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Overview of Gyre Therapeutics' Financial Results and Business Highlights for the First Quarter of Fiscal Year 2026

(Note) This document has been translated from the Japanese original for reference purposes only. In the event of any discrepancy between this translated document and the Japanese original, the Japanese original shall prevail.

Gyre Therapeutics, Inc. ("Gyre"), a consolidated subsidiary of GNI Group Ltd. (the "Company"), has announced its financial results and business updates for the first quarter of fiscal year 2026, covering the period from January 1, 2026 to March 31, 2026. The Company hereby provides the following summary.

1. Gyre's Highlights for the First Quarter of Fiscal Year 2026

	Q1 FY2025	Q1 FY2026
Revenue	US\$22.1 million	US\$22.5 million (JPY 3,578 million)
Operating income / loss	US\$2.3 million	US\$(9.4) million (operating loss of JPY 1,495 million)
Net income / loss	US\$3.7 million	US\$(9.9) million (net loss of JPY 1,574 million)
Cash and cash equivalents	US\$75.9 million	US\$79.2 million (JPY 12,593 million)

Accounting standard: U.S. GAAP

Japanese yen amounts are independently translated by GNI Group at an exchange rate of US\$1 = JPY 159.

Factors Contributing to the Change in Operating Income / Loss

Operating loss for the first quarter was US\$9.4 million, or approximately JPY 1,495 million, based on GNI Group's independent conversion at an exchange rate of US\$1 = JPY 159. This represented a decrease of

US\$11.7 million, or approximately JPY 1,860 million, from operating income of US\$2.3 million, or approximately JPY 366 million, in the same period of the previous fiscal year.

The decrease was primarily attributable to a US\$12.1 million, or approximately JPY 1,924 million, increase in total operating expenses, mainly due to the following factors:

- Advisory service fees related to the Cullgen acquisition: US\$2.5 million, or approximately JPY 398 million
- Increase in Gyre's stock-based compensation expenses: US\$2.1 million, or approximately JPY 334 million
- Promotional activities and initial preparation activities for the commercialization of F351: US\$2.9 million, or approximately JPY 461 million
- Increase in research and development expenses: US\$3.6 million, or approximately JPY 572 million

Breakdown of the US\$3.6 million increase in research and development expenses:

1. China-based Phase 3c clinical trial of F351 and other clinical trial-related expenses: US\$2.0 million, or approximately JPY 318 million
2. Increase in material costs, utilities and related expenses: US\$0.5 million, or approximately JPY 80 million
3. Preclinical activities in preparation for the submission of an Investigational New Drug application (IND) for F351 in the United States: US\$1.1 million, or approximately JPY 175 million

Note: The year-on-year comparison is based on the first quarter of fiscal year 2025.

Note: Gyre prepares its financial statements in accordance with U.S. GAAP. Accordingly, the figures may differ from those used in the Company's consolidated financial statements, which are prepared in accordance with IFRS.

2. Key Business Progress and Topics

Comment from Ying Luo, CEO of Gyre Therapeutics:

"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."

Strategic Review:

"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."

(a) F351, a Liver Fibrosis Treatment Candidate: Progress in China and the United States

- China — Priority Review designation: In March 2026, F351 received Priority Review designation from China's National Medical Products Administration (NMPA), for the treatment of liver fibrosis associated with chronic hepatitis B.
- China — NDA submission: In the same month, Gyre submitted a New Drug Application (NDA), to the CDE seeking conditional approval for F351 for this indication. The application is currently undergoing formal review toward acceptance.

- United States development: In the United States, Gyre completed a Phase 1 clinical trial in healthy adult subjects to evaluate the safety, tolerability and pharmacokinetics (PK), of F351. Gyre plans to submit an IND, in the United States by the end of 2026 and, following the effectiveness of the IND, to initiate a Phase 2 clinical trial.

(b) Completion of the Acquisition of Cullgen and Strategic Development

- Completion of the acquisition: In May 2026, Gyre completed the acquisition of Cullgen Inc. through an all-stock transaction valued at approximately US\$300 million, or approximately JPY 47,700 million.
- Expansion of pipeline: Through the acquisition, Gyre obtained targeted protein degrader (TPD), and degrader antibody conjugate (DAC) technologies, significantly expanding its portfolio from fibrosis into inflammatory diseases and oncology.

(c) Core Product and Other Pipeline Programs

- ETUARY (Pirfenidone): Revenue from ETUARY was US\$21.0 million, or approximately JPY 3,339 million. Revenue in the same period of the previous fiscal year was US\$21.7 million.
- Indication expansion — pneumoconiosis (PD): The Phase 3 clinical trial of pirfenidone for the treatment of pneumoconiosis in China completed patient enrollment in 2025. A total of 272 subjects were enrolled in the placebo-controlled trial, which is evaluating the efficacy and safety of 52 weeks of treatment. The last subject is expected to complete the trial in the third quarter of 2026.
- Indication expansion — radiation-induced lung injury (RILI): In April 2026, Gyre initiated an adaptive-design Phase 2/3 clinical trial for cancer-related pulmonary complications, and the first subject was enrolled. The trial is evaluating RILI, including cases complicated by immune checkpoint inhibitor-related pneumonitis, at leading cancer treatment institutions.

3. Gyre's Highlights for the First Quarter of Fiscal Year 2026

- Sales and marketing expenses: Sales and marketing expenses for the first quarter were US\$14.1 million, or approximately JPY 2,242 million, an increase of US\$3.3 million, or approximately JPY 525 million, or 30%, from US\$10.8 million, or approximately JPY 1,717 million, in the same period of the previous fiscal year. The increase was primarily attributable to a US\$2.9 million, or approximately JPY 461 million, increase in promotional expenses for Etoel and Contiva and initial preparation activities for the commercialization of F351, as well as a US\$1.0 million, or approximately JPY 159 million, increase in stock-based compensation expenses.
- Research and development expenses: Research and development expenses for the first quarter were US\$6.7 million, or approximately JPY 1,065 million, an increase of US\$3.6 million, or approximately JPY 572 million, or 118%, from US\$3.1 million, or approximately JPY 493 million, in the same period of the previous fiscal year. The increase was primarily attributable to Gyre Pharmaceuticals and was mainly driven by a US\$2.0 million, or approximately JPY 318 million, increase in clinical research expenses related to the Phase 3c clinical trial of F351 in China, as required by the NMPA, and other clinical trials. The increase also reflected a US\$0.5 million, or approximately JPY 80 million, increase in material costs, utilities and related expenses, and a US\$1.1 million, or approximately JPY 175 million, increase in preclinical activity expenses incurred by Gyre Therapeutics in preparation for a future IND submission in the United States.

- General and administrative expenses: General and administrative expenses for the first quarter were US\$7.3 million, or approximately JPY 1,161 million, an increase of US\$2.3 million, or approximately JPY 366 million, or 46%, from US\$5.0 million, or approximately JPY 795 million, in the same period of the previous fiscal year. The increase was primarily attributable to a US\$0.8 million, or approximately JPY 127 million, increase in stock-based compensation expenses, a US\$0.9 million, or approximately JPY 143 million, increase in personnel expenses associated with internal organizational restructuring and compensation adjustments, and a US\$0.6 million, or approximately JPY 95 million, increase in other expenses.
- Advisory service fees: Gyre recorded US\$2.5 million, or approximately JPY 398 million, in advisory service fees related to the acquisition of Cullgen. As the merger transaction was completed in early May 2026, expenses are expected to continue to be incurred after the first quarter, through around mid-May.
- Cash balance: As a result of progress in collections from customers, Gyre held cash and cash equivalents of US\$79.2 million, or approximately JPY 12,593 million, as of the end of March 2026.

4. Full-Year Financial Guidance

Gyre has maintained its full-year revenue guidance for fiscal year 2026 as follows:

Full-year revenue guidance: US\$100.5 million to US\$111.0 million

Japanese yen reference amount*1: approximately JPY 16,000 million to JPY 17,600 million

*1: The Japanese yen reference amount is calculated based on the exchange rate as of the date of preparation of this document, using US\$1 = JPY 159.

In the timely disclosure titled “Notice Regarding Disclosure of Consolidated Earnings Forecast for the Fiscal Year Ending December 31, 2026” dated March 31, 2026, GNI Group adopted, based on its own view, a revenue forecast of JPY 16,000 million for the overall Pharma business for the fiscal year ending December 31, 2026.

[Reference]

Gyre Therapeutics, Inc. press release dated May 8, 2026

[Gyre Therapeutics Reports First Quarter 2026 Results and Provides Business Update | Gyre Therapeutics, Inc](#)

The Japanese yen amounts have been independently calculated and presented by GNI Group.