UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from __________ to

Commission file number: 000-51173

Gyre Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**56-2020050**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
12770 High Bluff Drive Suite 150 San Diego, California	**92130**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 567-7770
(Registrant's Telephone Number, Including Area Code)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	GYRE	The Nasdaq Capital Market

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 6, 2024, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 93,424,184, which includes 7,815,396 shares of common stock issued in the name of the registrant to a stock plan administrator of the registrant (see Note 8—Stockholders' Equity).

GYRE THERAPEUTICS, INC.
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2024 (Unaudited)	December 31, 2023
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	53,519	57,221
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	$ 120,929	$ 116,539
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	15,574	20,047
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	27,583	38,065
Commitments and Contingencies (Note 12)		
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

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 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	21,963	24,355	41,064	42,622
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	(68)	—	(68)	—
Income before income taxes	6,035	5,854	18,516	12,125
Provision for income taxes	(1,497)	(2,084)	(4,043)	(4,138)
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	$ 3,528	$ 1,853	$ 11,060	$ 4,097
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
Other comprehensive income:				
Net income	$ 4,538	$ 3,770	$ 14,473	$ 7,987
Foreign currency translation adjustments	(420)	(3,634)	(561)	(2,736)
Comprehensive income	4,118	136	13,912	5,251
Net income attributable to noncontrolling interest	1,010	1,917	3,413	3,890
Foreign currency translation adjustments attributable to noncontrolling interest	(146)	(1,608)	(195)	(1,213)
Comprehensive income attributable to noncontrolling interest	864	309	3,218	2,677
Comprehensive income (loss) attributable to common stockholders	$ 3,254	$ (173)	$ 10,694	$ 2,574

The accompanying notes are an integral part of these condensed consolidated financial statements.

Gyre Therapeutics, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Equity
(In thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Statutory	Accumulated	Accumulated Other Comprehensive	Total Gyre Stockholders' (Deficit)	Non-controlling	Total
	Shares	Amount	Shares	Amount	Capital	Reserve	Deficit	Loss	Equity	Interest	Equity
Balance at December 31, 2023	13,151	$ 64,525	76,595,616	$ 77	$ 68,179	$ 3,098	$ (85,538)	$ (1,644)	$ (15,828)	$ 29,777	$ 13,949
Stock-based compensation expense	—	—	—	—	11	—	—	—	11	—	11
Stock options exercised	—	—	60,297	—	492	—	—	—	492	—	492
Convertible preferred stock conversion	(13,151)	(64,525)	8,767,333	8	64,517	—	—	—	64,525	—	64,525
Foreign currency translation adjustments	—	—	—	—	—	—	—	(92)	(92)	(49)	(141)
Net income	—	—	—	—	—	—	7,532	—	7,532	2,403	9,935
Balance at March 31, 2024	—	—	85,423,246	85	133,199	3,098	(78,006)	(1,736)	56,640	32,131	88,771
Stock-based compensation expense	—	—	—	—	16	—	—	—	16	—	16
Stock options exercised	—	—	114,528	—	441	—	—	—	441	—	441
Foreign currency translation adjustment	—	—	—	—	—	—	—	(274)	(274)	(146)	(420)
Net income	—	—	—	—	—	—	3,528	—	3,528	1,010	4,538
Balance at June 30, 2024	—	$ —	85,537,774	$ 85	$ 133,656	$ 3,098	$ (74,478)	$ (2,010)	$ 60,351	$ 32,995	$ 93,346

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Statutory	Retained Earnings	Accumulated Other Comprehensive (Loss)	Total Gyre Stockholders'	Non-controlling	Total
	Shares	Amount	Shares	Amount	Capital	Reserve		Income	Equity	Interest	Equity
Balance at December 31, 2022	—	$ —	63,588,119	$ 64	$ 32,795	$ 2,660	$ 7,395	$ (392)	$ 42,522	$ 29,695	$ 72,217
Foreign currency translation adjustments	—	—	—	—	—	—	—	503	503	395	898
Net income	—	—	—	—	—	—	2,244	—	2,244	1,973	4,217
Balance at March 31, 2023	—	$ —	63,588,119	$ 64	$ 32,795	$ 2,660	$ 9,639	$ 111	$ 45,269	$ 32,063	$ 77,332
Foreign currency translation adjustment	—	—	—	—	—	—	—	(2,026)	(2,026)	(1,608)	(3,634)
Net income	—	—	—	—	—	—	1,853	—	1,853	1,917	3,770
Balance at June 30, 2023	—	$ —	63,588,119	$ 64	$ 32,795	$ 2,660	$ 11,492	$ (1,915)	$ 45,096	$ 32,372	$ 77,468

The accompanying notes are an integral part of these condensed consolidated financial statements.

Gyre Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2024	2023
Operating Activities		
Net income	$ 14,473	$ 7,987
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	27	—
Equity in loss of unconsolidated affiliate	—	446
Depreciation and amortization	643	584
Noncash lease expense	300	198
Amortization of land use rights	20	20
Deferred income taxes, net	(410)	(558)
Bad debt expense and other non-cash items	99	(53)
Accrued interest on certificates of deposit	(486)	(285)
Change in fair value of long-term receivable	(117)	—
Change in fair value of derivative liabilities	117	—
Change in fair value of warrant liability	(7,201)	—
Loss on disposal of property and equipment	68	—
Changes in operating assets and liabilities:		
Accounts and note receivables	(3,277)	3,461
Inventories	(1,385)	642
Prepaid and other assets	(2,181)	(655)
Income tax payable	(2,766)	693
Accounts payable	(83)	39
Other noncurrent liabilities	19	(823)
Due to related parties	114	526
Accrued expenses and other liabilities	(2,171)	2,956
Operating lease liabilities	1,588	(228)
Net cash (used in) provided by operating activities	(2,609)	14,950
Investing Activities		
Acquisition of intangible assets	—	(66)
Purchase of certificates of deposit	(14,074)	(11,548)
Purchase of property and equipment	(1,687)	(4,219)
Proceeds from sale of equipment	268	134
Net cash used in investing activities	(15,493)	(15,699)
Financing Activities		
Deferred financing costs	(119)	—
Proceeds from the exercise of stock options	933	—
Net cash provided by financing activities	814	—
Effect of exchange rate changes on cash and cash equivalents	(124)	(700)
Net decrease in cash and cash equivalents	(17,412)	(1,449)
Cash and cash equivalents at beginning of the period	33,509	25,175
Cash and cash equivalents at end of the period	$ 16,097	$ 23,726
Supplemental Disclosure of Non-Cash Financing and Investing Activities:		
Convertible preferred stock conversion	$ 64,525	$ —
Non-cash acquisition of property and equipment through prepaid conversion	$ —	$ 455
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	$ 7,220	$ 4,003

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Nature of Operations and Liquidity

Description of Business

Gyre Therapeutics, Inc. (the “Company,” “Gyre,” or the “combined company”), formerly known as Catalyst Biosciences, Inc. (“Catalyst”), is a biopharmaceutical company originally incorporated in Delaware on March 7, 1997 under the name Targacept, Inc. Catalyst was a biopharmaceutical company with expertise in protease engineering. Prior to ceasing research and development activities in March 2022, Catalyst had several protease assets that were designed to address unmet medical needs in disorders of the complement or coagulation systems.

On October 30, 2023, the Company consummated the transactions (the “Contributions”) contemplated by the Business Combination Agreement as described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023 (the “Annual Report”), which were accounted for as a reverse asset acquisition and a purchase of noncontrolling interest in accordance with United States (“U.S.”) generally accepted accounting principles (“GAAP”). Continent Pharmaceuticals Inc. (“CPI”) was treated as the accounting acquirer of the reverse asset acquisition and is presented as the predecessor for post-acquisition financial reporting purposes. CPI holds an indirect controlling interest in Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals Co., Ltd., “Gyre Pharmaceuticals”), a commercial-stage biopharmaceutical company registered and established in the People’s Republic of China (“PRC”) in 2002.

After consummation of the Contributions, the immediate holding company of CPI became Gyre. The Company holds in aggregate a 65.2% indirect interest in Gyre Pharmaceuticals. The majority shareholder of Gyre is GNI USA, Inc. (“GNI USA”), which is indirectly wholly owned by GNI Group Ltd. (“GNI Japan”). Gyre is a financially-sustainable pharmaceutical company with a record of financial success that develops and commercializes small-molecule anti-inflammatory and anti-fibrotic drugs targeting organ diseases, focusing specifically on organ fibrosis. Fibrotic diseases represent a large patient population with significant unmet medical needs.

Liquidity

For the six months ended June 30, 2024, the Company had net income of $14.5 million, while net cash used in operating activities was $2.6 million. As of June 30, 2024, the Company had an accumulated deficit of $74.5 million and cash and cash equivalents of $16.1 million. Based on the Company’s current operating plan, management believes that existing cash and cash equivalents, cash flows from operations, and access to capital markets will be sufficient to fund the Company’s operating activities and obligations for at least 12 months following the issuance of these condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of the Company and its controlled subsidiaries. All intercompany accounts and transactions among consolidated entities were eliminated upon consolidation. The condensed consolidated financial statements have been prepared in accordance with GAAP and following the requirements of the Securities and Exchange Commission (the “SEC”) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the Company’s annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company’s condensed consolidated financial information. These condensed consolidated results of operations and cash flows for any interim period are not necessarily indicative of the results to be expected for the year ending December 31, 2024, or for any other future annual or interim period.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the consolidated financial statements filed with the Annual Report.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, allowance of doubtful accounts, long-term receivable, contingent value right ("CVR") derivative liability, warrant liability, allowance for credit losses, reserves for excess or obsolete inventory, operating lease right-of-use assets and liabilities, recognition of research and development expenses to the appropriate financial reporting period based on the progress of the research and development projects, income taxes, stock-based compensation and useful lives of property and equipment and intangibles with definite lives. The Company bases its estimates on various assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Risks and Uncertainties

The Company is subject to a number of risks associated with companies at a similar stage, including dependence on key individuals, competition from larger and established companies, uncertainty of clinical results, ability to obtain adequate financing to support growth, the ability to attract and retain additional qualified personnel to manage the anticipated growth of the Company, and general economic conditions.

Concentration of Credit Risk

In May 2015, a new Deposit Insurance System ("DIS") managed by the People's Bank of China was implemented by the Chinese government. Deposits in the licensed banks in mainland China are protected by DIS, up to a limit of Chinese Renminbi ("RMB") 500,000. The Company maintains cash and deposits at commercial banks in excess of the amount protected by DIS and the Federal Deposit Insurance Corporation and in the event of bankruptcy of one of these financial institutions, the Company may be unable to claim its deposits back in full. Management believes that these financial institutions are of high credit quality and continually monitors the creditworthiness of these financial institutions. As of June 30, 2024 and December 31, 2023, the Company had cash and cash equivalents of $16.1 million and $33.5 million, and long-term certificates of deposit of $28.8 million and $23.4 million, respectively. In addition, the Company had short-term bank deposits of $9.0 million as of June 30, 2024. $49.4 million cash and cash equivalents, short-term bank deposits and long-term certificates of deposits exceeded the PRC DIS coverage for both periods ended June 30, 2024 and December 31, 2023.

Accounts receivable are typically unsecured and are derived from product sales. The Company manages credit risk related to the accounts receivable through ongoing monitoring of outstanding balances and limiting the amount of credit extended based upon payment history and creditworthiness. Historically, the Company has collected receivables from customers within the credit terms with no significant credit losses incurred.

Concentration of Customer Risk

For the three months ended June 30, 2024, the Company had three customers, Sinopharm Group Co., Ltd. ("Sinopharm"), China Resources Pharmaceutical Group Ltd. ("Resources Pharmaceutical"), and Shanghai Pharmaceuticals Holding Co., Ltd. ("Shanghai Pharmaceuticals"), who accounted for approximately 49.2%, 13.7% and 13.1% of total revenue, respectively. For the three months ended June 30, 2023, the Company had three customers, Sinopharm, Resources Pharmaceutical, and Shanghai Pharmaceuticals who accounted for approximately 52.9%, 13.2% and 11.5% of total revenue, respectively.

For the six months ended June 30, 2024, the Company had three customers, Sinopharm, Resources Pharmaceutical, and Shanghai Pharmaceuticals, who accounted for approximately 48.2%, 15.5% and 12.1% of total revenue, respectively. For the six months ended June 30, 2023, the Company had three customers, Sinopharm, Resources

Pharmaceutical, and Shanghai Pharmaceuticals who accounted for approximately 51.4%, 13.3% and 11.0% of total revenue, respectively. All customers are located in mainland China.

As of June 30, 2024 and December 31, 2023, the Company had one customer Sinopharm, who accounted for approximately 45.5% and 50.5% of accounts receivable, respectively.

Foreign Currency Risk

The RMB is not a freely convertible currency. The State Administration for Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into other currencies. The value of the RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. 75.3% of the Company's cash and cash equivalents, and 100% of the Company's short-term bank deposits and long-term certificates of deposit as of June 30, 2024, in the amount of $12.1 million, $9.0 million and $28.8 million, respectively, were denominated in RMB.

Accounting Pronouncements Recently Adopted

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Improvements to Reportable Segment Disclosures (Topic 280)*. This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. The amendments in this ASU are effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company adopted this standard as of January 1, 2024. The adoption of this ASU did not have any material impact on the Company's interim condensed consolidated financial statements.

New Accounting Pronouncements – Issued But Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures (Topic 740)*. The ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is permitted. This ASU will result in the required additional disclosures being included in the Company's consolidated financial statements, once adopted. The Company plans to adopt ASU 2023-09 and related updates as of January 1, 2025. The Company is in the process of assessing the impact of adoption of this standard on its consolidated financial statements.

3. Fair Value Measurements and Financial Instruments

For a description of the fair value hierarchy and the Company's fair value methodology, see Note 2 – *Summary of Significant Accounting Policies* in the Annual Report. There were no significant changes in these methodologies during the six months ended June 30, 2024. As of June 30, 2024, the Company's highly liquid money market funds are included within cash equivalents.

The following tables present the fair value hierarchy for assets and liabilities measured at fair value on a recurring basis as of June 30, 2024 and December 31, 2023 (in thousands):

	June 30, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds[1]	$ 2,884	$ —	$ —	$ 2,884
Long-term receivable from GCBP	—	—	4,839	4,839
Total financial assets	$ 2,884	$ —	$ 4,839	$ 7,723
Financial liabilities:				
CVR derivative liability, noncurrent	$ —	$ —	$ 4,839	$ 4,839
Warrant liability, noncurrent	—	—	5,634	5,634
Total financial liabilities	$ —	$ —	$ 10,473	$ 10,473

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds[1]	$ 5,860	$ —	$ —	$ 5,860
Long-term receivable from GCBP	—	—	4,722	4,722
Total financial assets	$ 5,860	$ —	$ 4,722	$ 10,582
Financial liabilities:				
CVR derivative liability	$ —	$ —	$ 4,722	$ 4,722
Warrant liability, noncurrent	—	—	12,835	12,835
Total financial liabilities	$ —	$ —	$ 17,557	$ 17,557

(1) Included in cash and cash equivalents on the accompanying condensed consolidated balance sheets.

The carrying amounts of cash, accounts and note receivables, net, other receivables, accounts payable, due to related parties, CVR excess closing cash payable, and accrued liabilities approximate their fair values due to the short-term maturity of these instruments.

During the six months ended June 30, 2024 and the year ended December 31, 2023, there were no transfers of fair value measurement between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and liabilities.

Long-term Receivables and Derivative Liabilities

Concurrent with the signing of the Business Combination Agreement on December 26, 2022, Catalyst and the Rights Agent (as defined in the CVR Agreement) executed a contingent value rights agreement (the "CVR Agreement"), as amended on March 29, 2023, pursuant to which each holder of Catalyst common stock as of January 5, 2023 (each, a "CVR Holder"), excluding GNI Japan and GNI Hong Kong Limited ("GNI HK"), received one contractual CVR for each share of Catalyst common stock held by such holder. Each CVR entitles the holder thereof to receive certain cash payments in the future.

The long-term receivable and the corresponding CVR derivative liability, noncurrent relate to the asset purchase agreement with GC Biopharma Corp. ("GCBP"). The fair value of this long-term receivable and derivative liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The estimated fair value of the long-term receivable and CVR derivative liability, noncurrent was determined based on the anticipated amount and timing of projected cash flows to be received from GCBP pursuant to the GCBP asset purchase agreement discounted to their present values using an estimated discount rate of 5.05%. As of June 30, 2024, the Company expects to receive a $5.0 million hold-back payment from GCBP in the first quarter of 2025, which will be distributed, net of expenses, to the CVR Holders. The change in fair value of the long-term receivable from GCBP and the corresponding CVR derivative liability, noncurrent was recorded in interest and other income, net on the condensed consolidated statement of operations and comprehensive income.

Warrant Liability

In October 2023, Catalyst entered into a Securities Purchase Agreement for a private placement with GNI USA (the "Private Placement"). The Private Placement closed immediately following the Contributions, on October 30, 2023. Upon closing of the Private Placement, the Company issued 811 shares of Series X Convertible Preferred Stock, par value $0.001 per share (the "Convertible Preferred Stock"), and warrants to purchase up to 811 shares of Convertible Preferred Stock (the "Preferred Stock Warrants") to GNI USA for an aggregate purchase price of approximately $5.0 million. The Preferred Stock Warrants are immediately exercisable at an exercise price of $4,915.00 per share of Convertible Preferred Stock and expire on October 30, 2033. The number of shares of common stock issuable upon exercise and conversion of the Preferred Stock Warrants is 540,666. The Company accounted for the Private Placement as a non-arm's length transaction. The Preferred Stock Warrants were initially recognized at fair value upon issuance and the remaining proceeds from the Private Placement were allocated to the Convertible Preferred Stock.

The Preferred Stock Warrants are freestanding financial instruments classified as a warrant liability on the Company's condensed consolidated balance sheet. The Preferred Stock Warrants are revalued in each reporting period with the change in fair value recorded as change in fair value of warrant liability in other income (expense), net on the condensed consolidated statement of operations and comprehensive income.

The fair value of the warrant liability is estimated based on the Black-Scholes option pricing model using the following weighted-average assumptions:

	June 30, 2024	December 31, 2023
Share price	$ 11.93	$ 25.70
Exercise price	$ 4,915.00	$ 4,915.00
Dividend yield	—%	—%
Risk-free interest	4.35%	3.88%
Term (years)	9.33	9.83
Expected volatility	83.00%	84.00%

The following table sets forth the changes in the estimated fair value of the Company's Level 3 financial assets and liabilities (in thousands):

	Long-term receivable from GCBP	CVR derivative liability, noncurrent	Warrant liability
Balance at December 31, 2023	$ 4,722	$ 4,722	$ 12,835
Changes in fair value	117	117	(7,201)
Balance at June 30, 2024	$ 4,839	$ 4,839	$ 5,634

Financial Instruments

Cash equivalents consisted of the following (in thousands):

June 30, 2024	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Money market funds (cash equivalents)	$ 2,884	$ —	$ —	$ 2,884
Total financial assets	$ 2,884	$ —	$ —	$ 2,884
Classified as:				
Cash and cash equivalents				$ 2,884
Total financial assets				$ 2,884

December 31, 2023	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Money market funds (cash equivalents)	$ 5,860	$ —	$ —	$ 5,860
Total financial assets	$ 5,860	$ —	$ —	$ 5,860
Classified as:				
Cash and cash equivalents				$ 5,860
Total financial assets				$ 5,860

4. Balance Sheet Components

Inventories, net

Inventories, net of reserves of $11,000 and $46,000 as of June 30, 2024 and December 31, 2023, respectively, consisted of the following components (in thousands):

	June 30, 2024	December 31, 2023
Raw materials	$ 1,173	$ 919
Work in progress	2,916	1,997
Finished goods	1,546	1,365
Inventories, net	$ 5,635	$ 4,281

The provision for inventory and write-downs for the periods ended June 30, 2024 and December 31, 2023 were immaterial.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Accrued payroll and welfare	$ 5,658	$ 5,790
Accrued expenses - selling expenses	1,793	44
Supplier reimbursement	1,355	2,247
Accrued sales discount	850	903
Accrued expenses - general and administrative	472	1,190
Accrued expenses - research and development	94	161
Deferred government grants	40	40
Employee reimbursement	61	648
Accrued professional services	113	837
Other accrued liabilities	77	75
Accrued expenses and other current liabilities	$ 10,513	$ 11,935

Accounts and Note Receivables, Net

Accounts and note receivables, net consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Accounts receivable	$ 18,460	$ 15,204
Note receivable	302	389
Allowance for credit losses	(140)	(41)
Allowance and note receivables, net	$ 18,622	$ 15,552

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Buildings	$ 18,278	$ 12,289
Construction in progress	301	7,875
Machinery and electronic devices	9,073	6,598
Furniture and fixtures	640	606
Motor vehicles	184	185
Property and equipment, gross	28,476	27,553
Less: Accumulated depreciation	(4,804)	(4,265)
Property and equipment, net	$ 23,672	$ 23,288

5. Intangible Assets

The gross carrying amounts and accumulated amortization of the Company's intangible assets with determinable lives as of June 30, 2024 and December 31, 2023 were as follows (in thousands):

	June 30, 2024		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	$ 428	$ (298)	$ 130
Computer software	170	(114)	56
Total intangible assets	$ 598	$ (412)	$ 186

	December 31, 2023		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	$ 430	$ (290)	$ 140
Computer software	171	(106)	65
Total intangible assets	$ 601	$ (396)	$ 205

Intangible assets are carried at cost less accumulated amortization and impairment, if applicable, and the amortization expense is recorded in operating expenses. The weighted average amortization period for the intangible assets as of June 30, 2024 is 4.8 years.

Amortization expense was $8,500 and $48,000 for three months ended June 30, 2024 and 2023, respectively. Amortization expense was $16,000 and $93,000 for six months ended June 30, 2024 and 2023, respectively. Based on finite-lived intangible assets recorded as of June 30, 2024, the estimated future amortization expense is as follows (in thousands):

	Estimated amortization expense
2024	$ 17
2025	34
2026	34
2027	33
2028	18
Thereafter	50
Total	$ 186

6. Revenue

The Company's product revenues were mainly generated from the sale of ETUARY. Sales of ETUARY accounted for 99.3% and 98.8% of total revenue for the three months ended June 30, 2024 and 2023, respectively. Sales of ETUARY accounted for 99.3% and 98.7% of total revenue for the six months ended June 30, 2024 and 2023, respectively.

Sales of Pharmaceutical Products

The Company generates revenue mostly through sales of ETUARY and certain generic drugs. The distributors are the Company's direct customers, and sales to distributors account for 100.0% of revenue from ETUARY. The distributors sell ETUARY to outlets, including hospitals and other medical institutions, as well as pharmacies.

Product returns to date have not been significant and the Company has not considered it necessary to record a reserve for product returns. The Company's product revenues were recognized at a point in time when the underlying product was delivered to the customer, which was when the customer obtained control of the product. Revenue from sales of pharmaceutical products was $25.2 million and $29.3 million for the three months ended June 30, 2024 and 2023, respectively. Revenue from sales of pharmaceutical products was $52.4 million and $54.3 million for the six months ended June 30, 2024 and 2023, respectively. All sales are generated in the PRC. Deferred revenue recognized for the three and six months ended June 30, 2024 were immaterial.

7. Leases

Operating Leases

In April 2024, Gyre Pharmaceuticals entered into a lease arrangement for its new corporate headquarters, an approximately 2,130 square meter office space in Beijing, PRC, which lease is set to expire in June 2027. The lease for Gyre Pharmaceuticals' former corporate headquarters, a 968 square meter office space in Beijing, PRC, expired in June 2024. In 2022, Gyre Pharmaceuticals secured a lease for an office space of approximately 180 square meters in Zhengzhou, PRC, which was renewed in July 2024 and is set to expire in August 2026. In November 2023, the Company secured a lease for its U.S. headquarters in San Diego, California, with the lease set to expire in the first quarter of 2027.

The Company also has multiple short-term leased properties used as offices and employee dormitories. The Company recorded a total of $17,000 and $23,000 in short-term rent expenses during the three months ended June 30, 2024 and 2023, respectively. The Company recorded a total of $35,000 and $49,000 in short-term rent expenses during the six months ended June 30, 2024 and 2023, respectively. The short-term rent expense amounts are recorded in operating expenses in the accompanying condensed consolidated statements of operations and comprehensive income.

As of June 30, 2024, the Company recorded an aggregate right-of-use asset of $2.1 million and an aggregate lease liability of $2.0 million in the accompanying condensed consolidated balance sheets.

For the three months ended June 30, 2024 and 2023, the Company's operating lease expense was $0.1 million and $0.1 million, respectively. For the six months ended June 30, 2024 and 2023, the Company's operating lease expense was $0.3 million and $0.2 million, respectively. Variable lease payments for the three and six months ended June 30, 2024 and 2023 were immaterial.

Supplemental cash flow information related to operating leases was as follows (in thousands):

	Six Months Ended June 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities	$ 383	$ 243

The present value assumptions used in calculating the present value of the lease payments were as follows:

	June 30, 2024	December 31, 2023
Weighted-average remaining lease term	2.9 years	2.2 years
Weighted-average discount rate	4.76%	4.78%

As of June 30, 2024, undiscounted future minimum payments under the Company's operating leases were as follows (in thousands):

	Amount
Remaining in 2024	$ 474
2025	735
2026	598
2027	281
Total undiscounted lease payments	2,088
Less: imputed interest	(132)
Total lease liabilities	1,956
Less: current portion of lease liabilities	(659)
Lease liabilities, net of current portion	$ 1,297

The Company is required to maintain security deposits of $0.4 million in connection with various leases, which amounts are included in other assets, noncurrent on the Company's condensed consolidated balance sheets.

Land Use Rights

As of June 30, 2024, the Company held land use rights for two land parcels in Beijing's Shunyi District, expiring in 2053, and in Cangzhou, Hebei Province, expiring from 2067 to 2070. These parcels, with a combined area of approximately 66,559 square meters, are utilized as manufacturing facilities. As of June 30, 2024, the aggregate recorded land use rights, net assets for these parcels was $1.5 million.

8. Stockholders' Equity

Common Stock

Common stock reserved for future issuance is as follows:

	June 30, 2024		December 31, 2023
Options issued and outstanding	18,103,967	[1]	18,280,548
Preferred Stock Warrants issued and outstanding	540,666		540,666
Convertible Preferred Stock issued and outstanding	—		8,767,332
Total common stock reserved	18,644,633		27,588,546

[1] Includes 7,815,396 options exercisable for shares of common stock, which underlying shares of common stock were transferred in the name of the Company to Futu Network Technology Limited, the stock plan administrator of the 2023 Omnibus Incentive Sub-Plan for Chinese Participants.

2021 ATM Program

On October 15, 2021, Catalyst entered into an Equity Distribution Agreement (the "ATM Agreement") with Piper Sandler & Co. ("Piper Sandler") as sales agent, pursuant to which Catalyst was previously able to offer and sell, from time to time, through Piper Sandler, shares of Catalyst's common stock, par value of $0.001 per share, with aggregate gross sales proceeds of up to $50.0 million through an at-the-market offering program (the "ATM Program"). Catalyst was to pay Piper Sandler a commission of 3% of the gross proceeds of any shares sold. Catalyst also agreed to reimburse Piper Sandler for certain expenses incurred in connection with its services under the ATM Agreement, including up to $50,000 for legal expenses in connection with the establishment of the ATM Program.

Sales of shares of common stock under the ATM Program were previously made pursuant to the registration statement on Form S-3 (File No. 333-253874), which was declared effective by the SEC on May 3, 2021, and a related prospectus supplement filed with the SEC on October 15, 2021. The registration statement expired in May 2024 and the ATM Program was terminated. The Company wrote off $168,000 issuance cost during the quarter ended June 30, 2024.

Restricted Net Assets

Under PRC laws and regulations, Gyre Pharmaceuticals is subject to restrictions on foreign exchange and cross-border cash transfers, including to parent companies and U.S. stockholders. The ability to distribute earnings to the parent companies and U.S. stockholders is also limited. Current PRC regulations permit Gyre Pharmaceuticals to pay dividends to BJContinent Pharmaceuticals Limited ("BJC") only out of its accumulated profits as determined in accordance with PRC accounting standards and regulations. Amounts restricted include paid-in capital and the statutory reserves of Gyre Pharmaceuticals. The aggregate amounts of restricted capital and statutory reserves of the relevant subsidiaries not available for distribution were $64.3 million as of June 30, 2024 and December 31, 2023.

Statutory Reserve

Gyre Pharmaceuticals is required to set aside at least 10% of its after-tax profits as the statutory reserve fund until the cumulative amount of the statutory reserve fund reaches 50% or more of its registered capital, if any, to fund its statutory reserves, which are not available for distribution as cash dividends. At the Company's discretion, the Company may allocate a portion of after-tax profits based on PRC accounting standards to a discretionary reserve fund.

There were no appropriations to these reserves during the six months ended June 30, 2024 or during the year ended December 31, 2023.

9. Convertible Preferred Stock

In December 2022, Catalyst issued an aggregate of 12,340 shares of Convertible Preferred Stock to GNI Japan and GNI HK in connection with the F351 Asset Acquisition (see Note 1 — *Organization and Nature of Operations* of the Annual Report), which were subsequently transferred to GNI USA in October 2023.

In October 2023, immediately following the closing of the Contributions, the Company issued 811 shares of Convertible Preferred Stock and 811 Preferred Stock Warrants to GNI USA under the Private Placement. For additional information, see Note 3 — *Fair Value Measurements and Financial Instruments*.

In November 2023, GNI USA provided notice to the Company to convert its 13,151 shares of Convertible Preferred Stock. Each share of Convertible Preferred Stock was convertible into approximately 666.67 shares of common stock. On January 22, 2024, subject to the terms and conditions of the Convertible Preferred Stock Certificate of Designation, 8,767,333 shares of common stock were issued to GNI USA upon such conversion.

10. Stock Based Compensation

2023 Omnibus Incentive Plan

The 2023 Omnibus Incentive Plan was approved by Catalyst's stockholders in August 2023 and ratified by Gyre's board of directors (the "Board") in October 2023. The 2023 Omnibus Incentive Plan became effective on October 30, 2023. The 2023 Omnibus Incentive Plan permits the Company to issue up to 17,845,496 shares of common stock and will automatically increase by the lesser of (i) 5% of the total number of outstanding shares of common stock on December 31st of the preceding calendar year and (ii) such smaller number of shares of common stock as determined by the Board on the first day of each fiscal year beginning on January 1, 2024. On January 1, 2024, pursuant to the automatic increase in the number of shares reserved, an additional 3,829,780 shares of common stock were reserved and made available for issuance under the 2023 Omnibus Incentive Plan.

The following table summarizes stock option activity considering the conversion of Gyre Pharmaceuticals options to Gyre options to purchase shares of Gyre common stock upon completion of the Contributions:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Outstanding — December 31, 2023	18,280,548	$ 1.49	6.9
Options granted	1,866	$ 17.86	
Options exercised	(174,825)	$ 5.33	
Options forfeited and cancelled	(3,622)	$ 22.85	
Outstanding — June 30, 2024	18,103,967	$ 1.45	6.6
Exercisable — June 30, 2024	18,092,771	$ 1.44	6.6

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. Due to its limited relevant historical data, the Company estimated its volatility considering a number of factors, including the use of the volatility of comparable public companies. The expected term of options granted under the 2023 Omnibus Incentive Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to the Company's limited relevant history. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period.

Since no stock options were granted during the six months ended June 30, 2023, all weighted-average assumptions for that period were not applicable. The fair value of employee stock options granted during the three and six months ended June 30, 2024 and 2023 was estimated using the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Risk-free interest rate (%)	n/a	n/a	4.2 %	n/a
Expected option life (in years)	n/a	n/a	6.0	n/a
Expected dividend yield (%)	n/a	n/a	— %	n/a
Volatility (%)	n/a	n/a	84.3 %	n/a
Weighted average share price of the Company (USD per share)	n/a	n/a	$ 17.86	n/a

Total stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
General and administrative	$ 16	$ —	$ 27	$ —
Total stock-based compensation expense	$ 16	$ —	$ 27	$ —

As of June 30, 2024, the Company had an unrecognized stock-based compensation expense of $0.1 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 2.5 years.

11. Net Income per Share ("EPS") Attributable to Common Stockholders

The dilutive effect of outstanding stock options and warrants is calculated using the treasury stock method. Stock options and warrants are anti-dilutive and excluded from the diluted EPS attributable to common stock calculation if the exercise price exceeds the average market price of the common shares.

The following table sets forth the computation of EPS attributable to common stockholders, basic and diluted (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net income	$ 4,538	$ 3,770	$ 14,473	$ 7,987
Less: Allocation of undistributed earnings to noncontrolling interest	1,010	1,917	3,413	3,890
Net income attributable to common stockholders - basic	$ 3,528	$ 1,853	$ 11,060	$ 4,097
Less: Change in fair value of warrant liability	2,913	—	7,201	—
Net income attributable to common stockholders - diluted	$ 615	$ 1,853	$ 3,859	$ 4,097
Denominator:				
Basic common shares outstanding:				
Weighted average common shares outstanding	85,502,403	63,588,119	84,384,141	63,588,119
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
Dilutive potential common shares:				
Weighted average of common stock options	16,453,298	15,316,205	16,688,181	15,321,289
Weighted average of Convertible Preferred Stock (as converted)	2,119,575	—	1,059,788	—
Weighted average of Preferred Stock Warrants (as converted)	250,187	—	288,974	—
Weighted average shares used in calculating net income per share attributable to common stockholders, diluted	104,325,463	78,904,324	102,421,084	78,909,408
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

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Options to purchase common stock	244,094	—	191,520	—
Total	244,094	—	191,520	—

12. Commitments and Contingencies

Contingent Value Rights Agreement

Each CVR under the CVR Agreement entitles the holder to receive (i) certain cash payments from the net proceeds related to the disposition of Catalyst's legacy assets, (ii) 100% of the excess cash (net of all current or contingent liabilities, including transaction-related expenses) retained by the Company in excess of $1.0 million as of the closing date of the Contributions and (iii) 100% of the excess amount, by which the preapproved costs to manage, negotiate, settle and finalize certain third party claims exceed the costs actually incurred with respect to such claims. The CVRs are not transferable, except in certain limited circumstances as provided for in the CVR Agreement, will not be certificated or evidenced by any instrument, and will not be registered with the SEC or listed for trading on any exchange.

In February 2023, Catalyst sold its legacy rare bleeding disorder program to GCBP. As a result, the Company distributed the net cash proceeds received from the GCBP asset sale of $0.2 million to the CVR Holders as well as 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 condensed consolidated balance sheet. Refer to Note 3 — *Fair Value Measurements and Financial Instruments* for additional information regarding the CVR derivative liability and GCBP asset sale.

On October 30, 2023, pursuant to the CVR Agreement, the Company recorded a $1.1 million CVR excess closing cash payable upon closing of the Contributions. The CVR excess closing cash payable is anticipated to be distributed among the CVR Holders. The balance of $0.3 million remained outstanding as of June 30, 2024.

Litigation and Legal Matters

The Company is subject to claims and legal proceedings that arise in the ordinary course of business. Such matters are inherently uncertain, and there can be no guarantee that the outcome of any such matter will be decided favorably to the Company or that the resolution of any such matter will not have a material adverse effect upon the Company's condensed consolidated financial statements.

Purchasing Commitments

Property and Equipment

The Company's commitments related to purchase of property and equipment contracted but not yet reflected in the condensed consolidated financial statements were $1.6 million as of June 30, 2024 and were expected to be incurred within one year.

F351

In September 2020, Gyre Pharmaceuticals entered into an intellectual property ("IP") transfer agreement (the "F351 Transfer Agreement") with GNI Japan and certain of its wholly owned subsidiaries (the "GNI Group" or "GNI"). According to the F351 Transfer Agreement, Gyre Pharmaceuticals acquired the exclusive right to use Hydronidone IP rights in mainland China and the right of first offer for the global IP rights (the "F351 IP Rights").

Under the F351 Transfer Agreement, in exchange for the F351 IP Rights, Gyre Pharmaceuticals is obligated to pay GNI Group $4.6 million upon submission of the F351 New Drug Application (the "NDA") to Center for Drug Evaluation of the National Medical Products Administration (the "NMPA") of the PRC, $1.2 million after the NDA passes the NMPA's Center for Food and Drug Review and Inspection's on-site registration inspection for the F351 product, and $7.0 million upon NMPA's approval of the NDA.

Research and Development Programs

In addition to the F351 program, as of June 30, 2024, Gyre Pharmaceuticals has committed to allocate $19.0 million toward future research and development activities for various programs.

Investment commitments

Other long-term investment

On June 28, 2024, Gyre Pharmaceuticals, as a limited partner, entered into a partnership agreement with other investors and subscribed up to $4.2 million for a maximum 18.9% equity interest in the partnership. On July 17, 2024, Gyre Pharmaceuticals paid the initial investment of approximately $1.7 million to the partnership. Pursuant to the partnership agreement, Gyre Pharmaceuticals, as a limited partner, shall not participate in any activities related to the management of the investment business. It may, however, appoint a member to the advisory committee of the partnership.

13. Income Taxes

During the three and six months ended June 30, 2024, the Company recorded an income tax expense of approximately $1.5 million and $4.0 million. During the three and six months ended June 30, 2024 and 2023, the Company recorded the following income tax provision (in thousands) and effective tax rate:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Income tax provision	$ 1,497	$ 2,084	$ 4,043	$ 4,138
Effective tax rate	21.00 %	35.60 %	20.60 %	34.13 %

The change of effective tax rate for the three months ended June 30, 2024 and 2023 was primarily due the consummation of the Contributions in October 2023.

As of June 30, 2024, after consideration of certain limitations (see below), the Company had approximately $193.5 million federal and $10.5 million state net operating loss (“NOL”) carryforwards for U.S. tax purposes available to reduce future taxable income which, if unused, will begin to expire in 2037 for federal and 2034 for state tax purposes. The federal NOL carryforward includes $191.9 million that have an indefinite life.

If the Company experiences a greater than 50% aggregate change in ownership over a three-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards are subject to annual limitation under Section 382 of the Internal Revenue Code (California has similar provisions). The annual limitation is determined by multiplying the value of the Company’s stock at the time of such ownership change by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. The Company determined that ownership changes under Section 382 occurred on December 31, 2007, August 20, 2015, April 13, 2017, February 15, 2018, February 18, 2020, and December 26, 2022. Approximately $156.5 million and $75.2 million of the NOL carryforwards will expire unutilized for federal and California state income tax purposes, respectively. The ability of the Company to use its remaining NOL and tax credit carryforwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in its stock ownership.

14. Related Party Transactions

Research and Development with GNI

Research and development fees paid to GNI during three and six months ended June 30, 2024 were $0.1 million. No research and development fees were paid to GNI during the three and six months ended June 30, 2023. As of June 30, 2024 and December 31, 2023, the Company had $1.5 million and $1.4 million related parties payable due to GNI.

Other Receivables from GNI

As of June 30, 2024 and December 31, 2023, the Company had recorded $1.3 million in other receivables from GNI, of which $0.8 million was from CPI’s restructuring transaction (see Note 8 – *Restructuring* in the Annual Report) and $0.5 million was from Gyre’s cost sharing with GNI.

15. Employee Benefit Plans

Mainland China Contribution Plan

Pursuant to relevant PRC regulations, the Company is required to make contributions to various defined contribution plans organized by municipal and provincial PRC governments. The contribution for each employee is based on a percentage of the employee's current compensation as required by the local government. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme. The total contributions for such employee benefits were $1.2 million and $1.0 million for the three months ended June 30, 2024 and 2023, respectively. The total contributions for such employee benefits were $2.4 million and $2.0 million for the six months ended June 30, 2024 and 2023, respectively.

Defined-Contribution Savings Plan

In the U.S., the Company maintains a defined-contribution savings plan pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan is available to employees who meet the minimum age and length of service requirements. The contributions made during the three and six months ended June 30, 2024 were immaterial.

16. Segment Information

The Company is a consolidated entity comprised of two distinct operating segments: Gyre Pharmaceuticals and Gyre after the Contributions. The Company's reportable segments are based upon internal organizational structure, the manner in which operations are managed, the criteria used by CODM to evaluate segment performance, the availability of separate financial information, and overall materiality considerations. All Gyre's operations are within the U.S., while all of Gyre Pharmaceuticals' operations are in mainland China.

Gyre Pharmaceuticals

Gyre Pharmaceuticals has one major commercial drug product, ETUARY, and several product candidates in pre-clinical and clinical development. Gyre Pharmaceuticals' product revenues are mainly generated from the sale of ETUARY and certain generic drugs. Gyre Pharmaceuticals primarily sells its pharmaceutical products to distributors in the PRC, who ultimately sell the products to hospitals, other medical institutions and pharmacies. Gyre Pharmaceuticals also generates revenue from license agreements. However, the license agreements did not generate any revenue for the three and six months ended June 30, 2024 or 2023.

Gyre

Gyre is a biopharmaceutical company focused on the development and commercialization of F351 for the treatment of non-alcoholic steatohepatitis-associated liver fibrosis in the United States. Other than the IP associated with F351 in the U.S., Gyre has no other product candidates since the Company sold all of its legacy IP assets prior to the closing of the Contributions. Subsequent to the closing of the Contributions, Gyre has not generated any revenue.

Other

Other represents the financial information from other subsidiaries, consisting of mainly CPI, GNI HK, and Continent Pharmaceuticals U.S., Inc. During the year ended December 31, 2023, prior to the Contributions, CPI divested almost all of its assets other than its 56.0% indirect ownership interest in Gyre Pharmaceuticals (see Note 8 – *Restructuring* in the Annual Report).

Segment information for the three and six months ended June 30, 2024 and 2023 is as follows (in thousands):

	Three Months Ended June 30, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	$ 25,225	$ —	$ —	$ 25,225
Cost of revenues	770	—	—	770
Gross profit	24,455	—	—	24,455
Operating expenses excluding cost of revenues:				
Selling and marketing	14,414	—	—	14,414
Research and development	3,077	278	—	3,355
General and administrative	2,549	874	1	3,424
Total operating expenses excluding cost of revenues	20,040	1,152	1	21,193
Income (loss) from operations	$ 4,415	$ (1,152)	$ (1)	$ 3,262
Supplemental disclosure of stock-based compensation expense:				
General and administrative	$ —	$ 16	$ —	$ 16
Stock-based compensation total	$ —	$ 16	$ —	$ 16

	Six Months Ended June 30, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	$ 52,397	$ —	$ —	$ 52,397
Cost of revenues	1,749	—	—	1,749
Gross profit	50,648	—	—	50,648
Operating expenses excluding cost of revenues:				
Selling and marketing	26,956	—	—	26,956
Research and development	5,086	451	—	5,537
General and administrative	4,806	2,015	1	6,822
Total operating expenses excluding cost of revenues	36,848	2,466	1	39,315
Income (loss) from operations	$ 13,800	$ (2,466)	$ (1)	$ 11,333
Supplemental disclosure of stock-based compensation expense:				
General and administrative	$ —	$ 27	$ —	$ 27
Stock-based compensation total	$ —	$ 27	$ —	$ 27

	Three Months Ended June 30, 2023			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	$ 29,329	$ —	$ —	$ 29,329
Cost of revenues	1,077	—	—	1,077
Gross profit	28,252	—	—	28,252
Operating expenses excluding cost of revenues:				
Selling and marketing	17,999	—	—	17,999
Research and development	3,568	—	—	3,568
General and administrative	1,174	—	537	1,711
Total operating expenses excluding cost of revenues	22,741	—	537	23,278
Income (loss) from operations	$ 5,511	$ —	$ (537)	$ 4,974
Supplemental disclosure of stock-based compensation expense:				
Stock-based compensation total	$ —	$ —	$ —	$ —

	Six Months Ended June 30, 2023			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	$ 54,260	$ —	$ —	$ 54,260
Cost of revenues	2,202	—	—	2,202
Gross profit	52,058	—	—	52,058
Operating expenses excluding cost of revenues:				
Selling and marketing	30,767	—	—	30,767
Research and development	6,203	—	—	6,203
General and administrative	2,896	—	554	3,450
Total operating expenses excluding cost of revenues	39,866	—	554	40,420
Income (loss) from operations	$ 12,192	$ —	$ (554)	$ 11,638
Supplemental disclosure of stock-based compensation expense:				
Stock-based compensation total	$ —	$ —	$ —	$ —

The table below presents total assets as of June 30, 2024 and December 31, 2023.

	June 30, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Total assets	$ 109,484	$ 10,533	$ 912	$ 120,929

	December 31, 2023			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Total assets	$ 101,761	$ 13,865	$ 913	$ 116,539

The table below only includes cash outflows for the purchase of property and equipment and excludes non-cash activities.

	Six Months Ended June 30, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Purchase of property and equipment	$ 1,673	$ 14	$ —	$ 1,687

	Six Months Ended June 30, 2023			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Purchase of property and equipment	$ 4,219	$ —	$ —	$ 4,219

17. Subsequent Events

None.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

In this Quarterly Report on Form 10-Q (this "Quarterly Report"), unless otherwise specified, references to "we," "our," "us" and "our company" refer to Gyre Therapeutics, Inc. and our majority indirectly owned subsidiary, Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals Co., Ltd.) ("Gyre Pharmaceuticals"). The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and related notes that appear in this Quarterly Report and with the audited consolidated financial statements and related notes that are included as part of our Annual Report on Form 10-K for the year ended December 31, 2023 (the "Annual Report").

In addition to historical information, this Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended ("the Exchange Act"). Forward-looking statements are identified by words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially" "predict," "should," "will," or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. For example, forward-looking statements include any statements regarding: the strategies, prospects, plans, expectations or objectives of management for future operations or the distribution of cash to Company stockholders, the benefits that may be derived from product candidates or the commercial or market opportunity in any target indication, our ability to protect intellectual property rights, our anticipated operations, financial position, revenues, costs or expenses, future economic conditions or performance, and statements of belief and any assumptions underlying any of the foregoing. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors," and in Part I - Item 1A – "Risk Factors" in the Annual Report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a financially-sustainable commercial-stage biotechnology company with a record of financial success that develops and commercializes small-molecule anti-inflammatory and anti-fibrotic drugs targeting organ diseases, focusing specifically on organ fibrosis. Fibrotic diseases represent a large patient population with significant unmet medical needs. Fibrosis involves a complex, multi-stage process with multiple pathways. While there are numerous potential targets for anti-fibrotic therapy, both established and emerging, addressing a single molecular pathway may not be sufficient to prevent, halt, or reverse fibrosis.

Our strategy is to use our experience in the successful development and commercialization of ETUARY® (Pirfenidone) to expand into new indications and develop similar drug candidates. Pirfenidone, the first anti-fibrotic drug approved for idiopathic pulmonary fibrosis ("IPF") in Japan, the European Union, the United States, and the People's Republic of China ("PRC"), is a small molecule drug that inhibits the synthesis of Transforming Growth Factor ("TGF")-ß1, Tumor Necrosis Factor-α, and other fibrosis and inflammation modulators. We have obtained approval for ETUARY (pirfenidone) in the PRC for IPF.

Gyre Pharmaceuticals successfully advanced Pirfenidone from research and development to commercialization in the PRC for the treatment of IPF. In addition to IPF, Pirfenidone is undergoing three additional Phase 3 clinical trials for connective tissue disease-associated interstitial lung diseases (sclerosis-related interstitial lung disease and dermatomyositis-related interstitial lung disease) and pneumoconiosis to broaden its indications and market. In May 2024, Gyre Pharmaceuticals executed a comprehensive agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. to acquire the rights to nintedanib, a small-molecule drug for the treatment of IPF. With this acquisition, we acquired a second product approved for the treatment of idiopathic pulmonary fibrosis and expect to provide patients more choices and benefits, and further enhance Gyre Pharmaceuticals' leading position in the pulmonary fibrosis market.

F351, our lead development candidate in both the United States and the PRC, is a structural derivative of ETUARY (Pirfenidone). It is a new oral chemical entity with an anti-fibrotic, TGF-ß1-targeting mechanism of action. Studies suggest that F351 and its major metabolites have minimal drug-drug interaction risks. We are prioritizing F351 for the treatment of liver fibrosis due to the large potential addressable market and significant unmet need.

Gyre Pharmaceuticals has completed a Phase 2 trial of F351 in the PRC for chronic hepatitis B ("CHB")-associated liver fibrosis. The Phase 2 trial showed that F351 was well-tolerated without notable toxicity and patients treated showed statistically-significant improvement of liver fibrosis, with the best efficacy results achieved at 270 mg/day dosing. Based on these results, a confirmatory Phase 3 trial is ongoing in the PRC 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. The enrollment of 248 patients for the confirmatory Phase 3 trial has been completed, with the last patient expected to complete the 52-week study by the end of 2024 and clinical results expected by early 2025.

In the United States, we have completed a Phase 1 clinical trial of F351 in healthy volunteers. We are preparing an investigational new drug ("IND") application and expect to submit it in late 2024. Following results from the PRC Phase 3 trial in CHB-associated liver fibrosis and pending approval of our IND, we expect to initiate a Phase 2a trial to evaluate F351 for the treatment of non-alcoholic steatohepatitis-associated liver fibrosis in 2025.

In parallel, we are also 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 the treatment of acute/acute on-chronic liver failure. In addition, in May 2024, we obtained the approval from the PRC's National Medical Products Administration ("NMPA") for the IND to launch a new clinical trial in the PRC of another new drug candidate, F230, a selective endothelin receptor agonist for the treatment of pulmonary arterial hypertension. We are preparing for the anticipated launch of the clinical trial in the PRC.

In June 2024, Gyre Pharmaceuticals received approval from the NMPA for avatrombopag maleate tablets for the treatment of thrombocytopenia ("TP") associated with chronic liver disease ("CLD") in adult patients undergoing elective diagnostics procedures or therapy. TP is the most common hematologic complication in patients with CLD and can be life threatening in severe cases. Avatrombopag is an oral thrombopoietin receptor agonist. Avatrombopag was approved by the U.S. Food and Drug Administration for the treatment of adults with CLD-associated TP in May 2018, and its indication was subsequently expanded to include the treatment of immune thrombocytopenia in June 2019. Gyre Pharmaceuticals acquired avatrombopag under a transfer agreement with Nanjing Healthnice Pharmaceutical Technology, Co., Ltd. ("Nanjing Healtnice") in June 2021.

Nasdaq Continued Listing Requirements Compliance

On June 28, 2024, Nassim Usman, Ph.D. resigned from our Board of Directors (the "Board") and stepped down as a chair of the Audit Committee of the Board (the "Audit Committee"), effective as of June 30, 2024. Dr. Usman's resignation was not due to any disagreements with the Company relating to our operations, policies or practices. In connection with his resignation, we agreed to a full acceleration of all of Dr. Usman's outstanding stock options (the "Outstanding Option Awards"). On June 30, 2024, we notified Nasdaq that, following Dr. Usman's resignation as a member of the Board and as a member of the Audit Committee, we have a vacancy on our Audit Committee and intend to rely on the cure period set forth in the Nasdaq Listing Rules while we recruit a new Audit Committee member.

On July 2, 2024, we received a letter from Nasdaq confirming that we are no longer in compliance with Nasdaq's audit committee composition requirements as set forth in Nasdaq Listing Rule 5605, which requires that the audit committee of a listed company be comprised of at least three "independent directors" (as defined in Nasdaq Listing Rule 5605(a)(2)). Pursuant to Nasdaq Listing Rule 5605(c)(4), we intend to rely on the cure period to reestablish compliance with Nasdaq Listing Rule 5605. The cure period is generally defined as until the earlier of our next annual meeting of stockholders or June 30, 2025.

In June 2024, the former Audit Committee Chair of the Company stepped down from the position. On August 6, 2024, we appointed a new Audit Committee Chair, Rodney Nussbaum.

On August 6, 2024, the Board appointed David Epstein, Ph.D. as a Class II director to serve until our 2026 Annual Meeting of Stockholders and until his successor is duly elected and qualified. Dr. Epstein was also appointed as a member of the Board's Audit Committee and Compensation Committee. On August 9, 2024, we informed Nasdaq that, following Dr. Epstein's appointment as a member of the Board and as a member of the Audit Committee we regained compliance with Nasdaq's audit committee composition requirements as set forth in Nasdaq Listing Rule 5605, which requires that the audit committee of a listed company be comprised of at least three "independent directors" (as defined in Nasdaq Listing Rule 5605(a)(2)).

Business Combination Agreement

On December 26, 2022, Catalyst Biosciences, Inc., a Delaware corporation ("Catalyst") entered into a Business Combination Agreement, as amended on March 29, 2023 and August 30, 2023 (the "Business Combination Agreement") with GNI USA, Inc., a Delaware corporation ("GNI USA"), GNI Japan, GNI Hong Kong Limited ("GNI HK"), Shanghai Genomics, Inc., a company organized under the laws of the PRC (collectively with GNI USA, GNI Japan and GNI HK, the "Contributors," and each a "Contributor"), certain individuals and Continent Pharmaceuticals Inc., a Cayman Islands company limited by shares ("CPI"). On October 30, 2023 (the "Effective Time"), the Contributions (as defined below) became effective and Catalyst acquired an indirect controlling interest in Gyre Pharmaceuticals.

Pursuant to the Business Combination Agreement, at the Effective Time of the Contributions:

a) GNI USA contributed all of its ordinary shares in the capital of CPI to Catalyst in exchange for 45,923,340 shares of Common Stock (the "CPI Contribution"),

b) GNI USA contributed its interest in Further Challenger International Limited ("Further Challenger") for 17,664,779 shares of Common Stock (the "FC Contribution" and together with the CPI Contribution, the "GNI USA Contributions"), and

c) each Minority Holder contributed 100% of the interest he or she held in his or her respective entity in exchange for an aggregate of 10,463,627 shares of Common Stock (the "Minority Holder Contributions" and together with the GNI USA Contributions, the "Contributions").

As a result of the GNI USA Contributions, Gyre directly and indirectly holds 100% of CPI's shares. Through Gyre's ownership of CPI, prior to the Minority Holder Contributions, Gyre held a 56.0% indirect interest in Gyre Pharmaceuticals. Upon completion of the Minority Holder Contributions, Gyre obtained additional indirect interests in Gyre Pharmaceuticals and holds, in aggregate, a 65.2% indirect interest in Gyre Pharmaceuticals. Each share of Common Stock and option to purchase Common Stock that was issued and outstanding at the Effective Time remained issued and outstanding, and such shares and options were unaffected by the Contributions.

At the Effective Time, Gyre Pharmaceuticals terminated its 2021 Stock Incentive Plan (the "2021 Plan") and the options (the "Gyre Pharmaceuticals Options") outstanding under the 2021 Plan were terminated and replaced with options granted under a subplan for Chinese participants under the Gyre 2023 Omnibus Incentive Plan (the "2023 Omnibus Incentive Plan") that are substantially similar in all material respects to the Gyre Pharmaceuticals Options previously outstanding under the 2021 Plan.

The majority shareholder of Gyre Pharmaceuticals is BJContinent Pharmaceuticals Limited ("BJC"). The immediate holding company of BJC is CPI. Immediately following the GNI USA Contributions, the immediate holding company of CPI is Gyre. The majority stockholder of Gyre is GNI USA, which is indirectly wholly owned by GNI Japan.

The GNI USA Contributions were treated as an asset acquisition under U.S. generally accepted accounting principles, with CPI treated as the accounting acquirer and presented as the predecessor for post-acquisition reporting purposes. Since Catalyst is the legal acquirer, the GNI USA Contributions were accounted for as a reverse asset acquisition. This determination was based upon the terms of the Business Combination Agreement and other factors including that, immediately following the GNI USA Contributions: (i) GNI USA (as the parent company of CPI immediately prior to the GNI USA Contributions) owns a substantial majority of the voting power of the combined company; (ii) GNI USA has the ability to control the board of directors of the combined company; and (iii) senior management of Gyre Pharmaceuticals and GNI USA hold a majority of the key positions in senior management of the combined company. Immediately prior to the closing of the GNI USA Contributions, Catalyst did not meet the definition of a business because Catalyst did not have an organized workforce that significantly contributed to its ability to create output, and substantially all of its fair value was concentrated in in-process research and development ("IPR&D").

As of the closing date of the GNI USA Contributions, the net assets of Catalyst were recorded at their acquisition-date relative fair values in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report and the reported operating results prior to the GNI USA Contributions are those of CPI.

The Minority Holder Contributions were treated as an equity transaction, where we obtained additional indirect interests in and maintained our control over Gyre Pharmaceuticals.

Contingent Value Rights Agreement

Concurrent with the signing of the Business Combination Agreement on December 26, 2022, Catalyst and the Rights Agent (as defined in the CVR Agreement) executed a contingent value rights agreement (the "CVR Agreement"), as amended on March 29, 2023, pursuant to which each CVR Holder, excluding GNI Japan and GNI HK, received one contractual contingent value right (a "CVR") issued by the Company for each share of Catalyst common stock held by such holders. Each CVR entitles the CVR Holder thereof to receive certain cash payments in the future. For additional information, see Note 12 — *Commitments and Contingencies* to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report.

Private Placement and Securities Purchase Agreement

On October 27, 2023, we entered into the Securities Purchase Agreement for a private placement with GNI USA (the "Private Placement"). Pursuant to the Securities Purchase Agreement, GNI USA agreed to purchase (i) 811 shares of Series X Convertible Preferred Stock, par value $0.001 per share (the "Convertible Preferred Stock") and (ii) warrants to purchase up to 811 shares of Convertible Preferred Stock (the "Preferred Stock Warrants") for an aggregate purchase price of $5.0 million. The Private Placement closed immediately after the closing of the Contributions.

The Preferred Stock Warrants are exercisable at an exercise price of $4,915.00 per share of Convertible Preferred Stock and expire on October 30, 2033. In January 2024, all shares of Convertible Preferred Stock were converted into Gyre common stock. The Preferred Stock Warrants issued are considered freestanding financial instruments and classified as a liability.

Jiangsu Wangao Agreement

In May 2024, Gyre Pharmaceuticals entered into an agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. (the "Jiangsu Wangao Agreement"), effective from May 7, 2024 to May 6, 2035. Pursuant to the Jiangsu Wangao Agreement, Gyre Pharmaceuticals obtained the drug registration certificate for and became the marketing authorization holder of nintedanib, a small-molecule drug for the treatment of idiopathic pulmonary fibrosis, within the PRC. The total minimum payments under the Jiangsu Wangao Agreement are RMB 35.0 million, or approximately $4.8 million, based on the May 7, 2024 spot exchange rate. This includes an upfront transfer fee of RMB 15.0 million, or approximately $2.1 million, payable in three installments, and subsequent low- to mid-single-digit royalty payments over eight years following the commencement of sales. Additionally, Gyre Pharmaceuticals will bear the costs associated with relocating the production site to a designated location and will cover all expenses related to the manufacturing process.

Financial Operations Overview

During the three months ended June 30, 2024, we had net income of $4.5 million and net income attributable to common stockholders of $3.5 million. For the six months ended June 30, 2024, we had net income of $14.5 million and a net income attributable to common stockholders of $11.1 million. During the three months ended June 30, 2023, we had net income of $3.8 million and a net income attributable to common stockholders of $1.9 million. During six months ended June 30, 2023, we had net income of $8.0 million and a net income attributable to common stockholders of $4.1 million. As of June 30, 2024, we had an accumulated deficit of $74.5 million and cash and cash equivalents of $16.1 million. As of December 31, 2023, we had an accumulated deficit of $85.5 million and cash and cash equivalents of $33.5 million.

Components of Results of Operations

Revenues

Sales of Pharmaceutical Products

We generate revenue primarily through sales of ETUARY and certain generic drugs in the PRC. Distributors are our direct customers, and sales to distributors accounted for 100.0% of the revenue from ETUARY. Such distributors sell ETUARY to certain outlets, including hospitals and other medical institutions, as well as pharmacies.

Operating Expenses

Cost of Revenue

Cost of revenue mainly consists of cost of sales representing direct and indirect costs incurred to bring the product to saleable condition. Cost of sales primarily consists of (i) raw material costs; (ii) staff costs for production employees; (iii) depreciation and amortization related to property and equipment and intangible assets used in production; (iv) taxes and surcharges; (v) transportation costs; and (vi) miscellaneous other costs.

Selling and Marketing Expenses

Selling and marketing expenses primarily relate to selling and marketing our product ETUARY in the PRC and consist of expenses incurred from hosting academic conferences, seminars and symposia; promotional expenses associated with market education on ETUARY for its use in hospitals; and staff costs primarily consisting of salaries and benefits for in-house marketing and promotion staff.

Research and Development Expenses

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services used in research and development are initially deferred and capitalized in prepaid and other current assets. The capitalized amounts are then expensed as the related goods are delivered or services are performed, or until it is no longer expected that the goods or services will be delivered.

Research and development costs consist primarily of costs related to the pre-clinical and clinical development of our product candidates, which include payroll and other personnel-related expenses, laboratory supplies and reagents, contract research and development services for pre-clinical research and clinical trials, materials, and consulting costs, as well as allocations of facilities, depreciation, and other overhead costs.

General and Administrative Expenses

General and administrative expenses consist of (i) accounting, IT, legal, administrative, and other internal service staff costs; (ii) stock-based compensation representing share options granted to our functional employees; (iii) professional service fees, primarily for legal and accounting services; and (iv) other miscellaneous expenses.

Other Income (Expense), Net

Interest Income, Net

Interest income consists primarily of interest earned on our certificates of deposit. Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Other (Expense) Income, Net

Other income consists mostly of government grants. Government grants are recognized at their fair value where there is reasonable assurance that the grant will be received, and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed. Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual installments or deducted from the carrying amount of the asset and released to profit or loss by way of a reduced depreciation charge.

Other expenses consist of any non-operating costs, such as loss from equity method investments.

Change in Fair Value of Warrant Liability

In connection with the Private Placement, we issued the Preferred Stock Warrants, which are freestanding financial instruments classified as warrant liability since the underlying securities are contingently redeemable upon the occurrence of events which are outside of our control. The Preferred Stock Warrants are recorded at fair value upon issuance and are subject to remeasurement at the end of each reporting period, with any change in fair value recognized in our statements of operations as other (income) expense.

Provision for Income Taxes

Provision for income taxes are comprised primarily of current income tax provision, mainly attributable to the profitable Gyre Pharmaceuticals operations in the PRC, and deferred income tax provision, mainly including deferred tax recognized for temporary differences in relation to research and development tax credit and net operating loss carryforwards for U.S. tax purposes, deemed income inclusions from controlled foreign corporations for U.S. tax purposes, and fixed and intangible assets, net of valuation allowances.

Results of Operations

Comparison of the three months ended June 30, 2024 and 2023

The following table summarizes our results of operations for the periods presented (in thousands, except percentage change):

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Change ($)	Change (%)
Revenues	$ 25,225	$ 29,329	$ (4,104)	(14)%
Cost of revenues	770	1,077	(307)	(29)%
Gross profit	24,455	28,252	(3,797)	(13)%
Operating expenses excluding cost of revenues:				
Selling and marketing	14,414	17,999	(3,585)	(20)%
Research and development	3,355	3,568	(213)	(6)%
General and administrative	3,424	1,711	1,713	100%
Total operating expenses excluding cost of revenues	21,193	23,278	(2,085)	(9)%
Income from operations	3,262	4,974	(1,712)	(34)%
Other income (expense), net:				
Interest income, net	350	251	99	39%
Other (expense) income, net	(422)	629	(1,051)	(167)%
Change in fair value of warrant liability	2,913	—	2,913	*
Loss on disposal of assets, net	(68)	—	(68)	*
Income before income taxes	6,035	5,854	181	3%
Provision for income taxes	(1,497)	(2,084)	587	(28)%
Net income	4,538	3,770	768	20%
Net income attributable to noncontrolling interest	1,010	1,917	(907)	(47)%
Net income attributable to common stockholders	$ 3,528	$ 1,853	$ 1,675	90%

*Not meaningful

Revenues

Revenues for the three months ended June 30, 2024 and 2023 were $25.2 million and $29.3 million, respectively. 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

Cost of revenues for the three months ended June 30, 2024 and 2023 was $0.8 million and $1.1 million, respectively. The 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 and Marketing Expenses

Selling and marketing expenses decreased by $3.6 million, or 20%, for the three months ended June 30, 2024 compared to the three months ended June 30, 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.

Research and Development Expenses

The table below details our costs for research and development for the periods presented (in thousands, except percentage change):

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Change ($)	Change (%)
Direct program expenses:				
Clinical trials	$ 1,632	$ 1,319	$ 313	24 %
Materials and utilities	443	731	(288)	(39)%
Pre-clinical research	25	392	(367)	(94)%
Indirect expenses:				
Personnel-related costs	797	988	(191)	(19)%
Facilities, depreciation and other	458	138	320	232 %
Total research and development expenses	$ 3,355	$ 3,568	$ (213)	(6)%

Research and development expenses decreased by $0.2 million, or 6%, for the three months ended June 30, 2024 compared to the three months ended June 30, 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.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million, or 100%, for the three months ended June 30, 2024 compared to the three months ended June 30, 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.

Other Income (Expense), Net

Interest income increased by $0.1 million, or 39%, for the three months ended June 30, 2024 compared to the three months ended June 30, 2023, primarily due to additional investments in certificates of deposit.

Other income (expenses), net decreased by $1.1 million, or 167%, for the three months ended June 30, 2024 compared to the three months ended June 30, 2023. The decline was primarily due to a $0.9 million decrease in government grant, a $0.3 million decrease from the combination of equity method investments loss, foreign exchange losses, and miscellaneous non-operating expenses, offset by a $0.1 million increase in Gyre Pharmaceuticals' donation expense.

Change in fair value of warrant liability was $2.9 million for the three months ended June 30, 2024. It was related to the remeasurement of the Preferred Stock Warrants liability.

Provision for Income Taxes

Provision for income taxes was $1.5 million and $2.1 million for the three months ended June 30, 2024 and 2023, respectively. The decrease was primarily attributable to a lower profit from Gyre Pharmaceuticals' operations for the three months ended June 30, 2024.

Comparison of the six months ended June 30, 2024 and 2023

The following table summarizes our results of operations for the periods presented (in thousands, except percentage change):

	Six Months Ended June 30, 2024		Six Months Ended June 30, 2023		Change ($)		Change (%)
Revenues	$	52,397	$	54,260	$	(1,863)	(3)%
Cost of revenues		1,749		2,202		(453)	(21)%
Gross profit		50,648		52,058		(1,410)	(3)%
Operating expenses excluding cost of revenues:							
Selling and marketing		26,956		30,767		(3,811)	(12)%
Research and development		5,537		6,203		(666)	(11)%
General and administrative		6,822		3,450		3,372	98%
Total operating expenses excluding cost of revenues		39,315		40,420		(1,105)	(3)%
Income from operations		11,333		11,638		(305)	(3)%
Other income (expense), net:							
Interest income, net		678		435		243	56%
Other (expense) income, net		(628)		52		(680)	(1308)%
Change in fair value of warrant liability		7,201		—		7,201	*
Loss on disposal of assets, net		(68)		—		(68)	*
Income before income taxes		18,516		12,125		6,391	53%
Provision for income taxes		(4,043)		(4,138)		95	(2)%
Net income		14,473		7,987		6,486	81%
Net income attributable to noncontrolling interest		3,413		3,890		(477)	(12)%
Net income attributable to common stockholders	$	11,060	$	4,097	$	6,963	170%

Revenues

Revenues for the six months ended June 30, 2024 and 2023 were $52.4 million and $54.3 million, respectively. 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. 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.

Cost of Revenues

Cost of revenues for the six months ended June 30, 2024 and 2023 was $1.7 million and $2.2 million, respectively. 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 and Marketing Expenses

Selling and marketing expenses decreased by $3.8 million, or 12%, for the six months ended June 30, 2024 compared to the six months ended June 30, 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.

Research and Development Expenses

The table below details our costs for research and development for the periods presented (in thousands, except percentage change):

	Six Months Ended June 30,			
	2024	2023	Change ($)	Change (%)
Direct program expenses:				
Clinical trials	$ 1,985	$ 2,151	$ (166)	(8)%
Materials and utilities	945	1,269	(324)	(26)%
Pre-clinical research	174	647	(473)	(73)%
Indirect expenses:				
Personnel-related costs	1,773	1,779	(6)	0%
Facilities, depreciation and other	660	357	303	85%
Total research and development expenses	$ 5,537	$ 6,203	$ (666)	(11)%

Research and development expenses decreased by $0.7 million, or 11%, for the six months ended June 30, 2024 compared to the six months ended June 30, 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.

General and Administrative Expenses

General and administrative expenses increased by $3.4 million, or 98%, for the six months ended June 30, 2024 compared to the six months ended June 30, 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 in general and administrative expenses in Gyre Therapeutics.

Other Income (Expense), Net

Interest income increased by $0.2 million, or 56%, for the six months ended June 30, 2024 compared to the six months ended June 30, 2023, primarily due to additional investments in certificates of deposit.

Other income (expenses), net decreased by $0.7 million, or 1,308%, for the six months ended June 30, 2024 compared to the six months ended June 30, 2023. The decrease was primarily due to a $0.9 million decrease in government grants, offset by a $0.2 million increase in miscellaneous non-operating expenses and Gyre Pharmaceuticals' donation expense.

Change in fair value of warrant liability was $7.2 million for the six months ended June 30, 2024. It was related to the remeasurement of the Preferred Stock Warrants liability.

Provision for Income Taxes

Provision for income taxes was $4.0 million and $4.1 million for the six months ended June 30, 2024 and 2023, respectively. The decrease was primarily due to the projected effective tax rate decreased for the six months ended June 30, 2024, as compared to the six months ended June 30, 2023.

Recent Accounting Pronouncements

Refer to Note 2 – *Summary of Significant Accounting Policies* to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for more information about recent accounting pronouncements.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2024, we 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, which are available to fund operations, and an accumulated deficit of $74.5 million. Our net income during the three and six months ended June 30, 2024 was $4.5 million and $14.5 million, while cash used in operating activities was $5.5 million and $2.6 million. We believe that our existing cash and cash equivalents, cash flows from operations, and access to capital markets will be sufficient to fund our operating activities and obligations for at least 12 months following the filing date of this Quarterly Report.

Future Funding Requirements

We expect to use cash flows from operations to meet our current and future financial obligations, including funding our operations, and capital expenditures. Our ability to make these payments depends on our future performance, which will be affected by financial, business, economic, regulatory, and other factors, many of which we cannot control. Factors that may affect financing requirements include, but are not limited to:

- the timing, progress, cost and results of our clinical trials, preclinical studies and other discovery and research and development activities;
- the timing and outcome of, and costs involved in, seeking and obtaining marketing approvals for our products, and in maintaining quality systems standards for our products;
- the timing of, and costs involved in, commercial activities, including product marketing, sales and distribution;
- our ability to successfully commercialize and to obtain regulatory approval for, and successfully commercialize our other or future product candidates;
- increases or decreases in revenue from our marketed products, including decreases in revenue resulting from generic entrants or health epidemics or pandemics;
- the number and development requirements of other product candidates that we pursue;
- our ability to manufacture sufficient quantities of our products to meet expected demand;
- the costs of preparing, filing, prosecuting, maintaining and enforcing any patent claims and other intellectual property rights, litigation costs and the results of litigation;
- our ability to enter into collaboration, licensing or distribution arrangements and the terms and timing of these arrangements;
- the potential need to expand our business, resulting in additional payroll and other overhead expenses;
- the potential in-licensing of other products or technologies;
- the emergence of competing technologies or other adverse market or technological developments; and
- the impacts of inflation and resulting cost increases.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies.

The following table summarizes our cash flows for the periods presented (in thousands):

	Six Months Ended June 30,	
	2024	2023
Cash Flow Data:		
Net cash (used in) provided by operating activities	$ (2,609)	$ 14,950
Net cash used in investing activities	(15,493)	(15,699)
Net cash provided by financing activities	814	—
Effect of exchange rate changes on cash and cash equivalents	(124)	(700)
Net change in cash and cash equivalents	$ (17,412)	$ (1,449)

Cash Flows from Operating Activities

Cash used in operating activities for the six months ended June 30, 2024 was $2.6 million, reflecting our net income of $14.5 million, offset by non-cash items of $6.9 million primarily related to the change in fair value of warrant liability of $7.2 million. Additionally, cash used in operating activities reflected changes in net operating assets and liabilities of $10.1 million.

Cash provided by operating activities for the six months ended June 30, 2023 was $15.0 million, reflecting our net income of $8.0 million and additional positive non-cash items impact of $0.4 million. Additionally, cash provided by operating activities reflected changes in net operating assets and liabilities of $6.6 million.

Cash Flows from Investing Activities

Cash used in investing activities for the six months ended June 30, 2024 was $15.5 million, which consisted of $14.1 million in purchases of certificates of deposit and $1.7 million in purchases of property and equipment, partially offset by $0.3 million proceeds from sale of equipment.

Cash used in investing activities for the six months ended June 30, 2023 was $15.7 million, which consisted of $11.5 million in purchases of certificates of deposit and $4.2 million in purchases of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the six months ended June 30, 2024 was $0.8 million due to deferred financing costs, as well as proceeds from the exercise of stock options. The Company did not have cash provided by financing activities for the six months ended June 30, 2023.

Restricted Net Assets

Under PRC laws and regulations, Gyre Pharmaceuticals is subject to restrictions on foreign exchange and cross-border cash transfers, including to parent companies and U.S. stockholders. The ability to distribute earnings to the parent companies and U.S. stockholders is also limited. Current PRC regulations permit Gyre Pharmaceuticals to pay dividends to BJC only out of its accumulated profits as determined in accordance with PRC accounting standards and regulations. Amounts restricted include paid-in capital and the statutory reserves of Gyre Pharmaceuticals. The aggregate amounts of restricted capital and statutory reserves of the relevant subsidiaries not available for distribution were $64.3 million as of June 30, 2024 and December 31, 2023. We do not expect the restrictions described above to have a material impact on our ability to meet our cash obligations.

Contractual Obligations and Other Commitments

Leases

We have entered into lease arrangements in (1) San Diego, California for our headquarters, which expires on the last day of the 38th full calendar month beginning on or after November 11, 2023, and (2) the PRC, for office and laboratory spaces through May 2027. As of June 30, 2024, our fixed lease payment obligations were $2.1 million, with $0.7 million payable within 12 months.

Other Contractual Obligations and Commitments

In June 2021, we entered into a transfer agreement with Nanjing Healthnice, an independent third party, pursuant to which Nanjing Healthnice agreed to transfer to us the avatrombopag maleate tablets for the treatment of CLD-associated thrombocytopenia and all relevant technologies, complete any research or trials and transfer to us all materials necessary for the application of marketing approval by CDE. We were approved by the NMPA as the marketing authorization holder of the avatrombopag maleate tablets on June 25, 2024. In exchange, we paid a total of approximately $2.3 million upon certain milestones (e.g., the completion of bioequivalence study, or the registration application to CDE) being met. We have completed the bioequivalence study and received CDE acceptance on August 1, 2022, and as of June 30, 2024, we have made total payments of approximately $1.8 million.

In September 2022, we entered into a transfer agreement with New Jiyuan (Beijing) Pharmaceutical Technology Co., Ltd. (“New Jiyuan”), an independent third party, pursuant to which New Jiyuan agreed to transfer to us the minocycline hydrochloride foam for the treatment of moderate to severe acne and all relevant technologies, complete product development and transfer to us all materials necessary for the application of marketing approval of CDE. Upon the completion of the transfer, we expect that we will be approved by NMPA as the marketing authorization holder of the minocycline hydrochloride foam. In exchange, we will pay a total amount of $1.0 million and the payments will be made by installments conditioned upon certain milestones (*e.g.*, the completion of bioequivalence study, or the registration application to CDE) being met. Process verification has been completed. As of June 30, 2024, we have made total payments of approximately $0.7 million.

In December 2022, we entered into a transfer agreement with Hangzhou Baicheng Pharmaceutical Technology Co., Ltd. and Zhejiang CDMO Pharmaceutical Co., Ltd., an independent third party, pursuant to which Baicheng agreed to transfer to us the acetylcysteine injection for the treatment of respiratory diseases with excessive thick mucus discharge and all relevant technologies, assist us in completing any research, trial and other required procedures and transfer to us all materials necessary for the application of marketing approval of CDE. Upon the completion of this transfer agreement, we expect that we will be approved by NMPA as the marketing authorization holder of the acetylcysteine injection. We have received CDE acceptance on January 8, 2024. As of June 30, 2024, we have made payments totaling approximately $0.5 million under this agreement. Upon receiving the CDE's final approval, we will make an additional $40,000 in payments.

Research and Development Programs

As of June 30, 2024, we have committed to allocate $31.7 million toward future research and development activities for various programs.

Property and Equipment

Our commitments related to the purchase of property and equipment contracted but not yet reflected in the unaudited consolidated condensed financial statements were $1.6 million as of June 30, 2024 and are expected to be incurred within one year.

Critical Accounting Policies and Estimates

There have been no significant changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in our Annual Report.

Smaller Reporting Company and Accelerated Filer Status

We are a "smaller reporting company" as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Based on the aggregate market value of our common stock held by non-affiliates as of June 30, 2024, we believe we will become a "large accelerated filer" and no longer qualify as a smaller reporting company as of December 31, 2024. Because we believe our non-accelerated filer status will expire on December 31, 2024, we may be required, pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, to include in our Annual Report on Form 10-K for the year ending December 31, 2024 an attestation report as to the effectiveness of our internal control over financial reporting that is issued by our independent registered public accounting firm. In addition, beginning with our Quarterly Report on Form 10-Q for the quarter ending March 31, 2024, we expect to no longer be permitted to take advantage of the reduced reporting requirements applicable to smaller reporting companies.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2024, our management, with the participation and supervision of our principal executive officer and our principal financial officer, evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2024 to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are currently not a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

ITEM 1A. RISK FACTORS

You should carefully consider the factors discussed in Part I, Item 1A, “Risk Factors” in our Annual Report, which could materially affect our business, financial position, or future results of operations. The risks described in our Annual Report are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial position, or future results of operations. We may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC. There have been no material changes from the risk factors disclosed in Part I, Item 1A, “Risk Factors” in our Annual Report.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Trading Arrangements

None of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the three months ended June 30, 2024, as such terms are defined under Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

The exhibits filed or furnished as part of this Quarterly Report are set forth below.

Exhibit Number	Exhibit Title	Form	File No.	Incorporated by reference Exhibit No.	Filing Date
2.1(a)†#	Asset Purchase Agreement, dated as of December 26, 2022, by and among Catalyst Biosciences, Inc., GNI Group Ltd., and GNI Hong Kong Limited.	8-K	000-51173	2.1	Dec. 27, 2022
2.1(b)	Agreement and Amendment to Asset Purchase Agreement, dated as of March 29, 2023, by and among Catalyst Biosciences, Inc., GNI Group Ltd., and GNI Hong Kong Limited.	8-K	000-51173	2.2	Mar. 30, 2023
2.2(a)#	Business Combination Agreement, dated as of December 26, 2022, by and among Catalyst Biosciences, Inc., GNI USA, Inc., GNI Group Ltd., GNI Hong Kong Limited, Shanghai Genomics, Inc., the individuals listed on Annex A thereto and Continent Pharmaceuticals Inc.	8-K	000-51173	2.2	Dec. 27, 2022
2.2(b)	Amendment to Business Combination Agreement, dated as of March 29, 2023, by and among Catalyst Biosciences, Inc., GNI USA, Inc., GNI Group Ltd., GNI Hong Kong Limited, Shanghai Genomics, Inc., the Minority Holders and Continent Pharmaceuticals Inc.	8-K	000-51173	2.1	Mar. 30, 2023
2.2(c)	Second Amendment to Business Combination Agreement, dated as of August 30, 2023, by and among Catalyst Biosciences, Inc., GNI USA, Inc., GNI Group Ltd., GNI Hong Kong Limited, Shanghai Genomics, Inc. and Continent Pharmaceuticals Inc.	8-K	000-51173	2.1	Aug. 31, 2023
3.1	Fourth Amended and Restated Certificate of Incorporation of the Company.	S-8	333-133881	4.1	May 8, 2006
3.2	Certificate of Amendment to Fourth the Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Aug. 20, 2015
3.3	Second Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Feb. 10, 2017

3.4	Third Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Oct. 30, 2023
3.5	Fourth Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	June 17, 2024
3.6	Amended and Restated Bylaws of the Company.	8-K	000-51173	3.3	Oct. 30, 2023
3.7(a)	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, filed with the Delaware Secretary of State on April 10, 2017.	10-Q	000-51173	3.1	Aug. 3, 2017
3.7(b)	Certificate of Elimination of Series A Preferred Stock, filed with the Delaware Secretary of State on March 25, 2024.	10-K	000-51173	3.6(b)	Mar. 27, 2024
3.8(a)	Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, filed with the Delaware Secretary of State on December 27, 2022.	8-K	000-51173	3.1	Dec. 27, 2022
3.8(b)	Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, filed with the Delaware Secretary of State on October 30, 2023.	8-K	000-51173	3.2	Oct. 30, 2023
3.9(a)	Certificate of Designation of Preferences, Rights and Limitations of Series Y Preferred Stock, filed with the Delaware Secretary of State on June 20, 2023, with respect to the Series Y Preferred Stock.	8-K	000-51173	3.1	June 20, 2023
3.9(b)	Certificate of Elimination of Series Y Preferred Stock, filed with the Delaware Secretary of State on August 31, 2023.	8-K	000-51173	3.1	Aug. 31, 2023
4.1	Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to Silicon Valley Bank on March 3, 2005.	10-K	000-51173	4.4	Mar. 9, 2016
4.2	Form of Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to purchasers of convertible promissory notes.	10-K	000-51173	4.6	Mar. 9, 2016
4.3	Form of Warrant to Purchase Series X Convertible Preferred Stock.	8-K	000-51173	4.1	Oct. 30, 2023

31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Interim Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Interim Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL (extensible Business Reporting Language) Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.
** Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.
† The annexes, schedules, and certain exhibits to this Exhibit have been omitted pursuant to Item 601(a)(5).
# Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) the Company customarily and actually treats that information as private or confidential and (ii) the information was not material.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	GYRE THERAPEUTICS, INC.
Date: August 13, 2024	/s/ Han Ying, Ph.D.
	Han Ying, Ph.D. **Chief Executive Officer** (*Principal Executive Officer*)
Date: August 13, 2024	/s/ Ruoyu Chen
	Ruoyu Chen **Chief Financial Officer** (*Principal Financial and Accounting Officer*)

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Han Ying, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Gyre Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2024

/s/ Han Ying, Ph.D.

Han Ying, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ruoyu Chen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Gyre Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2024

/s/ Ruoyu Chen

Ruoyu Chen
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Gyre Therapeutics, Inc. (the “Company”) for the period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Han Ying, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2024	/s/ Han Ying, Ph.D.
	Han Ying, Ph.D.
	Chief Executive Officer and Director
	(*Principal Executive Officer*)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by § 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Gyre Therapeutics, Inc. (the "Company") for the period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ruoyu Chen, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2024

/s/ Ruoyu Chen

Ruoyu Chen
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by § 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.