

**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 September 30, 2025

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
(State or Other Jurisdiction of
Incorporation or Organization)
12770 High Bluff Drive Suite 150
San Diego, California
(Address of Principal Executive Offices)

56-2020050
(I.R.S. Employer
Identification No.)

92130
(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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 October 31, 2025, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 96,333,157, which includes 5,442,776 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.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	<u>September 30, 2025</u> (Unaudited)	<u>December 31, 2024</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 40,402	\$ 11,813
Short-term bank deposits	19,647	14,858
Notes receivable	693	4,373
Accounts receivable, net	25,877	19,589
Other receivables from GNI	230	230
Inventories	8,854	6,337
Receivable from GCBP	—	4,961
Prepaid assets and other current assets	2,873	2,625
Total current assets	<u>98,576</u>	<u>64,786</u>
Property and equipment, net	23,608	23,880
Intangible assets, net	4,847	273
Deferred tax assets	6,714	5,619
Long-term certificates of deposit	20,317	24,568
Other assets, noncurrent	5,322	6,280
Total assets	<u>\$ 159,384</u>	<u>\$ 125,406</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 556	\$ 108
Contract liabilities	58	61
Due to related parties	228	227
Accrued expenses and other current liabilities	11,799	10,615
Income tax payable	2,646	2,831
Operating lease liabilities, current	626	713
CVR derivative liability	—	4,961
Total current liabilities	<u>15,913</u>	<u>19,516</u>
Operating lease liabilities, noncurrent	539	885
Deferred government grants	866	928
Warrant liability, noncurrent	3,224	5,668
Other noncurrent liabilities	1,427	7
Total liabilities	<u>21,969</u>	<u>27,004</u>
Commitments and Contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.001 par value, 400,000,000 shares authorized; 90,890,381 shares and 86,307,544 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	91	86
Additional paid-in capital	167,134	136,185
Statutory reserve	3,098	3,098
Accumulated deficit	(66,703)	(73,453)
Accumulated other comprehensive loss	(1,700)	(2,597)
Total Gyre stockholders' equity	<u>101,920</u>	<u>63,319</u>
Noncontrolling interest	35,495	35,083
Total equity	<u>137,415</u>	<u>98,402</u>
Total liabilities and stockholders' equity	<u>\$ 159,384</u>	<u>\$ 125,406</u>

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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues	\$ 30,564	\$ 25,488	\$ 79,393	\$ 77,885
Operating expenses:				
Cost of revenues	1,628	958	3,673	2,707
Selling and marketing	15,328	13,699	41,363	40,655
Research and development	2,363	2,775	8,883	8,312
General and administrative	4,319	3,823	14,103	10,645
Loss on disposal of assets, net	1	—	2	68
Total operating expenses	23,639	21,255	68,024	62,387
Income from operations	6,925	4,233	11,369	15,498
Other income, net:				
Change in fair value of warrant liability	(23)	(228)	2,444	6,973
Other income (expense), net	727	(75)	689	(25)
Income before income taxes	7,629	3,930	14,502	22,446
Provision for income taxes	(1,693)	(1,074)	(3,256)	(5,117)
Net income	5,936	2,856	11,246	17,329
Net income attributable to noncontrolling interest	2,326	1,732	4,496	5,145
Net income attributable to common stockholders	\$ 3,610	\$ 1,124	\$ 6,750	\$ 12,184
Net income per share attributable to common stockholders:				
Basic	\$ 0.04	\$ 0.01	\$ 0.08	\$ 0.14
Diluted	\$ 0.03	\$ 0.01	\$ 0.04	\$ 0.05
Weighted average shares used in calculating net income per share attributable to common stockholders:				
Basic	90,850,040	85,643,646	88,707,709	84,807,041
Diluted	103,971,546	102,640,373	102,813,522	102,505,585
Other comprehensive income:				
Net income	\$ 5,936	\$ 2,856	\$ 11,246	\$ 17,329
Foreign currency translation adjustments	843	1,632	1,317	1,071
Comprehensive income	6,779	4,488	12,563	18,400
Net income attributable to noncontrolling interest	2,326	1,732	4,496	5,145
Foreign currency translation adjustments attributable to noncontrolling interest	255	568	419	373
Comprehensive income attributable to noncontrolling interest	2,581	2,300	4,915	5,518
Comprehensive income attributable to common stockholders	\$ 4,198	\$ 2,188	\$ 7,648	\$ 12,882

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	Total Gyre Stockholders'	Non-controlling	Total
	Shares	Amount	Shares	Amount	Capital	Reserve	Deficit	Comprehensive Loss	Equity	Interest	Equity
Balance at December 31, 2024	—	\$ —	86,307,544	\$ 86	\$ 136,185	\$ 3,098	\$ (73,453)	\$ (2,597)	\$ 63,319	\$ 35,083	\$ 98,402
Stock-based compensation expense	—	—	—	—	507	—	—	—	507	—	507
Stock options exercised	—	—	1,273,931	1	955	—	—	—	956	—	956
Issuance of common stock in ATM program	—	—	54,734	—	509	—	—	—	509	—	509
CVR liability settlement	—	—	—	—	25	—	—	—	25	—	25
Deferred offering costs amortization	—	—	—	—	(2)	—	—	—	(2)	—	(2)
Foreign currency translation adjustments	—	—	—	—	—	—	—	111	111	60	171
Net income	—	—	—	—	—	—	2,698	—	2,698	1,036	3,734
Balance at March 31, 2025	—	\$ —	87,636,209	\$ 87	\$ 138,179	\$ 3,098	\$ (70,755)	\$ (2,486)	\$ 68,123	\$ 36,179	\$ 104,302
Stock-based compensation expense	—	—	—	—	906	—	—	—	906	—	906
Stock options exercised	—	—	631,064	1	1,031	—	—	—	1,032	—	1,032
Issuance of common stock	—	—	2,555,555	—	—	—	—	—	—	—	—
Stock insurance cost	—	—	5	3	22,997	—	—	—	23,000	—	23,000
Foreign currency translation adjustments	—	—	—	—	(1,676)	—	—	—	(1,676)	—	(1,676)
Net income	—	—	—	—	—	—	442	—	442	104	303
Balance at June 30, 2025	—	\$ —	90,822,828	\$ 91	\$ 161,437	\$ 3,098	\$ (70,313)	\$ (2,287)	\$ 92,026	\$ 37,417	\$ 129,443
Stock-based compensation expense	—	—	—	—	1,147	—	—	—	1,147	—	1,147
Stock options exercised	—	—	67,553	—	50	—	—	—	50	—	50
Deferred offering costs amortization	—	—	—	—	(3)	—	—	—	(3)	—	(3)
Foreign currency translation adjustments	—	—	—	—	—	—	—	587	587	255	842
Capital injection in a subsidiary	—	—	—	—	4,503	—	—	—	4,503	(4,503)	—
Net income	—	—	—	—	—	—	3,610	—	3,610	2,326	5,936
Balance at September 30, 2025	—	\$ —	90,890,381	\$ 91	\$ 167,134	\$ 3,098	\$ (66,703)	\$ (1,700)	\$ 101,920	\$ 35,495	\$ 137,415

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Statutory	Accumulated	Accumulated Other	Total Gyre Stockholders'	Non-controlling	Total
	Shares	Amount	Shares	Amount	Capital	Reserve	Deficit	Comprehensive Loss	(Deficit) 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	3	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
Stock-based compensation expense	—	—	—	—	237	—	—	—	237	—	237
Stock options exercised	—	—	231,752	—	374	—	—	—	374	—	374
CVR Liability settlement	—	—	—	—	29	—	—	—	29	—	29
Foreign currency translation adjustment	—	—	—	—	—	—	—	1,064	1,064	568	1,632
Net income	—	—	—	—	—	—	1,124	—	1,124	1,732	2,856
Balance at September 30, 2024	—	\$ —	85,769,526	\$ 85	\$ 134,296	\$ 3,098	\$ (73,354)	\$ (946)	\$ 63,179	\$ 35,295	\$ 98,474

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)

	Nine Months Ended September 30,	
	2025	2024
Operating Activities		
Net income	\$ 11,246	\$ 17,329
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	2,560	264
Equity in loss of unconsolidated affiliate	57	20
Depreciation and amortization	1,825	1,088
Noncash lease expense	606	474
Deferred income taxes	(1,022)	(410)
Bad debt expense and other non-cash items	(29)	99
Accrued interest on certificates of deposit	(78)	(775)
Change in fair value of long-term receivable	(39)	(178)
Change in fair value of derivative liabilities	39	178
Change in fair value of warrant liability	(2,444)	(6,973)
Loss on disposal of property and equipment	2	68
Changes in operating assets and liabilities:		
Notes receivable	3,701	298
Accounts receivable	(5,981)	(4,111)
Inventories	(2,423)	(2,021)
Prepaid and other assets	303	(1,783)
Income tax payable	(217)	(2,231)
Accounts payable	446	(55)
Accrued expenses and other liabilities	(1,434)	(3,585)
Operating lease liabilities	(508)	1,421
Net proceeds from CVR liability settlement	25	—
Net cash provided by (used in) operating activities	<u>6,635</u>	<u>(883)</u>
Investing Activities		
Purchase of short-term investments	(564)	—
Acquisition of intangible assets	(737)	(3)
Purchase of certificates of deposit	(11,184)	(14,074)
Purchase of property and equipment	(1,046)	(2,380)
Proceeds from the sale of equipment	19	263
Cash paid for equity method investment	—	(1,686)
Maturity of certificates of deposit	11,190	—
Net cash used in investing activities	<u>(2,322)</u>	<u>(17,880)</u>
Financing Activities		
Offering costs paid	(1,487)	(169)
Proceeds from the exercise of stock options	2,038	1,307
Proceeds from the issuance of common stock in a public offering	23,000	—
Proceeds from the issuance of common stock in ATM program	509	—
Net cash provided by financing activities	<u>24,060</u>	<u>1,138</u>
Effect of exchange rate changes on cash and cash equivalents	216	(18)
Net increase (decrease) in cash and cash equivalents	28,589	(17,643)
Cash and cash equivalents at the beginning of the period	11,813	33,509
Cash and cash equivalents at the end of the period	<u>\$ 40,402</u>	<u>\$ 15,866</u>
Supplemental Disclosure of Non-Cash Financing and Investing Activities:		
Convertible preferred stock conversion	\$ —	\$ 64,525
Right-of-use asset obtained in exchange for operating lease liabilities	\$ 62	\$ —
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	\$ 4,493	\$ 7,757

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

Gyre Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Nature of Operations and Liquidity

Description of Business

Gyre Therapeutics, Inc. (the “Company” or “Gyre”), formerly known as Catalyst Biosciences, Inc. (“Catalyst”), is a commercial-stage biotechnology company originally incorporated in Delaware on March 7, 1997 under the name Targacept, Inc.

As of September 30, 2025, the Company holds a 69.7% indirect 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. 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 commercial-stage biotechnology company with a proven track record of success in developing and commercializing 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 nine months ended September 30, 2025, the Company had a net income of \$11.2 million, while net cash provided by operating activities was \$6.6 million. As of September 30, 2025, the Company had an accumulated deficit of \$66.7 million and cash and cash equivalents of \$40.4 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 U.S. generally accepted accounting principles (“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, 2025, 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 on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 17, 2025 (the “Annual Report”).

Reclassifications

Certain prior period balances have been reclassified to conform to the current period presentation in the condensed consolidated financial statements and the accompanying notes. The Company combined certain line items in the condensed consolidated financial statements. Such reclassifications have no effect on previously reported current assets, total assets, income before income taxes or net income.

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, 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.

Noncontrolling Interest

The Company reports noncontrolling interest (“NCI”) in a subsidiary as a separate component of equity in the condensed consolidated balance sheets. Additionally, the Company reports the portion of net income and comprehensive income attributed to the Company and NCI separately in the condensed consolidated statements of operations and comprehensive income.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker (“CODM”) in deciding how to allocate resources to an individual segment and in assessing performance. The measure of segment profit or loss is reported on the income statement as consolidated net income. The CODM uses net income to evaluate income generated from segment assets in deciding whether to reinvest profits and monitor budget versus actual results in assessing the performance of the segment. The Company’s CODM, as a group, includes (i) the Executive Chairman of Gyre’s Board of Directors (“Gyre’s Board”) who also serves as Gyre’s Interim Chief Executive Officer and (ii) Gyre’s Chief Operating Officer who also serves as Gyre Pharmaceuticals’ General Manager. The Company has determined that it operates in two distinct operating segments and has two reportable segments.

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

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, accounts receivable, note receivable, long-term certificates of deposits, short-term bank deposits and short-term investments.

The Company is exposed to United States credit risk in the event of default by the United States institutions holding cash to the extent beyond the amount insured by the United States federal depository insurance corporation.

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, or approximately \$70,368, based on the September 30, 2025 spot exchange rate. 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 September 30, 2025 and December 31, 2024, the Company had cash and cash equivalents of \$40.4 million and \$11.8 million, and long-term certificates of deposit of \$20.3 million and \$24.6 million, respectively. In addition, the Company had short-term bank deposits of \$19.6 million and \$14.9 million as of September 30, 2025 and December 31, 2024, respectively.

For the periods ended September 30, 2025 and December 31, 2024, cash and cash equivalents, short-term bank deposits and long-term certificates of deposits exceeded the PRC DIS coverage by \$52.2 million and \$46.3 million, respectively.

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 September 30, 2025, 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 50.6%, 12.2% and 11.5% of total revenue, respectively. For the three months ended September 30, 2024, the Company had three customers, Sinopharm, Resources Pharmaceutical, and Shanghai Pharmaceuticals, who accounted for approximately 44.8%, 12.9% and 12.1% of total revenue, respectively. All customers are located in mainland China.

For the nine months ended September 30, 2025, the Company had three customers, Sinopharm, Resources Pharmaceutical, and Shanghai Pharmaceuticals, who accounted for approximately 51.5%, 13.2% and 12.3% of total revenue, respectively. For the nine months ended September 30, 2024, the Company had three customers, Sinopharm, Resources Pharmaceutical, and Shanghai Pharmaceuticals who accounted for approximately 47.1%, 14.6% and 12.1% of total revenue, respectively. All customers are located in mainland China.

As of September 30, 2025 and December 31, 2024, the Company had one customer Sinopharm, who accounted for approximately 50.3% and 54.3% 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. 31.2% 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 September 30, 2025, in the amount of \$12.6 million, \$19.6 million, and \$20.3 million, respectively, were denominated in RMB.

Accounting Pronouncements Recently Adopted

In December 2023, the Financial Accounting Standards Board ("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 became effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company adopted this standard as of January 1, 2025, and the adoption will be reflected on the annual consolidated financial statements for its annual period ending December 31, 2025. The Company is currently evaluating the impact of the adoption of this ASU.

New Accounting Pronouncements – Issued But Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative* ("ASU 2023-06"). ASU 2023-06 modifies the disclosure or presentation requirements of a variety of topics in the Financial Accounting Standards Codification (the "Codification"). Certain of the amendments represent clarifications to or technical corrections of the current requirements. Because of the variety of topics amended, a broad range of entities may be affected by one or more of those amendments. Many of the amendments allow users to more easily compare entities subject to the SEC's existing

disclosures with those entities that were not previously subject to the SEC’s requirements. Also, the amendments align the requirements in the Codification with the SEC’s regulations. For entities subject to the SEC’s existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each amendment will be the date on which the SEC’s removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all other entities, the amendments will be effective two years later. The amendments in this update should be applied prospectively. For all entities, if by June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the related amendment will be removed from the Codification and will not become effective for any entity. The Company is currently evaluating the potential impact this standard will have on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses (Subtopic 220-40)* (“ASU 2024-03”). The ASU requires the disaggregated disclosure of specific expense categories, including purchases of inventory, employee compensation, depreciation, and amortization, within relevant income statement captions. This ASU also requires disclosure of the total amount of selling expenses along with the definition of selling expenses. The ASU is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. In January 2025, the FASB issued ASU 2025-01, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40) - Clarifying the Effective Date* to clarify the effective date of ASU 2024-03 for non-calendar year-end entities. ASU 2024-03 is effective for the Company’s fiscal year 2028, and interim periods starting in fiscal year 2029. Early adoption is permitted. The amendments in this ASU are to be applied retrospectively to any or all prior periods presented in the consolidated financial statements. Early adoption is also permitted. This ASU will likely result in the required additional disclosures being included in our consolidated financial statements, once adopted. The Company is currently assessing the impact of the disclosure requirements 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 nine months ended September 30, 2025. As of September 30, 2025, the Company’s highly liquid money market funds are included within cash equivalents, and short-term investments are included within prepaid assets and other current assets.

The following tables present the fair value hierarchy for assets and liabilities measured at fair value on a recurring basis as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds ⁽¹⁾	\$ 26,654	\$ —	\$ —	\$ 26,654
Short-term investments ⁽²⁾	566	—	—	566
Total financial assets	\$ 27,220	\$ —	\$ —	\$ 27,220
Financial liabilities:				
Warrant liability, noncurrent	—	—	3,224	3,224
Total financial liabilities	\$ —	\$ —	\$ 3,224	\$ 3,224

	December 31, 2024			Total
	Level 1	Level 2	Level 3	
Financial assets:				
Money market funds ⁽¹⁾	\$ 3,300	\$ —	\$ —	\$ 3,300
Receivable from GCBP	—	—	4,961	4,961
Total financial assets	\$ 3,300	\$ —	\$ 4,961	\$ 8,261
Financial liabilities:				
CVR derivative liability	\$ —	\$ —	\$ 4,961	\$ 4,961
Warrant liability, noncurrent	—	—	5,668	5,668
Total financial liabilities	\$ —	\$ —	\$ 10,629	\$ 10,629

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

(2) Included in prepaid assets and other current assets 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 maturities.

During the nine months ended September 30, 2025 and the year ended December 31, 2024, 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. As of September 30, 2025, the Company had fully settled the CVR liability and collected all outstanding amounts related to CVR receivables.

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 811 warrants to purchase Convertible Preferred Stock (the “Preferred Stock Warrants”) to purchase shares of Convertible Preferred Stock to GNI 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, par value \$0.001 per share (“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 fair value of the Preferred Stock Warrants is subject to uncertainty due to unobservable inputs, including the expected volatility of the Company’s stock price, the likelihood of warrant exercise, and the estimated term of the warrants. Since there is limited market activity for the Preferred Stock Warrants, their fair value is determined using an option pricing model, which incorporates subjective inputs such as the Company’s stock price volatility, derived from historical and peer company data, as well as management’s expectations regarding future performance. As these assumptions evolve due to market conditions or company specific factors, the warrant liability may experience fluctuations. The Preferred Stock Warrants are revalued each reporting period with the change in fair value recorded as change in fair value of warrant liability in other income, net on the 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:

	September 30, 2025		December 31, 2024	
Share price	\$	7.46	\$	12.10
Exercise price	\$	4,915.00	\$	4,915.00
Dividend yield		—%		—%
Risk-free interest		3.93%		4.54%
Term (years)		8.08		8.83
Expected volatility		83.00%		83.00%

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

	Receivable from GCBP		CVR derivative liability		Warrant liability	
Balance at December 31, 2024	\$	4,961	\$	4,961	\$	5,668
Changes in fair value		39		39		(2,444)
Change due to settlements		(5,000)		(5,000)		—
Balance at September 30, 2025	\$	—	\$	—	\$	3,224

Financial Instruments

Cash equivalents, short-term investments and held-to-maturity debt securities consisted of the following (in thousands):

September 30, 2025	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Money market funds (cash equivalents)	\$ 26,654	\$ —	\$ —	\$ 26,654
Short-term investments	566	—	—	566
Short-term bank deposits	19,647	—	—	19,647
Long-term certificates of deposit	20,317	—	—	20,317
Total financial assets	\$ 67,184	\$ —	\$ —	\$ 67,184

Classified as:

Cash and cash equivalents				\$ 26,654
Short-term bank deposits				19,647
Short-term investments				566
Long-term certificates of deposit				20,317
Total financial assets				\$ 67,184

December 31, 2024	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Money market funds (cash equivalents)	\$ 3,300	\$ —	\$ —	\$ 3,300
Short-term bank deposits	14,858	—	—	14,858
Long-term certificates of deposit	24,568	—	—	24,568
Total financial assets	\$ 42,726	\$ —	\$ —	\$ 42,726

Classified as:

Cash and cash equivalents				\$ 3,300
Short-term bank deposits				14,858
Long-term certificates of deposit				24,568
Total financial assets				\$ 42,726

The fair value and amortized cost of the Company's held-to-maturity debt securities and redemption date were as follows:

	September 30, 2025	
	Amortized Cost	Fair Value
Due in one year	\$ 19,647	\$ 19,647
Due in one to five years	20,317	20,317
Total	<u>\$ 39,964</u>	<u>\$ 39,964</u>

Interest income from the short-term bank deposits is recognized on an accrual basis over the term of the deposits. The accrued interest income from short-term bank deposits for the three months ended September 30, 2025 and 2024 was \$0.1 million and \$0.1 million, respectively. The accrued interest income from short-term bank deposits for the nine months ended September 30, 2025 and 2024 was \$0.4 million and \$0.3 million, respectively.

Interest income from the long-term certificates of deposit is recognized on an accrual basis over the term of the deposits. The accrued interest income from the long-term certificates of deposit for the three months ended September 30, 2025 and 2024 was \$0.1 million and \$0.2 million, respectively. The accrued interest income from the long-term certificates of deposit for the nine months ended September 30, 2025 and 2024 was \$0.4 million and \$0.5 million, respectively.

4. Balance Sheet Components

Inventories

Inventories as of September 30, 2025 and December 31, 2024, respectively, consisted of the following components (in thousands):

	September 30, 2025	December 31, 2024
Raw materials	\$ 1,099	\$ 794
Work in progress	4,434	2,929
Finished goods	3,321	2,614
Inventories	<u>\$ 8,854</u>	<u>\$ 6,337</u>

Accrued Expenses and Other Current Liabilities

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

	September 30, 2025	December 31, 2024
Accrued payroll and welfare	\$ 4,724	\$ 4,765
Payable to PPE & intangible asset suppliers	2,242	1,219
Payable to selling expense suppliers	1,462	900
Accrued sales discount	1,147	908
Accrued expenses - research and development	578	57
Accrued professional services	563	667
Accrued expenses - general and administrative	497	1,005
Deferred government grants	96	95
Employee reimbursement	44	737
Other accrued liabilities	446	262
Accrued expenses and other current liabilities	<u>\$ 11,799</u>	<u>\$ 10,615</u>

Accounts and Note Receivables, Net

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

	September 30, 2025	December 31, 2024
Accounts receivable	\$ 26,059	\$ 19,798
Note receivable	693	4,373
Allowance for credit losses	(182)	(209)
Accounts and note receivables, net	<u>\$ 26,570</u>	<u>\$ 23,962</u>

Property and Equipment, Net

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

	September 30, 2025	December 31, 2024
Buildings	\$ 19,229	\$ 18,980
Construction in progress	844	222
Machinery and electronic devices	9,559	9,442
Furniture and fixtures	723	653
Motor vehicles	187	182
Property and equipment, gross	<u>30,542</u>	<u>29,479</u>
Less: Accumulated depreciation	(6,934)	(5,599)
Property and equipment, net	<u>\$ 23,608</u>	<u>\$ 23,880</u>

Long-Term Investment Measured Under Equity Method

On June 28, 2024, Gyre Pharmaceuticals entered into a partnership agreement as a limited partner with other investors and is obligated to pay \$4.2 million for an 18.93% equity interest in the partnership. In April 2025, a new investor joined the partnership agreement, and as a result, Gyre Pharmaceuticals' equity interest was adjusted to 18.35%. 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. However, Gyre Pharmaceuticals may appoint a member to the advisory committee of the partnership.

As of September 30, 2025 and December 31, 2024, the Company's total investment in the partnership was \$1.7 million and \$1.7 million, respectively, and the carrying value of the Company's long-term investment in this affiliate, which was included in "Other assets, noncurrent" on the balance sheet, was \$1.6 million and \$1.6 million, respectively.

5. Intangible Assets

Intangible assets with finite lives consist primarily of patents, technological know-how, computer software, and technology rights. Technology rights refer to the intellectual property ("IP") associated with Etoresol® (nintedanib, ethanesulfonate soft capsules), which were obtained upon the successful transfer of the marketing authorization holder following approval by the PRC's National Medical Products Administration (the "NMPA") in March 2025, and the commercial sales of Etoresol® commenced in June 2025. As of September 30, 2025, the Company recognized the total consideration for the Etoresol® technology rights in the amount of RMB 35.0 million, or approximately \$4.9 million, based on the September 30, 2025 spot exchange rate.

The gross carrying amounts and accumulated amortization of the Company's intangible assets with determinable lives as of September 30, 2025 and December 31, 2024 were as follows (in thousands):

	September 30, 2025		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	\$ 428	\$ (320)	\$ 108
Computer software	333	(161)	172
Technology rights	4,926	(359)	4,567
Total intangible assets	<u>\$ 5,687</u>	<u>\$ (840)</u>	<u>\$ 4,847</u>

	December 31, 2024		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	\$ 423	\$ (303)	\$ 120
Computer software	278	(125)	153
Total intangible assets	<u>\$ 701</u>	<u>\$ (428)</u>	<u>\$ 273</u>

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 was 7.2 years as of September 30, 2025, compared to 4.0 years as of December 31, 2024.

Amortization expense was \$170,000 and \$10,000 for the three months ended September 30, 2025 and 2024, respectively. Amortization expense was \$404,000 and \$26,000 for the nine months ended September 30, 2025 and 2024, respectively. Based on finite-lived intangible assets recorded as of September 30, 2025, the estimated future amortization expense is as follows (in thousands):

	Estimated amortization expense
2025	\$ 172
2026	686
2027	682
2028	653
2029	652
Thereafter	2,002
Total	<u>\$ 4,847</u>

6. Revenue

The Company's product revenues are mainly generated from the sale of ETUARY®. The Company launched two new products: Contiva® (avatrombopag maleate tablets), which commenced commercialization in March 2025, and Etozel®, which commenced commercialization in June 2025.

The following table summarizes the composition of product revenues for the three and nine months ended September 30, 2025 and 2024:

Product Revenue Composition	For the Three Months Ended September 30,				For the nine months ended September 30,			
	2025		2024		2025		2024	
ETUARY®	\$ 27,694	90.6%	\$ 25,285	99.2%	\$ 72,916	91.8%	\$ 77,290	99.2%
Contiva®	1,245	4.1%	—	—%	3,024	3.8%	—	—%
Etozel®	1,544	5.1%	—	—%	3,140	4.0%	—	—%
Other Products	81	0.2%	203	0.8%	313	0.4%	595	0.8%
Total	<u>\$ 30,564</u>	<u>100.0%</u>	<u>\$ 25,488</u>	<u>100.0%</u>	<u>\$ 79,393</u>	<u>100.0%</u>	<u>\$ 77,885</u>	<u>100.0%</u>

Sales of Pharmaceutical Products

The Company generates revenue mostly through sales of ETUARY®, Contiva®, Etozel® and certain generic drugs. The distributors are the Company's direct customers, and sales to distributors account for 100.0% of revenue. The distributors sell pharmaceutical products 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 \$30.6 million and \$25.5 million for the three months ended September 30, 2025 and 2024, respectively. Revenue from sales of pharmaceutical products was \$79.4 million and \$77.9 million for the nine months ended September 30, 2025 and 2024, respectively. All sales are generated in the PRC. Contract liabilities recognized for the three and nine months ended September 30, 2025 were immaterial.

7. Leases

Operating Leases

As of September 2025, Gyre Pharmaceuticals maintained leases for office spaces in the following locations: in Beijing, comprising approximately 2,130 square meters with a lease expiration in June 2027; in Zhengzhou, comprising approximately 180 square meters with a lease expiration in August 2026; in Shanghai, comprising approximately 224 square meters with a lease expiration in December 2026; in Nanjing, comprising approximately 70 square meters with a lease expiration in February 2027; and in Beijing, for a staff dormitory comprising approximately 249 square meters with a lease expiration in March 2028. The Company also holds a lease for its U.S. headquarters in San Diego, California, which was secured in November 2023 and is 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 \$19,000 in short-term rent expenses during the three months ended September 30, 2025 and 2024, respectively. The Company recorded a total of \$49,000 and \$54,000 in short-term rent expenses during the nine months ended September 30, 2025 and 2024, 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 September 30, 2025, the Company recorded an aggregate right-of-use asset of \$1.3 million, which amount is included in other assets, noncurrent, and an aggregate lease liability of \$1.2 million in the accompanying condensed consolidated balance sheets.

For the three months ended September 30, 2025 and 2024, the Company's operating lease expense was \$0.2 million and \$0.3 million, respectively. For the nine months ended September 30, 2025 and 2024, the Company's operating lease expense was \$0.6 million and \$0.5 million, respectively. Variable lease payments for the three and nine months ended September 30, 2025 and 2024 were immaterial.

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

	Nine Months Ended September 30,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities	\$ 564	\$ 631

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

	September 30, 2025	December 31, 2024
Weighted-average remaining lease term	1.6 years	2.3 years
Weighted-average discount rate	4.76%	4.76%

As of September 30, 2025, undiscounted future minimum payments under the Company’s operating leases were as follows (in thousands):

	Amount	
Remaining in 2025	\$	249
2026		661
2027		300
Total undiscounted lease payments		1,210
Less: imputed interest		(45)
Total lease liabilities		1,165
Less: current portion of lease liabilities		(626)
Lease liabilities, net of current portion	\$	539

The Company is required to maintain security deposits of \$0.3 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 September 30, 2025, the Company held land use rights for two land parcels in Beijing’s Shunyi District, expiring in 2053, and in Cangzhou, Hebei Province, expiring between 2067 and 2070. These parcels, with a combined area of approximately 66,559 square meters, are utilized as manufacturing facilities. As of September 30, 2025, the aggregate recorded land use rights, net assets for these parcels was \$1.4 million, which amount is included in other assets, noncurrent on the Company’s condensed consolidated balance sheets.

8. Stockholders’ Equity

Common Stock

Common stock reserved for future issuance is as follows:

	<u>September 30, 2025</u>		<u>December 31, 2024</u>
Options issued and outstanding	18,044,321	(1)	18,077,869
Preferred Stock Warrants issued and outstanding	540,666		540,666
Total common stock reserved	<u>18,584,987</u>		<u>18,618,535</u>

(1) Includes 5,442,776 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.

2024 ATM Program

On November 27, 2024, Gyre entered into an Open Market Sale Agreement (the “ATM Agreement”) with Jefferies LLC (the “Sales Agent”) as sales agent, pursuant to which the Company may offer and sell, from time to time, through the Sales Agent, shares of common stock with aggregate gross sales proceeds of up to \$50.0 million through an at-the-market offering program (the “ATM Program”). The Company will pay the Sales Agent a commission of up to 3% of the gross proceeds of any shares sold. The Company also agreed to reimburse the Sales Agent for certain expenses incurred in connection with its services under the ATM Agreement, including up to \$0.1 million for legal expenses in connection with the establishment of the ATM Program. During the three months ended September 30, 2025, there were no sales under the ATM Program. During the nine months ended September 30, 2025, the Company sold 54,734 shares of common stock under ATM Program and received net proceeds of \$0.5 million, after deducting commissions and offering costs of \$8.6 thousand.

Sales of shares of common stock under the ATM Program may be made pursuant to the registration statement on Form S-3 (File No. 333-283237), which was declared effective by the SEC on November 22, 2024 (the “Shelf Registration Statement”), and a related prospectus supplement filed with the SEC on November 27, 2024.

May 2025 Underwritten Public Offering

On May 22, 2025, Gyre entered into an underwriting agreement (the “Underwriting Agreement”) with Jefferies LLC, as representative of the several underwriters (the “Underwriters”), pursuant to which the Company agreed to issue and sell 2,222,222 shares of common stock, at a public offering price of \$9.00 per share (the “Offering”). In addition, the Company granted the Underwriters an option for a period of 30 days to purchase up to an additional 333,333 shares of common stock at the public offering price, less the underwriting discounts and commissions (the “Greenshoe Option”).

The Offering closed on May 27, 2025. On May 29, 2025, the Underwriters exercised the Greenshoe Option in full, and the issuance of the additional 333,333 shares was settled on the same day.

During the nine months ended September 30, 2025, the Company sold an aggregate of 2,555,555 shares of common stock under the Underwriting Agreement, including the full exercise of the Greenshoe Option, and received gross proceeds of approximately \$23.0 million. After deducting the Underwriters’ discounts and commissions of \$1.4 million and offering costs of \$0.3 million, the Company received net proceeds of approximately \$21.3 million.

The Offering was made pursuant to the Shelf Registration Statement, as supplemented by a prospectus supplement, dated May 22, 2025, filed with the SEC on May 23, 2025.

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 \$66.4 million as of September 30, 2025 and \$64.3 million as of December 31, 2024.

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 nine months ended September 30, 2025 or during the year ended December 31, 2024.

Noncontrolling Interest

The noncontrolling interests in the Company’s consolidated financial statements represent the economic interests in Gyre Pharmaceuticals held by shareholders other than BJC and four other holding company subsidiaries of the Company.

In the third quarter of 2025, the Company’s indirect ownership in Gyre Pharmaceuticals increased from 65.2% to 69.7% as a result of an additional capital contribution of \$1.28 million by BJC in exchange for 9,184,910 additional shares of Gyre Pharmaceuticals, which diluted the noncontrolling shareholders’ ownership from 34.8% to 30.3%. The transaction was accounted for as an equity transaction and reflected as a reclassification from noncontrolling interests to Gyre stockholders’ equity with no gain or loss recognized.

9. Convertible Preferred Stock

In December 2022, Catalyst issued an aggregate of 12,340 shares of Convertible Preferred Stock to GNI Japan and GNI Hong Kong Limited (“GNI HK”) in connection with the F351 (“Hydronidone”) Asset Acquisition (see Note 1 — *Organization and Nature of Operations* in 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, 8,767,332 shares of common stock were issued to GNI USA upon such conversion.

10. Stock Based Compensation

2023 Omnibus Incentive Plan

The Gyre 2023 Omnibus Incentive Plan (the “2023 Omnibus Incentive Plan”) was approved by Catalyst’s stockholders in August 2023 and ratified by Gyre’s 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 Gyre’s 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. On January 1, 2025, pursuant to the automatic increase in the number of shares reserved, an additional 4,315,377 shares of common stock were reserved and made available for issuance under the 2023 Omnibus Incentive Plan. During the nine months ended September 30, 2025, certain members of senior management were granted both awards subject solely to time-based vesting requirements and awards that are subject to the achievement of certain levels of specific performance, in addition to time-based vesting requirements (the “Performance-Based Awards”). These Performance-Based Awards are subject to the achievement of certain sales metrics and approval of Hydronidone for commercialization. The number of Performance-Based Awards that may vest in full after two or three years ranges. The awards become eligible to vest only if the goals are achieved and will vest only if the grantee remains employed by us through each applicable vesting date.

The following table summarizes stock option activity for the nine months ended September 30, 2025:

	Number of Shares Underlying Outstanding Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)
Outstanding — December 31, 2024	18,077,869	\$ 1.75	6.0
Options granted	1,939,000	\$ 9.68	
Options exercised	(1,972,548)	\$ 1.03	0.0
Options forfeited and cancelled	—		
Outstanding — September 30, 2025	18,044,321	\$ 2.68	5.8
Exercisable — September 30, 2025	15,782,865	\$ 1.68	5.2

Valuation Assumptions

The Company estimated the fair value of time-based 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.

The Company also granted performance-based stock options, which vest based on two independent performance conditions. One condition is tied to a performance target that is deemed probable as of September 30, 2025. The other condition is tied to the approval in the PRC of a New Drug Application (“NDA”) for Hydronidone, which is not considered probable as of September 30, 2025. The grant-date fair value of these awards was determined using the Black-Scholes Option Pricing Model, which incorporates key inputs such as stock price, strike price, expected volatility, risk-free interest rate, time to expiration, and a zero-dividend yield.

The following table shows the weighted-average grant date fair value of options and the assumptions used to estimate the fair value for time-based awards, and for performance-based awards during the three and nine months ended September 30, 2025 and 2024:

Time-based and performance-based awards	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Weighted-average grant-date fair value	\$ 5.09	\$ 7.23	\$ 6.97	\$ 7.25
Risk-free interest rate (%)	3.84% - 3.91%	3.7%	3.84% - 4.40%	3.7%
Expected option life (in years)	5.81 - 6.08	5.9	5.27 - 6.41	5.9
Expected dividend yield (%)	—%	—%	—%	—%
Volatility (%)	81.5%	84.1%	81.5% - 84.3%	84.1%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
General and administrative	\$ 1,085	\$ 237	\$ 2,422	\$ 264
Cost of revenue	38	—	85	—
Selling and marketing	24	—	53	—
Total stock-based compensation expense	\$ 1,147	\$ 237	\$ 2,560	\$ 264

As of September 30, 2025, the Company had an unrecognized stock-based compensation expense of \$15.1 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 3.1 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):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Numerator:				
Net income	\$ 5,936	\$ 2,856	\$ 11,246	\$ 17,329
Less: Allocation of undistributed earnings to noncontrolling interest	2,326	1,732	4,496	5,145
Net income attributable to common stockholders - basic	\$ 3,610	\$ 1,124	\$ 6,750	\$ 12,184
Less: Change in fair value of warrant liability	(23)	(228)	2,444	6,973
Net income attributable to common stockholders - diluted	\$ 3,633	\$ 1,352	\$ 4,306	\$ 5,211
Denominator:				
Basic common shares outstanding:				
Weighted average common shares outstanding	90,850,040	85,643,646	88,707,709	84,807,041
Weighted average shares used in calculating net income per share attributable to common stockholders, basic	<u>90,850,040</u>	<u>85,643,646</u>	<u>88,707,709</u>	<u>84,807,041</u>
Dilutive potential common shares:				
Weighted average of common stock options	13,105,808	16,765,219	14,005,173	16,722,627
Weighted average of Convertible Preferred Stock (as converted)	—	—	—	703,946
Weighted average of Preferred Stock Warrants (as converted)	15,698	231,508	100,640	271,971
Weighted average shares used in calculating net income per share attributable to common stockholders, diluted	<u>103,971,546</u>	<u>102,640,373</u>	<u>102,813,522</u>	<u>102,505,585</u>
Net income per share attributable to common stockholders:				
Basic	\$ 0.04	\$ 0.01	\$ 0.08	\$ 0.14
Diluted	<u>\$ 0.03</u>	<u>\$ 0.01</u>	<u>\$ 0.04</u>	<u>\$ 0.05</u>

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Options to purchase common stock	257,464	922,960	439,464	870,386
Total	<u>257,464</u>	<u>922,960</u>	<u>439,464</u>	<u>870,386</u>

12. Commitments and Contingencies

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 \$4.6 million as of September 30, 2025 and were expected to be incurred within one year.

Etores® IP Rights

In May 2024, the Company entered into an IP rights transfer agreement with a third party, Jiangsu Wangao Pharmaceuticals Co., Ltd., to acquire the intellectual property associated with Etores® (the "Etores® IP Rights"). The Etores® IP Rights are recorded as technology rights in Intangible Assets in Note 5 — *Intangible Assets*. The commercial sales of Etores® commenced in June 2025.

According to the agreement, except for RMB 35.0 million, or approximately \$4.9 million, based on the September 30, 2025 spot exchange rate, the Company is committed to additional annual payments over eight years following the commencement of commercial sales in June 2025, which will be contingent consideration based on actual annual sales in future years. For each of the first two years starting from June 2025, the minimum annual commission is RMB 10 million, or approximately \$1.4 million, based on the September 30, 2025 spot exchange rate, which has already been included in the IP cost. If the sales-based commission calculated at 5% of annual sales in the first year exceeds RMB 10 million (approximately \$1.4 million, based on the September 30, 2025 spot exchange rate) or the commission calculated at 4% of annual sales in the second year exceeds RMB 10 million (approximately \$1.4 million, based on the September 30, 2025 spot exchange rate), the excess amount for each year will be recognized as contingent consideration. For the third year through the eighth year, the contingent payments will be calculated at 3%, 2%, 2%, 1%, 1%, and 1% of sales in each year, respectively.

As of September 30, 2025, the Company assessed the possibility that annual sales commissions in either of the first two years would exceed RMB 10 million, or approximately \$1.4 million, based on the September 30, 2025 spot exchange rate, as remote and did not accrue any contingent consideration.

Hydronidone

In September 2020, Gyre Pharmaceuticals entered into an IP transfer agreement (the "Hydronidone Transfer Agreement") with GNI Japan and certain of its wholly owned subsidiaries (the "GNI Group"). According to the Hydronidone 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 "Hydronidone IP Rights").

Under the Hydronidone Transfer Agreement, in exchange for the Hydronidone IP Rights, Gyre Pharmaceuticals is obligated to pay GNI Group three payments based on the achievement of the respective milestones: RMB 33.1 million, or approximately \$4.7 million, based on the September 30, 2025 spot exchange rate, upon submission of the Hydronidone NDA to the Center for Drug Evaluation of the NMPA; RMB 8.3 million, or approximately \$1.2 million, based on the September 30, 2025 spot exchange rate, after the NDA passes the NMPA's Center for Food and Drug Review and Inspection's on-site registration inspection for the Hydronidone product; and RMB 49.6 million, or approximately \$7.0 million, based on the September 30, 2025 spot exchange rate, upon NMPA's approval of the NDA. As of September 30, 2025, the payment conditions have not been met, and no payments have been made.

Upon Hydronidone product achieving commercialization, the Company will be required to make annual royalty payments based on future product sales. These contingent payments are structured as twelve annual royalties equal to 10%, 14%, 16%, 16%, 16%, 16%, 16%, 15%, 14%, 12%, 10%, and 8% of annual sales. As of September 30, 2025, commercialization has not yet been achieved, and no royalty payments have been incurred or accrued.

Research and Development Programs

In addition to the \$12.9 million commitment to GNI for the Hydronidone program, as of September 30, 2025, Gyre Pharmaceuticals has committed to allocate \$24.7 million toward future research and development activities for various programs.

Indemnification Agreements

In the normal course of business, the Company enters into agreements that indemnify others for certain liabilities that may arise in connection with a transaction or certain events and activities. If the indemnified party were to make a successful claim pursuant to the terms of the indemnification, the Company may be required to reimburse the loss. These indemnifications are generally subject to various restrictions and limitations. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations.

13. Income Taxes

During the three and nine months ended September 30, 2025 and 2024, the Company recorded the following income tax provision (in thousands) and effective tax rate:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Income tax provision	\$ 1,693	\$ 1,074	\$ 3,256	\$ 5,117
Effective tax rate	22.19%	27.33%	22.45%	22.80%

The change of effective tax rate for the three and nine months ended September 30, 2025 and 2024 was primarily due to stock-based compensation deduction from the exercise of stock options and change in fair value of warrant liability.

As of September 30, 2025, after consideration of certain limitations (see below), the Company had approximately \$193.4 million federal and \$13.8 million state net operating loss carryforwards ("NOL") 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 net operating loss carryforward includes \$191.9 million that have an indefinite life.

If the Company experiences a greater than 50 percent 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 NOLs 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 Group

No research and development fees were paid to GNI Group during the three and nine months ended September 30, 2025. Research and development fees paid to GNI during three and nine months ended September 30, 2024 were \$0.1 million and \$0.2 million, respectively. As of September 30, 2025 and December 31, 2024, the Company had \$0.2 million related parties payable due to GNI Group.

Other Receivables from GNI

As of September 30, 2025 and December 31, 2024, the Company had recorded \$0.2 million in other receivables from GNI Group, all of which related to CPI's restructuring transaction (see Note 8 — *Restructuring* in the Annual Report).

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 \$1.4 million and \$1.4 million for the three months ended September 30, 2025 and 2024, respectively. The total contributions for such employee benefits were \$4.0 million and \$3.8 million for the nine months ended September 30, 2025 and 2024, respectively.

Defined-Contribution Savings Plan

In the United States, 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 nine months ended September 30, 2025 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 the CODM to evaluate segment performance, the availability of separate financial information, and overall materiality considerations. All Gyre's operations are within the United States, while all of Gyre Pharmaceuticals' operations are in mainland China.

Gyre Pharmaceuticals

Gyre Pharmaceuticals has three major commercial drug products—ETUARY®, Etores®, and Contiva®—as well as several product candidates in pre-clinical and clinical development. Gyre Pharmaceuticals' product revenues are mainly generated from the sale of ETUARY®, Etores®, Contiva®, 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

Gyre is a biopharmaceutical company focused on the development and commercialization of Hydronidone for the treatment of MASH-associated liver fibrosis in the United States. Other than the IP associated with Hydronidone in the United States, Gyre has had 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 and BJC. 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). As of September 30, 2025, CPI holds a 61.7% indirect ownership interest in Gyre Pharmaceuticals following an additional capital contribution of \$1.28 million by BJC in exchange for 9,184,910 additional shares of Gyre Pharmaceuticals.

Segment information for the three and nine months ended September 30, 2025 and 2024 is as follows (in thousands):

	Three Months Ended September 30, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	\$ 30,564	\$ —	\$ —	\$ 30,564
Cost of revenues	1,628	—	—	1,628
Gross profit	28,936	—	—	28,936
Operating expenses excluding cost of revenues:				
Selling and marketing	15,328	—	—	15,328
Research and development	2,146	217	—	2,363
General and administrative	2,595	1,713	11	4,319
Loss on disposal of assets, net	1	—	—	1
Total operating expenses excluding cost of revenues	20,070	1,930	11	22,011
Income (loss) from operations	8,866	(1,930)	(11)	6,925
Other income, net	510	217	—	727
Change in fair value of warrant liability	—	(23)	—	(23)
Income tax expense	(1,691)	(2)	—	(1,693)
Net income (loss)	\$ 7,685	\$ (1,738)	\$ (11)	\$ 5,936
Supplemental disclosure of stock-based compensation expense:				
Cost of revenue	\$ 38	\$ —	\$ —	\$ 38
Selling and marketing	24	—	—	24
General and administrative	277	808	—	1,085
Stock-based compensation total	\$ 339	\$ 808	\$ —	\$ 1,147

	Nine Months Ended September 30, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	\$ 79,393	\$ —	\$ —	\$ 79,393
Cost of revenues	3,673	—	—	3,673
Gross profit	75,720	—	—	75,720
Operating expenses excluding cost of revenues:				
Selling and marketing	41,363	—	—	41,363
Research and development	8,512	371	—	8,883
General and administrative	9,008	5,079	16	14,103
Loss on disposal of assets, net	2	—	—	2
Total operating expenses excluding cost of revenues	58,885	5,450	16	64,351
Income (loss) from operations	16,835	(5,450)	(16)	11,369
Other income, net	335	354	—	689
Change in fair value of warrant liability	—	2,444	—	2,444
Income tax expense	(3,254)	(2)	—	(3,256)
Net income (loss)	\$ 13,916	\$ (2,654)	\$ (16)	\$ 11,246
Supplemental disclosure of stock-based compensation expense:				
Cost of revenue	\$ 85	\$ —	\$ —	\$ 85
Selling and marketing	53	—	—	53
General and administrative	628	1,794	—	2,422
Stock-based compensation total	\$ 766	\$ 1,794	\$ —	\$ 2,560

	Three Months Ended September 30, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	\$ 25,488	\$ —	\$ —	\$ 25,488
Cost of revenues	958	—	—	958
Gross profit	24,530	—	—	24,530
Operating expenses excluding cost of revenues:				
Selling and marketing	13,699	—	—	13,699
Research and development	2,553	222	—	2,775
General and administrative	2,225	1,593	5	3,823
Loss on disposal of assets, net	—	—	—	—
Total operating expenses excluding cost of revenues	18,477	1,815	5	20,297
Income (loss) from operations	6,053	(1,815)	(5)	4,233
Change in fair value of warrant liability	—	(228)	—	(228)
Other expense, net	(4)	(71)	—	(75)
Income tax expense	(1,074)	—	—	(1,074)
Net income (loss)	\$ 4,975	\$ (2,114)	\$ (5)	\$ 2,856
Supplemental disclosure of stock-based compensation expense:				
General and administrative	\$ —	237	—	\$ 237
Stock-based compensation total	\$ —	\$ 237	\$ —	\$ 237

	Nine Months Ended September 30, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	\$ 77,885	\$ —	\$ —	\$ 77,885
Cost of revenues	2,707	—	—	2,707
Gross profit	75,178	—	—	75,178
Operating expenses excluding cost of revenues:				
Selling and marketing	40,655	—	—	40,655
Research and development	7,639	673	—	8,312
General and administrative	7,031	3,608	6	10,645
Loss on disposal of assets, net	68	—	—	68
Total operating expenses excluding cost of revenues	55,393	4,281	6	59,680
Income (loss) from operations	19,785	(4,281)	(6)	15,498
Change in fair value of warrant liability	—	6,973	—	6,973
Other income (expense), net	111	(136)	—	(25)
Income tax expense	(5,117)	—	—	(5,117)
Net income (loss)	\$ 14,779	\$ 2,556	\$ (6)	\$ 17,329
Supplemental disclosure of stock-based compensation expense:				
General and administrative	\$ —	\$ 264	\$ —	\$ 264
Stock-based compensation total	\$ —	\$ 264	\$ —	\$ 264

The table below presents total assets as of September 30, 2025 and December 31, 2024.

	September 30, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Total assets	\$ 130,030	\$ 28,997	\$ 357	\$ 159,384

	December 31, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Total assets	\$ 114,248	\$ 10,790	\$ 368	\$ 125,406

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

	Nine Months Ended September 30, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Purchase of property and equipment	\$ 1,046	\$ —	\$ —	\$ 1,046

	Nine Months Ended September 30, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Purchase of property and equipment	\$ 2,366	\$ 14	\$ —	\$ 2,380

17. Subsequent Event

On November 7, 2025, the National Healthcare Security Administration (“NHSA”) released the *Announcement of the Winning Bids for the National Centralized Drug Procurement*, under which Etozel® (nintedanib, ethanesulfonate soft capsules) has been selected.

At present, the Company has not yet entered into or executed a procurement contract. The Company is currently assessing the potential impact of this development on its future operating performance.

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. (“Gyre”) 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, 2024 (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 commercial-stage biotechnology company with a proven track record of financial success developing and commercializing 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 and 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 build on our success in the development and commercialization of ETUARY® (pirfenidone) to expand into new indications and advance our pipeline of innovative 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 (the “PRC”), is a small molecule drug that inhibits the synthesis of TGF-β1, Tumor Necrosis Factor-α, and other fibrosis and inflammation modulators. We have obtained approval for ETUARY® in the PRC for IPF.

Pirfenidone

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 one additional Phase 3 trial in the PRC for the treatment of pneumoconiosis to broaden its indications and market, and in the third quarter of 2025, this trial completed patient enrollment. In March 2025, we received approval from the PRC’s National Medical Products Administration (the “NMPA”) for a clinical trial application for the treatment of radiation-induced lung injury, including cases complicated by immune-related pneumonitis. We are currently preparing to initiate the anticipated adaptive Phase 2/3 clinical trial, which will combine dose exploration with efficacy confirmation, to efficiently evaluate pirfenidone’s potential in this new indication. This Phase 2/3 clinical trial is expected to initiate in the fourth quarter of 2025.

Etozel®

In May 2024, Gyre Pharmaceuticals executed a comprehensive agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. to acquire the commercial rights to Etozel® (nintedanib, ethanesulfonate soft capsules). Etozel® has been approved for the treatment of patients with systemic sclerosis-associated interstitial lung disease (“SSc-ILD”) and progressive fibrosing interstitial lung disease (“PF-ILD”). Etozel® is expected to provide patients with more choices and benefits. Gyre Pharmaceuticals successfully initiated a commercial launch of Etozel® in the PRC in the second quarter of 2025. We believe that this launch can drive meaningful revenue growth, expand our market penetration, and enhance brand recognition within the respiratory disease space. Additionally, the commercialization of Etozel® aligns with our broader strategy of building a comprehensive pulmonary care portfolio, potentially creating opportunities for synergies with our existing and future product offerings. We expect to continue to invest in commercialization efforts, including market access, physician education, and patient support programs, to optimize uptake and maximize the long-term value of this product.

Contiva®

In March 2025, Gyre Pharmaceuticals initiated commercialization of Contiva® in the PRC for the treatment of thrombocytopenia (“TCP”) in adults with chronic liver disease (“CLD”) and immune thrombocytopenic purpura (“ITP”). Gyre Pharmaceuticals received approval from the NMPA for Contiva® maleate tablets for the treatment of CLD-associated TCP and ITP. TCP is the most common hematologic complication in patients with CLD and can be life threatening in severe cases. Contiva® is an oral thrombopoietin receptor agonist. Contiva® was approved by the U.S. Food and Drug Administration for the treatment of adults with CLD-associated TCP in May 2018, and its indication was subsequently expanded to include the treatment of ITP in June 2019. Gyre Pharmaceuticals acquired Contiva® under a transfer agreement with Nanjing Healthnice Pharmaceutical Technology, Co., Ltd. (“Nanjing Healthnice”) in June 2021.

Hydronidone

Hydronidone, our lead development candidate in both the United States and the PRC, is a structural derivative of ETUARY®. It is a new oral chemical entity with an anti-fibrotic, TGF-β1-targeting mechanism of action. Studies suggest that Hydronidone and its major metabolites have minimal drug-drug interaction risks. We are prioritizing Hydronidone for the treatment of liver fibrosis due to the large potential addressable market and significant unmet need.

Gyre Pharmaceuticals completed a pivotal Phase 3 trial of Hydronidone in the PRC evaluating its safety and efficacy for the treatment of liver fibrosis in patients with chronic hepatitis B (“CHB”) associated liver fibrosis. Building on the positive Phase 3 trial results, Gyre Pharmaceuticals is actively engaging with the NMPA to confirm Priority Review eligibility for Hydronidone’s New Drug Application. The 52-week, multicenter, double-blind, placebo-controlled trial enrolled 248 patients with CHB fibrosis across 39 hospitals in the PRC. Patients were randomized 1:1 to receive either entecavir anti-viral therapy plus Hydronidone (270 mg/day, orally) or entecavir antiviral therapy alone. The trial met its primary endpoint, with a statistically significant proportion of patients receiving Hydronidone achieving a ≥1-stage regression in liver fibrosis compared to placebo (P=0.0002). In addition, Hydronidone met a key secondary endpoint with statistically significant inflammation improvement without fibrosis progression at Week 52 versus the placebo arm. Hydronidone was well tolerated with a comparable incidence of serious adverse events (4.88% vs. 6.45% in the placebo group) and no discontinuations due to adverse events in either group.

Based on these positive results, we plan to file a New Drug Application with the NMPA and the submission process is ongoing. In parallel, we continue to engage with the U.S. Federal Food and Drug Administration regarding the investigational new drug application (“IND”) requirements for a Phase 2 trial evaluating Hydronidone for the treatment of metabolic dysfunction-associated steatohepatitis (“MASH”)-associated liver fibrosis. Pending regulatory feedback, we plan to file the U.S. IND for Hydronidone for the treatment of MASH-associated liver fibrosis in 2026 and, subject to clearance, initiate a Phase 2 clinical trial. We plan to conduct a hepatic impairment study in U.S. subjects under our active U.S. IND. Results from this study are expected to help optimize dose selection and safe enrollment criteria in populations with reduced hepatic function, supporting a more robust Phase 2 development plan. A prior U.S. Phase 1 trial in healthy volunteers confirmed Hydronidone’s tolerability and demonstrated a pharmacokinetic profile consistent with the results of clinical trials of Hydronidone in the PRC.

Other Product Candidates

We are currently enrolling patients in 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 June 2025, we successfully dosed the first volunteer in a Phase 1 in the PRC trial evaluating F230, a selective endothelin receptor agonist, for the treatment of pulmonary arterial hypertension. We are also evaluating F528, a novel anti-inflammation agent that targets the inhibition of multiple inflammatory cytokines, in preclinical studies as a potential first-line therapy for the treatment of chronic obstructive pulmonary disease.

Historical 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 (“GAAP”), 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.

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.

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 our 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 common stock. The Preferred Stock Warrants issued are considered freestanding financial instruments and classified as a liability.

Share Capital Increase Agreement

In the third quarter of 2025, pursuant to an agreement previously entered into by and among BJC, Gyre Pharmaceuticals and the other parties thereto, BJC increased its capital contribution in Gyre Pharmaceuticals by \$1.28 million in exchange for 9,184,910 additional shares of Gyre Pharmaceuticals. As a result, our indirect interest in Gyre Pharmaceuticals increased from 65.2% to 69.7%.

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 Etozel® (nintedanib, ethanesulfonate soft capsules), a small-molecule drug for the treatment of SSc-ILD and PF-ILD, within the PRC. The total minimum payments under the Jiangsu Wangao Agreement are RMB 35.0 million, or approximately \$4.9 million, based on the September 30, 2025 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 payments based on annual sales over eight years following the commencement of commercial 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. As of September 30, 2025, we had paid three installments totaling RMB 15.0 million, or approximately \$2.1 million, based on the September 30, 2025 spot exchange rate.

Financial Operations Overview

During the three months ended September 30, 2025, we had net income of \$5.9 million and net income attributable to common stockholders of \$3.6 million. For the nine months ended September 30, 2025, we had net income of \$11.2 million and net income attributable to common stockholders of \$6.8 million. During the three months ended September 30, 2024, we had net income of \$2.9 million and net income attributable to common stockholders of \$1.1 million. For the nine months ended September 30, 2024, we had net income of \$17.3 million and net income attributable to common stockholders of \$12.2 million. As of September 30, 2025, we had an accumulated deficit of \$66.7 million and cash and cash equivalents of \$40.4 million. As of December 31, 2024, we had an accumulated deficit of \$73.5 million and cash and cash equivalents of \$11.8 million.

Components of Results of Operations

Revenues

Sales of Pharmaceutical Products

We generate revenue primarily through sales of ETUARY®, Contiva®, Etoxel® and certain generic drugs in the PRC. Distributors are our direct customers, and sales to distributors accounted for 100% of the revenue. Such distributors sell pharmaceutical products 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 products 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.

We manage our research and development expenses by identifying the research and development activities we expect to be performed during a given period and then prioritizing efforts based on anticipated probability of successful technical development and regulatory approval, market potential, available human and capital resources, scientific data and other considerations. We regularly review our research and development activities based on unmet medical need and, as necessary, reallocate resources among our research and development portfolio that we believe will best support the long-term growth of our business.

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

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.

Other Income (Expense), Net

Interest income consists primarily of interest earned on our long-term 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 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.

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.

On July 4, 2025, the One Big Beautiful Bill Act (the “OBBA”) was enacted into law, including, among other things, provisions allowing accelerated tax deductions for qualified property and research expenditures. We are evaluating the future impact of the OBBA on our financial statements.

Results of Operations

Comparison of the three months ended September 30, 2025 and 2024

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

	Three Months Ended September 30,		Change (\$)	Change (%)
	2025	2024		
Revenues	\$ 30,564	\$ 25,488	\$ 5,076	20%
Cost of revenues	1,628	958	670	70%
Gross profit	28,936	24,530	4,406	18%
Operating expenses excluding cost of revenues:				
Selling and marketing	15,328	13,699	1,629	12%
Research and development	2,363	2,775	(412)	(15)%
General and administrative	4,319	3,823	496	13%
Loss on disposal of assets, net	1	—	1	*
Total operating expenses excluding cost of revenues	22,011	20,297	1,714	8%
Income from operations	6,925	4,233	2,692	64%
Other income, net:				
Change in fair value of warrant liability	(23)	(228)	205	(90)%
Other income (expense), net	727	(75)	802	(1069)%
Income before income taxes	7,629	3,930	3,699	94%
Provision for income taxes	(1,693)	(1,074)	(619)	58%
Net income	5,936	2,856	3,080	108%
Net income attributable to noncontrolling interest	2,326	1,732	594	34%
Net income attributable to common stockholders	\$ 3,610	\$ 1,124	\$ 2,486	221%

*Not meaningful

Revenues

Revenues for the three months ended September 30, 2025 and 2024 were \$30.6 million and \$25.5 million, respectively. The \$5.1 million, or 20%, increase was primarily due to \$1.5 million from Etores[®] sales, \$1.2 million from Contiva[®] sales and a \$2.4 million increase in revenue from ETUARY[®] sales. The increase in ETUARY[®] sales was mainly driven by a shift in marketing focus in the third quarter. We continue to anticipate revenue growth over the remainder of the year, driven by the growth of ETUARY[®] sales and supplemented by the commercialization of Etores[®] and Contiva[®] in 2025.

Cost of Revenues

Cost of revenues for the three months ended September 30, 2025 and 2024 was \$1.6 million and \$1.0 million, respectively. The \$0.6 million, or 70%, increase was primarily attributable to a \$0.2 million increase in the costs associated with Contiva[®] and Etores[®], in line with the corresponding increase in their sales, and a \$0.5 million increase in costs associated with ETUARY[®] due to higher sales and increased production costs for the product batch related to such sales, partially offset by a \$0.1 million decrease in costs associated with generic drugs due to the decrease of sales.

Selling and Marketing Expenses

Selling and marketing expenses increased by \$1.6 million, or 12%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The increase was primarily attributable to a \$0.5 million increase in payroll costs, driven by higher headcount and an increase of sales in the three months ended September 30, 2025 and a \$1.1 million increase in promotion and conference 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 September 30,			
	2025	2024	Change (\$)	Change (%)
Direct program expenses:				
Clinical trials	\$ 271	\$ 701	\$ (430)	(61)%
Materials and utilities	\$ 552	507	45	9%
Pre-clinical research	\$ 365	533	(168)	(32)%
Indirect expenses:				
Personnel-related costs	983	793	190	24%
Facilities, depreciation and other	192	241	(49)	(20)%
Total research and development expenses	\$ 2,363	\$ 2,775	\$ (412)	(15)%

Research and development expenses decreased by \$0.4 million, or 15%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The decrease was primarily attributable to a \$0.4 million decrease in clinical trial costs resulting from the completion of the Phase 3 trial of Hydronidone in the second quarter of 2025, and a \$0.2 million decrease in pre-clinical research expenses, partially offset by \$0.2 million increase in staff costs.

General and Administrative Expenses

General and administrative expenses increased by \$0.5 million, or 13%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The increase was primarily driven by a \$1.1 million increase in functional and administrative department's personnel and stock compensation costs and a \$0.2 million increase in miscellaneous expenses, partially offset by a \$0.8 million decrease in professional fees.

Change in Fair Value of Warrant Liability

Change in fair value of warrant liability increased \$0.2 million, or 90%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The increase was related to the remeasurement of the Preferred Stock Warrants liability.

Other Income (Expense), Net

The Company recorded other income of \$0.7 million for the three months ended September 30, 2025 compared to other expense of \$0.1 million for the three months ended September 30, 2024. The other income recorded was primarily due to a \$0.6 million increase in government grant and a \$0.2 million decrease in the write-off of deferred financing fees.

Provision for Income Taxes

Provision for income taxes was \$1.7 million and \$1.1 million for the three months ended September 30, 2025 and 2024, respectively. The increase was primarily attributable to a higher profit from Gyre Pharmaceuticals' operations for the three months ended September 30, 2025.

Comparison of the nine months ended September 30, 2025 and 2024

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

	Nine Months Ended September 30,		Change (\$)	Change (%)
	2025	2024		
Revenues	\$ 79,393	\$ 77,885	\$ 1,508	2%
Cost of revenues	3,673	2,707	966	36%
Gross profit	75,720	75,178	542	1%
Operating expenses excluding cost of revenues:				
Selling and marketing	41,363	40,655	708	2%
Research and development	8,883	8,312	571	7%
General and administrative	14,103	10,645	3,458	32%
Loss on disposal of assets, net	2	68	(66)	(97)%
Total operating expenses excluding cost of revenues	64,351	59,680	4,671	8%
Income from operations	11,369	15,498	(4,129)	(27)%
Other income, net:				
Change in fair value of warrant liability	2,444	6,973	(4,529)	(65)%
Other income (expense), net	689	(25)	714	(2856)%
Income before income taxes	14,502	22,446	(7,944)	(35)%
Provision for income taxes	(3,256)	(5,117)	1,861	(36)%
Net income	11,246	17,329	(6,083)	(35)%
Net income attributable to noncontrolling interest	4,496	5,145	(649)	(13)%
Net income attributable to common stockholders	\$ 6,750	\$ 12,184	\$ (5,434)	(45)%

Revenues

Revenues for the nine months ended September 30, 2025 and 2024 were \$79.4 million and \$77.9 million, respectively. The \$1.5 million, or 2%, increase was primarily due to the increase in new product sales of Contiva® by \$3.0 million and Etozel® by \$3.1 million, partially offset by a \$4.4 million decline in ETUARY® sales and a \$0.2 million decrease in generic drug revenue. The decrease in ETUARY® sales was primarily due to the allocation of marketing resources towards the launches of two new products during the first half of the year. In the third quarter, Gyre refocused marketing efforts on ETUARY® in response to market uncertainties related to nintedanib and avatrombopag, both of which were included in the latest national volume-based procurement catalog. For the three months ended September 30, 2025, Gyre recorded an increase in ETUARY® sales compared to the same period in 2024, and Gyre expects ETUARY® sales will continue to grow in the three months ended December 31, 2025 compared to the same period in 2024.

We anticipate revenue growth over the remainder of the year, driven by the continued expansion of new products commercial franchises.

Cost of Revenues

Cost of revenues for the nine months ended September 30, 2025 and 2024 was \$3.7 million and \$2.7 million, respectively. The \$1.0 million, or 36%, increase was driven by a \$0.1 million increase in stock-based compensation and a \$0.4 million increase in the costs of Etozel® and Contiva®, in line with the corresponding increase in their sales, as well as a \$0.8 million increase in ETUARY®'s cost due to the higher plant, property and equipment depreciation from a plant renovation, partially offset by a \$0.3 million decrease in costs related to generic drugs due to the decrease of sales.

Selling and Marketing Expenses

Selling and marketing expenses increase by \$0.7 million, or 2%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was primarily driven by a \$0.9 million increase in conference expenses and a \$0.1 million increase in stock compensation costs, partially offset by a \$0.3 million reduction in staff costs.

Research and Development Expenses

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

	<u>Nine Months Ended September 30,</u>		<u>Change (\$)</u>	<u>Change (%)</u>
	<u>2025</u>	<u>2024</u>		
Direct program expenses:				
Clinical trials	\$ 3,474	\$ 2,433	\$ 1,041	43%
Materials and utilities	1,208	1,452	(244)	(17)%
Pre-clinical research	966	1,158	(192)	(17)%
Indirect expenses:				
Personnel-related costs	2,715	2,566	149	6%
Facilities, depreciation and other	520	703	(183)	(26)%
Total research and development expenses	<u>\$ 8,883</u>	<u>\$ 8,312</u>	<u>\$ 571</u>	<u>7%</u>

Research and development expenses increased by \$0.6 million, or 7%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was primarily attributable to a \$1.0 million increase in clinical trial costs, primarily as a result of data analysis costs for Hydronidone in the first half of 2025. This increase was offset by a \$0.2 million decrease in materials and utilities expenses and a \$0.2 million decrease in pre-clinical research expenses.

General and Administrative Expenses

General and administrative expenses increased by \$3.5 million, or 32%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was primarily driven by a \$2.8 million increase in functional and administrative department's personnel and stock compensation costs, and a \$0.9 million increase in miscellaneous expense, mainly due to the increase in expenses related to Gyre Pharmaceuticals' annual employee appreciation event, partially offset by a \$0.2 million decrease in professional fees.

Change in Fair Value of Warrant Liability

Change in fair value of warrant liability decreased \$4.5 million, or 65%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The decrease was related to the remeasurement of the Preferred Stock Warrants liability.

Other Income (Expense), Net

Other Income (Expense), net increased by \$0.7 million, or 2856%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was primarily due to a \$0.7 million increase in government grant.

Provision for Income Taxes

Provision for income taxes was \$3.3 million and \$5.1 million for the nine months ended September 30, 2025 and 2024, respectively. The decrease was primarily attributable to a lower profit from Gyre Pharmaceuticals' operations and impact of the option exercising for the nine months ended September 30, 2025.

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 September 30, 2025, we had cash and cash equivalents of \$40.4 million, short-term bank deposits of \$19.6 million and long-term certificates of deposit of \$20.3 million, which are available to fund operations, and an accumulated deficit of \$66.7 million. Our net income during the three and nine months ended September 30, 2025 was \$5.9 million and \$11.2 million, respectively, while cash provided by operating activities was \$4.7 million and \$6.6 million, respectively. 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 the next 12 months following the filing date of this Quarterly Report and thereafter for the foreseeable future.

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. In particular, following results from the PRC Phase 3 trial in CHB-associated liver fibrosis and pending approval of an IND submission, we expect to initiate a Phase 2 trial to evaluate Hydronidone for the treatment of MASH-associated liver fibrosis in 2026. We cannot guarantee that a Phase 2 trial will be initiated or estimate the funding needed for such trial at this time, but may need to raise additional capital to fund this program.

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):

	Nine Months Ended September 30,	
	2025	2024
Cash Flow Data:		
Net cash provided by (used in) operating activities	\$ 6,635	\$ (883)
Net cash used in investing activities	(2,322)	(17,880)
Net cash provided by financing activities	24,060	1,138
Effect of exchange rate changes on cash and cash equivalents	216	(18)
Net change in cash and cash equivalents	<u>\$ 28,589</u>	<u>\$ (17,643)</u>

Cash Flows from Operating Activities

Cash provided by operating activities for the nine months ended September 30, 2025 was \$6.6 million, reflecting our net income of \$11.2 million and non-cash items of \$1.5 million, which primarily includes \$2.6 million in stock-based compensation and \$1.8 million in depreciation and amortization, offset by \$2.4 million related to the change in the fair value of warrant liability. Additionally, cash used in operating activities reflected changes in net operating assets and liabilities of \$6.1 million.

The increase in cash provided by operating activities for the nine months ended September 30, 2025 compared with cash used in operating activities for the nine months ended September 30, 2024 was primarily attributable to higher customer collections, increased government grants, reduced payments for raw materials and services, and lower tax payments resulting from employee stock option exercises.

Cash used in operating activities for the nine months ended September 30, 2024 was \$0.9 million, reflecting our net income of \$17.3 million, offset by non-cash items of \$6.1 million primarily related to the change in fair value of warrant liability of \$7.0 million. Additionally, cash used in operating activities reflected changes in net operating assets and liabilities of \$12.1 million.

Cash Flows from Investing Activities

Cash used in investing activities for the nine months ended September 30, 2025 was \$2.3 million, which consisted of \$11.2 million in purchases of certificates of deposit, \$1.0 million in purchases of property and equipment, \$0.7 million in acquisition of intangible assets, and \$0.6 million in purchase of short-term investments, partially offset by \$11.2 million of proceeds from the maturity of certificates of deposit.

Cash used in investing activities for the nine months ended September 30, 2024 was \$17.9 million, which consisted of \$14.1 million in purchases of certificates of deposit, \$2.4 million in purchases of property and equipment, and \$1.7 million in equity method investment, partially offset by \$0.3 million in proceeds from sale of equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2025 was \$24.1 million due to \$23.0 million in proceeds from the issuance of common stock pursuant to our public offering of 2,555,555 shares of common stock, \$2.0 million in proceeds from the exercise of stock options, and \$0.5 million in proceeds from the issuance of common stock under our at-the-market offering program with Jefferies LLC, partially offset by \$1.5 million of cash used in connection with deferred offering costs.

Cash provided by financing activities for the nine months ended September 30, 2024 was \$1.1 million due to deferred financing costs, as well as proceeds from the exercise of stock options.

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 \$66.4 million and \$64.3 million as of September 30, 2025 and December 31, 2024, respectively. 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 September 30, 2025, our fixed lease payment obligations were \$1.2 million, with \$0.3 million payable within the remaining three months of 2025.

Research and Development Programs

As of September 30, 2025, we have committed to allocate \$37.6 million toward future research and development activities for various programs, including the Hydronidone program.

Property and Equipment

Our commitments related to the purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statements were \$4.6 million as of September 30, 2025 and are expected to be incurred within one year.

Etolel® IP Rights

We are committed to annual payments to the Etolel® IP Rights transferor over eight years following the commencement of commercial sales. See Note 12 — *Commitments and Contingencies*.

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, 2025, we remain a smaller reporting company and continue to qualify as an “accelerated filer”. As a result of our accelerated filer status, we were required, pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), to include in our Annual Report an attestation report from our independent registered public accounting firm regarding the effectiveness of our internal control over financial reporting, and we have complied with this requirement by including the attestation report in our Annual Report. However, we expect to continue 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 Exchange Act 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 September 30, 2025, 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 September 30, 2025 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 September 30, 2025 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

On September 13, 2025, the spouse of Songjiang Ma, the President and a director of the Company, entered into a Rule 10b5-1 trading arrangement (as defined in Item 408 of Regulation S-K). Ms. Ma’s plan provides for the potential exercise of vested stock options and the associated sale of up to 700,000 shares of common stock. The trading arrangement terminates upon the earlier of 15 months after the effective date of the trading arrangement and sale of all shares pursuant to the trading arrangement. During the three months ended September 30, 2025, no other director or executive officer adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, 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	Restated Certificate of Incorporation of the Company.	10-Q	000-51173	3.1	Nov. 13, 2024
3.2	Amended and Restated Bylaws of the Company.	8-K	000-51173	3.3	Oct. 30, 2023
3.3(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
3.3(b)	Certificate of Elimination of Series A Preferred Stock, filed with the	10-K	000-51173	3.6(b)	Mar. 27, 2024

	<u>Delaware Secretary of State on March 25, 2024.</u>				
3.4(a)	<u>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.</u>	8-K	000-51173	3.1	Dec. 27, 2022
3.4(b)	<u>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.</u>	8-K	000-51173	3.2	Oct. 30, 2023
3.5(a)	<u>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.</u>	8-K	000-51173	3.1	June 20, 2023
3.5(b)	<u>Certificate of Elimination of Series Y Preferred Stock, filed with the Delaware Secretary of State on August 31, 2023.</u>	8-K	000-51173	3.1	Aug. 31, 2023
4.1	<u>Form of Warrant to Purchase Series X Convertible Preferred Stock.</u>	8-K	000-51173	4.1	Oct. 30, 2023
31.1*	<u>Certification of the Interim 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.</u>				
31.2*	<u>Certification of the 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.</u>				
32.1**	<u>Certification of the Interim 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.</u>				
32.2**	<u>Certification of the 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.</u>				

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: November 7, 2025

/s/ Ping Zhang

Ping Zhang
Executive Chairman and Interim Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2025

/s/ Ruoyu Chen

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

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, Ping Zhang, 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: November 7, 2025

/s/ Ping Zhang

Ping Zhang
Executive Chairman and Interim Chief Executive Officer
(Principal Executive Officer)

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: November 7, 2025

/s/ Ruoyu Chen

Ruoyu Chen

Chief Financial Officer

(Principal Financial and Accounting Officer)

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 September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ping Zhang, 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: November 7, 2025

/s/ Ping Zhang

Ping Zhang
Executive Chairman and Interim Chief Executive Officer
(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.

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 September 30, 2025 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: November 7, 2025

/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.
