March 24, 2026

Company Name: GNI Group Ltd.

Representative: Director, Representative Executive Officer, President and CEO
Ying Luo, PhD
(Security Code: 2160, TSE Growth)

Contact Person: Director, Executive Officer, Vice President COO and CFO
Ryosuke Matsui
(TEL. 03-6214-3600)

Notice Regarding Submission of New Drug Application (NDA) for F351 in China for the Treatment for Chronic Hepatitis B–Induced Liver Fibrosis

(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.

On March 22, 2026, Gyre Therapeutics, Inc. (hereinafter "Gyre Therapeutics"), submitted a New Drug Application (NDA) to the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) in China. The application is for F351, the Group's lead development candidate for the treatment of liver fibrosis associated with chronic hepatitis B.

The submitted application materials will first undergo a preliminary review to confirm compliance with required formats and completeness. Gyre Therapeutics intends to work closely with the CDE and will provide additional materials if requested. Subsequently, prior to the commencement of the full substantive review process, the CDE is expected to issue an acceptance number to Gyre Therapeutics.

[For Reference]

Press release issued by Gyre Therapeutics, Inc.

Form 8-K for Gyre Therapeutics INC filed 03/23/2026

Note: The statements below represent GNI's independent interpretation and may differ from the views of Gyre Therapeutics. This document also contains forward-looking statements, including market forecasts and development outlooks, which are subject to various risks and uncertainties that could cause actual results to differ materially.

Appendix (Explanation for General Shareholders and Investors)

This press release marks an important first step toward the commercialization of our lead drug candidate, which has the potential to be a game changer for the Company.

1. About the drug candidate F351 and the target indication

- **Target indication: liver fibrosis associated with chronic hepatitis B (CHB)**
  F351 is designed to treat liver fibrosis, a condition in which prolonged liver inflammation causes the tissue to become hardened. If left untreated, liver fibrosis can progress to serious and life-threatening conditions such as cirrhosis and liver failure. In this application, F351 is specifically indicated for liver fibrosis caused by chronic hepatitis B.
- **We bring new hope to Life**
  China has a very large population of patients with chronic hepatitis B, and accordingly, a substantial number of patients suffer from liver fibrosis associated with CHB. Currently, effective treatment options in this area remain limited. In China, the standard treatment approach for chronic hepatitis B typically involves a combination of: (1) Western antiviral therapies, and (2) Traditional Chinese medicine (TCM), a practice commonly referred to as “integrated Chinese and Western medicine.”

  (1) Antiviral agents directly inhibit viral replication and dramatically reduce HBV DNA levels in the blood, thereby suppressing hepatocyte damage, controlling hepatitis activity, and reducing the risk of liver cancer. However, their anti-fibrotic effects—namely, the ability to reverse already hardened liver tissue—are limited.

  (2) Traditional Chinese medicines primarily contribute through anti-fibrotic effects and immune modulation. By improving blood circulation in the liver (so-called “blood-activating” effects), they help prevent tissue stiffening and support tissue repair as an adjunctive therapy. It is estimated that approximately 80% of patients with chronic hepatitis B in China use some form of TCM in combination with other treatments.

  Hepatology (2010 / the journal of the American Association for the Study of Liver Diseases) Lingyi Zhang / Contemporary Clinical Research of Traditional Chinese Medicines for Chronic Hepatitis B in China: An Analytical Review. "Despite the availability of IFN and/or nucleoside analogues, almost **80%** of the patients with CHB in China rely on TCM therapy."
  ⇒『BMJ Open』（2017） Tzung-Yi Tsai/Associations between prescribed Chinese herbal medicine and risk of hepatocellular carcinoma in patients with chronic hepatitis B: a nationwide population-based cohort study. “Owing to its low cost and low toxicity, about **80%** of patients with CHB in China and Taiwan have received CHM treatment”

  In the current landscape of anti-fibrotic treatment, traditional Chinese medicines are primarily prescribed by physicians who are receptive to integrated Chinese–Western approaches. However, physicians trained in Western medicine, who place strong emphasis on rigorous clinical evidence, often refrain from prescribing such treatments due to insufficient data.

  In contrast, our investigational drug F351 has generated robust evidence demonstrating a improvement of liver fibrosis in a well-controlled, placebo-controlled Phase 3 clinical trial. Based on this level of

evidence, we expect F351 to gain adoption among physicians who have previously been reluctant to prescribe traditional Chinese medicines, thereby expanding the overall market opportunity.

Furthermore, following its launch, GNI believes that F351 is highly likely to be recommended as a first-line anti-fibrotic therapy in clinical guidelines issued by leading hepatology societies in China. If realized, this would support its establishment as a standard of care across medical institutions nationwide, enabling the treatment of a large patient population while also serving as a major driver of revenue growth for the Group.

Product Name	Key Manufacturer	Estimated Wholesale Value	Market Share	Estimated Retail Value	Market Positioning & Share Status	Recommended in China's National Clinical Guidelines / Covered by Public Insurance	Annual Cost	Raw Materials
Fuzheng Huayu	Shanghai Huanghai Pharmaceutical (subsidiary of Baiyang Pharmaceuticals)	FY2024 (Full Year): RMB 631 million (+16.6% YoY) (approx. JPY 14.6 billion) H1 FY2025: RMB 371 million (+37.4% YoY) (approx. JPY 8.6 billion)	31.50%	Estimated RMB 1.6–2.1 billion (JPY 33.6–44.1 billion)	A core product of Shanghai Huanghai Pharmaceutical (a subsidiary of Baiyang Pharmaceuticals), with annual sales of approximately RMB 500 million (approx. JPY 10.5 billion). It is estimated to hold a top-tier market share of around 25–30% in China's anti-liver fibrosis market. It has also completed U.S. FDA Phase II clinical trials and has a strong presence in hospital channels where scientific evidence is highly valued.	○	RMB 6,000–8,000 (approx. JPY 120,000–160,000)	Cordyceps sinensis mycelium (fungal biomass)
Biejia Ruangan Tablets (Biejia Ruangan)	Inner Mongolia Furui Medical	FY2024: approx. RMB 300 million (approx. JPY 7.0 billion) H1 FY2025: Approximately RMB 150 million (+1.6% YoY)	15%	Estimated RMB 0.8–1.0 billion (JPY 17.0–21.0 billion)	One of the two dominant products alongside Fuzheng Huayu. It was the first drug approved in China for the treatment of liver fibrosis in 1999 and, as a pioneer, has achieved very high nationwide recognition and extensive prescription history. In China's hospital market for anti-liver fibrosis traditional Chinese medicines, it holds an estimated market share of 25–30%. GNI estimates its market size at RMB 0.8–1.0 billion (approximately JPY 16–21 billion).	○	RMB 12,000–14,000 (approx. JPY 250,000–290,000)	Turtle shell (Biejia)
Anluo Huaxian Pills (Anluo Huaxian)	Senlong Pharmaceutical	Approx. RMB 100 million (approx. JPY 2.3 billion)	5%	Estimated RMB 0.2–0.3 billion (JPY 4.2–6.3 billion)	A key product following the top two. It is included in clinical guidelines and maintains a stable market presence, with an estimated market share of several percent to around 10%.	○	RMB 4,000–5,000 (approx. JPY 80,000–100,000)	
Top 3 Products	Top 3 companies	RMB 1.03 billion (JPY 23.8 billion)	51%	RMB 2.6–3.4 billion (JPY 54.8–71.4 billion)				
Total Market	Entire market	RMB 2.02 billion (JPY 46.7 billion)	100%	RMB 5.1–6.7 billion (JPY 107.5–140.0 billion)				

*Created by GNI. The above estimates have been calculated by the GNI based on publicly available information from each company and other external sources.

In China, the "clinical guidelines issued by hepatology societies" represent the highest authority in liver disease treatment and serve as the official rulebook that physicians nationwide are expected to follow. These guidelines are jointly developed by the hepatology and infectious diseases branches of the Chinese Medical Association.

In the fields of hepatitis B and liver fibrosis, two key guidelines are particularly important. The first is the *Guidelines for the Prevention and Treatment of Chronic Hepatitis B*, widely regarded as the definitive

reference for hepatitis B treatment in China, which specifies recommended antiviral therapies and approaches to fibrosis management. The second is the *Consensus on the Diagnosis and Treatment of Liver Fibrosis*, which directly covers the target area of the new drug F351 as well as traditional Chinese medicines. Whether a drug is included as a "recommended therapy" in this guideline can effectively determine its future.
[For further details, please refer to slide #21 of the explanatory materials published on August 14, 2025]

GNI believes that achieving the highest ranking in these guidelines would have three decisive business implications.

First, it serves as an "automatic passport" to hospitals nationwide. In China, hospitals are classified by scale and capability, with the top tier being large, government-designated general hospitals known as "Class 3A hospitals." Physicians at these institutions are strictly required to follow the latest academic guidelines rather than relying on individual judgment or experience. As a result, once a new drug is designated as a first-line therapy, these physicians are among the first to prescribe it. Given that Class 3A hospitals serve as opinion leaders for the entire medical community, adoption at these institutions typically drives rapid follow-on adoption across smaller regional hospitals nationwide.

Second, it provides strong support for inclusion in the National Reimbursement Drug List (NRDL). Widespread adoption requires reducing patient out-of-pocket costs through public insurance coverage, and in practice, strong endorsement in academic guidelines is a prerequisite for such inclusion.

Third, it enables clear differentiation from competing traditional Chinese medicines. The guidelines rank therapies based on the strength of scientific evidence. If F351, supported by rigorous clinical data, achieves the highest evidence rating, it can demonstrate a clear and officially endorsed advantage over long-established traditional Chinese medicines, positioning it as a highly reliable treatment option.

2. Current Development Status and Path to Commercialization

The submission of the NDA (New Drug Application) announced this time does not represent the final goal, but rather marks the beginning of the formal regulatory review process to obtain marketing approval from the authorities.
An important point to note is that the Company has already completed a Pre-NDA meeting (pre-submission consultation) with the regulatory authority (CDE) and has also been granted Priority Review designation prior to this submission. As the necessary data requirements and expectations have been aligned with the authority in advance, it is the Company's view that the risk of major setbacks has been reduced, and a smoother review process can be expected.

The anticipated overall process going forward is as follows:

1. **Pre-NDA meeting** (completed: prior alignment with the regulatory authority)
2. **NDA submission** (completed: current milestone)

3. **Formal review (administrative check)** (current stage): a procedural review to confirm completeness of the application materials
4. **Issuance of acceptance number** (next key milestone): formal confirmation that the application has been accepted
5. **Technical review (substantive review)**: the most critical stage, where efficacy and safety are evaluated based on scientific and clinical data
6. **Approval**
7. **Launch / Commercialization: pricing as a self-pay (out-of-pocket) drug and commencement of sales**
8. **Reimbursement application and price negotiations**

At present, the application is at the entry point of Step 3. Going forward, key investment milestones will include the timing of the issuance of the acceptance number and the successful completion of the technical review process.