Gyre Therapeutics Reports Full Year 2023 Financial Results and Provides Business Update

March 26, 2024

Data readout from Phase 3 clinical trial in the People's Republic of China ("PRC") evaluating F351 for the treatment of CHB-associated liver fibrosis expected by early 2025

U.S. Phase 2a clinical trial evaluating F351 for the treatment of NASH-associated liver fibrosis planned for 2025

Appointed Dr. Han Ying as Chief Executive Officer

Acquired indirect controlling interest in Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals Co., Ltd) as part of business combination agreement with GNI

Cash and cash equivalents totaled $33.5 million as of December 31, 2023

SAN DIEGO, March 26, 2024 (GLOBE NEWSWIRE) -- Gyre Therapeutics, Inc. ("Gyre") (Nasdaq: GYRE), a clinical-stage biotechnology company developing anti-fibrotic therapeutics for a variety of chronic organ diseases, today announced financial results for the full year ended December 31, 2023 and provided a business update.

"2023 was a transformational year for Gyre as we successfully monetized our legacy assets, returned cash to stockholders, and expanded into the attractive liver fibrosis space with the acquisition of F351, a structural analogue of the approved anti-fibrotic drug ETUARY® (Pirfenidone). We are extremely encouraged by the data from our Phase 1 clinical trial in healthy volunteers in the United States, which demonstrated a safety profile consistent with that observed in the Phase 2 proof-of-concept trial completed in the PRC. We expect to receive clearance from the U.S. FDA for the initiation of a Phase 2a trial in NASH-associated liver fibrosis by the end of 2024," said Han Ying, Ph.D., Chief Executive Officer of Gyre. "In addition, we remain on track to report data from Gyre Pharmaceuticals' Phase 3 trial evaluating F351 for the treatment of CHB-associated liver fibrosis in the PRC by early 2025. Sales of ETUARY remained strong, increasing 13% from 2022 as Gyre Pharmaceuticals maintained its market-leading position in the PRC IPF market, providing funding for our clinical development plans."

Full Year 2023 Business Highlights and Upcoming Milestones

Corporate Updates

- **Appointed Rodney L. Nussbaum to the Company's Board of Directors and as a member of its Audit Committee.** In March 2024, Rodney L. Nussbaum was appointed to the Company's Board of Directors and as a member of its Audit Committee. Mr. Nussbaum brings nearly four decades of experience in accounting and financial reporting in the U.S. and Asia Pacific Region. He currently serves as a Managing Executive at Atago Advisory, which provides accounting and financial reporting services to clients in the United States and the Asia Pacific Region. Prior to that, Mr. Nussbaum was a Senior Partner with clients in Japan and the Asia Pacific Region with Ernst & Young (2004-2016) and KPMG (2002-2004), and a Partner with Arthur Andersen (2000-2002). Prior to his position as Partner, Mr. Nussbaum spent over 20 years at Arthur Andersen.

- **Appointed Han Ying, Ph.D., as Chief Executive Officer.** In January 2024, Han Ying, Ph.D., a member of Gyre's board of directors, was appointed Chief Executive Officer. Dr. Ying brings over two decades of experience in immunology, biotech startups, operational management, and fundraising. He most recently served as co-founder and Chief Operating Officer of Base Therapeutics and, prior to that, as the Chief Technology Officer for Tactiva Therapeutics and as a venture partner at Panacea Venture.

- **Completed business combination with GNI Group Ltd.** In October 2023, Gyre (formerly known as Catalyst Biosciences, Inc. ("Catalyst")) completed the previously announced business combination with GNI Group Ltd. ("GNI") and related entities. In connection with the closing, the combined company changed its name from Catalyst Biosciences, Inc. to Gyre Therapeutics, Inc. As a result of the business combination, Gyre acquired an indirect controlling interest in Gyre Pharmaceuticals (also known as Beijing Continent Pharmaceuticals Co., Ltd.).

- **Sold legacy rare bleeding disorders programs.** In February 2023, Gyre signed an asset purchase agreement with GC Biopharma Corp. ("GCBP") to sell Catalyst's legacy rare bleeding disorders programs, including marzeptacog alpha activated, dalcinonacog alpha and CB-2679d-GT. As a result, net cash proceeds received from the GCBP asset sale of $0.2 million were distributed to the holders of Catalyst contingent value rights and Gyre recorded a $4.5 million long-term CVR derivative liability for the future distribution of the hold-back amount to be received in May 2025. As of December 31, 2023, the carrying value of the CVR derivative liability was $4.7 million on the consolidated balance sheet.

ETUARY (Pirfenidone capsules) Sales Update

ETUARY (Pirfenidone): Pirfenidone, the first anti-fibrotic drug approved for idiopathic pulmonary fibrosis ("IPF") in Japan, the EU, the United States and the PRC, is a small molecule drug that inhibits the synthesis of tumor growth transforming ("TGF")-β1, TNF-α, and other fibrosis and inflammation modulators. ETUARY became commercially available in the PRC in 2011 and has been included in the National Reimbursement Drug List since 2017.

- **Generated sales of $112.1 million in 2023.** For the year ended December 31, 2023, Gyre Pharmaceuticals generated $112.1 million in sales of ETUARY, representing an increase of 13% from the previous year. As of year-end, Gyre's sales and marketing team included 391 employees with an average of nine years of experience and covered 35,512 hospitals and pharmacies across 30 provinces, autonomous regions and municipalities across the PRC. Gyre expects 2024 sales of ETUARY to grow due to ETUARY's prominent market position and anticipated sustained increases in the prevalence of IPF.

Clinical Development Updates

F351 (Hydronidone): F351 is a structural derivative of the approved anti-fibrotic drug ETUARY (Pirfenidone) with a TGF-β1 mechanism of action and is currently being evaluated by Gyre for the treatment of nonalcoholic steatohepatitis ("NASH")-associated liver fibrosis in the U.S. and by Gyre Pharmaceuticals for the treatment of chronic hepatitis B ("CHB")-associated liver fibrosis in the PRC.

- **Expects to report topline data from Phase 3 clinical trial evaluating F351 for the treatment of CHB-associated liver fibrosis in 2025.** In October 2023, Gyre Pharmaceuticals completed enrollment of its Phase 3 trial in patients with CHB-associated liver fibrosis in the PRC. The study is evaluating 248 patients with a primary endpoint of the reduction of the liver fibrosis score (Ishak Scoring System) by at least one grade after taking F351 in combination with Entecavir.

F573: Gyre Pharmaceuticals is developing F573, a caspase inhibitor and potential Category 1 new drug, for the treatment of acute/acute-on-chronic liver failure ("ALF/ACLF").

- Gyre Pharmaceuticals is conducting a randomized, double-blind, placebo-controlled Phase 2 clinical trial in the PRC to assess the safety and efficacy of F573 for injection in the treatment of liver injury/failure.

Preclinical Development Updates

- **F528:** Gyre Pharmaceuticals is evaluating F528 in preclinical studies as a potential first-line therapy for the treatment of chronic obstructive pulmonary disease ("COPD"). F528 is a novel anti-inflammation agent that targets inhibition of multiple inflammatory cytokines and has the potential to modify the progression of COPD with low toxicity *in vivo*.

- **F230:** Gyre Pharmaceuticals is evaluating F230 for the treatment of pulmonary arterial hypertension ("PAH"). F230 is a selective endothelian receptor antagonist.

Financial Results

Cash Position

As of December 31, 2023, Gyre had cash and cash equivalents of $33.5 million, compared to $25.2 million as of December 31, 2022. The $8.3 million change was primarily due to a $25.9 million increase from net cash provided by operating activities, a $19.8 million decrease from net cash used in investing activities and a $2.5 million increase from net cash provided by financing activities.

Financial Results for the Full Year Ended December 31, 2023

- **Revenues:** For the full year ended December 31, 2023, revenues were $113.5 million as a result of Gyre's indirect controlling interest in Gyre Pharmaceuticals. For the full year ended December 31, 2022, revenues were $102.3 million. The increase was driven by a $12.6 million increase in sales of pharmaceuticals products, driven by enhanced marketing and sales initiatives in regions of the PRC where sales were previously lower in 2022, partially offset by a $1.4 million decrease in revenue related to a one-time licensing fee recognized in 2022.

- **Cost of Revenues:** For the full year ended December 31, 2023, cost of revenues was $4.6 million as a result of Gyre's indirect controlling interest in Gyre Pharmaceuticals. For the full year ended December 31, 2022, cost of revenues was $4.8 million. The decrease was primarily driven by a $0.3 million reduction attributed to favorable foreign exchange rate fluctuations and a $0.2 million decrease in stock-based compensation. These reductions were partially offset by a $0.3 million increase in cost of revenues due to increased sales.

- **Selling and Marketing Expense:** For the full year ended December 31, 2023, selling and marketing expense was $61.2 million, compared to $54.2 million for the same period in 2022. The increase was primarily driven by a $3.8 million increase in selling and marketing payroll costs due to increased staff, a $3.5 million increase in promotional expenses and a $0.7 million increase in traveling expenses, partially offset by a $1.3 million decrease in stock-based compensation.

- **R&D Expense:** For the full year ended December 31, 2023, research and development expense was $13.8 million, compared to $16.7 million for the same period in 2022. The decrease was primarily attributable to a decrease in stock-based compensation and pre-clinical research expenses.

- **G&A Expense:** For the full year ended December 31, 2023, general & administrative expense was $14.7 million, compared to $17.4 million for the same period in 2022. The decrease was primarily attributable to a decrease in stock-based compensation.

- **Operating Loss:** For the full year ended December 31, 2023, loss from operations was $67.2 million, compared to $9.2 million in operating income for the same period in 2022.

- **Net Loss:** For the full year ended December 31, 2023, net loss was $85.5 million, compared to $4.3 million in net income for the same period in 2022.

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 (loss)," which is not calculated in accordance with GAAP. The most directly comparable GAAP measure for this non-GAAP financial measure is "net income (loss)." Adjusted net income (loss) presents Gyre's results of operations after excluding acquired in-process research and development, loss from change in fair value of warrants, stock-based compensation, divestiture losses, and income tax adjustments. This is meant to supplement, and not substitute, Gyre's financial information presented in accordance with GAAP. Adjusted net income (loss) as defined by Gyre may not be comparable to similar non-GAAP measures presented by other companies. Management believes that presenting adjusted net income (loss) provides investors with additional useful information in evaluating the Gyre's performance and valuation. See the reconciliation of adjusted net income (loss) to net income (loss) in the section titled "Reconciliation of GAAP to Non-GAAP Financial Measures" below.

About F351 (Hydronidone)

F351 is a structural analogue of the approved anti-fibrotic (IPF) drug Pirfenidone and has been shown to inhibit *in vitro* both p38γ kinase activity and TGF-β1-induced excessive collagen synthesis in hepatic stellate cells ("HSCs"), which are recognized as critical event in the development and progression of fibrosis in the liver. This is further supported by its anti-proliferative effects on the HSCs in the liver. *In vitro* anti-fibrotic effects of F351 were also confirmed in several established *in vivo* models of liver fibrosis such as $CC1_4$-induced liver fibrosis mouse model, DMN-induced liver fibrosis rat model, and HSA-induced liver rat model, as well as mouse model of NASH fibrosis ($CC1_4$+Western High Fat Diet).

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 (Pirfenidone capsule), was the first approved treatment for IPF in the PRC in 2011 and has maintained a prominent market share (2023 net sales of $112.1 million). In addition, Gyre Pharmaceuticals is evaluating F351 in a Phase 3 clinical trial in CHB-associated liver fibrosis in the PRC, which is expected to readout topline data by early 2025. F351 received Breakthrough Therapy designation by the National Medical Products Administration's ("NMPA") Center for Drug Evaluation in March 2021. Gyre Pharmaceuticals is also developing treatments for COPD, PAH and ALF/ACLF. In October 2023, Gyre Therapeutics acquired an indirect majority interest in Gyre Pharmaceuticals (also known as Beijing Continent Pharmaceuticals Co., Ltd.).

About Gyre Therapeutics

Gyre Therapeutics is a biopharmaceutical company headquartered in San Diego, CA, with a primary focus on the development and commercialization of F351 (Hydronidone) for the treatment of NASH-associated fibrosis in the U.S. Gyre's development strategy for F351 in NASH is based on the company's experience in NASH rodent model mechanistic studies and CHB-induced liver fibrosis clinical studies. Gyre is also advancing a diverse pipeline in the PRC through its indirect controlling interest in Gyre Pharmaceuticals, including ETUARY therapeutic expansions, 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 expectations regarding and goals of Gyre's research and development efforts, timing of expected clinical readouts, initiation of Gyre's Phase 2 trial in the U.S. for F351, interactions with regulators, expectations regarding future product sales, and Gyre's financial position and cash resources, 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: 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. Additional risks and factors are identified under "Risk Factors" in Gyre's Annual Report on Form 10-K filed on March 27, 2023 and subsequent reports filed with the Securities and Exchange Commission, including in the Definitive Proxy Statement filed on July 20, 2023.

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:

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

	Year Ended December 31,	
	2023	**2022**
Revenues	$ 113,450	$ 102,290
Operating expenses:		
Cost of revenues	4,636	4,793
Selling and marketing	61,159	54,238
Research and development	13,780	16,686
General and administrative	14,662	17,370
Acquired in-process research and development	83,104	—
Divestiture losses	2,711	—
Loss on disposal of property and equipment	628	—
Total operating expenses	180,680	93,087
(Loss) income from operations	(67,230)	9,203
Other income (expense), net:		
Interest income, net	1,044	726
Other income	1,076	857
Change in fair value of warrant liability	(9,261)	—
Other expenses	(2,594)	(1,374)
(Loss) income before income taxes	(76,965)	9,412
Provision for income taxes	(8,515)	(5,098)
Net (loss) income from operations	(85,480)	4,314
Net income attributable to noncontrolling interest	7,453	2,012
Net (loss) income attributable to common stockholders	$ (92,933)	$ 2,302
Net (loss) income per share attributable to common stockholders:		
Basic	$ (1.41)	$ 0.04
Diluted	$ (1.41)	$ 0.03
Weighted average shares used in calculating net (loss) income per share attributable to common stockholders:		
Basic	65,831,675	63,588,119
Diluted	65,831,675	75,686,406

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

	December 31, 2023	**December 31, 2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 33,509	$ 25,175
Accounts and note receivables, net	15,552	17,136
Other receivables from GNI	1,287	—
Inventories, net	4,281	6,122
Prepaid assets	1,547	377
Other current assets	1,045	843
Total current assets:	57,221	49,653
Property and equipment, net	23,288	17,709
Long-term receivable from GCBP	4,722	—
Intangible assets, net	205	297
Right-of-use assets	489	666
Land use rights, net	1,493	1,559
Deferred tax assets	4,695	4,081
Long-term certificates of deposit	23,431	7,394
Other assets, noncurrent	995	3,394

Total assets	$ 116,539	$ 84,753
Liabilities, convertible preferred stock, and equity		
Current liabilities:		
Accounts payable	$ 355	$ 122
Deferred revenue	39	145
Due to related parties	1,369	118
CVR excess closing cash payable	1,085	—
Accrued expenses and other current liabilities	11,935	9,264
Income tax payable	5,054	2,101
Operating lease liabilities, current	210	492
Total current liabilities:	20,047	12,242
Operating lease liabilities, noncurrent	199	121
Deferred government grants	213	118
CVR derivative liability, noncurrent	4,722	—
Warrant liability, noncurrent	12,835	—
Other noncurrent liabilities	49	55
Total liabilities	$ 38,065	$ 12,536
Convertible Preferred Stock, $0.001 par value, 5,000,000 shares authorized; 13,151 shares and nil shares issued and outstanding at December 31, 2023 and 2022, respectively	64,525	—
Equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized; 76,595,616 shares and 63,588,119 shares issued and outstanding at December 31, 2023 and 2022, respectively	77	64
Additional paid-in capital	68,179	32,795
Statutory reserve	3,098	2,660
(Accumulated deficit) retained earnings	(85,538)	7,395
Accumulated other comprehensive loss	(1,644)	(392)
Total Gyre stockholders' (deficit) equity	(15,828)	42,522
Noncontrolling interest	29,777	29,695
Total equity	13,949	72,217
Total liabilities, convertible preferred stock, and equity	$ 116,539	$ 84,753

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

	Years Ended December 31,	
	2023	**2022**
Net (loss) income from operations	$ (85,480)	$ 4,314
Acquired in-process research and development [(1)]	83,104	—
Loss from change in fair value of warrants [(2)]	9,261	—
Stock-based compensation	7,281	13,366
Divestiture losses [(3)]	2,711	—
Provision for income taxes	8,515	5,098
Non-GAAP adjusted net income from consolidated operations	$ 25,392	$ 22,778

(1) Reflects adjustments for a reverse asset acquisition with CPI as the accounting acquirer and Catalyst as the legal acquirer.

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

(3) Reflects adjustments loss from the divestiture of all assets other than 56.0% indirect ownership interest in BC (d/b/a Gyre Pharmaceuticals).