



Gyre Therapeutics Reports Second Quarter 2024 and Year-To-Date Financial Results and Provides Business Update

August 13, 2024

Received NMPA approval of avatrombopag maleate tablets for the treatment of CLD-associated thrombocytopenia, expanding rare disease product lines

Received IND approval from NMPA to evaluate F230 for the treatment of pulmonary arterial hypertension

U.S. IND submission for F351 in MASH-associated liver fibrosis expected in late 2024 and data readout from Phase 3 trial in CHB-associated liver fibrosis in the PRC expected by early 2025

Cash and cash equivalents totaled \$16.1 million as of June 30, 2024

SAN DIEGO, Aug. 13, 2024 (GLOBE NEWSWIRE) -- Gyre Therapeutics ("Gyre") (Nasdaq: GYRE), a self-sustainable, commercial-stage biotechnology company with clinical development programs focusing on a variety of chronic organ diseases, today announced financial results for the second quarter ended June 30, 2024 and Year-To-Date 2024, and provided a business update.

"We are extremely proud of our advancements expanding our commercial product offerings and therapeutic reach in the PRC," said Han Ying, Ph.D., Chief Executive Officer of Gyre Therapeutics. "Building on our complementary acquisition of rights to nintedanib, a small-molecule drug for the treatment of IPF, we recently received NMPA approval for avatrombopag in CLD-associated thrombocytopenia. Further, our IND application for F230 was approved by the NMPA and we expect to initiate a Phase 1 trial in PAH in 2025. In parallel, we expect to report data from our Phase 3 trial of F351 in CHB-associated liver fibrosis in the PRC by early 2025, and pending these results and approval of our IND application, we plan to initiate a U.S. Phase 2a trial of F351 in MASH-associated liver fibrosis in 2025."

Second Quarter 2024 Business Highlights and Upcoming Milestones

Commercial-Stage Updates

- **ETUARY (Pirfenidone) sales update:** For the quarter ended June 30, 2024, Gyre Pharmaceuticals, Gyre's majority indirectly owned subsidiary in the People's Republic of China ("PRC"), generated \$25.1 million in sales of ETUARY. To support future revenue growth, we acquired the rights to complementary assets and know-how relating to generic nintedanib for the treatment of IPF and plan to commercially launch Avatrombopag, both of which will be supported by our extensive sales and marketing platform across the PRC.
- **Avatrombopag:** In July 2024, Gyre Pharmaceuticals received approval from China's National Medical Products Administration ("NMPA") for avatrombopag maleate tablets for the treatment of thrombocytopenia associated with chronic liver disease ("CLD") in adult patients undergoing elective diagnostics procedures or therapy. This approval expands Gyre's rare disease product lines and provides a treatment option for a common and potentially life-threatening hematologic complication in patients with CLD.
- **Nintedanib:** In May 2024, Gyre Pharmaceuticals executed a comprehensive agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. to acquire the rights to complementary assets and know-how relating to nintedanib, a small-molecule drug for the treatment of idiopathic pulmonary fibrosis ("IPF"). With this acquisition, Gyre Pharmaceuticals acquired a second product approved for the treatment of idiopathic pulmonary fibrosis and expects to provide patients more choices and benefits, and further enhance Gyre Pharmaceuticals' leading position in the pulmonary fibrosis market.

Clinical Development Updates

F351 (Hydronidone):

- **Manuscript highlighting preclinical data published in the Journal of Gastroenterology and Hepatology.** In June 2024, Gyre Therapeutics announced the publication of the manuscript titled "Hydronidone induces apoptosis in activated hepatic stellate cells through endoplasmic reticulum stress-associated mitochondrial apoptotic pathway" in the Journal of Gastroenterology and Hepatology. The publication included both in vivo and in vitro studies supporting the potential of F351 as a promising therapy for the treatment of liver fibrosis and strengthens Gyre's understanding of its therapeutic potential.
- **Phase 3 trial evaluating F351 for the treatment of Chronic Hepatitis B ("CHB")-associated liver fibrosis topline data expected by early 2025.** In October 2023, Gyre Pharmaceuticals completed enrollment of its Phase 3 trial in patients with CHB-associated liver fibrosis in the PRC. The trial 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. Gyre Pharmaceuticals expects to report topline data by early 2025.
- **Plans to initiate a Phase 2a clinical trial in metabolic dysfunction-associated steatohepatitis, ("MASH")-associated**

liver fibrosis in 2025. Gyre expects to file an investigational new drug (“IND”) application with the U.S. Food and Drug Administration (“FDA”) by the end of 2024. Pending FDA review and the results from the PRC Phase 3 trial in CHB-associated liver fibrosis, Gyre intends to initiate a Phase 2a proof-of-concept clinical trial to evaluate F351 for the treatment of MASH-associated liver fibrosis associated in 2025.

- **Ongoing Phase 2 trial in the PRC.** 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, a caspase inhibitor for injection in the treatment of acute/acute on-chronic liver failure.

F573:

- **Ongoing Phase 2 trial in the PRC.** 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, a caspase inhibitor for injection in the treatment of acute/acute on-chronic liver failure.

Preclinical Development Updates

- **F230:** F230 is a selective endothelin receptor agonist for the treatment of pulmonary arterial hypertension (“PAH”). In May 2024, Gyre Pharmaceuticals received NMPA approval for its IND application to evaluate for F230 tablets for the treatment of PAH.
- **F528:** F528 is a novel anti-inflammation agent that targets the inhibition of multiple inflammatory cytokines and has the potential to modify the progression of chronic obstructive pulmonary disease (“COPD”) with low toxicity in vivo. Gyre Pharmaceuticals is evaluating F528 in preclinical studies as a potential first-line therapy for the treatment of COPD.

Corporate Updates

- In August 2024, Gyre announced the appointment of David M. Epstein to the company’s Board of Directors. Dr. Epstein has extensive experience in the pharmaceutical industry across both the U.S. and Asia. Prior to joining Gyre’s Board of Directors, Dr. Epstein was President & CEO of Black Diamond Therapeutics. Dr. Epstein was formerly the Vice Dean of Innovation & Entrepreneurship and an Associate Professor at Duke-NUS Medical School in Singapore. Before his time at Duke, he was the Chief Scientific Officer at OSI Pharmaceuticals.
- In June 2024, Gyre Therapeutics was added to the small-cap Russell 2000 and all-cap Russell 3000 Indexes at the conclusion of the 2024 Russell Indexes annual reconstitution.

Financial Results

Cash Position

As of June 30, 2024, Gyre had cash and cash equivalents of \$16.1 million, short-term bank deposits of \$9.0 million and long-term certificates of deposit of \$28.8 million. Based on current plans, Gyre anticipates that its cash resources as of June 30, 2024 will enable it to fund operations through at least 12 months following the issuance of the condensed consolidated financial statements.

Financial Results for the Three Months Ended June 30, 2024

- **Revenues:** Revenues for the three months ended June 30, 2024 were \$25.2 million as a result of Gyre’s indirect controlling interest in Gyre Pharmaceuticals, compared to \$29.3 million for the same period in 2023. The \$4.1 million decrease was primarily driven by a \$3.9 million decrease in sales volume due to normalized anti-fibrosis drug sales. In the first half of 2023, a surge in COVID infection among the overall population in the PRC temporarily increased the anti-fibrosis auxiliary treatment by ETUARY from COVID-19. Further, \$0.2 million of revenues were negatively impacted by the foreign currency exchange rate as compared to the same period in the prior year.
- **Cost of Revenues:** For the three months ended June 30, 2024, cost of revenues was \$0.8 million as a result of Gyre’s indirect controlling interest in Gyre Pharmaceuticals, compared to \$1.1 million for the same period in 2023. The \$0.3 million decrease was primarily driven by a \$0.1 million in factory stoppage loss due to factory renovation in 2023, and a \$0.1 million due to the decrease of sales quantity.
- **Selling & Marketing Expense:** For the three months ended June 30, 2024, selling and marketing expense was \$14.4 million, compared to \$18.0 million for the same period in 2023. The decrease was primarily driven by a \$2.6 million decrease in conference costs due to a decrease in conference activity, a \$0.5 million decrease in promotional expenses, a \$0.4 million decrease in staff cost, as well as a \$0.2 million decrease in other expenses, partially offset by a \$0.1 million increase in traveling expenses.
- **R&D Expense:** For the three months ended June 30, 2024, research and development expense was \$3.4 million, compared to \$3.6 million for the same period in 2023. The \$0.5 million decrease from Gyre Pharmaceuticals was primarily driven by a \$0.2 million decrease in staff cost due to the decrease of the headcounts in the department, a \$0.1 million decrease in pre-clinical research expense and clinical trial costs, and a \$0.2 million decrease in materials and utilities. These decreases were partially offset by a \$0.3 million increase in Gyre Therapeutics research costs for F351 stability testing.

- **G&A Expense:** For the three months ended June 30, 2024, general and administrative expense was \$3.4 million, compared to \$1.7 million for the same period in 2023. The increase was primarily driven by costs associated with being a public company, including a \$0.9 million increase in functional and administrative department's personnel costs, a \$0.6 million increase in miscellaneous expenses, and a \$0.2 million increase in professional expense.
- **Income from operations:** For the three months ended June 30, 2024, income from operations was \$3.3 million, compared to \$5.0 million for the same period in 2023.
- **Net Income:** For the three months ended June 30, 2024, net income was \$4.5 million, compared to \$3.8 million in net income for the same period in 2023.

Financial Results for the Six Months Ended June 30, 2024

- **Revenues:** For the six months ended June 30, 2024, revenues were \$52.4 million as a result of Gyre's indirect controlling interest in Gyre Pharmaceuticals, compared to \$54.3 million for the same period in 2023. The \$1.9 million decrease was primarily driven by a \$0.8 million decrease in sales volume due to normalized anti-fibrosis drug sales. In the first half of 2023, a surge in COVID infection among the overall population in the PRC temporarily increased the anti-fibrosis auxiliary treatment by ETUARY from COVID-19. Further, \$1.1 million of revenues were negatively impacted by the foreign currency exchange rate as compared to the same period in the prior year.
- **Cost of Revenues:** For the six months ended June 30, 2024, cost of revenues was \$1.7 million as a result of Gyre's indirect controlling interest in Gyre Pharmaceuticals, compared to \$2.2 million for the same period in 2023. The decrease was primarily driven by a \$0.3 million factory stoppage loss due to factory renovation in 2023, and a \$0.3 million decrease in generic drug cost due to the decrease of sales, offset by a \$0.2 million increase due to the increase of the staff cost and new equipment depreciation.
- **Selling & Marketing Expense:** For the six months ended June 30, 2024, selling and marketing expense was \$27.0 million, compared to \$30.8 million for the same period in 2023. The decrease was primarily driven by a \$0.5 million decrease in promotional expenses, and a \$4.4 million decrease in conference costs due to a decrease in conference activity, offset by a \$1.1 million increase in staff costs due to an increase in staff headcount.
- **R&D Expense:** For the six months ended June 30, 2024, research and development expense was \$5.5 million, compared to \$6.2 million for the same period in 2023. The \$1.2 million decrease from Gyre Pharmaceuticals was primarily driven by a \$0.3 million decrease in materials and utilities, a \$0.5 million decrease in pre-clinical research expenses, and a \$0.4 million decrease in clinical trial costs. These decreases were offset by a \$0.5 million increase from Gyre Therapeutics, which was primarily driven by a \$0.3 million increase in clinical trial costs and a \$0.2 million increase in research and development consulting fees.
- **G&A Expense:** For the six months ended June 30, 2024, general and administrative expense was \$6.8 million, compared to \$3.5 million for the same period in 2023. The increase was primarily driven by costs associated with being a public company, including a \$1.4 million increase in functional and administrative department's personnel costs from Gyre Pharmaceuticals and a \$2.0 million increase in general and administrative expenses in Gyre Therapeutics.
- **Income from operations:** For the six months ended June 30, 2024, income from operations was \$11.3 million, compared to \$11.6 million for the same period in 2023.
- **Net Income:** For the six months ended June 30, 2024, net income was \$14.5 million, compared to \$8.0 million for the same period in 2023.

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 the 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 Hydronidone (F351)

F351 is a structural analogue of the approved anti-fibrotic (IPF) drug Pirfenidone and has been shown to inhibit *in vitro* both p38 γ kinase activity and TGF- β 1-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 CCl₄-induced liver fibrosis mouse model, DMN-induced liver fibrosis rat model, and HSA-induced liver rat model, as well as mouse model of MASH fibrosis (CCl₄+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 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 MASH-associated fibrosis in the U.S. Gyre's development strategy for F351 in MASH is based on the company's experience in MASH 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, are forward-looking statements, including statements concerning: the expectations regarding Gyre's research and development efforts, timing of expected clinical readouts, including timing of topline data from Gyre Pharmaceuticals' Phase 3 clinical trial evaluating F351 for the treatment of CHB-associated liver fibrosis in the PRC, the U.S. IND submission of F351, initiation of Gyre's Phase 2a trial and comprehensive Phase 2/3 clinical program in the U.S. for F351, the expectations regarding generic drug nintedanib, interactions with regulators, expectations regarding future product sales, and Gyre's financial position and cash resources. 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 for the year ended December 31, 2023 filed on March 27, 2024 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.

For Investors:

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|-----------------------------|-----------------|---------------------------|-----------------|
| | 2024 | 2023 | 2024 | 2023 |
| Revenues | \$ 25,225 | \$ 29,329 | \$ 52,397 | \$ 54,260 |
| Operating expenses: | | | | |
| Cost of revenues | 770 | 1,077 | 1,749 | 2,202 |
| Selling and marketing | 14,414 | 17,999 | 26,956 | 30,767 |
| Research and development | 3,355 | 3,568 | 5,537 | 6,203 |
| General and administrative | 3,424 | 1,711 | 6,822 | 3,450 |
| Total operating expenses | <u>21,963</u> | <u>24,355</u> | <u>41,064</u> | <u>42,622</u> |
| Income from operations | 3,262 | 4,974 | 11,333 | 11,638 |
| Other income (expense), net: | | | | |
| Interest income, net | 350 | 251 | 678 | 435 |
| Other (expense) income, net | (422) | 629 | (628) | 52 |
| Change in fair value of warrant liability | 2,913 | — | 7,201 | — |
| Loss on disposal of assets, net | <u>(68)</u> | <u>—</u> | <u>(68)</u> | <u>—</u> |
| Income before income taxes | 6,035 | 5,854 | 18,516 | 12,125 |
| Provision for income taxes | <u>(1,497)</u> | <u>(2,084)</u> | <u>(4,043)</u> | <u>(4,138)</u> |
| Net income | 4,538 | 3,770 | 14,473 | 7,987 |
| Net income attributable to noncontrolling interest | 1,010 | 1,917 | 3,413 | 3,890 |
| Net income attributable to common stockholders | <u>\$ 3,528</u> | <u>\$ 1,853</u> | <u>\$ 11,060</u> | <u>\$ 4,097</u> |

Net income per share attributable to common stockholders:

| | | | | |
|---------|---------|---------|---------|---------|
| Basic | \$ 0.04 | \$ 0.03 | \$ 0.13 | \$ 0.06 |
| Diluted | \$ 0.01 | \$ 0.02 | \$ 0.04 | \$ 0.05 |

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

| | | | | |
|---------|-------------|------------|-------------|------------|
| Basic | 85,502,403 | 63,588,119 | 84,384,141 | 63,588,119 |
| Diluted | 104,325,463 | 78,904,324 | 102,421,084 | 78,909,408 |

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

| | <u>June 30, 2024</u> | <u>December 31, 2023</u> |
|---|----------------------|--------------------------|
| | <u>(Unaudited)</u> | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 16,097 | \$ 33,509 |
| Short-term bank deposits | 9,003 | — |
| Accounts and note receivables, net | 18,622 | 15,552 |
| Other receivables from GNI | 1,287 | 1,287 |
| Inventories, net | 5,635 | 4,281 |
| Prepaid assets | 1,153 | 1,547 |
| Other current assets | 1,722 | 1,045 |
| Total current assets | <u>53,519</u> | <u>57,221</u> |
| Property and equipment, net | 23,672 | 23,288 |
| Long-term receivable from GCBP | 4,839 | 4,722 |
| Intangible assets, net | 186 | 205 |
| Right-of-use assets | 2,097 | 489 |
| Land use rights, net | 1,464 | 1,493 |
| Deferred tax assets | 5,075 | 4,695 |
| Long-term certificates of deposit | 28,799 | 23,431 |
| Other assets, noncurrent | 1,278 | 995 |
| Total assets | <u>\$ 120,929</u> | <u>\$ 116,539</u> |
| Liabilities, convertible preferred stock, and equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 271 | \$ 355 |
| Deferred revenue | 57 | 39 |
| Due to related parties | 1,484 | 1,369 |
| CVR excess closing cash payable | 328 | 1,085 |
| Accrued expenses and other current liabilities | 10,513 | 11,935 |
| Income tax payable | 2,262 | 5,054 |
| Operating lease liabilities, current | 659 | 210 |
| Total current liabilities | <u>15,574</u> | <u>20,047</u> |
| Operating lease liabilities, noncurrent | 1,297 | 199 |
| Deferred government grants | 192 | 213 |
| CVR derivative liability, noncurrent | 4,839 | 4,722 |
| Warrant liability, noncurrent | 5,634 | 12,835 |
| Other noncurrent liabilities | 47 | 49 |
| Total liabilities | <u>27,583</u> | <u>38,065</u> |
| Convertible Preferred Stock, \$0.001 par value, 5,000,000 shares authorized; nil shares and 13,151 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | — | 64,525 |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value, 400,000,000 shares authorized; 85,537,774 shares and 76,595,616 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | 85 | 77 |
| Additional paid-in capital | 133,656 | 68,179 |

| | | |
|---|-------------------|-------------------|
| Statutory reserve | 3,098 | 3,098 |
| Accumulated deficit | (74,478) | (85,538) |
| Accumulated other comprehensive loss | (2,010) | (1,644) |
| Total Gyre stockholders' equity (deficit) | 60,351 | (15,828) |
| Noncontrolling interest | 32,995 | 29,777 |
| Total equity | 93,346 | 13,949 |
| Total liabilities, convertible preferred stock, and equity | \$ 120,929 | \$ 116,539 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|-----------------------------|----------|---------------------------|-----------|
| | 2024 | 2023 | 2024 | 2023 |
| Net income | \$ 4,538 | \$ 3,770 | \$ 14,473 | \$ 7,987 |
| Gain from change in fair value of warrants ⁽¹⁾ | (2,913) | — | (7,201) | — |
| Stock-based compensation | 16 | — | 27 | — |
| Provision for income taxes | 1,497 | 2,084 | 4,043 | 4,138 |
| Non-GAAP adjusted net income | \$ 3,138 | \$ 5,854 | \$ 11,342 | \$ 12,125 |

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