

**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 March 31, 2026

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)
12730 High Bluff Drive Suite 250
San Diego, California
(Address of Principal Executive Offices)

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

92130
(Zip Code)

(858) 284-0115

(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 May 1, 2026, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 97,028,322, which includes 5,656,379 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)
(Unaudited)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,501	\$ 37,070
Short-term bank deposits	12,307	15,355
Notes receivable	3,817	5,638
Accounts receivables, net	22,763	31,078
Other receivables from GNI	230	230
Inventories	11,352	10,171
Prepaid assets and other current assets	3,762	2,827
Total current assets:	91,732	102,369
Property and equipment, net	23,572	23,599
Intangible assets, net	4,627	4,727
Deferred tax assets	7,723	6,873
Long-term certificates of deposit	29,419	23,516
Other assets, noncurrent	4,942	5,048
Total assets	<u>\$ 162,015</u>	<u>\$ 166,132</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 265	\$ 124
Due to related parties	226	227
Accrued expenses and other current liabilities	15,415	14,359
Income tax payable	3,131	2,940
Operating lease liabilities, current	751	636
Total current liabilities:	19,788	18,286
Operating lease liabilities, noncurrent	72	303
Deferred government grants	840	852
Warrant liability, noncurrent	2,872	2,961
Other noncurrent liabilities	1,458	1,448
Total liabilities	<u>25,030</u>	<u>23,850</u>
Commitments and Contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.001 par value, 400,000,000 shares authorized; 91,337,121 shares and 91,314,007 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	91	91
Additional paid-in capital	174,651	172,047
Statutory reserve	3,648	3,098
Accumulated deficit	(77,667)	(68,426)
Accumulated other comprehensive income (loss)	586	(779)
Total Gyre stockholders' equity	<u>101,309</u>	<u>106,031</u>
Noncontrolling interest	35,676	36,251
Total equity	<u>136,985</u>	<u>142,282</u>
Total liabilities and stockholders' equity	<u>\$ 162,015</u>	<u>\$ 166,132</u>

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

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

	Three Months Ended March 31,	
	2026	2025
Revenues	\$ 22,519	\$ 22,058
Operating expenses:		
Cost of revenues	1,227	894
Selling and marketing	14,136	10,841
Research and development	6,738	3,095
General and administrative	7,220	4,955
Transaction costs	2,553	—
Total operating expenses	31,874	19,785
(Loss) income from operations	(9,355)	2,273
Other income, net:		
Change in fair value of warrant liability	89	2,255
Other income, net	29	107
(Loss) income before income taxes	(9,237)	4,635
Provision for income taxes	(621)	(901)
Net (loss) income	(9,858)	3,734
Net (loss) income attributable to noncontrolling interest	(1,167)	1,036
Net (loss) income available to common stockholders	\$ (8,691)	\$ 2,698
Net (loss) income per share attributable to common stockholders:		
Basic	\$ (0.10)	\$ 0.03
Diluted	\$ (0.10)	\$ 0.00
Weighted average shares used in calculating net (loss) income per share attributable to common stockholders:		
Basic	91,317,142	86,420,530
Diluted	91,344,584	101,970,672
Other comprehensive (loss) income:		
Net (loss) income from operations	\$ (9,858)	\$ 3,734
Foreign currency translation adjustments	1,957	171
Comprehensive (loss) income from operations	(7,901)	3,905
Net (loss) income attributable to noncontrolling interest	(1,167)	1,036
Foreign currency translation adjustments attributable to noncontrolling interest	592	60
Comprehensive (loss) income attributable to noncontrolling interest	(575)	1,096
Comprehensive (loss) income attributable to common stockholders	\$ (7,326)	\$ 2,809

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

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

	Common Stock		Additional Paid-In Capital	Statutory Reserve	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Gyre Stockholders' Equity	Non-controlling Interest	Total Equity
	Shares	Amount							
Balance at December 31, 2025	91,314,007	\$ 91	\$ 172,047	\$ 3,098	\$ (68,426)	\$ (779)	\$ 106,031	\$ 36,251	\$ 142,282
Appropriation of statutory reserve	—	—	—	550	(550)	—	—	—	—
Stock-based compensation expense	—	—	2,583	—	—	—	2,583	—	2,583
Stock options exercised	23,114	—	21	—	—	—	21	—	21
Foreign currency translation adjustment	—	—	—	—	—	1,365	1,365	592	1,957
Net loss	—	—	—	—	(8,691)	—	(8,691)	(1,167)	(9,858)
Balance at March 31, 2026	<u>91,337,121</u>	<u>\$ 91</u>	<u>\$ 174,651</u>	<u>\$ 3,648</u>	<u>\$ (77,667)</u>	<u>\$ 586</u>	<u>\$ 101,309</u>	<u>\$ 35,676</u>	<u>\$ 136,985</u>

	Common Stock		Additional Paid-In Capital	Statutory Reserve	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Gyre Stockholders' Equity	Non-controlling Interest	Total Equity
	Shares	Amount							
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 upon ATM Program	54,734	—	509	—	—	—	509	—	509
CVR Liability settlement	—	—	25	—	—	—	25	—	25
Deferred Financing Costs Amortization	—	—	(2)	—	—	—	(2)	—	(2)
Foreign currency translation adjustment	—	—	—	—	—	111	111	60	171
Net income	—	—	—	—	2,698	—	2,698	1,036	3,734
Balance at March 31, 2025	<u>87,636,209</u>	<u>\$ 87</u>	<u>\$ 138,179</u>	<u>\$ 3,098</u>	<u>\$ (70,755)</u>	<u>\$ (2,486)</u>	<u>\$ 68,123</u>	<u>\$ 36,179</u>	<u>\$ 104,302</u>

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)

	Three Months Ended March 31,	
	2026	2025
Operating Activities		
Net (loss) income	\$ (9,858)	\$ 3,734
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Stock-based compensation	2,583	507
Equity in loss of unconsolidated affiliate	21	19
Depreciation and amortization	672	535
Noncash lease expense	217	197
Deferred income taxes, net	(738)	(191)
Bad debt expense and other non-cash items	195	188
Accrued interest on long-term certificates of deposit	647	483
Change in fair value of long-term receivables	—	(39)
Change in fair value of derivative liabilities	—	39
Change in fair value of warrant liability	(89)	(2,255)
Loss on disposal of property and equipment	16	—
Changes in operating assets and liabilities:		
Notes receivable	1,902	2,243
Accounts receivable	8,573	(722)
Inventories	(1,015)	(1,541)
Prepaid assets and other current assets	(912)	(5,541)
Income tax payable	144	(2,266)
Accounts payable	139	14
Accrued expenses and other liabilities	683	4,442
Net proceeds from CVR liability settlement	—	25
Net cash provided by (used in) operating activities	<u>3,180</u>	<u>(129)</u>
Investing Activities		
Acquisition of intangible assets	(5)	(699)
Purchase of certificates of deposit	(12,951)	(8,403)
Purchase of property and equipment	(178)	(122)
Proceeds from sale of equipment	6	1
Maturity of certificates of deposit	10,073	11,190
Net cash (used in) provided by investing activities	<u>(3,055)</u>	<u>1,967</u>
Financing Activities		
Deferred financing costs	—	(121)
Proceeds from the exercise of stock options	21	956
Proceeds from the issuance of common stock in ATM Program	—	509
Net cash provided by financing activities	<u>21</u>	<u>1,344</u>
Effect of exchange rate changes on cash	285	50
Net increase in cash	431	3,232
Cash at beginning of the period	37,070	11,813
Cash at end of period	<u>\$ 37,501</u>	<u>\$ 15,045</u>
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	\$ 1,214	\$ 3,359

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 biopharmaceutical company originally incorporated in Delaware on March 7, 1997 under the name Targacept, Inc.

As of March 31, 2026, 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.

On November 7, 2025, the National Healthcare Security Administration in the PRC released the *Announcement of the Winning Bids for the National Centralized Drug Procurement*, under which EtoresTM was selected. As a result, Gyre Pharmaceuticals signed direct procurement contracts with various participating hospitals and distributors together under the National Centralized Drug Procurement Program, and implementation commenced in March 2026.

On May 4, 2026 (the “Merger Closing Date”), the Company acquired Cullgen Inc., a Delaware corporation (“Cullgen”), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated March 2, 2026 (the “Merger Agreement”), by and among the Company, Helix Merger Sub Corp., a Delaware corporation and wholly owned subsidiary of the Company (“Merger Sub”), and Cullgen. Pursuant to the Merger Agreement, among other matters, Merger Sub merged with and into Cullgen, with Cullgen continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the “Merger”). The related transaction costs were expensed as incurred. See Note 16 — Subsequent Events.

Liquidity

For the three months ended March 31, 2026, the Company had a net loss of \$9.9 million, while net cash provided by operating activities was \$3.2 million. As of March 31, 2026, the Company had an accumulated deficit of \$77.7 million and cash and cash equivalents of \$37.5 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. The December 31, 2025 consolidated balance sheet was derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2025, as filed with the SEC. 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, 2026, 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, 2025 filed with the SEC on March 13, 2026 (the “Annual Report”).

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, allowance of doubtful accounts, long-term receivable, 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. On the Merger Closing Date, Ying Luo was appointed as Gyre’s Chief Executive Officer.

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 and short-term bank deposits.

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 the United States, the Federal Deposit Insurance Corporation (“FDIC”) insures deposits at federally insured financial institutions up to a limit of \$250,000 per depositor, per insured bank, for each account ownership category. The Securities Investor Protection Corporation (“SIPC”) protects customer assets held by registered broker-dealers, with a standard limit of \$500,000 per customer. The Company maintains cash and deposits in excess of the amount protected by FDIC and SIPC insurance. In the event of failure or insolvency of one of these financial institutions, the Company may be unable to recover its deposits in full. Management believes that these financial institutions are of high credit quality and continually monitors the creditworthiness of these financial institutions. As of March 31, 2026 and December 31, 2025, the Company had cash and cash equivalents held in U.S. financial institutions of \$23.0 million and \$25.9 million, respectively. Of the 2026 balance, \$2.5 million represented general bank deposits and \$20.5 million represented investment related cash. At March 31, 2026, the Company’s U.S. cash balances exceeded FDIC insurance coverage by \$2.3 million and exceeded SIPC coverage by \$20.0 million.

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 \$72,261, based on the March 31, 2026 spot exchange rate. The Company maintains cash and deposits in excess of the amount protected by DIS 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 March 31, 2026 and December 31, 2025, the Company had cash and cash equivalents of \$37.5 million and \$37.1 million, and long-term certificates of deposit of \$29.4 million and \$23.5 million, respectively. In addition, the Company had short-term bank deposits of \$12.3 million and \$15.4 million as of March 31, 2026 and December 31, 2025, respectively. At March 31, 2026 and December 31, 2025, cash and cash equivalents, short-term bank deposits and long-term certificates of deposit exceeded the PRC DIS coverage by \$55.6 million and \$49.4 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. Note receivable is also subject to credit risk. The Company monitors the creditworthiness and repayment performance of the borrower on an ongoing basis and has not experienced significant credit losses related to such receivable.

Concentration of Customer Risk

For the three months ended March 31, 2026, 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 42.8%, 14.4% and 13.2% of total revenue, respectively. For the three months ended March 31, 2025, the Company had three customers, Sinopharm, Resources Pharmaceutical, and Shanghai Pharmaceuticals, who accounted for approximately 50.3%, 15.5% and 12.4% of total revenue, respectively. All customers are located in mainland China.

As of March 31, 2026 and December 31, 2025, the Company had one customer, Sinopharm, who accounted for approximately 47.2% and 53.3% 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. 38.4% of the Company’s cash and cash equivalents, 100.0% of the Company’s short-term bank deposits and 100% of the Company’s long-term certificates of deposit as of March 31, 2026 in the amount of \$14.4 million, \$12.3 million and \$29.4 million, respectively, were denominated in RMB.

Accounting Pronouncements – Recently Adopted

In July 2025, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2025-05, Financial Instruments—Credit Losses (Topic 326): *Measurement of Credit Losses for Accounts Receivable and Contract Assets* (“ASU 2025-05”). ASU 2025-05 provides a practical expedient for measuring expected credit losses for current accounts receivable and current contract assets that arise from revenue transactions within the scope of ASC 606, permitting an entity to assume that economic conditions as of the balance sheet date will remain unchanged over the remaining life of the financial assets when developing reasonable and supportable forecasts. ASU 2025-05 is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2025, with early adoption permitted. The amendments in this update should be applied on a prospective basis. The Company adopted the provisions of the amendments as of January 1, 2026. The adoption of this amendment did not have a material impact on the Company’s consolidated financial statements.

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 has elected not to early adopt ASU 2024-03. The Company is currently assessing the impact of the disclosure requirements on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*. This ASU provides guidance on the recognition, measurement, presentation and disclosure of government grants received by business entities. The ASU is effective for annual reporting periods beginning after December 15, 2028, and interim reporting periods within those annual periods, with early adoption permitted. The Company has elected not to early adopt ASU 2025-10. The Company is currently evaluating the impact that the adoption of ASU 2025-10 will have on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* (“ASU 2025-11”). ASU 2025-11 clarifies the applicability of the interim reporting guidance in Topic 270 and improves the navigability and organization of the guidance. The amendments also introduce a principle requiring entities that issue interim financial statements to disclose events and changes occurring after the end of the most recent annual reporting period that are expected to have a material impact on the entity. ASU 2025-11 does not change the recognition or measurement requirements for interim reporting. The ASU is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027 for public business entities, with early adoption permitted. The Company has elected not to early adopt ASU 2025-11. The Company is currently evaluating the potential impact of this guidance on its interim and annual financial statement disclosures.

Subsequent Events

The Company accounts for subsequent events in accordance with ASC 855, *Subsequent Events*, which defines subsequent events as events or transactions that occur after the balance sheet date but before the financial statements are issued. Management has evaluated subsequent events through the date the financial statements were issued and filed with the Securities and Exchange Commission. There were no subsequent events that required recognition or disclosure other than those disclosed in Note 16 — *Subsequent Events*.

3. Fair Value Measurements and Financial Instruments

For a description of the fair value hierarchy and the 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 three months ended March 31, 2026. As of March 31, 2026, the Company's highly liquid money market funds are included within cash equivalents.

The following tables present the fair value hierarchy for financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2026 and December 31, 2025 (in thousands):

	March 31, 2026			Total
	Level 1	Level 2	Level 3	
Financial assets:				
Money market funds ⁽¹⁾	\$ 21,990	\$ —	\$ —	\$ 21,990
Total financial assets	\$ 21,990	\$ —	\$ —	\$ 21,990
Financial liabilities:				
Warrant liability, noncurrent	\$ —	\$ —	\$ 2,872	\$ 2,872
Total financial liabilities	\$ —	\$ —	\$ 2,872	\$ 2,872
	December 31, 2025			Total
	Level 1	Level 2	Level 3	
Financial assets:				
Money market funds ⁽¹⁾	\$ 24,876	\$ —	\$ —	\$ 24,876
Total financial assets	\$ 24,876	\$ —	\$ —	\$ 24,876
Financial liabilities:				
Warrant liability, noncurrent	\$ —	\$ —	\$ 2,961	\$ 2,961
Total financial liabilities	\$ —	\$ —	\$ 2,961	\$ 2,961

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

The carrying amounts of cash, accounts and note receivables, net, other receivables, accounts payable, due to related parties, and accrued liabilities approximate their fair values due to their short maturities.

During the three months ended March 31, 2026 and the year ended December 31, 2025, 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.

Warrant Liability

In October 2023, Catalyst entered into a Securities Purchase Agreement for a private placement with GNI USA (the "Private Placement"). Upon closing of the Private Placement, the Company issued 811 shares of Series X Convertible Preferred Stock, par value \$0.001 per share (the "Series X Preferred Stock"), and 811 warrants to purchase Series X Preferred Stock (the "Preferred Stock Warrants") to GNI USA for an aggregate purchase price of approximately \$5.0 million. The Preferred Stock Warrants are immediately exercisable at an exercise price of \$4,915.00 per share of Series X 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 Series X 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:

	March 31, 2026		December 31, 2025	
Share price	\$	6.97	\$	7.06
Exercise price	\$	4,915.00	\$	4,915.00
Dividend yield		—%		—%
Risk-free interest		4.06%		3.93%
Term (years)		7.58		7.83
Expected volatility		80.00%		81.00%

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

	Warrant liability	
Balance at December 31, 2025	\$	2,961
Changes in fair value		(89)
Change due to settlements		—
Balance at March 31, 2026	\$	2,872

Financial Instruments

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

March 31, 2026	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Money market funds (cash equivalents)	\$ 21,990	\$ —	\$ —	\$ 21,990
Short-term bank deposits	12,307	—	—	12,307
Long-term certificates of deposit	29,419	—	—	29,419
Total financial assets	\$ 63,716	\$ —	\$ —	\$ 63,716
Classified as:				
Cash and cash equivalents				\$ 21,990
Short-term bank deposits				12,307
Long-term certificates of deposit				29,419
Total financial assets				\$ 63,716

December 31, 2025	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Money market funds (cash equivalents)	\$ 24,876	\$ —	\$ —	\$ 24,876
Short-term bank deposits	15,355	—	—	15,355
Long-term certificates of deposit	23,516	—	—	23,516
Total financial assets	\$ 63,747	\$ —	\$ —	\$ 63,747
Classified as:				
Cash and cash equivalents				\$ 24,876
Short-term bank deposits				15,355
Long-term certificates of deposit				23,516
Total financial assets				\$ 63,747

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

	March 31, 2026	
	Amortized Cost	Fair Value
Due in one year	\$ 12,307	\$ 12,307
Due in one to five years	29,419	29,419
Total	\$ 41,726	\$ 41,726

Interest income from the short-term bank deposits is recognized on an accrual basis over the term of the deposits. The accrued interest income for the three months ended March 31, 2026 and 2025 was \$0.1 million and \$0.1 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 for the three months ended March 31, 2026 and 2025 was \$0.2 million and \$0.1 million, respectively.

4. Balance Sheet Components

Inventories

Inventories as of March 31, 2026 and December 31, 2025, respectively, consisted of the following components (in thousands):

	March 31, 2026	December 31, 2025
Raw materials	\$ 1,174	\$ 970
Work in progress	5,993	6,307
Finished goods	4,185	2,894
Inventories	<u>\$ 11,352</u>	<u>\$ 10,171</u>

Accrued Expenses and Other Current Liabilities

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

	March 31, 2026	December 31, 2025
Accrued payroll and welfare	\$ 5,616	\$ 7,621
Accrued professional services	2,625	352
Payable to property and equipment & intangible asset suppliers	2,018	2,161
Accrued sales rebates	1,633	1,382
Payable to selling expense suppliers	1,521	270
Accrued expenses - research and development	1,084	1,115
Accrued expenses - general and administrative	491	757
Deferred government grants	99	97
Employee reimbursement	18	12
Other accrued liabilities	310	578
Contract liabilities	—	14
Accrued expenses and other current liabilities	<u>\$ 15,415</u>	<u>\$ 14,359</u>

Accounts and Note Receivables, Net

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

	March 31, 2026	December 31, 2025
Accounts receivable	\$ 23,112	\$ 31,229
Note receivable	3,817	5,638
Allowance for credit losses	(349)	(151)
Accounts and note receivables, net	<u>\$ 26,580</u>	<u>\$ 36,716</u>

Property and Equipment, Net

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

	March 31, 2026	December 31, 2025
Buildings	\$ 19,872	\$ 19,569
Construction in progress	689	765
Machinery and electronic devices	10,202	9,895
Furniture and fixtures	783	757
Motor vehicles	192	189
Property and equipment, gross	31,738	31,175
Less: Accumulated depreciation	(8,166)	(7,576)
Property and equipment, net	<u>\$ 23,572</u>	<u>\$ 23,599</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 March 31, 2026 and December 31, 2025, the Company's total investment into 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 EtozelTM (nintedanib, ethanesulfonate soft capsules) (the "EtozelTM IP Rights"), which were obtained upon the successful transfer of the marketing authorization holder following approval by the PRC National Medical Products Administration (the "NMPA") in March 2025, and the commercial sales of EtozelTM commenced in June 2025. As of March 31, 2026, the Company recognized the total consideration for the EtozelTM technology rights in the amount of RMB 35.0 million, or approximately \$5.1 million, based on the March 31, 2026 spot exchange rate.

The gross carrying amounts and accumulated amortization of the Company's intangible assets with determinable lives as of March 31, 2026 and December 31, 2025 were as follows (in thousands):

	March 31, 2026		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	\$ 440	\$ (338)	\$ 102
Computer software	344	(193)	151
Technology rights	5,059	(685)	4,374
Total intangible assets	\$ 5,843	\$ (1,216)	\$ 4,627

	December 31, 2025		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	\$ 433	\$ (328)	\$ 105
Computer software	337	(176)	161
Technology rights	4,980	(519)	4,461
Total intangible assets	\$ 5,750	\$ (1,023)	\$ 4,727

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 6.7 years as of March 31, 2026, compared to 7.0 years as of December 31, 2025.

Amortization expense was \$175 thousand and \$67 thousand for the three months ended March 31, 2026 and 2025, respectively. Based on finite-lived intangible assets recorded as of March 31, 2026, the estimated future amortization expense is as follows (in thousands):

	<u>Estimated amortization expense</u>
2026	\$ 529
2027	701
2028	671
2029	670
2030	659
Thereafter	1,397
Total	<u>\$ 4,627</u>

6. Revenue

The Company's product revenues were mainly generated from the sale of ETUARY™. The Company launched two new products: Contiva™ (avatrombopag maleate tablets), which commenced commercialization in March 2025, and Etoresol™, which commenced commercialization in June 2025. The following table summarizes the composition of product revenues for the three months ended March 31, 2026 and 2025.

Product Revenue Composition	Three Months Ended March 31,			
	2026		2025	
ETUARY™	\$ 20,967	93.1%	\$ 21,706	98.4%
Contiva™	849	3.8%	279	1.3%
Etoresol™	672	3.0%	—	0.0%
Other Products	31	0.1%	73	0.3%
Total	<u>\$ 22,519</u>	<u>100%</u>	<u>\$ 22,058</u>	<u>100%</u>

Sales of Pharmaceutical Products

The Company generates revenue mostly through sales of ETUARY™, Contiva™, Etoresol™ and certain generic drugs. The distributors were the Company's direct customers, and sales to distributors accounted 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 \$22.5 million and \$22.1 million for the three months ended March 31, 2026 and 2025, respectively. All sales are generated in the PRC. Contract liabilities recognized for the three months ended March 31, 2026 were immaterial.

7. Leases

Operating Leases

As of March 2026, 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 thousand and \$16 thousand in short-term rent expenses during the three months ended March 31, 2026 and 2025, 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 March 31, 2026, the Company recorded an aggregate right-of-use asset of \$2.4 million, and an aggregate lease liability of \$0.8 million in the accompanying condensed consolidated balance sheets.

For the three months ended March 31, 2026 and 2025, the Company's operating lease expense was \$0.2 million and \$0.2 million, respectively. Variable lease payments for the three months ended March 31, 2026 and 2025 were immaterial.

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

	Three Months Ended March 31,	
	2026	2025
Cash paid for amounts included in the measurement of lease liabilities	\$ 139	\$ 47

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

	March 31, 2026	December 31, 2025
Weighted-average remaining lease term	1.2 years	1.4 years
Weighted-average discount rate	4.75%	4.76%

As of March 31, 2026, undiscounted future minimum payments under the Company's operating leases were as follows (in thousands):

	Amount
Remaining in 2026	\$ 537
2027	307
Total undiscounted lease payments	844
Less: imputed interest	(21)
Total lease liabilities	823
Less: current portion of lease liabilities	(751)
Lease liabilities, net of current portion	\$ 72

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 March 31, 2026, the Company held land use rights for two land parcels in Beijing's Shunyi District, expiring in 2053, and in Cangzhou, Hebei Province, expiring from 2067 to 2070. These parcels, with a combined area of approximately 66,559 square meters, are utilized as manufacturing facilities. As of March 31, 2026, the aggregate recorded land use rights, net assets for these parcels was \$1.4 million.

8. Stockholders' Equity

Common Stock

Common stock reserved for future issuance is as follows:

	<u>March 31, 2026</u>	<u>December 31, 2025</u>
Options issued and outstanding	19,642,094 [1]	19,483,378
Preferred Stock Warrants issued and outstanding	540,666	540,666
Total common stock reserved	<u>20,182,760</u>	<u>20,024,044</u>

[1] Includes 5,656,880 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, the Company 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 \$135,000 for legal expenses in connection with the establishment of the ATM Program. During the three months ended March 31, 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. During the three months ended March 31, 2026, there were no sales under the ATM Program.

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, the Company 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.

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, which represented the amount of net assets of the relevant subsidiaries not available for distribution were \$72.4 million and \$70.1 million as of March 31, 2026 and December 31, 2025, respectively.

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. Appropriations to these reserves were \$0.6 million and \$0 for the three months ended March 31, 2026 and 2025, respectively.

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. As of March 31, 2026, the Company's indirect ownership in Gyre Pharmaceuticals is 69.7%.

9. Stock Based Compensation

2023 Omnibus Incentive Plan

The Gyre Therapeutics, Inc. 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 three months ended March 31, 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"). The Performance-Based Awards are subject to the achievement of certain sales metrics and approval of Hydronidone for commercialization. The Performance-Based Awards may vest in full after two or three years. 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.

On November 20, 2025, the Company granted non-qualified stock options to employees of Gyre Pharmaceuticals, pursuant to the 2023 Omnibus Incentive Sub-Plan for Chinese Participants under the Company's equity incentive arrangements. The awards covered an aggregate of 2,100,000 shares of common stock and were granted as part of the Company's employee compensation program.

The stock options were granted with an exercise price of \$7.57 per share and have a contractual term of ten years from the grant date, subject to earlier termination upon cessation of employment. The awards generally vest based on a combination of time-based and performance-based vesting conditions. Specifically, 25% of the options vest immediately on the grant date, 35% vest in substantially equal monthly installments over a 24-month service period, and the remaining options are subject to the achievement of specified performance targets related to the Company's consolidated revenue and the employee's individual performance for the 2025 and 2026 calendar years. Performance-Based Awards vest only if the applicable performance conditions are achieved and the employee remains in service through the applicable vesting determination date.

The following table summarizes stock option activity for the three months ended March 31, 2026:

	Number of Shares Underlying Outstanding Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)
Outstanding — December 31, 2025	19,483,378	\$ 3.09	6.0
Options granted	210,000	\$ 7.31	
Options exercised	(23,114)	\$ 0.89	
Options forfeited and cancelled	(28,170)	\$ 7.57	
Outstanding — March 31, 2026	19,642,094	\$ 3.14	5.8
Exercisable — March 31, 2026	16,165,455	\$ 1.95	5.4

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 that vest under two types of independent performance conditions. One condition is tied to a certain sales target that is deemed not probable as of March 31, 2026. The other condition is tied to the approval in the PRC of a New Drug Application (“NDA”) for Hydronidone. 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, exercise 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 months ended March 31, 2026 and 2025:

	Three Months Ended March 31,			
	2026		2025	
Time-based and performance-based awards				
Weighted-average grant-date fair value	\$	5.18	\$	7.46
Risk-free interest rate (%)		3.8%		4.07% - 4.40%
Expected option life (in years)		6.1		5.41 - 6.41
Expected dividend yield (%)		—%		—%
Volatility (%)		79.3%		81.5% - 84.3%

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

	Three Months Ended March 31,			
	2026		2025	
Cost of revenues	\$	178	\$	—
Selling and marketing		985		—
Research and development		115		—
General and administrative		1,305		507
Total stock-based compensation expense	\$	2,583	\$	507

As of March 31, 2026, the Company had an unrecognized stock-based compensation expense of \$12.6 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 2.3 years.

10. Net (Loss) 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 excluded from the diluted EPS attributable to common stock calculation if they have an anti-dilutive effect. If there is a net loss for the period, all options are excluded from the diluted EPS calculation.

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

	Three Months Ended March 31,	
	2026	2025
Numerator:		
Net (loss) income	\$ (9,858)	\$ 3,734
Less: Allocation of undistributed (losses) earnings to noncontrolling interest	(1,167)	1,036
Net (loss) income attributable to common stockholders - basic	\$ (8,691)	\$ 2,698
Less: Change in fair value of warrant liability	89	2,255
Net (loss) income attributable to common stockholders - diluted	\$ (8,780)	\$ 443
Denominator:		
Basic common shares outstanding:		
Weighted average common shares outstanding	91,317,142	86,420,530
Weighted average shares used in calculating net income per share attributable to common stockholders, basic	<u>91,317,142</u>	<u>86,420,530</u>
Dilutive potential common shares:		
Weighted average of common stock options	—	15,372,925
Weighted average of Preferred Stock Warrants (as converted)	27,442	177,217
Weighted average shares used in calculating net income per share attributable to common stockholders, diluted	<u>91,344,584</u>	<u>101,970,672</u>
Net (loss) income per share attributable to common stockholders:		
Basic	<u>\$ (0.10)</u>	<u>\$ 0.03</u>
Diluted	<u>\$ (0.10)</u>	<u>\$ 0.00</u>

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

	Three Months Ended March 31,	
	2026	2025
Options to purchase common stock	17,118,695	1,154,866
Total	<u>17,118,695</u>	<u>1,154,866</u>

11. 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 \$1.5 million as of March 31, 2026 and were expected to be incurred within one year.

Etorel™ 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 "Etorel™ IP Rights". The Etorel™ IP Rights are recorded as technology rights in Intangible Assets in Note 5 — Intangible Assets. The commercial sales of Etorel™ commenced in June 2025.

According to the agreement, except for RMB 35.0 million, or approximately \$5.1 million, based on the March 31, 2026 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 March 31, 2026 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 March 31, 2026 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 March 31, 2026 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 March 31, 2026, 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 March 31, 2026 spot exchange rate, as remote and did not accrue any contingent consideration.

As of March 31, 2026, the total accrued contract consideration was \$2.9 million, which was recorded under accrued expenses and other current liabilities, and other noncurrent liabilities.

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 \$4.8 million, based on the March 31, 2026 spot exchange rate upon submission of the Hydronidone NDA to the Center for Drug Evaluation (“CDE”) of the NMPA and its acceptance by CDE; RMB 8.3 million, or approximately \$1.2 million, based on the March 31, 2026 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 \$7.2 million, based on the March 31, 2026 spot exchange rate upon NMPA’s approval of the NDA. As of March 31, 2026, the next payment conditions have not been met, as such, no payments have been accrued.

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 March 31, 2026, commercialization has not yet been achieved, and no royalty payments have been incurred or accrued.

SDM Service

In December 2025, the Company entered into a clinical trial service agreement with a third-party contract research organization in connection with a Phase 3c confirmatory clinical trial for Hydronidone (the “SDM Clinical Trial Agreement”). The Phase 3c trial is designed to evaluate clinical endpoint events and satisfy the safety exposure requirements for the potential conditional approval and subsequent conventional marketing authorization of Hydronidone capsules.

Under the SDM Clinical Trial Agreement, the Company is obligated to make payments based on the achievement of specified clinical and operational milestones and the performance of clinical trial-related services, including trial preparation, patient enrollment and follow-up, site management, interim analyses, data management-related activities, and preparation of the clinical study report. The aggregate contractual amount under the agreement is approximately RMB 114.0 million, or approximately \$16.5 million, based on the March 31, 2026 spot exchange rate.

As of March 31, 2026, the Company recognized \$0.8 million in research and development expenses and made payments of \$1.6 million under the SDM Clinical Trial Agreement.

Research and Development Programs

In addition to the \$13.1 million commitment to GNI Group for the Hydronidone program, as of March 31, 2026, Gyre Pharmaceuticals has committed to allocate \$51.0 million toward future research and development activities for various programs. Gyre Therapeutics has committed to allocate \$1.2 million toward research and development activities.

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.

12. Income Taxes

During the three months ended March 31, 2026 and 2025, the Company recorded the following income tax provision (in thousands) and effective tax rate:

	Three Months Ended March 31,	
	2026	2025
Income tax provision	\$ 621	\$ 901
Effective tax rate	-6.72%	19.44%

The change in effective tax rate for the three months ended March 31, 2026 and 2025 was primarily due to the Company experiencing a loss before income tax. The Company expects to incur income tax expense for the current period as a result of the impact of valuation allowance. Accordingly, the effective tax rate for the three months ended March 31, 2026 was negative.

As of March 31, 2026, after consideration of certain limitations (see below), the Company had approximately \$193.3 million federal and \$21.7 million state net operating loss (“NOL”) carryforwards for U.S. tax purposes available to reduce future taxable income which, if unused, will begin to expire in 2037 for federal and 2034 for state tax purposes. The federal net operating loss carryforward includes \$191.9 million that have an indefinite life.

If the Company experiences a greater than 50 percentage point aggregate change in ownership over a three-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards is 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 immediately before 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 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.

13. Related Party Transactions

Research and Development with GNI Group

No research and development fees were paid to GNI Group during the three months ended March 31, 2026 and 2025. As of March 31, 2026 and December 31, 2025, the Company had \$0.2 million related parties payable due to GNI Group.

Other Receivables from GNI

As of March 31, 2026 and December 31, 2025, the Company had recorded \$0.2 million in other receivables from GNI Group, all of which related to Continent Pharmaceuticals Inc.’s (“CPI”) restructuring transaction.

14. 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 \$1.5 million and \$1.3 million for the three months ended March 31, 2026 and 2025, respectively.

Defined-Contribution Savings Plan

In the U.S., the Company maintains a defined-contribution savings plan pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan is available to employees who meet the minimum age and length of service requirements. The contributions made during the three months ended March 31, 2026 and the year ended December 31, 2025 were immaterial.

15. Segment Information

The Company is a consolidated entity comprised of two distinct operating segments: Gyre Pharmaceuticals and Gyre. 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 metabolic dysfunction-associated steatohepatitis ("MASH")-associated liver fibrosis in the United States. Other than the IP associated with Hydronidone, Etores™, Contiva™ in the United States, Gyre has no other product candidates since the Company sold all of its legacy IP assets. Subsequent to October 2023, Gyre has not generated any revenue.

Other

Other represents the financial information from other subsidiaries, consisting of mainly CPI and BJC. As of March 31, 2026, CPI holds a 61.7% indirect ownership interest in Gyre Pharmaceuticals.

Segment information for the three months ended March 31, 2026 and 2025 is as follows (in thousands):

	Three Months Ended March 31, 2026			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	\$ 22,519	\$ —	\$ —	\$ 22,519
Operating expenses:				
Cost of revenues	1,227	—	—	1,227
Selling and marketing	14,136	—	—	14,136
Research and development	5,466	1,272	—	6,738
General and administrative	4,757	2,457	6	7,220
Transaction costs	—	2,553	—	2,553
Total operating expenses	25,586	6,282	6	31,874
Loss from operations	(3,067)	(6,282)	(6)	(9,355)
Change in fair value of warrant liability	—	89	—	89
Other (expense) income, net	(162)	191	—	29
Income tax expense	(621)	—	—	(621)
Net loss	<u>\$ (3,850)</u>	<u>\$ (6,002)</u>	<u>\$ (6)</u>	<u>\$ (9,858)</u>

Supplemental disclosure of stock-based compensation expense:

Cost of revenues	178	—	—	178
Selling and marketing	985	—	—	985
Research and development	115	—	—	115
General and administrative	435	870	—	1,305
Stock-based compensation total	<u>\$ 1,713</u>	<u>\$ 870</u>	<u>\$ —</u>	<u>\$ 2,583</u>

	Three Months Ended March 31, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	\$ 22,058	\$ —	\$ —	\$ 22,058
Operating expenses:				
Cost of revenues	894	—	—	894
Selling and marketing	10,841	—	—	10,841
Research and development	3,029	66	—	3,095
General and administrative	3,556	1,396	3	4,955
Total operating expenses	18,320	1,462	3	19,785
Income (loss) from operations	3,738	(1,462)	(3)	2,273
Change in fair value of warrant liability	—	2,255	—	2,255
Other income, net	62	45	—	107
Income tax expense	(901)	—	—	(901)
Net income (loss)	<u>\$ 2,899</u>	<u>\$ 838</u>	<u>\$ (3)</u>	<u>\$ 3,734</u>

Supplemental disclosure of stock-based compensation expense:

General and administrative	\$ 78	\$ 429	\$ —	\$ 507
Stock-based compensation total	<u>\$ 78</u>	<u>\$ 429</u>	<u>\$ —</u>	<u>\$ 507</u>

The table below presents total assets as of March 31, 2026 and December 31, 2025.

	March 31, 2026			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Total assets	\$ 137,350	\$ 24,308	\$ 357	\$ 162,015

	December 31, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Total assets	\$ 138,407	\$ 27,369	\$ 356	\$ 166,132

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

	Three Months Ended March 31, 2026			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Purchase of property and equipment	\$ 178	\$ —	\$ —	\$ 178

	Three Months ended March 31, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Purchase of property and equipment	\$ 122	\$ —	\$ —	\$ 122

16. Subsequent Events

On the Merger Closing Date, the Company evaluated subsequent events and transactions that occurred after the balance sheet date through the date that the condensed consolidated financial statements were issued. Other than as set forth below, there were no material subsequent events that required recognition or additional disclosure in the condensed consolidated financial statements presented.

Agreement and Plan of Merger and Reorganization

On the Merger Closing Date, the Company acquired Cullgen in accordance with the terms of the Merger Agreement. Pursuant to the Merger Agreement, Merger Sub merged with and into Cullgen, with Cullgen continuing as a wholly owned subsidiary of the Company and the surviving corporation of the Merger. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Under the terms of the Merger Agreement, the Company acquired Cullgen in an all-stock transaction that valued Cullgen at approximately \$300 million. At the effective time of the Merger (the "Effective Time"), each then outstanding share of Cullgen capital stock (the "Cullgen Capital Stock"), excluding shares of Cullgen Capital Stock held as treasury stock immediately prior to the Effective Time and any dissenting shares, converted into (1) with respect to shares of Cullgen Capital Stock held by certain designated holders, (i) for each share of Cullgen common stock ("Cullgen Common Stock") held by such holders, a number of shares of the Company's Series B Convertible Preferred Stock, par value \$0.001 per share (the "Series B Preferred Stock"), equal to (x) 0.4753 (the "Exchange Ratio") divided by five, and (ii) for each share of Cullgen preferred stock ("Cullgen Preferred Stock") held by such designated holders, a number of shares of Series B Preferred Stock equal to (x) the number of shares of Cullgen Common Stock issuable upon conversion of each share of Cullgen Preferred Stock, multiplied by the Exchange Ratio, and divided by five, and (2) with respect to shares of Cullgen Capital Stock held by each other holder, (i) for each share of Cullgen Common Stock held by such holders, a number of shares of common stock equal to the Exchange Ratio, and (ii) for each share of Cullgen Preferred Stock held by such holders, a number of shares of common stock equal to the number of shares of Cullgen Common Stock issuable upon conversion of each share of Cullgen Preferred Stock, multiplied by the Exchange Ratio. Each share of Series B Preferred Stock received in the Merger is convertible into five shares of common stock, subject to certain conditions described below with respect to the Conversion Proposal (as defined below). Notwithstanding anything herein to the contrary, in no event will the Company issue greater than 19.99% of its issued and outstanding common stock or its voting power prior to the approval of the Conversion Proposal.

In addition, at the Effective Time (1) each then-outstanding in-the-money option to purchase shares of Cullgen Common Stock that was outstanding and unexercised immediately prior to the Effective Time, whether vested or unvested, ceased to represent a right to acquire shares of Cullgen Common Stock and converted into and became an option to purchase shares of common stock on the existing terms and conditions (including with respect to vesting and accelerated vesting), subject to adjustment as set forth in the Merger Agreement, (2) each then-outstanding option to purchase shares of Cullgen Common Stock that was not an in-the-money option and was outstanding and unexercised immediately prior to the Effective Time was cancelled at the Effective Time for no consideration, and (3) each Cullgen restricted stock unit will vest and be settled for Cullgen Common Stock and the holder thereof received a number of shares of common stock calculated in accordance with the Merger Agreement.

Pursuant to the Merger Agreement, the Company has agreed to convene a meeting of its stockholders to submit to its stockholders for their consideration the approval of the conversion of the Series B Preferred Stock into shares of common stock in accordance with certain of the rules of the Nasdaq Stock Market LLC (the "Conversion Proposal"). In connection with these matters, the Company filed with the SEC its Definitive Proxy Statement on Schedule 14A on April 27, 2026 and will hold the meeting of its stockholders on June 10, 2026.

With respect to the Merger, we have evaluated the transaction in accordance with the guidance in ASC Subtopic 850-50, Business Combinations - Related Issues, and have determined that the Merger is a combination of entities under common control. Specifically, the Company and Cullgen were controlled by the same parent, GNI Japan, both prior to and subsequent to the Merger, and such control was not considered transitory. As a result, the Merger does not meet the definition of a business combination under the guidance outlined in ASC 805-10 because the acquired net assets have already been included in GNI Japan's consolidated group structure. We determined that the net assets to be transferred in the Merger represent a business, as defined under ASC 805-10-55-4, which will result in a change in reporting entity, as defined under ASC 250-10-20. In this context, the Company has been identified as the receiving entity for accounting purposes that will issue its equity interests in exchange for the net assets of Cullgen. The assets and liabilities to be transferred will be recognized by the Company at their historical carrying amounts on the Merger Closing Date, and the Company's financial statements will be retrospectively adjusted to reflect the combination as if it had occurred at the beginning of the earliest period presented. This presentation reflects the continuity of control and is consistent with the accounting and disclosure requirements of ASC 805-50 and applicable SEC rules and regulations. As of the date the Company's unaudited condensed consolidated financial statements were issued, the method of accounting applied or to be applied was incomplete.

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, 2025 (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 biopharmaceutical company focused on the development and commercialization of small-molecule therapies for the treatment of organ fibrosis and inflammatory diseases. We operate through our majority indirectly owned subsidiary, Gyre Pharmaceuticals, in the People’s Republic of China (the “PRC”), and through our U.S. operations headquartered in San Diego, California.

Our strategy is to leverage our established commercial portfolio to support and de-risk the advancement of late-stage product candidates, expand approved products into additional indications, and build a diversified pipeline targeting significant unmet medical needs in fibrosis and related inflammatory diseases.

In May 2026, we acquired Cullgen Inc., a Delaware corporation (“Cullgen”), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated March 2, 2026 (the “Merger Agreement”), by and among the Company, Helix Merger Sub Corp., a Delaware corporation and wholly owned subsidiary of the Company (“Merger Sub”), and Cullgen. Pursuant to the Merger Agreement, among other matters, Merger Sub merged with and into Cullgen, with Cullgen continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the “Merger”). The related transaction costs were expensed as incurred. See Note 16 — *Subsequent Events* to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

The Company has been, and continues to be, engaged in an evaluation of its pipeline and clinical development strategy, including in connection with the Cullgen acquisition, to optimize capital allocation and prioritize programs across the organization. As a result of the Cullgen acquisition, the Company intends to leverage Cullgen’s capabilities in the PRC for the development and early-stage clinical trials of various product candidates.

Our Commercial Portfolio

ETUARY™ (pirfenidone)

Pirfenidone is a small-molecule anti-fibrotic therapy for the treatment of idiopathic pulmonary fibrosis (“IPF”). It was first approved in Japan and subsequently approved in the PRC, the European Union (“EU”), and the United States. These approvals were obtained by different sponsors in their respective jurisdictions under separate regulatory frameworks.

In the PRC, we conducted independent research and development to support our regulatory submission and received first-in-class approval in 2011 as a National Category 1.1 New Drug. We commercialized pirfenidone under the brand name ETUARY™, which was included in the National Reimbursement Drug List in 2017 and has since maintained a leading market position.

In addition to IPF, we are pursuing potential label expansion into additional indications in the PRC, including pneumoconiosis, for which, in 2025, we completed enrollment of 272 patients in our 52-week Phase 3 trial, and radiation-induced lung injury (“RILI”), including cases with or without immune-related pneumonitis, for which the National Medical Products Administration (“NMPA”) approved our clinical trial application in March 2025, and we initiated an adaptive Phase 2/3 study in April 2026.

Etorel™ (nintedanib esilate soft capsules)

In May 2024, Gyre Pharmaceuticals entered into a comprehensive agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. to obtain the drug registration certificate for Etorel™ (nintedanib) and become the marketing authorization holder in the PRC. Etorel™ is approved as a standard-of-care therapy for IPF, systemic sclerosis-associated interstitial lung disease (“SSc-ILD”), and progressive pulmonary fibrosis (“PPF”). The addition of Etorel™ to our commercial portfolio expanded treatment options for patients and strengthened Gyre’s leading position in the pulmonary fibrosis market. Commercialization of Etorel™ in the PRC commenced in June 2025.

On November 7, 2025, the National Healthcare Security Administration in the PRC released the Announcement of the Winning Bids for the National Centralized Drug Procurement, under which Etorel™ was selected. As a result, we signed direct procurement contracts with various participating hospitals under the National Centralized Drug Procurement Program, and implementation commenced in March 2026.

Contiva™ (avatrombopag maleate tablets)

In June 2021, Gyre Pharmaceuticals acquired avatrombopag maleate tablets pursuant to a transfer agreement with Nanjing Healthnice Pharmaceutical Technology Co., Ltd. Avatrombopag is an oral thrombopoietin receptor agonist. In June 2024, the NMPA approved avatrombopag maleate tablets for the treatment of thrombocytopenia (“TP”) associated with chronic liver disease (“CLD”) in adult patients undergoing elective diagnostic procedures or therapy. In January 2025, the NMPA approved an additional indication for chronic immune thrombocytopenic purpura (“ITP”). Gyre Pharmaceuticals commenced commercialization of avatrombopag under the brand name Contiva™ in the PRC in March 2025.

Our Product Candidate Pipeline

Hydronidone

Hydronidone is our lead development candidate for the treatment of liver fibrosis. It is a structurally modified derivative of pirfenidone designed to optimize metabolic properties while targeting the transforming growth factor (“TGF”)-β1 signaling pathway, a key mediator of fibrogenesis. We are developing Hydronidone for two primary indications: chronic hepatitis B (“CHB”)-associated liver fibrosis in the PRC and metabolic dysfunction-associated steatohepatitis (“MASH”)-associated liver fibrosis in the United States. Hydronidone represents our primary liver-focused development program and reflects our commitment to advancing therapies targeting both viral- and metabolic-associated liver fibrosis.

CHB-Associated Liver Fibrosis (PRC)

For CHB-associated liver fibrosis, antiviral therapy may suppress viral infection but is not able to prevent, slow or reverse fibrosis progression, and anti-fibrotic treatment is recommended for intermediate and advanced liver fibrosis and early-stage cirrhosis. As of December 31, 2025, no small molecule or biologic drugs treating CHB-associated liver fibrosis have been approved globally. In recognition of the severity of the disease and the preliminary clinical evidence generated to date, the Center for Drug Evaluation (“CDE”) of the NMPA granted Hydronidone Breakthrough Therapy designation in March 2021.

We conducted a Phase 3 randomized, double-blind, placebo controlled, Entecavir-based, multi-center trial in the PRC assessing Hydronidone in CHB-associated liver fibrosis. This trial was designed to randomize 248 patients, with a primary endpoint of ≥ 1 -stage reduction in Ishak fibrosis score at Week 52 for Hydronidone in combination with Entecavir.

In May 2025, we reported that in the pivotal Phase 3 trial, Hydronidone met its primary endpoint: 52.85% of treated patients achieved ≥ 1 -stage fibrosis regression at Week 52, compared with 29.84% in the placebo group ($p=0.0002$), based on centralized, blinded Ishak histologic assessment. Hydronidone also met a key secondary endpoint with statistically significant inflammation improvement without fibrosis progression at Week 52 versus placebo. Hydronidone was well tolerated, with a comparable incidence of serious adverse events (4.88% vs. 6.45% in placebo) and no discontinuations due to adverse events in the Hydronidone group.

The CDE of the NMPA granted priority review status to the New Drug Application (“NDA”) for Hydronidone in March 2026. On March 22, 2026, Gyre Pharmaceuticals submitted its NDA to the CDE of the NMPA to seek conditional approval for Hydronidone, the Company’s lead product candidate, for the treatment of CHB-induced liver fibrosis. The submission of the NDA will be subject to initial formatting and completeness verification, and the Company plans to work with the CDE to submit any supplementary materials, if requested by the CDE. Thereafter, the CDE is anticipated to issue to the Company an acceptance number before initiating its technical review process.

MASH-Associated Liver Fibrosis (United States)

In the United States, we have completed a Phase 1 clinical trial in healthy volunteers evaluating Hydronidone’s safety, tolerability, and PK. We continue to engage with the U.S. Food and Drug Administration regarding investigational new drug (“IND”) requirements for a Phase 2 clinical trial in MASH-associated liver fibrosis. Pending regulatory feedback, we intend to file a U.S. IND in 2026 and, if the IND becomes effective, initiate a Phase 2 clinical trial.

Other Product Candidates

We have completed a Phase 1 clinical trial of F573 in healthy volunteers in the PRC and are currently evaluating it in a multi-stage Phase 2 clinical trial initiated in March 2023 in patients with liver injury and liver failure.

F230 is our clinical-stage product candidate for the treatment of pulmonary arterial hypertension (“PAH”) in the PRC. F230 is a selective endothelin receptor A antagonist designed to address vascular remodeling and elevated pulmonary arterial pressure associated with PAH. F230 complements our broader organ-focused portfolio by expanding our development efforts into pulmonary vascular disease while remaining aligned with our strategy of targeting fibrotic and inflammatory pathways across organ systems. We submitted an IND application for F230 to the NMPA in March 2024, and the IND was approved in May 2024. The first subject was enrolled in the Phase 1 clinical trial in June 2025.

F528 is our preclinical-stage product candidate for the treatment of chronic obstructive pulmonary disease in the PRC. F528 is an anti-inflammatory small-molecule compound designed to inhibit multiple inflammatory cytokines and potentially modify disease progression. F528 expands our pulmonary-focused development efforts beyond fibrosis and vascular disease into chronic inflammatory respiratory conditions, supporting our broader strategy of addressing organ diseases driven by inflammatory and fibrotic pathways. We anticipate submitting an IND application to the NMPA for F528 in 2026.

Etorel™ IP Rights

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 Etorel™ (nintedanib, ethanesulfonate soft capsules), a small-molecule drug for the treatment of IPF, SSc-ILD and progressive pulmonary fibrosis, within the PRC. The total minimum payments under the Jiangsu Wangao Agreement are Chinese Renminbi (“RMB”) 35.0 million, or approximately \$5.1 million, based on the March 31, 2026 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 March 31, 2026, we had paid three installments totaling RMB 15.0 million, or approximately \$2.2 million, based on the March 31, 2026 spot exchange rate.

Long-Term Investment Measured Under Equity Method

On June 28, 2024, Gyre Pharmaceuticals entered into a partnership agreement as a limited partner 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 March 31, 2026 and 2025, our total investment into 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 was \$1.6 million and \$1.6 million, respectively.

Financial Operations Overview

During the three months ended March 31, 2026, we had a net loss of \$9.9 million and net loss attributable to common stockholders of \$8.7 million. During the three months ended March 31, 2025, we had net income of \$3.7 million and net income attributable to common stockholders of \$2.7 million. As of March 31, 2026, we had an accumulated deficit of \$77.7 million and cash and cash equivalents of \$37.5 million. As of December 31, 2025, we had an accumulated deficit of \$68.4 million and cash and cash equivalents of \$37.1 million.

Components of Results of Operations

Revenues

Sales of Pharmaceutical Products

We generate revenue primarily through sales of ETUARY™, Contiva™, Etorel™ 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 our 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, including stock-based compensation; (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 our products for their use in hospitals; and staff costs primarily consisting of salaries, benefits and stock-based compensation 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, including stock-based compensation, 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. Although we do track and allocate certain operational research and development costs, as described above, we do not fully track and allocate research and development expenses at the individual product candidate level.

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, Net

Change in Fair Value of Warrant Liability

In connection with a private placement conducted in October 2023 with GNI USA, Inc., we issued (i) 811 shares of our Series X Convertible Preferred Stock, par value \$0.001 per share (the "Series X Preferred Stock") and (ii) warrants to purchase up to 811 shares of Series X Preferred Stock (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.

Other Income, 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 and fixed and intangible assets, net of valuation allowances.

On July 4, 2025, the One Big Beautiful Bill Act (the “OBBBA”) was enacted into law, which introduced several U.S. income tax provisions that have and may continue to potentially impact our provision for income taxes. The provisions include, but are not limited to, the immediate expensing of domestic research and development expenses beginning in 2025, as well as a modification to the Global Intangible Low-Taxed Income effective in 2026. We have recognized the effects of the OBBBA provisions on our financial results to the extent they are applicable to the three months ended March 31, 2026. We will continue to evaluate the impact of the OBBBA on our condensed consolidated financial statements.

Results of Operations

Comparison of the three months ended March 31, 2026 and 2025

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

	Three Months Ended March 31,		Change (\$)	Change (%)
	2026	2025		
Revenues	\$ 22,519	\$ 22,058	\$ 461	2%
Operating expenses:				
Cost of revenues	1,227	894	333	37%
Selling and marketing	14,136	10,841	3,295	30%
Research and development	6,738	3,095	3,643	118%
General and administrative	7,220	4,955	2,265	46%
Transaction costs	2,553	—	2,553	100%
Total operating expenses	31,874	19,785	12,089	61%
(Loss) income from operations	(9,355)	2,273	(11,628)	(512)%
Other income, net:				
Change in fair value of warrant liability	89	2,255	(2,166)	(96)%
Other income, net	29	107	(78)	(73)%
(Loss) income before income taxes	(9,237)	4,635	(13,872)	(299)%
Provision for income taxes	(621)	(901)	280	(31)%
Net (loss) income	(9,858)	3,734	(13,592)	(364)%
Net (loss) income attributable to noncontrolling interest	(1,167)	1,036	(2,203)	(213)%
Net (loss) income attributable to common stockholders	\$ (8,691)	\$ 2,698	\$ (11,389)	(422)%

Revenues

Revenues for the three months ended March 31, 2026 and 2025 were \$22.5 million and \$22.1 million, respectively. The \$0.4 million, or 2%, increase was primarily due to the increase in Contiva™ and Etores™ sales by approximately \$0.5 million and \$0.7 million, respectively, partially offset by the decrease in ETUARY™ sales and other products sales by approximately \$0.7 million and \$0.1 million, respectively. Contiva™ was launched in March 2025, and Etores™ was not commercially launched until June 2025. ETUARY™ revenue declined by approximately 3% year-over-year, primarily attributable to the seasonal fluctuation in 2026 compared to 2025.

Cost of Revenues

Cost of revenues for the three months ended March 31, 2026 and 2025 were \$1.2 million and \$0.9 million, respectively. The \$0.3 million, or 37%, increase was primarily driven by a \$0.3 million rise in early production costs of EtoRel™ and a \$0.2 million increase in stock-based compensation expense, partially offset by a \$0.2 million decrease in ETUARY™ cost of sales.

Selling and Marketing Expenses

Selling and marketing expenses increased by \$3.3 million, or 30%, for the three months ended March 31, 2026 compared to the three months ended March 31, 2025. The increase was primarily driven by a \$2.9 million increase in promotion expenses for EtoRel™ and Contiva™ and early-stage preparation activities for F351 commercial launch, and a \$1.0 million increase in stock-based compensation expense, partially offset by a \$0.5 million decrease in staff cost due to a decrease in bonus and a \$0.1 million decrease in travel and other expenses.

Research and Development Expenses

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

	<u>Three Months Ended March 31,</u>		<u>Change (\$)</u>	<u>Change (%)</u>
	<u>2026</u>	<u>2025</u>		
Direct program expenses:				
Clinical trials	\$ 3,470	\$ 1,438	\$ 2,032	141%
Materials and utilities	869	322	547	170%
Pre-clinical research	1,316	255	1,061	416%
Personnel-related costs	841	858	(17)	(2)%
Facilities, depreciation and other	127	222	(95)	(43)%
Stock-based compensation	115	—	115	100%
Total research and development expenses	<u>\$ 6,738</u>	<u>\$ 3,095</u>	<u>\$ 3,643</u>	<u>118%</u>

Research and development expenses increased by \$3.6 million, or 118%, for the three months ended March 31, 2026 compared to the three months ended March 31, 2025. The increase was primarily attributable to Gyre Pharmaceuticals and was driven by a \$2.0 million increase in clinical research expenses, primarily relating to the Phase 3c clinical trial for Hydronidone in the PRC requested by the NMPA. The increase also reflects a \$0.5 million increase in materials and utilities expenses, and a \$1.1 million increase attributable to Gyre Therapeutics' pre-clinical activities for future IND filings in the United States. These costs represent planned investments and are expected to continue in the near- to medium-term.

General and Administrative Expenses

General and administrative expenses increased by \$2.3 million, or 46%, for the three months ended March 31, 2026 compared to the three months ended March 31, 2025. The increase was primarily driven by a \$0.8 million increase in stock-based compensation costs, a \$0.9 million increase in staff costs due to our internal realignment of responsibilities and compensation adjustments, and a \$0.6 million increase in miscellaneous expenses.

Transaction Costs

For the three months ended March 31, 2026, \$2.5 million in transaction costs were incurred in connection with the acquisition of Cullgen. As the Merger closed in early May 2026, we expect there will be additional non-recurring transaction costs incurred after the first quarter of 2026.

Change in Fair Value of Warrant Liability

Change in fair value of warrant liability decreased \$2.2 million, or 96%, for the three months ended March 31, 2026 compared to the three months ended March 31, 2025. The decrease was related to the remeasurement of the Preferred Stock Warrants liability.

Other Income, Net

Other income, net decreased by \$0.1 million, or 73%, for the three months ended March 31, 2026 compared to the three months ended March 31, 2025. The decrease was primarily due to increase in donation expense of \$0.3 million, partially offset by a \$0.1 million increase in interest income and a \$0.1 million increase in government grant.

Provision for Income Taxes

Provision for income taxes was \$0.6 million and \$0.9 million for the three months ended March 31, 2026 and 2025, respectively. The decrease was attributable to changes in the valuation allowance.

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 March 31, 2026, we had cash and cash equivalents of \$37.5 million, short-term bank deposits of \$12.3 million and long-term certificates of deposit of \$29.4 million, which are available to fund operations, and an accumulated deficit of \$77.7 million. Our net loss during the three months ended March 31, 2026 was \$9.9 million, while cash provided by operating activities was \$3.2 million. We believe that our existing cash and cash equivalents, cash flows from operations, and access to capital markets will be sufficient to fund our operating activities and obligations for at least 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 provided by operating activities, short-term deposits, and long-term certificate of deposits, as well as potential cash issuances to meet our current and future financial obligations, including funding our operations, research and development activities, clinical pipelines, 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, 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. In addition, we anticipate that we will incur expenses related to and in connection with the integration between our business and Cullgen. Factors that may affect financing requirements include, but are not limited to:

- integration between our business and Cullgen;
- 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):

	Three Months Ended March 31,	
	2026	2025
Cash Flow Data:		
Net cash provided by (used in) operating activities	\$ 3,180	\$ (129)
Net cash (used in) provided by investing activities	(3,055)	1,967
Net cash provided by financing activities	21	1,344
Effect of exchange rate changes on cash	285	50
Net change in cash and cash equivalents	<u>\$ 431</u>	<u>\$ 3,232</u>

Cash Flows from Operating Activities

Cash provided by operating activities for the three months ended March 31, 2026 was \$3.2 million, reflecting our net loss of \$9.9 million, offset by non-cash items of \$3.5 million primarily driven by a \$2.6 million increase in stock-based compensation, \$0.7 million in depreciation and amortization, \$0.2 million in non-cash lease expense, \$0.6 million in accrued interest, and \$0.2 million of bad debt expenses and other non-cash items, offset by \$0.7 million decrease in deferred income taxes, net, and \$0.1 million decrease in change in fair value of derivative liabilities. Additionally, cash provided by operating activities reflected changes in net operating assets and liabilities of \$9.5 million.

The increase in cash provided by operating activities for the three months ended March 31, 2026 compared with cash used in operating activities for the three months ended March 31, 2025 was primarily attributable to higher customer collections and lower tax payments.

Cash used in operating activities for the three months ended March 31, 2025 was \$0.1 million, reflecting our net income of \$3.7 million, offset by non-cash items of \$0.5 million primarily driven by a \$2.3 million change in the fair value of warrant liability, \$0.5 million in stock-based compensation, \$0.5 million in depreciation and amortization, \$0.5 million in accrued interest, and \$0.2 million in non-cash lease expense. Additionally, cash used in operating activities reflected changes in net operating assets and liabilities of \$3.3 million.

Cash Flows from Investing Activities

Cash used in investing activities for the three months ended March 31, 2026 was \$3.1 million, which consisted of \$10.1 million of cash acquired in connection with the maturity of certificates of deposit, offset by \$13.0 million in purchases of certificates of deposit and \$0.2 million in purchases of property and equipment.

Cash provided by investing activities for the three months ended March 31, 2025 was \$2.0 million, which consisted of \$11.2 million of cash acquired in connection with the maturity of certificates of deposit, partially offset by \$8.4 million in purchases of certificates of deposit, \$0.1 million in purchases of property and equipment, and \$0.7 million in acquisition of intangible assets.

Cash Flows from Financing Activities

Cash provided by financing activities for the three months ended March 31, 2026 was \$21 thousand due to proceeds from the exercise of stock options.

Cash provided by financing activities for the three months ended March 31, 2025 was \$1.3 million due to \$0.9 million in proceeds from the exercise of stock options and \$0.5 million in proceeds from the issuance of common stock under our ATM Program with Jefferies LLC, partially offset by \$0.1 million of cash used in connection with deferred financing costs.

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 \$72.4 million and \$70.1 million as of March 31, 2026 and December 31, 2025. 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

We expect to satisfy these contractual obligations and commitments through a combination of cash on hand, cash provided by operating activities, short-term deposits, and long-term certificate of deposits.

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 March 31, 2026, our fixed lease payment obligations were \$0.8 million, with \$0.5 million payable within the remaining nine months.

Research and Development Programs

As of March 31, 2026, we have committed to allocate \$64.1 million toward future research and development activities for various programs.

Property and Equipment

Our commitments related to the purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statements were \$1.5 million as of March 31, 2026 and are expected to be incurred within one year.

Etorel™ IP Rights

The Company is committed to annual payments to the *Etorel™* IP Rights transferor over eight years following the commencement of commercial sales. See Note 11 — *Commitments and Contingencies* to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

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 transition to 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 March 31, 2026, 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 March 31, 2026 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 March 31, 2026 that have materially affected, or are 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

During the three months ended March 31, 2026, no 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)†#	<u>Asset Purchase Agreement, dated as of December 26, 2022, by and among Catalyst Biosciences, Inc., GNI Group Ltd., and GNI Hong Kong Limited.</u>	8-K	000-51173	2.1	Dec. 27, 2022
2.1(b)	<u>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.</u>	8-K	000-51173	2.2	Mar. 30, 2023
2.2(a)#	<u>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.</u>	8-K	000-51173	2.2	Dec. 27, 2022
2.2(b)	<u>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.</u>	8-K	000-51173	2.1	Mar. 30, 2023
2.2(c)	<u>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.</u>	8-K	000-51173	2.1	Aug. 31, 2023
2.3	<u>Agreement and Plan of Merger and Reorganization, dated March 2, 2026, by and among Gyre Therapeutics, Inc., Helix Merger Sub Corp., and Cullgen Inc.</u>	8-K	000-51173	2.1	Mar. 2, 2026
3.1	<u>Restated Certificate of Incorporation of the Company.</u>	10-Q	000-51173	3.1	Nov. 13, 2024
3.2	<u>Amended and Restated Bylaws of the Company.</u>	8-K	000-51173	3.3	Oct. 30, 2023
3.3(a)	<u>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.</u>	10-Q	000-51173	3.1	Aug. 3, 2017

3.3(b)	Certificate of Elimination of Series A Preferred Stock, filed with the Delaware Secretary of State on March 25, 2024.	10-K	000-51173	3.6(b)	Mar. 27, 2024
3.4(a)	Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, filed with the Delaware Secretary of State on December 27, 2022.	8-K	000-51173	3.1	Dec. 27, 2022
3.4(b)	Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, filed with the Delaware Secretary of State on October 30, 2023.	8-K	000-51173	3.2	Oct. 30, 2023
3.5(a)	Certificate of Designation of Preferences, Rights and Limitations of Series Y Preferred Stock, filed with the Delaware Secretary of State on June 20, 2023, with respect to the Series Y Preferred Stock.	8-K	000-51173	3.1	June 20, 2023
3.5(b)	Certificate of Elimination of Series Y Preferred Stock, filed with the Delaware Secretary of State on August 31, 2023.	8-K	000-51173	3.1	Aug. 31, 2023
3.6	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.	8-K	000-51173	3.1	Mar. 2, 2026
4.1	Form of Warrant to Purchase Series X Convertible Preferred Stock.	8-K	000-51173	4.1	Oct. 30, 2023
10.1	Form of Gyre Therapeutics, Inc. Stockholder Support Agreement.	8-K	000-51173	10.2	Mar. 2, 2026
10.2	Form of Lock-Up Agreement.	8-K	000-51173	10.4	Mar. 2, 2026
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2**	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				

101.INS*	Inline XBRL (extensible Business Reporting Language) Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

† The annexes, schedules, and certain exhibits to this Exhibit have been omitted pursuant to Item 601(a)(5).

Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) the Company customarily and actually treats that information as private or confidential and (ii) the information was not material.

SIGNATURES

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

GYRE THERAPEUTICS, INC.

Date: May 8, 2026

/s/ Ying Luo

Ying Luo
Chief Executive Officer and President
(Principal Executive Officer)

Date: May 8, 2026

/s/ Thomas Eastling

Thomas Eastling
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, Ying Luo, 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: May 8, 2026

/s/ Ying Luo

Ying Luo
Chief Executive Officer and President
(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, Thomas Eastling, 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: May 8, 2026

/s/ Thomas Eastling

Thomas Eastling
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 March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ying Luo, 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: May 8, 2026

/s/ Ying Luo

Ying Luo
Chief Executive Officer and President
(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 March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas Eastling, 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: May 8, 2026

/s/ Thomas Eastling

Thomas Eastling
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.
