

**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, 2024

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-51173

**Gyre Therapeutics, Inc.**

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of  
Incorporation or Organization)

12770 High Bluff Drive Suite 150

San Diego, California

(Address of Principal Executive Offices)

56-2020050

(I.R.S. Employer  
Identification No.)

92130

(Zip Code)

(858) 567-7770

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

|                         |                                     |                           |                                     |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/>            | Accelerated filer         | <input type="checkbox"/>            |
| Non-accelerated filer   | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input type="checkbox"/>            |                           | <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 6, 2024, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 85,510,116.

**GYRE THERAPEUTICS, INC.**  
**TABLE OF CONTENTS**

|   | <u>Page No.</u> |
|---|-----------------|
| <b><u>PART I. FINANCIAL INFORMATION</u></b>   | 2               |
| Item 1. <a href="#"><u>Financial Statements:</u></a>  | 2               |
| <a href="#"><u>Condensed Consolidated Balance Sheets as of March 31, 2024 (unaudited) and December 31, 2023</u></a>   | 2               |
| <a href="#"><u>Condensed Consolidated Statements of Operations and Comprehensive Income for the three months ended March 31, 2024 and 2023 (unaudited)</u></a>    | 4               |
| <a href="#"><u>Condensed Consolidated Statements of Convertible Preferred Stock and Equity for the three months ended March 31, 2024 and 2023 (unaudited)</u></a> | 5               |
| <a href="#"><u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2024 and 2023 (unaudited)</u></a>                             | 6               |
| <a href="#"><u>Notes to the Unaudited Condensed Consolidated Financial Statements</u></a>   | 7               |
| Item 2. <a href="#"><u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></a>  | 24              |
| Item 3. <a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a>   | 34              |
| Item 4. <a href="#"><u>Controls and Procedures</u></a>  | 34              |
| <b><u>PART II. OTHER INFORMATION</u></b>  | 35              |
| Item 1. <a href="#"><u>Legal Proceedings</u></a>  | 35              |
| Item 1A. <a href="#"><u>Risk Factors</u></a>  | 35              |
| Item 2. <a href="#"><u>Unregistered Sales of Equity Securities and Use of Proceeds</u></a>  | 35              |
| Item 3. <a href="#"><u>Defaults Upon Senior Securities</u></a>  | 35              |
| Item 4. <a href="#"><u>Mine Safety Disclosures</u></a>  | 35              |
| Item 5. <a href="#"><u>Other Information</u></a>  | 35              |
| Item 6. <a href="#"><u>Exhibits</u></a>   | 36              |
| <a href="#"><u>Exhibit Index</u></a>  | 36              |
| <a href="#"><u>Signatures</u></a>   | 39              |

---

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

|  | <u>March 31, 2024</u><br>(Unaudited) | <u>December 31, 2023</u> |
|--|--------------------------------------|--------------------------|
| <b>Assets</b>  |                                      |                          |
| Current assets:  |                                      |                          |
| Cash and cash equivalents  | \$ 29,785                            | \$ 33,509                |
| Short-term bank deposits   | 7,567                                | —                        |
| Accounts and note receivables, net   | 15,458                               | 15,552                   |
| Other receivables from GNI   | 1,287                                | 1,287                    |
| Inventories, net   | 4,939                                | 4,281                    |
| Prepaid assets   | 1,790                                | 1,547                    |
| Other current assets   | 1,897                                | 1,045                    |
| Total current assets   | <u>62,723</u>                        | <u>57,221</u>            |
| Property and equipment, net  | 23,564                               | 23,288                   |
| Long-term receivable from GCBP   | 4,780                                | 4,722                    |
| Intangible assets, net   | 196                                  | 205                      |
| Right-of-use assets  | 359                                  | 489                      |
| Land use rights, net   | 1,480                                | 1,493                    |
| Deferred tax assets  | 5,000                                | 4,695                    |
| Long-term certificates of deposit  | 23,106                               | 23,431                   |
| Other assets, noncurrent   | 802                                  | 995                      |
| Total assets   | <u>\$ 122,010</u>                    | <u>\$ 116,539</u>        |
| <b>Liabilities, convertible preferred stock, and equity</b>  |                                      |                          |
| Current liabilities:   |                                      |                          |
| Accounts payable   | \$ 330                               | \$ 355                   |
| Deferred revenue   | 35                                   | 39                       |
| Due to related parties   | 1,362                                | 1,369                    |
| CVR excess closing cash payable  | 422                                  | 1,085                    |
| Accrued expenses and other current liabilities   | 10,767                               | 11,935                   |
| Income tax payable   | 6,470                                | 5,054                    |
| Operating lease liabilities, current   | 100                                  | 210                      |
| Total current liabilities  | <u>19,486</u>                        | <u>20,047</u>            |
| Operating lease liabilities, noncurrent  | 175                                  | 199                      |
| Deferred government grants   | 203                                  | 213                      |
| CVR derivative liability, noncurrent   | 4,780                                | 4,722                    |
| Warrant liability, noncurrent  | 8,547                                | 12,835                   |
| Other noncurrent liabilities   | 48                                   | 49                       |
| Total liabilities  | <u>33,239</u>                        | <u>38,065</u>            |
| Commitments and Contingencies (Note 12)  |                                      |                          |
| Convertible Preferred Stock, \$0.001 par value, 5,000,000 shares authorized;<br>nil shares and 13,151 shares issued and outstanding at March 31, 2024<br>and December 31, 2023, respectively | —                                    | 64,525                   |
| Stockholders' equity:  |                                      |                          |
| Common stock, \$0.001 par value, 400,000,000 shares authorized; 85,423,246 shares and<br>76,595,616 shares issued and outstanding at March 31, 2024 and<br>December 31, 2023, respectively   | 85                                   | 77                       |
| Additional paid-in capital   | 133,199                              | 68,179                   |
| Statutory reserve  | 3,098                                | 3,098                    |
| Accumulated deficit  | (78,006)                             | (85,538)                 |
| Accumulated other comprehensive loss   | (1,736)                              | (1,644)                  |
| Total Gyre stockholders' equity (deficit)  | <u>56,640</u>                        | <u>(15,828)</u>          |
| Noncontrolling interest  | 32,131                               | 29,777                   |
| Total equity   | <u>88,771</u>                        | <u>13,949</u>            |
| <b>Total liabilities, convertible preferred stock, and equity</b>  | <u>\$ 122,010</u>                    | <u>\$ 116,539</u>        |

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

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

|   | Three Months Ended March 31, |                   |
|---|------------------------------|-------------------|
|   | 2024                         | 2023              |
| Revenues  | \$ 27,172                    | \$ 24,931         |
| Operating expenses:   |                              |                   |
| Cost of revenues  | 979                          | 1,125             |
| Selling and marketing   | 12,542                       | 12,768            |
| Research and development  | 2,182                        | 2,635             |
| General and administrative  | 3,398                        | 1,739             |
| Total operating expenses  | <u>19,101</u>                | <u>18,267</u>     |
| Income from operations  | 8,071                        | 6,664             |
| Other income (expense), net:  |                              |                   |
| Interest income, net  | 328                          | 184               |
| Other income  | 109                          | 66                |
| Change in fair value of warrant liability   | 4,288                        | —                 |
| Other expenses  | <u>(315)</u>                 | <u>(643)</u>      |
| Income before income taxes  | 12,481                       | 6,271             |
| Provision for income taxes  | <u>(2,546)</u>               | <u>(2,054)</u>    |
| Net income  | 9,935                        | 4,217             |
| Net income attributable to noncontrolling interest  | 2,403                        | 1,973             |
| Net income attributable to common stockholders  | <u>\$ 7,532</u>              | <u>\$ 2,244</u>   |
| Net income per share attributable to common stockholders:   |                              |                   |
| Basic   | <u>\$ 0.09</u>               | <u>\$ 0.04</u>    |
| Diluted   | <u>\$ 0.03</u>               | <u>\$ 0.03</u>    |
| Weighted average shares used in calculating net income per share attributable to common stockholders: |                              |                   |
| Basic   | <u>83,265,879</u>            | <u>63,588,119</u> |
| Diluted   | <u>102,594,197</u>           | <u>78,921,366</u> |
| Other comprehensive income:   |                              |                   |
| Net income  | \$ 9,935                     | \$ 4,217          |
| Foreign currency translation adjustments  | <u>(141)</u>                 | <u>898</u>        |
| Comprehensive income  | 9,794                        | 5,115             |
| Net income attributable to noncontrolling interest  | 2,403                        | 1,973             |
| Foreign currency translation adjustments attributable to noncontrolling interest                      | <u>(49)</u>                  | <u>395</u>        |
| Comprehensive income attributable to noncontrolling interest  | 2,354                        | 2,368             |
| Comprehensive income attributable to common stockholders  | <u>\$ 7,440</u>              | <u>\$ 2,747</u>   |

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

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

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

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

*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, |           |
|---|------------------------------|-----------|
|   | 2024                         | 2023      |
| <b>Operating Activities</b>   |                              |           |
| Net income  | \$ 9,935                     | \$ 4,217  |
| Adjustments to reconcile net income to net cash provided by operating activities: |                              |           |
| Stock-based compensation  | 11                           | —         |
| Equity in loss of unconsolidated affiliate  | —                            | 343       |
| Depreciation and amortization   | 415                          | 276       |
| Noncash lease expense   | 109                          | 82        |
| Amortization of land use rights   | 10                           | 10        |
| Deferred income taxes, net  | (313)                        | (328)     |
| Bad debt expense and other non-cash items   | (7)                          | (63)      |
| Accrued interest on certificates of deposit                                       | (234)                        | (74)      |
| Change in fair value of long-term receivable                                      | (58)                         | —         |
| Change in fair value of derivative liabilities                                    | 58                           | —         |
| Change in fair value of warrant liability   | (4,288)                      | —         |
| Loss on disposal of property and equipment  | 3                            | —         |
| Changes in operating assets and liabilities:                                      |                              |           |
| Accounts and note receivables   | 1                            | 3,915     |
| Inventories   | (666)                        | 525       |
| Prepaid and other assets  | (1,524)                      | (678)     |
| Income tax payable  | 1,423                        | 1,919     |
| Accounts payable  | (23)                         | 156       |
| Other noncurrent liabilities  | (4)                          | (808)     |
| Due to related parties  | (6)                          | (1)       |
| Accrued expenses and other liabilities  | (1,839)                      | 1,028     |
| Operating lease liabilities   | (119)                        | (102)     |
| Net cash provided by operating activities   | 2,884                        | 10,417    |
| <b>Investing Activities</b>   |                              |           |
| Acquisition of intangible assets  | —                            | (65)      |
| Purchase of certificates of deposit   | (7,039)                      | (5,841)   |
| Purchase of property and equipment  | (231)                        | (1,742)   |
| Proceeds from sale of equipment   | 50                           | —         |
| Net cash used in investing activities   | (7,220)                      | (7,648)   |
| <b>Financing Activities</b>   |                              |           |
| Proceeds from the exercise of stock options                                       | 658                          | —         |
| Net cash provided by financing activities   | 658                          | —         |
| Effect of exchange rate changes on cash and cash equivalents                      | (46)                         | 200       |
| Net (decrease) increase in cash and cash equivalents                              | (3,724)                      | 2,969     |
| Cash and cash equivalents at beginning of the period                              | 33,509                       | 25,175    |
| Cash and cash equivalents at end of the period                                    | \$ 29,785                    | \$ 28,144 |
| <b>Supplemental Disclosure of Non-Cash Financing and Investing Activities:</b>    |                              |           |
| Convertible preferred stock conversion  | \$ 64,525                    | \$ —      |
| Non-cash acquisition of property and equipment through prepaid conversion         | \$ 453                       | \$ 252    |
| <b>Supplemental Disclosure of Cash Flow Information:</b>                          |                              |           |
| Cash paid for income taxes  | \$ 1,436                     | \$ 463    |

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

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

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

***Liquidity***

For the three months ended March 31, 2024, the Company had net income of \$9.9 million, while net cash provided by operating activities was \$2.9 million. As of March 31, 2024, the Company had an accumulated deficit of \$78.0 million and cash and cash equivalents of \$29.8 million. Based on the Company’s current operating plan, management believes that existing cash and cash equivalents, cash flows from operations, and access to capital markets will be sufficient to fund the Company’s operating activities and obligations for at least 12 months following the issuance of these condensed consolidated financial statements.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

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

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



### ***Use of Estimates***

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

### ***Risks and Uncertainties***

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

### ***Concentration of Credit Risk***

In May 2015, a new Deposit Insurance System (“DIS”) managed by the People’s Bank of China was implemented by the Chinese government. Deposits in the licensed banks in mainland China are protected by DIS, up to a limit of Chinese Renminbi (“RMB”) 500,000. The Company maintains cash and deposits at commercial banks in excess of the amount protected by DIS and the Federal Deposit Insurance Corporation and in the event of bankruptcy of one of these financial institutions, the Company may be unable to claim its deposits back in full. Management believes that these financial institutions are of high credit quality and continually monitors the creditworthiness of these financial institutions. As of March 31, 2024 and December 31, 2023, the Company had cash and cash equivalents of \$29.8 million and \$33.5 million, and long-term certificates of deposit of \$23.1 million and \$23.4 million, respectively. In addition, the Company had short-term bank deposits of \$7.6 million as of March 31, 2024.

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

### ***Concentration of Customer Risk***

For the three months ended March 31, 2024 and 2023, the Company had one customer, Sinopharm Group Co., Ltd. (“Sinopharm”), who accounted for approximately 45.4% and 48.7% of accounts receivable, respectively. For the three months ended March 31, 2024, there were three customers, Sinopharm, China Resources Pharmaceutical Group Ltd. (“Resources Pharmaceutical”), and Shanghai Pharmaceuticals Holding Co., Ltd. (“Shanghai Pharmaceuticals”), who accounted for approximately 47.3%, 17.2% and 11.1% of total revenue, respectively. For the three months ended March 31, 2023, there were three customers, Sinopharm, Shanghai Pharmaceuticals, and Resources Pharmaceutical who accounted for approximately 49.4%, 13.5% and 10.4% of total revenue, respectively. All customers are located in mainland China.

### ***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. 83.0% of the Company’s cash and cash equivalents, and 100% of the Company’s short-term bank deposits and long-term certificates of deposit as of

March 31, 2024, in the amount of \$24.7 million, \$7.6 million and \$23.1 million, respectively, were denominated in RMB.

### **Accounting Pronouncements Recently Adopted**

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

### **New Accounting Pronouncements – Issued But Not Yet Adopted**

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

### **3. Fair Value Measurements and Financial Instruments**

For a description of the fair value hierarchy and the Company’s fair value methodology, see Note 2 – *Summary of Significant Accounting Policies* in the Annual Report. There were no significant changes in these methodologies during the three months ended March 31, 2024. As of March 31, 2024, the Company’s highly liquid money market funds are included within cash equivalents.

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

|                                      | March 31, 2024  |             |                  |                  |
|--------------------------------------|-----------------|-------------|------------------|------------------|
|                                      | Level 1         | Level 2     | Level 3          | Total            |
| <b>Financial assets:</b>             |                 |             |                  |                  |
| Money market funds <sup>(1)</sup>    | \$ 3,904        | \$ —        | \$ —             | \$ 3,904         |
| Long-term receivable from GCBP       | —               | —           | 4,780            | 4,780            |
| <b>Total financial assets</b>        | <b>\$ 3,904</b> | <b>\$ —</b> | <b>\$ 4,780</b>  | <b>\$ 8,684</b>  |
| <b>Financial liabilities:</b>        |                 |             |                  |                  |
| CVR derivative liability, noncurrent | \$ —            | \$ —        | 4,780            | \$ 4,780         |
| Warrant liability, noncurrent        | —               | —           | 8,547            | 8,547            |
| <b>Total financial liabilities</b>   | <b>\$ —</b>     | <b>\$ —</b> | <b>\$ 13,327</b> | <b>\$ 13,327</b> |

|                                    | December 31, 2023 |             |                  |                  |
|------------------------------------|-------------------|-------------|------------------|------------------|
|                                    | Level 1           | Level 2     | Level 3          | Total            |
| <b>Financial assets:</b>           |                   |             |                  |                  |
| Money market funds <sup>(1)</sup>  | \$ 5,860          | \$ —        | \$ —             | \$ 5,860         |
| Long-term receivable from GCBP     | —                 | —           | 4,722            | 4,722            |
| <b>Total financial assets</b>      | <b>\$ 5,860</b>   | <b>\$ —</b> | <b>\$ 4,722</b>  | <b>\$ 10,582</b> |
| <b>Financial liabilities:</b>      |                   |             |                  |                  |
| CVR derivative liability           | \$ —              | \$ —        | \$ 4,722         | \$ 4,722         |
| Warrant liability, noncurrent      | —                 | —           | 12,835           | 12,835           |
| <b>Total financial liabilities</b> | <b>\$ —</b>       | <b>\$ —</b> | <b>\$ 17,557</b> | <b>\$ 17,557</b> |

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

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

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

### ***Long-term Receivables and Derivative Liabilities***

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

The long-term receivable and the corresponding CVR derivative liability, noncurrent relate to the asset purchase agreement with GC Biopharma Corp. (“GCBP”). The fair value of this long-term receivable and derivative liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The estimated fair value of the long-term receivable and CVR derivative liability, noncurrent was determined based on the anticipated amount and timing of projected cash flows to be received from GCBP pursuant to the GCBP asset purchase agreement discounted to their present values using an estimated discount rate of 5.05%. As of March 31, 2024, the Company expects to receive a \$5.0 million hold-back payment from GCBP in the first quarter of 2025, which will be distributed, net of expenses, to the CVR Holders. The change in fair value of the long-term receivable from GCBP and the corresponding CVR derivative liability, noncurrent was recorded in interest and other income, net on the condensed consolidated statement of operations and comprehensive income.

### ***Warrant Liability***

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

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

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

|                     | March 31, 2024 | December 31, 2023 |
|---------------------|----------------|-------------------|
| Share price         | \$ 17.48       | \$ 25.70          |
| Exercise price      | \$ 4,915.00    | \$ 4,915.00       |
| Dividend yield      | —%             | —%                |
| Risk-free interest  | 4.20%          | 3.88%             |
| Term (years)        | 9.58           | 9.83              |
| Expected volatility | 84.00%         | 84.00%            |

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

|                              | Long-term receivable<br>from GCBP | CVR derivative<br>liability, noncurrent | Warrant<br>liability |
|------------------------------|-----------------------------------|---|----------------------|
| Balance at December 31, 2023 | \$ 4,722                          | \$ 4,722                                | \$ 12,835            |
| Changes in fair value        | 58                                | 58                                      | (4,288)              |
| Balance at March 31, 2024    | \$ 4,780                          | \$ 4,780                                | \$ 8,547             |

### Financial Instruments

Cash equivalents consisted of the following (in thousands):

|                                       | Amortized<br>cost | Gross<br>unrealized<br>gains | Gross<br>unrealized<br>losses | Estimated<br>fair<br>value |
|---------------------------------------|-------------------|------------------------------|-------------------------------|----------------------------|
| <b>March 31, 2024</b>                 |                   |                              |                               |                            |
| Money market funds (cash equivalents) | \$ 3,904          | \$ —                         | \$ —                          | \$ 3,904                   |
| Total financial assets                | \$ 3,904          | \$ —                         | \$ —                          | \$ 3,904                   |
| Classified as:                        |                   |                              |                               |                            |
| Cash and cash equivalents             |                   |                              |                               | \$ 3,904                   |
| Total financial assets                |                   |                              |                               | \$ 3,904                   |
| <b>December 31, 2023</b>              |                   |                              |                               |                            |
| Money market funds (cash equivalents) | \$ 5,860          | \$ —                         | \$ —                          | \$ 5,860                   |
| Total financial assets                | \$ 5,860          | \$ —                         | \$ —                          | \$ 5,860                   |
| Classified as:                        |                   |                              |                               |                            |
| Cash and cash equivalents             |                   |                              |                               | \$ 5,860                   |
| Total financial assets                |                   |                              |                               | \$ 5,860                   |

#### 4. Balance Sheet Components

##### *Inventories, net*

Inventories, net of reserves of \$3,000 and \$46,000 as of March 31, 2024 and December 31, 2023, respectively, consisted of the following components (in thousands):

|                  | March 31, 2024  | December 31, 2023 |
|------------------|-----------------|-------------------|
| Raw materials    | \$ 724          | \$ 919            |
| Work in progress | 2,532           | 1,997             |
| Finished goods   | 1,683           | 1,365             |
| Inventories, net | <u>\$ 4,939</u> | <u>\$ 4,281</u>   |

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

##### *Accrued Expenses and Other Current Liabilities*

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

|  | March 31, 2024   | December 31, 2023 |
|--|------------------|-------------------|
| Accrued payroll and welfare                    | \$ 5,930         | \$ 5,790          |
| Accrued expenses - selling expenses            | 1,734            | 44                |
| Supplier reimbursement                         | 997              | 2,247             |
| Accrued sales discount                         | 912              | 903               |
| Accrued expenses - general and administrative  | 601              | 1,190             |
| Accrued professional services                  | 251              | 837               |
| Accrued expenses - research and development    | 236              | 161               |
| Deferred government grants                     | 40               | 40                |
| Employee reimbursement                         | 27               | 648               |
| Other accrued liabilities                      | 39               | 75                |
| Accrued expenses and other current liabilities | <u>\$ 10,767</u> | <u>\$ 11,935</u>  |

##### *Accounts and Note Receivables, Net*

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

|                                     | March 31, 2024   | December 31, 2023 |
|-------------------------------------|------------------|-------------------|
| Accounts receivable                 | \$ 15,209        | \$ 15,204         |
| Note receivable                     | 356              | 389               |
| Allowance for credit losses         | (107)            | (41)              |
| Allowance and note receivables, net | <u>\$ 15,458</u> | <u>\$ 15,552</u>  |

##### *Property and Equipment, Net*

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

|                                  | March 31, 2024   | December 31, 2023 |
|----------------------------------|------------------|-------------------|
| Buildings                        | \$ 12,294        | \$ 12,289         |
| Construction in progress         | 8,420            | 7,875             |
| Machinery and electronic devices | 6,732            | 6,598             |
| Furniture and fixtures           | 605              | 606               |
| Motor vehicles                   | 185              | 185               |
| Property and equipment, gross    | 28,236           | 27,553            |
| Less: Accumulated depreciation   | (4,672)          | (4,265)           |
| Property and equipment, net      | <u>\$ 23,564</u> | <u>\$ 23,288</u>  |

## 5. Intangible Assets

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

|   | March 31, 2024        |                          |                        |
|---|-----------------------|--------------------------|------------------------|
|   | Gross carrying amount | Accumulated amortization | Intangible assets, net |
| <b>Intangible assets with finite lives:</b> |                       |                          |                        |
| Technological know-how                      | \$ 430                | \$ (295)                 | \$ 135                 |
| Computer software                           | 171                   | (110)                    | 61                     |
| Total intangible assets                     | <u>\$ 601</u>         | <u>\$ (405)</u>          | <u>\$ 196</u>          |
| <br>  |                       |                          |                        |
|   | December 31, 2023     |                          |                        |
|   | Gross carrying amount | Accumulated amortization | Intangible assets, net |
| <b>Intangible assets with finite lives:</b> |                       |                          |                        |
| Technological know-how                      | \$ 430                | \$ (290)                 | \$ 140                 |
| Computer software                           | 171                   | (106)                    | 65                     |
| Total intangible assets                     | <u>\$ 601</u>         | <u>\$ (396)</u>          | <u>\$ 205</u>          |

Intangible assets are carried at cost less accumulated amortization and impairment, if applicable, and the amortization expense is recorded in operating expenses. The weighted average amortization period for the intangible assets as of March 31, 2024 is 4.9 years.

Amortization expense was \$100,000 and \$45,000 for the three months ended March 31, 2024 and 2023, respectively. Based on finite-lived intangible assets recorded as of March 31, 2024, the estimated future amortization expense is as follows (in thousands):

|            | <u>Estimated amortization expense</u> |
|------------|---------------------------------------|
| 2024       | \$ 26                                 |
| 2025       | 34                                    |
| 2026       | 34                                    |
| 2027       | 33                                    |
| 2028       | 18                                    |
| Thereafter | 51                                    |
| Total      | <u>\$ 196</u>                         |

## 6. Revenue

The Company's product revenues were mainly generated from the sale of ETUARY. Sales of ETUARY accounted for 99.2% and 98.7% of total revenue for the three months ended March 31, 2024 and 2023, respectively.

### *Sales of Pharmaceutical Products*

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

Product returns to date have not been significant and the Company has not considered it necessary to record a reserve for product returns. The Company's product revenues were recognized at a point in time when the underlying product was delivered to the customer, which was when the customer obtained control of the product. Revenue from sales of pharmaceutical products was \$27.2 million and \$24.9 million for the three months ended March 31, 2024 and 2023, respectively. All sales are generated in the PRC. Deferred revenue recognized during the quarter ended March 31, 2024 was immaterial.

The Company's sales by product categories for the three months ended March 31, 2024 and 2023 are as follows (in thousands):

|                                  | Three Months Ended March 31, |                  |
|----------------------------------|------------------------------|------------------|
|                                  | 2024                         | 2023             |
| Sales of Pharmaceutical Products | \$ 27,172                    | \$ 24,931        |
| Total                            | <u>\$ 27,172</u>             | <u>\$ 24,931</u> |

## 7. Leases

### Operating Leases

Gyre Pharmaceuticals' corporate headquarters, a 968 square meter office space, is situated in Beijing, PRC, with the lease expiring in June 2024. Additionally, a laboratory center spanning approximately 640 square meters was leased in Shanghai, PRC, which expired in November 2023. In 2022, the Company secured a new lease for an office space of approximately 180 square meters in Zhengzhou, PRC, with the lease set to expire in August 2024. In November 2023, the Company also secured a new lease for its U.S. headquarters in San Diego, California, with the lease set to expire in the first quarter of 2027.

The Company also has multiple short-term leased properties used as offices and employee dormitories. The Company recorded a total of \$18,000 and \$25,000 short-term rent expenses during the three months ended March 31, 2024 and 2023, respectively. The short-term rent expense amounts are recorded in operating expenses in the accompanying condensed consolidated statements of operations and comprehensive income.

As of March 31, 2024, the Company recorded an aggregate right-of-use asset of \$0.4 million and an aggregate lease liability of \$0.3 million in the accompanying condensed consolidated balance sheets.

For the three months ended March 31, 2024 and 2023, the Company's operating lease expense was \$0.1 million and \$0.1 million, respectively. Variable lease payments for the three months ended March 31, 2024 and 2023 were immaterial.

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

|  | Three Months Ended March 31, |        |
|--|------------------------------|--------|
|  | 2024                         | 2023   |
| Cash paid for amounts included in the measurement of lease liabilities | \$ 139                       | \$ 127 |

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

|                                       | March 31, 2024 | December 31, 2023 |
|---------------------------------------|----------------|-------------------|
| Weighted-average remaining lease term | 2.7 years      | 2.2 years         |
| Weighted-average discount rate        | 4.80 %         | 4.78 %            |

As of March 31, 2024, undiscounted future minimum payments under the Company's operating leases were as follows (in thousands):

|  | Amount        |
|--|---------------|
| Remaining in 2024                          | \$ 85         |
| 2025                                       | 103           |
| 2026                                       | 106           |
| Total undiscounted lease payments          | 294           |
| Less: imputed interest                     | (19)          |
| Total lease liabilities                    | 275           |
| Less: current portion of lease liabilities | (100)         |
| Lease liabilities, net of current portion  | <u>\$ 175</u> |

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

#### *Land Use Rights*

As of March 31, 2024, the Company held land use rights for two land parcels in Beijing's Shunyi District, expiring in 2053, and in Cangzhou, Hebei Province, expiring from 2067 to 2071. These parcels, with a combined area of approximately 66,559 square meters, are utilized as manufacturing facilities. As of March 31, 2024, the aggregate recorded land use rights, net assets for these parcels was \$1.5 million.

## **8. Stockholders' Equity**

### ***Common Stock***

Common stock reserved for future issuance is as follows:

|  | <b>March 31, 2024</b> | <b>December 31, 2023</b> |
|--|-----------------------|--------------------------|
| Options issued and outstanding                     | 18,218,495            | 18,280,548               |
| Preferred Stock Warrants issued and outstanding    | 540,666               | 540,666                  |
| Convertible Preferred Stock issued and outstanding | —                     | 8,767,332                |
| Total common stock reserved                        | <u>18,759,161</u>     | <u>27,588,546</u>        |

### ***2021 ATM Program***

On October 15, 2021, Catalyst entered into an Equity Distribution Agreement (the "ATM Agreement") with Piper Sandler & Co. ("Piper Sandler") as sales agent, pursuant to which the Company may offer and sell, from time to time, through Piper Sandler, shares of the Company's common stock, par value of \$0.001 per share, with aggregate gross sales proceeds of up to \$50.0 million through an at-the-market offering program (the "ATM Program"). The Company will pay Piper Sandler a commission of 3% of the gross proceeds of any shares sold. The Company also agreed to reimburse Piper Sandler for certain expenses incurred in connection with its services under the ATM Agreement, including up to \$50,000 for legal expenses in connection with the establishment of the ATM Program. The Company did not utilize this or any other ATM Program during the quarter ended March 31, 2024.

Sales of shares of common stock under the ATM Program may be made pursuant to the registration statement on Form S-3 (File No. 333-253874), which was declared effective by the SEC on May 3, 2021, and a related prospectus supplement filed with the SEC on October 15, 2021. For the three months ended March 31, 2024 and 2023, no shares of common stock were sold under the ATM Program.

### ***Restricted Net Assets***

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

### ***Statutory Reserve***

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



Company may allocate a portion of after-tax profits based on PRC accounting standards to a discretionary reserve fund.

There were no appropriations to these reserves during the three months ended March 31, 2024 or during the year ended December 31, 2023.

## 9. Convertible Preferred Stock

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

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

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

## 10. Stock Based Compensation

### 2023 Omnibus Incentive Plan

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

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

|                                 | Number of Shares<br>Underlying<br>Outstanding<br>Options | Weighted-<br>Average Exercise<br>Price | Weighted-<br>Average<br>Remaining<br>Contractual Term<br>(Years) |
|---------------------------------|--|--|--|
| Outstanding — December 31, 2023 | 18,280,548   | \$ 1.49                                | 6.9  |
| Options granted                 | 1,866  | \$ 17.86                               |  |
| Options exercised               | (60,297)   | \$ 8.15                                |  |
| Options forfeited and cancelled | (3,622)  | \$ 22.85                               |  |
| Outstanding — March 31, 2024    | 18,218,495   | \$ 1.46                                | 6.7  |
| Exercisable — March 31, 2024    | 18,205,433   | \$ 1.46                                | 6.7  |

### Valuation Assumptions

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

Since no stock options were granted during the three months ended March 31, 2023, all weighted-average assumptions for that period were not applicable. The fair value of employee stock options granted during the three months ended March 31, 2024 was estimated using the following weighted-average assumptions:

|   | Three Months Ended March 31, |      |
|---|------------------------------|------|
|   | 2024                         | 2023 |
| Risk-free interest rate (%)                                 | 4.2%                         | n/a  |
| Expected option life (in years)                             | 6.0                          | n/a  |
| Expected dividend yield (%)                                 | —%                           | n/a  |
| Volatility (%)  | 84.3%                        | n/a  |
| Weighted average share price of the Company (USD per share) | \$ 17.86                     | n/a  |

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

|  | Three Months Ended March 31, |      |
|--|------------------------------|------|
|  | 2024                         | 2023 |
| General and administrative             | \$ 11                        | \$ — |
| Total stock-based compensation expense | \$ 11                        | \$ — |

As of March 31, 2024, the Company had an unrecognized stock-based compensation expense of \$0.1 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 2.7 years.

### 11. Net Income per Share (“EPS”) Attributable to Common Stockholders

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

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

|   | Three Months Ended March 31, |            |
|---|------------------------------|------------|
|   | 2024                         | 2023       |
| Numerator:  |                              |            |
| Net income  | \$ 9,935                     | \$ 4,217   |
| Less: Allocation of undistributed earnings to noncontrolling interest   | 2,403                        | 1,973      |
| Net income attributable to common stockholders - basic  | \$ 7,532                     | \$ 2,244   |
| Less: Change in fair value of warrant liability   | 4,288                        | —          |
| Net income attributable to common stockholders - diluted  | \$ 3,244                     | \$ 2,244   |
| Denominator:  |                              |            |
| Basic common shares outstanding:  |                              |            |
| Weighted average common shares outstanding  | 83,265,879                   | 63,588,119 |
| Weighted average shares used in calculating net income per share attributable to common stockholders, basic   | 83,265,879                   | 63,588,119 |
| Dilutive potential common shares:   |                              |            |
| Weighted average of common stock options  | 16,889,266                   | 15,333,247 |
| Weighted average of Convertible Preferred Stock (as converted)  | 2,119,575                    | —          |
| Weighted average of Preferred Stock Warrants (as converted)   | 319,477                      | —          |
| Weighted average shares used in calculating net income per share attributable to common stockholders, diluted | 102,594,197                  | 78,921,366 |
| Net income per share attributable to common stockholders:   |                              |            |
| Basic   | \$ 0.09                      | \$ 0.04    |
| Diluted   | \$ 0.03                      | \$ 0.03    |

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

|                                  | As of March 31, |      |
|----------------------------------|-----------------|------|
|                                  | 2024            | 2023 |
| Options to purchase common stock | 128,027         | —    |
| Total                            | 128,027         | —    |

## 12. Commitments and Contingencies

### *Contingent Value Rights Agreement*

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

In February 2023, Catalyst sold its legacy rare bleeding disorder program to GCBP. As a result, the Company distributed the net cash proceeds received from the GCBP asset sale of \$0.2 million to the CVR Holders as well as recorded a \$4.5 million long-term CVR derivative liability for the future distribution of the hold-back amount to be received in May 2025. As of December 31, 2023, the carrying value of the CVR derivative liability was \$4.7 million

on the condensed consolidated balance sheet. Refer to Note 3 — *Fair Value Measurements and Financial Instruments* for additional information regarding the CVR derivative liability and GCBP asset sale.

On October 30, 2023, pursuant to the CVR Agreement, the Company recorded a \$1.1 million CVR excess closing cash payable upon closing of the Contributions. The CVR excess closing cash payable is anticipated to be distributed among the CVR Holders. The balance of \$0.4 million remained outstanding as of March 31, 2024.

### ***Litigation and Legal Matters***

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

In April 2023, separate stockholders of Catalyst filed lawsuits in the Delaware Chancery Court, captioned *Bushansky v. Catalyst Biosciences, Inc., et al* and *Scott v. Catalyst Biosciences, Inc., et al.*, alleging Catalyst violated its fiduciary duties under Delaware Law by failing to disclose purportedly material information regarding the proposed Business Combination Agreement. In February 2024, both lawsuits were dismissed with prejudice and the Company reimbursed the stockholders for their legal and other expenses related to the litigation in the aggregate amount of \$0.4 million.

### ***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 \$2.0 million as of March 31, 2024 and were expected to be incurred within one year.

#### ***F351***

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

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

#### ***Research and Development Programs***

In addition to the F351 program, as of March 31, 2024, the Company has committed to allocate \$13.0 million toward future research and development activities for various programs.

## **13. Income Taxes**

During the three months ended March 31, 2024 and 2023, the Company recorded the following income tax provision (in thousands) and effective tax rate:

|                      | <b>Three Months Ended March 31,</b> |             |
|----------------------|-------------------------------------|-------------|
|                      | <b>2024</b>                         | <b>2023</b> |
| Income tax provision | \$ 2,546                            | \$ 2,054    |
| Effective tax rate   | 20.40 %                             | 32.75 %     |

The change of effective tax rate for the three months ended March 31, 2024 and 2023 was primarily due the consummation of the Contributions in October 2023.

As of March 31, 2024, after consideration of certain limitations (see below), the Company had approximately \$193.5 million federal and \$10.5 million state net operating loss (“NOL”) carryforwards for U.S. tax purposes available to reduce future taxable income which, if unused, will begin to expire in 2037 for federal and 2034 for state tax purposes. The federal NOL carryforward includes \$191.9 million that have an indefinite life.

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

#### **14. Related Party Transactions**

##### *Research and Development with GNI*

No research and development fees were paid to GNI during the three months ended March 31, 2024 and 2023. As of March 31, 2024 and December 31, 2023, the Company had a \$1.4 million related parties payable due to GNI.

##### *Other Receivables from GNI*

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

#### **15. Employee Benefit Plans**

##### *Mainland China Contribution Plan*

Pursuant to relevant PRC regulations, the Company is required to make contributions to various defined contribution plans organized by municipal and provincial PRC governments. The contribution for each employee is based on a percentage of the employee’s current compensation as required by the local government. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme. The total contributions for such employee benefits were \$1.2 million and \$1.0 million for the three months ended March 31, 2024 and 2023, respectively.

##### *Defined-Contribution Savings Plan*

In the U.S., the Company maintains a defined-contribution savings plan pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan is available to employees who meet the minimum age and length of service requirements. The contributions made during the three months ended March 31, 2024 were immaterial.

#### **16. Segment Information**

The Company is a consolidated entity comprised of two distinct operating segments: Gyre Pharmaceuticals and Gyre after the Contributions. The Company’s reportable segments are based upon internal organizational structure, the manner in which operations are managed, the criteria used by CODM to evaluate segment performance, the

availability of separate financial information, and overall materiality considerations. All Gyre's operations are within the U.S., while all of Gyre Pharmaceuticals' operations are in mainland China.

### ***Gyre Pharmaceuticals***

Gyre Pharmaceuticals has one major commercial drug product, ETUARY, and several product candidates in pre-clinical and clinical development. Gyre Pharmaceuticals' product revenues are mainly generated from the sale of ETUARY and certain generic drugs. Gyre Pharmaceuticals primarily sells its pharmaceutical products to distributors in the PRC, who ultimately sell the products to hospitals, other medical institutions and pharmacies. Gyre Pharmaceuticals also generates revenue from license agreements. However, the license agreements did not generate any revenue for the three months ended March 31, 2024 or 2023.

### ***Gyre***

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

### ***Other***

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

Segment information for the three months ended March 31, 2024 and 2023 is as follows (in thousands):

|  | <b>Three Months Ended March 31, 2024</b> |             |              |                     |
|--|--|-------------|--------------|---------------------|
|  | <b>Gyre<br/>Pharmaceuticals</b>          | <b>Gyre</b> | <b>Other</b> | <b>Consolidated</b> |
| Revenues   | \$ 27,172                                | \$ —        | \$ —         | \$ 27,172           |
| Cost of revenues   | 979                                      | —           | —            | 979                 |
| Gross profit   | 26,193                                   | —           | —            | 26,193              |
| Operating expenses excluding cost of revenues:               |  |             |              |                     |
| Selling and marketing  | 12,542                                   | —           | —            | 12,542              |
| Research and development                                     | 2,009                                    | 173         | —            | 2,182               |
| General and administrative                                   | 2,257                                    | 1,141       | —            | 3,398               |
| Total operating expenses excluding cost of revenues          | 16,808                                   | 1,314       | —            | 18,122              |
| Income (loss) from operations                                | \$ 9,385                                 | \$ (1,314)  | \$ —         | \$ 8,071            |
| Supplemental disclosure of stock-based compensation expense: |  |             |              |                     |
| General and administrative                                   | \$ —                                     | \$ 11       | \$ —         | \$ 11               |
| Stock-based compensation total                               | \$ —                                     | \$ 11       | \$ —         | \$ 11               |

|              | <b>March 31, 2024</b>           |             |              |                     |
|--------------|---------------------------------|-------------|--------------|---------------------|
|              | <b>Gyre<br/>Pharmaceuticals</b> | <b>Gyre</b> | <b>Other</b> | <b>Consolidated</b> |
| Total assets | \$ 109,347                      | \$ 11,750   | \$ 913       | \$ 122,010          |

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

|  | Three Months Ended March 31, 2024 |       |         |              |
|--|-----------------------------------|-------|---------|--------------|
|  | Gyre<br>Pharmaceuticals           | Gyre  | Other   | Consolidated |
| Purchase of property and equipment                           | \$ 217                            | \$ 14 | \$ —    | \$ 231       |
|  |                                   |       |         |              |
|  | Three Months Ended March 31, 2023 |       |         |              |
|  | Gyre<br>Pharmaceuticals           | Gyre  | Other   | Consolidated |
| Revenues   | \$ 24,931                         | \$ —  | \$ —    | \$ 24,931    |
| Cost of revenues   | 1,125                             | —     | —       | 1,125        |
| Gross profit   | 23,806                            | —     | —       | 23,806       |
| Operating expenses excluding cost of revenues:               |                                   |       |         |              |
| Selling and marketing  | 12,768                            | —     | —       | 12,768       |
| Research and development                                     | 2,635                             | —     | —       | 2,635        |
| General and administrative                                   | 1,722                             | —     | 17      | 1,739        |
| Total operating expenses excluding cost of revenues          | 17,125                            | —     | 17      | 17,142       |
| Income (loss) from operations                                | \$ 6,681                          | \$ —  | \$ (17) | \$ 6,664     |
|  |                                   |       |         |              |
| Supplemental disclosure of stock-based compensation expense: |                                   |       |         |              |
| Stock-based compensation total                               | \$ —                              | \$ —  | \$ —    | \$ —         |

|              | December 31, 2023       |           |        |              |
|--------------|-------------------------|-----------|--------|--------------|
|              | Gyre<br>Pharmaceuticals | Gyre      | Other  | Consolidated |
| Total assets | \$ 101,761              | \$ 13,865 | \$ 913 | \$ 116,539   |

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

|                                    | Three Months Ended March 31, 2023 |      |       |              |
|------------------------------------|-----------------------------------|------|-------|--------------|
|                                    | Gyre<br>Pharmaceuticals           | Gyre | Other | Consolidated |
| Purchase of property and equipment | \$ 1,742                          | \$ — | \$ —  | \$ 1,742     |

## 17. Subsequent Events

### *Lease Agreement*

In April 2024, the Company entered into a lease arrangement to lease 2,129.1 square meters of office space located in 6F, Building 1, Zone 4, Wangjing Xiyuan, Chaoyang District, Beijing. The Company paid approximately \$0.3 million upon execution of the lease, which will be included in total lease costs. The monthly lease payment is approximately \$0.1 million. The initial lease term is three years, which will commence on June 2, 2024, and expire on June 1, 2027. The lease arrangement provides two options to extend for an additional three years beyond the initial lease term.

### ***Jiangsu Wangao Agreement***

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



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

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

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

### Overview

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

Our strategy is to use our experience in the successful development and commercialization of ETUARY® (Pirfenidone) to expand into new indications and develop similar drug candidates. Pirfenidone, the first anti-fibrotic drug approved for idiopathic pulmonary fibrosis (“IPF”) in Japan, the European Union, the United States, and the People’s Republic of China (“PRC”), is a small molecule drug that inhibits the synthesis of Transforming Growth Factor (“TGF”)-β1, Tumor Necrosis Factor (“TNF”)-α, and other fibrosis and inflammation modulators. We have obtained approval for ETUARY (pirfenidone) in the PRC for IPF.

Gyre Pharmaceuticals successfully advanced Pirfenidone from research and development (“R&D”) to commercialization in the PRC for the treatment of IPF. ETUARY’s annual sales have consistently grown each year, reaching \$112.1 million in 2023. In addition to IPF, Pirfenidone is undergoing three additional Phase 3 clinical trials for Connective Tissue Disease-associated Interstitial Lung Disease to broaden its indications and market: sclerosis-related interstitial lung disease, dermatomyositis-related interstitial lung disease and pneumoconiosis.

F351, our lead development candidate in both the United States and the PRC, is a structural derivative of ETUARY (Pirfenidone). It is a new oral chemical entity with an anti-fibrotic, TGF-β1-targeting mechanism of action, for which we hold patents in major markets. Studies suggest that F351 and its major metabolites have minimal drug-drug interaction risks. Despite potential efficacy in IPF, we are prioritizing F351 for the treatment of liver fibrosis due to the large potential addressable market and significant unmet need.

Gyre Pharmaceuticals has completed a Phase 2 trial of F351 in the PRC for Chronic Hepatitis B (“CHB”)-associated liver fibrosis. The Phase 2 trial showed that F351 was well-tolerated without notable toxicity and patients treated showed statistically-significant improvement of liver fibrosis, with the best efficacy results achieved at 270 mg/day dosing. Based on these results, a confirmatory Phase 3 trial is ongoing in the PRC with a primary endpoint of the reduction of the liver fibrosis score (Ishak Scoring System) by at least one grade after taking F351 in combination with Entecavir. The enrollment of 248 patients for the confirmatory Phase 3 trial has been completed, with last patient out expected in 2024 and clinical results expected by early 2025.

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

In parallel, we are also conducting a randomized, double-blind, placebo-controlled Phase 2 clinical trial in the PRC to assess the safety and efficacy of F573, a caspase inhibitor for the treatment of acute/acute on-chronic liver failure.

### ***Business Combination Agreement***

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

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

- a) GNI USA contributed all of its ordinary shares in the capital of CPI to Catalyst in exchange for 45,923,340 shares of Common Stock (the “CPI Contribution”),
- b) GNI USA contributed its interest in Further Challenger International Limited (“Further Challenger”) for 17,664,779 shares of Common Stock (the “FC Contribution” and together with the CPI Contribution, the “GNI USA Contributions”), and
- c) each Minority Holder contributed 100% of the interest he or she held in his or her respective entity in exchange for an aggregate of 10,463,627 shares of Common Stock (the “Minority Holder Contributions” and together with the GNI USA Contributions, the “Contributions”).

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

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

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

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

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

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

#### ***Contingent Value Rights Agreement***

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

#### ***Private Placement and Securities Purchase Agreement***

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

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

### ***Jiangsu Wangao Agreement***

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

### ***Financial Operations Overview***

During the three months ended March 31, 2024, we had net income of \$9.9 million and net income attributable to common stockholders of \$7.5 million. For the three months ended March 31, 2023, we had net income of \$4.2 million and a net income attributable to common stockholders of \$2.2 million. As of March 31, 2024, we had an accumulated deficit of \$78.0 million and cash and cash equivalents of \$29.8 million. As of December 31, 2023, we had an accumulated deficit of \$85.5 million and cash and cash equivalents of \$33.5 million.

### **Components of Results of Operations**

#### ***Revenues***

##### *Sales of Pharmaceutical Products*

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

#### ***Operating Expenses***

##### *Cost of Revenue*

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

##### *Selling and Marketing Expenses*

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

##### *Research and Development Expenses*

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

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

#### *General and Administrative Expenses*

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

#### ***Other Income (Expense), Net***

##### *Interest Income, Net*

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

##### *Other Income*

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.

##### *Change in Fair Value of Warrant Liability*

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

##### *Other Expenses*

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

#### ***Provision for Income Taxes***

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

## Results of Operations

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

|   | Three Months Ended March 31, |           | Change (\$) | Change (%) |
|---|------------------------------|-----------|-------------|------------|
|   | 2024                         | 2023      |             |            |
| Revenues  | \$ 27,172                    | \$ 24,931 | \$ 2,241    | 9%         |
| Cost of revenues                                    | 979                          | 1,125     | (146)       | (13)%      |
| Gross profit  | 26,193                       | 23,806    | 2,387       | 10%        |
| Operating expenses excluding cost of revenues:      |                              |           |             |            |
| Selling and marketing                               | 12,542                       | 12,768    | (226)       | (2)%       |
| Research and development                            | 2,182                        | 2,635     | (453)       | (17)%      |
| General and administrative                          | 3,398                        | 1,739     | 1,659       | 95%        |
| Total operating expenses excluding cost of revenues | 18,122                       | 17,142    | 980         | 6%         |
| Income from operations                              | 8,071                        | 6,664     | 1,407       | 21%        |
| Other income (expense), net:                        |                              |           |             |            |
| Interest income, net                                | 328                          | 184       | 144         | 78%        |
| Other income  | 109                          | 66        | 43          | 65%        |
| Change in fair value of warrant liability           | 4,288                        | —         | 4,288       | *          |
| Other expenses                                      | (315)                        | (643)     | 328         | (51)%      |
| Income before income taxes                          | 12,481                       | 6,271     | 6,210       | 99%        |
| Provision for income taxes                          | (2,546)                      | (2,054)   | (492)       | 24%        |
| Net income  | 9,935                        | 4,217     | 5,718       | 136%       |
| Net income attributable to noncontrolling interest  | 2,403                        | 1,973     | 430         | 22%        |
| Net income attributable to common stockholders      | \$ 7,532                     | \$ 2,244  | \$ 5,288    | 236%       |

\*Not meaningful

## Comparison of the Three Months Ended March 31, 2024 and 2023

### Revenues

Revenues for the three months ended March 31, 2024 and 2023 were \$27.2 million and \$24.9 million, respectively. The increase was primarily due to a \$2.2 million increase in pharmaceutical product sales, driven by enhanced marketing and sales initiatives in regions of the PRC where sales were previously lower in the first quarter of 2023.

### Cost of Revenues

Cost of revenues for the three months ended March 31, 2024 and 2023 was \$1.0 million and \$1.1 million, respectively. The decrease was primarily driven by a decrease in raw material costs mainly due to the stoppage loss that occurred at the Cangzhou factory in 2023.

### Selling and Marketing Expenses

Selling and marketing expenses decreased by \$0.2 million, or 2%, for the three months ended March 31, 2024 compared to the three months ended March 31, 2023. The decrease was primarily driven by a \$1.8 million decrease in conference costs due to a decrease in conference activity, offset by a \$1.5 million increase in staff costs due to an increase in staff headcount.

### **Research and Development Expenses**

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

|   | Three Months Ended March 31, |                 | Change (\$)     | Change (%)   |
|---|------------------------------|-----------------|-----------------|--------------|
|   | 2024                         | 2023            |                 |              |
| Direct program expenses:                |                              |                 |                 |              |
| Clinical trials                         | \$ 353                       | \$ 832          | \$ (479)        | (58)%        |
| Materials and utilities                 | 502                          | 538             | (36)            | (7)%         |
| Pre-clinical research                   | 149                          | 255             | (106)           | (42)%        |
| Indirect expenses:                      |                              |                 |                 |              |
| Personnel-related costs                 | 976                          | 791             | 185             | 23%          |
| Facilities, depreciation and other      | 202                          | 219             | (17)            | (8)%         |
| Total research and development expenses | <u>\$ 2,182</u>              | <u>\$ 2,635</u> | <u>\$ (453)</u> | <u>(17)%</u> |

Research and development expenses decreased by \$0.5 million, or 17%, for the three months ended Month 31, 2024 compared to the three months ended March 31, 2023. The decrease was primarily driven by a \$0.5 million decrease in clinical trials expenses, as well as by a \$0.1 million decrease in pre-clinical research expenses. The latter is a result of several research and development projects advancing to the clinical trials stage or reaching the application phase in 2023. This overall decrease was partially offset by a \$0.2 million increase in research and development payroll costs due to increased headcount.

### **General and Administrative Expenses**

General and administrative expenses increased by \$1.7 million, or 95%, for the three months ended March 31, 2024 compared to the three months ended March 31, 2023. The increase was primarily driven by a \$1.2 million increase in payroll expenses, with \$1.0 million attributable to Gyre Pharmaceuticals and \$0.2 million attributable to Gyre, due to an increase in staff. Additionally, there was a \$0.6 million increase in miscellaneous expenses, including \$0.2 million attributable to Gyre Pharmaceuticals and \$0.3 million attributable to Gyre, primarily related to general office expenses.

### **Other Income (Expense), Net**

Interest income increased by \$0.1 million, or 78%, for the three months ended March 31, 2024 compared to the three months ended March 31, 2023, primarily due to additional investments in certificates of deposit.

Change in fair value of warrant liability was \$4.3 million for the three months ended March 31, 2024, and was related to the remeasurement of the Preferred Stock Warrants liability.

Other expenses decreased by \$0.3 million, or 51%, for the three months ended March 31, 2024 compared to the three months ended March 31, 2023. The decrease was primarily due to a \$0.3 million loss from equity method investments, recorded during the three months ended March 31, 2023, but not during the three months ended March 31, 2024, because CPI had divested nearly all of its assets except for its indirect ownership interest in Gyre Pharmaceuticals in October 2023.

### **Provision for Income Taxes**

Provision for income taxes was \$2.5 million and \$2.1 million for the three months ended March 31, 2024 and 2023, respectively. The increase was primarily attributable to a higher profit from Gyre Pharmaceuticals' operations.

### **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, 2024, we had cash and cash equivalents of \$29.8 million, short-term bank deposits of \$7.6 million and long-term certificates of deposit of \$23.1 million, which are available to fund operations, and an accumulated deficit of \$78.0 million. Our net income during the three months ended March 31, 2024 was \$9.9 million, while cash provided by operating activities was \$2.9 million. We believe that our existing cash and cash equivalents, cash flows from operations, and access to capital markets will be sufficient to fund our operating activities and obligations for at least 12 months following the filing date of this Quarterly Report.

### Future Funding Requirements

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

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

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

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

|  | Three Months Ended March 31, |                 |
|--|------------------------------|-----------------|
|  | 2024                         | 2023            |
| Cash Flow Data:  |                              |                 |
| Net cash provided by operating activities                    | \$ 2,884                     | \$ 10,417       |
| Net cash used in investing activities                        | (7,220)                      | (7,648)         |
| Net cash provided by financing activities                    | 658                          | —               |
| Effect of exchange rate changes on cash and cash equivalents | (46)                         | 200             |
| Net change in cash and cash equivalents                      | <u>\$ (3,724)</u>            | <u>\$ 2,969</u> |



### ***Cash Flows from Operating Activities***

Cash provided by operating activities for the three months ended March 31, 2024 was \$2.9 million, reflecting our net income of \$9.9 million, offset by non-cash items of \$4.3 million primarily related to the change in fair value of warrant liability of \$4.3 million. Additionally, cash provided by operating activities reflected changes in net operating assets and liabilities of \$2.8 million.

Cash provided by operating activities for the three months ended March 31, 2023 was \$10.4 million, reflecting our net income of \$4.2 million and additional positive non-cash items impact of \$0.2 million. Additionally, cash provided by operating activities reflected changes in net operating assets and liabilities of \$6.0 million.

### ***Cash Flows from Investing Activities***

Cash used in investing activities for the three months ended March 31, 2024 was \$7.2 million, which consisted of \$7.0 million in purchases of certificates of deposit and \$0.2 million in purchases of property and equipment, partially offset by \$0.1 million proceeds from sale of equipment.

Cash used in investing activities for the three months ended March 31, 2023 was \$7.6 million, which consisted of \$5.8 million in purchases of certificates of deposit and \$1.7 million in purchases of property and equipment.

### ***Cash Flows from Financing Activities***

Cash provided by financing activities for the three months ended March 31, 2024 was \$0.7 million due to proceeds from the exercise of stock options.

### ***Restricted Net Assets***

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

### **Contractual Obligations and Other Commitments**

#### ***Leases***

We have entered into lease arrangements in (1) San Diego, California for our headquarters, which expires on the last day of the 38th full calendar month beginning on or after November 11, 2023, and (2) the PRC, for office and laboratory spaces through August 2024. As of March 31, 2024, our fixed lease payment obligations were \$0.3 million, with \$0.1 million payable within 12 months.

#### **Other Contractual Obligations and Commitments**

In June 2021, we entered into a transfer agreement with Nanjing Healthnice Pharmaceutical Technology Co., Ltd. (“Nanjing Healthnice”), an independent third party, pursuant to which Nanjing Healthnice agreed to transfer to us the avatrombopag maleate tablets for the treatment of CLD-associated thrombocytopenia and all relevant technologies, complete any research or trials and transfer to us all materials necessary for the application of marketing approval by CDE. Upon the completion of the transfer, we expect that we will be approved by NMPA as the marketing authorization holder of the avatrombopag maleate tablets. In exchange, we will pay a total of approximately \$2.3 million upon certain milestones (e.g., the completion of bioequivalence study, or the registration application to CDE) being met. We have completed the bioequivalence study and received CDE acceptance on August 1, 2022, and as of March 31, 2024, we have made total payments of approximately \$1.8 million.

In September 2022, we entered into a transfer agreement with New Jiyuan (Beijing) Pharmaceutical Technology Co., Ltd. (“New Jiyuan”), an independent third party, pursuant to which New Jiyuan agreed to transfer to us the

minocycline hydrochloride foam for the treatment of moderate to severe acne and all relevant technologies, complete product development and transfer to us all materials necessary for the application of marketing approval of CDE. Upon the completion of the transfer, we expect that we will be approved by NMPA as the marketing authorization holder of the minocycline hydrochloride foam. In exchange, we will pay a total amount of \$1.0 million and the payments will be made by installments conditioned upon certain milestones (e.g., the completion of bioequivalence study, or the registration application to CDE) being met. Process verification has been completed. As of March 31, 2024, we have made total payments of approximately \$0.7 million.

In December 2022, we entered into a transfer agreement with Hangzhou Baicheng Pharmaceutical Technology Co., Ltd. and Zhejiang CDMO Pharmaceutical Co., Ltd., an independent third party, pursuant to which Baicheng agreed to transfer to us the acetylcysteine injection for the treatment of respiratory diseases with excessive thick mucus discharge and all relevant technologies, assist us in completing any research, trial and other required procedures and transfer to us all materials necessary for the application of marketing approval of CDE. Upon the completion of this transfer agreement, we expect that we will be approved by NMPA as the marketing authorization holder of the acetylcysteine injection. We have received CDE acceptance on January 8, 2024. As of March 31, 2024, we have made payments totaling approximately \$0.5 million under this agreement. Upon receiving the CDE's final approval, we will make an additional \$40,000 in payments.

#### Research and Development Programs

As of March 31, 2024, we have committed to allocate \$25.8 million toward future research and development activities for various programs.

#### Property and Equipment

Our commitments related to the purchase of property and equipment contracted but not yet reflected in the unaudited consolidated condensed financial statements were \$2.0 million as of March 31, 2024 and are expected to be incurred within one year.

#### **Critical Accounting Policies and Estimates**

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

#### **Smaller Reporting Company 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.

**ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

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

**ITEM 4. CONTROLS AND PROCEDURES*****Evaluation of Disclosure Controls and Procedures***

As of March 31, 2024, our management, with the participation and supervision of our principal executive officer and our principal financial officer, evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2024 to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

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

### **ITEM 1A. RISK FACTORS**

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

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

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **ITEM 5. OTHER INFORMATION**

#### ***Trading Arrangements***

None of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the three months ended December 31, 2023, 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.

| <b>Exhibit Number</b> | <b>Exhibit Title</b>   | <b>Form</b> | <b>File No.</b> | <b>Incorporated by reference Exhibit No.</b> | <b>Filing Date</b> |
|-----------------------|--|-------------|-----------------|--|--------------------|
| 2.1(a)†#              | <a href="#"><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></a>  | 8-K         | 000-51173       | 2.1  | Dec. 27, 2022      |
| 2.1(b)                | <a href="#"><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></a>  | 8-K         | 000-51173       | 2.2  | Mar. 30, 2023      |
| 2.2(a)#               | <a href="#"><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></a> | 8-K         | 000-51173       | 2.2  | Dec. 27, 2022      |
| 2.2(b)                | <a href="#"><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></a>            | 8-K         | 000-51173       | 2.1  | Mar. 30, 2023      |
| 2.2(c)                | <a href="#"><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></a>                          | 8-K         | 000-51173       | 2.1  | Aug. 31, 2023      |
| 3.1                   | <a href="#"><u>Fourth Amended and Restated Certificate of Incorporation of the Company.</u></a>  | S-8         | 333-133881      | 4.1  | May 8, 2006        |
| 3.2                   | <a href="#"><u>Certificate of Amendment to Fourth the Amended and Restated Certificate of Incorporation of the Company.</u></a>  | 8-K         | 000-51173       | 3.1  | Aug. 20, 2015      |
| 3.3                   | <a href="#"><u>Second Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Company.</u></a>   | 8-K         | 000-51173       | 3.1  | Feb. 10, 2017      |

|        |  |      |           |        |               |
|--------|--|------|-----------|--------|---------------|
| 3.4    | <a href="#"><u>Third Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Company.</u></a>  | 8-K  | 000-51173 | 3.1    | Oct. 30, 2023 |
| 3.5    | <a href="#"><u>Amended and Restated Bylaws of the Company.</u></a>   | 8-K  | 000-51173 | 3.3    | Oct. 30, 2023 |
| 3.6(a) | <a href="#"><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></a>                                  | 10-Q | 000-51173 | 3.1    | Aug. 3, 2017  |
| 3.6(b) | <a href="#"><u>Certificate of Elimination of Series A Preferred Stock, filed with the Delaware Secretary of State on March 25, 2024.</u></a>   | 10-K | 000-51173 | 3.6(b) | Mar. 27, 2024 |
| 3.7(a) | <a href="#"><u>Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, filed with the Delaware Secretary of State on December 27, 2022.</u></a>                               | 8-K  | 000-51173 | 3.1    | Dec. 27, 2022 |
| 3.7(b) | <a href="#"><u>Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, filed with the Delaware Secretary of State on October 30, 2023.</u></a>                   | 8-K  | 000-51173 | 3.2    | Oct. 30, 2023 |
| 3.8(a) | <a href="#"><u>Certificate of Designation of Preferences, Rights and Limitations of Series Y Preferred Stock, filed with the Delaware Secretary of State on June 20, 2023, with respect to the Series Y Preferred Stock.</u></a> | 8-K  | 000-51173 | 3.1    | June 20, 2023 |
| 3.8(b) | <a href="#"><u>Certificate of Elimination of Series Y Preferred Stock, filed with the Delaware Secretary of State on August 31, 2023.</u></a>  | 8-K  | 000-51173 | 3.1    | Aug. 31, 2023 |
| 4.1    | <a href="#"><u>Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to Silicon Valley Bank on March 3, 2005.</u></a>  | 10-K | 000-51173 | 4.4    | Mar. 9, 2016  |
| 4.2    | <a href="#"><u>Form of Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to purchasers of convertible promissory notes.</u></a>  | 10-K | 000-51173 | 4.6    | Mar. 9, 2016  |
| 4.3    | <a href="#"><u>Form of Warrant to Purchase Series X Convertible Preferred Stock.</u></a>   | 8-K  | 000-51173 | 4.1    | Oct. 30, 2023 |
| 31.1*  | <a href="#"><u>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</u></a>  |      |           |        |               |

pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

|          |  |
|----------|--|
| 31.2*    | <a href="#"><u>Certification of the Interim Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a> |
| 32.1**   | <a href="#"><u>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.</u></a>               |
| 32.2**   | <a href="#"><u>Certification of the Interim Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>       |
| 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 13, 2024

/s/ Han Ying, Ph.D.

---

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

Date: May 13, 2024

/s/ Ruoyu Chen

---

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



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

I, Han Ying, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Gyre Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ Han Ying, Ph.D.

---

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

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

I, Ruoyu Chen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Gyre Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ Ruoyu Chen

---

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

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

In connection with the Quarterly Report on Form 10-Q of Gyre Therapeutics, Inc. (the "Company") for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Han Ying, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 13, 2024

/s/ Han Ying, Ph.D.

---

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

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

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

---

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, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ruoyu Chen, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: May 13, 2024

/s/ Ruoyu Chen

---

**Ruoyu Chen**

**Chief Financial Officer**

*(Principal Financial and Accounting Officer)*

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

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

---

