Gyre Therapeutics Completes Acquisition of Cullgen to Create U.S.- and China-based Fully Integrated Biopharmaceutical Company

May 4, 2026

- *Post-closing combined company has revenue-producing commercial asset and a robust pipeline of products and product candidates to address multiple therapeutic areas with a focus on fibrosis and inflammatory diseases.*
- *China innovation engine provides cost-efficient vehicle for discovery and early-stage development of targeted protein degraders and degrader-antibody conjugates.*
- *Strengthened leadership team in U.S., coupled with China operating presence to support future global growth.*

SAN DIEGO, May 04, 2026 (GLOBE NEWSWIRE) -- Gyre Therapeutics, Inc. (“Gyre”, “Gyre Therapeutics” or the “Company”) (Nasdaq: GYRE), an innovative, commercial-stage biopharmaceutical company dedicated to advancing fibrosis-first therapies across organ systems affected by chronic diseases, today announced the closing of its acquisition of Cullgen Inc. (Cullgen), a privately-held, clinical-stage biopharmaceutical company focused on the discovery and development of targeted protein degrader (TPD) and degrader antibody conjugate (DAC) therapies, in an all-stock transaction valued at approximately $300 million.

Following the closing of the acquisition, Cullgen became a wholly owned subsidiary of Gyre, and the former Chief Executive Officer of Cullgen, Dr. Ying Luo, was appointed President and Chief Executive Officer and as a member of the Gyre Board of Directors. Ping Zhang will continue at Gyre as Chairman of the Board of Directors. The new combined entity will continue to be listed on the Nasdaq Capital Market under the ticker “GYRE”.

Dr. Luo, President and Chief Executive Officer of Gyre, commented, “We are eager to move forward as a U.S.- and China-based fully integrated biopharmaceutical company. Through this combination, we have created an entity that not only offers a commercial-stage product with ETUARY®, on the market in China for the treatment of lung fibrosis, but also a full-spectrum pipeline of products from discovery to Phase 3, primarily focused on fibrosis and inflammatory diseases. This includes our lead product candidate, F351 (hydronidone) for the treatment of chronic hepatitis B (CHB)-induced liver fibrosis, as well as a strong preclinical and clinical pipeline, including TPDs and DACs.”

Mr. Zhang, Chairman of Gyre, commented, “This combination occurs at an exciting time for Gyre as we recently received priority review status from the Center for Drug Evaluation of China’s National Medical Products Administration for the F351 NDA in March. We are also exploring the expansion of F351’s development in ex-China territories including the U.S. In addition, we have completed enrollment in our 52-week Phase 3 ETUARY® trial for pneumoconiosis, and have also enrolled the first patient in a Phase 3 study evaluating ETUARY® in a new indication: radiation-induced lung injury with or without immune checkpoint inhibitor-related pneumonitis, further strengthening our late-stage inflammatory portfolio. Additionally, we believe the innovative discovery engine that has produced several promising degraders and DACs acquired from Cullgen strengthens our asset portfolio and provides long-term value to Gyre.”

About Gyre Pharmaceuticals

Gyre Pharmaceuticals Co., Ltd., a subsidiary of Gyre Therapeutics, Inc. (“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® (pirfenidone capsule), was the first approved treatment for IPF in the People’s Republic of China (PRC) in 2011 and has maintained a prominent market share over the past several years. In addition, Gyre Pharmaceuticals’ pipeline includes F351 (hydronidone), 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 CDE of the NMPA in March 2021. Gyre Pharmaceuticals is also developing treatments for PD, RILI with or without immune-related pneumonitis, COPD, PAH and ALF/ACLF. As of December 31, 2025, Gyre Therapeutics owns a 69.7% equity interest in Gyre Pharmaceuticals.

About Gyre Therapeutics

Gyre Therapeutics is a biopharmaceutical company headquartered in San Diego, CA, primarily focused on the development and commercialization of F351 for liver fibrosis including MASH in the U.S., and, with its recent acquisition, now has a portfolio of highly selective targeted protein degrader product candidates designed to potently and efficiently eliminate therapeutically relevant proteins in patients, as well as preclinical programs including next-generation degrader-antibody conjugates.

In the PRC, Gyre Therapeutics is advancing a broad pipeline through its controlling interest in Gyre Pharmaceuticals, including therapeutic expansions of ETUARY, and development programs for F573, and F528.

Advisory and Legal Counsel

Moelis & Company LLC is acting as financial advisor to the special committee to Gyre's Board of Directors, and Gyre's legal counsel is Gibson, Dunn & Crutcher LLP.

Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C. is serving as legal counsel to Cullgen.

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 future operations of the combined entity; the nature, strategy and focus of the combined entity; the development and commercial potential and potential benefits of any product candidates of the combined entity; potential expansion of F351 in ex-China territories including the U.S.; the ability of Cullgen's degraders and DACs to strengthen Gyre's asset portfolio; and the additional expected benefits of the acquisition, including its 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: unexpected costs, charges or expenses resulting from the acquisition; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the acquisition; the risk that the combined company may not be able to successfully integrate the businesses and realize the expected benefits of the acquisition in a timely manner or at all; the uncertainties associated with Gyre's and Cullgen's product candidates, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; risks related to the inability of the combined entity to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; risks associated with the possible failure to realize certain anticipated benefits of the acquisition, including with respect to future financial and operating results. 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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