
Prepaid assets and other current assets	3,762	2,827
Total current assets:	91,732	102,369
Property and equipment, net	23,572	23,599
Intangible assets, net	4,627	4,727
Deferred tax assets	7,723	6,873
Long-term certificates of deposit	29,419	23,516
Other assets, noncurrent	4,942	5,048
Total assets	<u>\$ 162,015</u>	<u>\$ 166,132</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 265	\$ 124
Due to related parties	226	227
Accrued expenses and other current liabilities	15,415	14,359
Income tax payable	3,131	2,940
Operating lease liabilities, current	751	636
Total current liabilities:	19,788	18,286
Operating lease liabilities, noncurrent	72	303
Deferred government grants	840	852
Warrant liability, noncurrent	2,872	2,961
Other noncurrent liabilities	1,458	1,448
Total liabilities	<u>25,030</u>	<u>23,850</u>
Stockholders' equity:		
Common stock, \$0.001 par value, 400,000,000 shares authorized; 91,337,121 shares and 91,314,007 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	91	91
Additional paid-in capital	174,651	172,047
Statutory reserve	3,648	3,098
Accumulated deficit	(77,667)	(68,426)
Accumulated other comprehensive income (loss)	586	(779)
Total Gyre stockholders' equity	<u>101,309</u>	<u>106,031</u>
Noncontrolling interest	35,676	36,251
Total equity	<u>136,985</u>	<u>142,282</u>

Total liabilities and stockholders' equity

\$ 162,015 \$ 166,132

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

	Three Months Ended March 31,	
	2026	2025
Net (loss) income	\$ (9,858)	\$ 3,734
Gain from change in fair value of warrant liability ⁽¹⁾	(89)	(2,255)
Stock-based compensation	2,583	507
Provision for income taxes	621	901
Transaction costs ⁽²⁾	2,553	—
Loss on disposal of assets, net ⁽³⁾	16	—
Non-GAAP adjusted net (loss) income	<u>\$ (4,174)</u>	<u>\$ 2,887</u>

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

(2) Reflects non-recurring expenses related to the transaction costs to acquire Cullgen Inc.

(3) Reflects non-recurring losses from the disposal of assets that are not part of the Company's ongoing operations.