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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from _____ to

Commission file number: 000-51173

Gyre Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**56-2020050**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
12730 High Bluff Drive Suite 250 San Diego, California	**92130**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 284-0115
(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

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

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

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

As of November 1, 2026, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 115,321,017, which includes 5,869,446 shares of common stock issued in the name of the registrant to a stock plan administrator of the registrant (see Note 8 — *Stockholders' Equity*).

GYRE THERAPEUTICS, INC.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2026	December 31, 2025 (As Recast)
Assets		
Current assets:		
Cash and cash equivalents	$ 41,643	$ 49,192
Short-term bank deposits	15,772	15,355
Short-term investment	12,629	28,085
Notes receivable	793	5,638
Accounts receivables, net	32,663	31,078
Other receivables from GNI	263	230
Inventories	12,219	10,171
Prepaid assets and other current assets	7,419	9,613
Total current assets	123,401	149,362
Property and equipment, net	27,011	27,549
Intangible assets, net	4,404	4,727
Long-term prepayments	741	112
Deferred tax assets	10,130	6,873
Long-term certificates of deposit	28,775	23,516
Other assets, noncurrent	6,789	7,624
Total assets	$ 201,251	$ 219,763
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,636	$ 1,335
Due to related parties	4,933	227
Accrued expenses and other current liabilities	17,044	18,161
Income tax payable	2,830	2,940
Operating lease liabilities, current	1,143	1,119
Total current liabilities	28,586	23,782
Operating lease liabilities, noncurrent	1,867	2,303
Deferred government grants	1,555	852
Warrant liability, noncurrent	3,056	2,961
Other noncurrent liabilities	119	1,506
Total liabilities	35,183	31,404
Commitments and Contingencies (Note 11)		
Series B preferred stock, $0.001 par value, 5,000,000 shares authorized; 3,552,427 shares and zero shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	21,551	—
Redeemable convertible preferred stock, $0.001 par value, 5,000,000 shares authorized; zero shares and 2,601,826 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	—	15,784
Redeemable noncontrolling interests — Cullgen redeemable convertible preferred stock	—	113,030
Stockholders' equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized; 107,068,625 shares and 91,314,007 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	107	91
Additional paid-in capital	243,489	172,819
Statutory reserve	3,648	3,098
Accumulated deficit	(142,015)	(112,603)
Accumulated other comprehensive income (loss)	2,725	(908)
Total Gyre stockholders' equity	107,954	62,497
Noncontrolling interest	36,563	(2,952)
Total equity	144,517	59,545
Total liabilities, Series B preferred stock, redeemable convertible preferred stock, and stockholders' equity	$ 201,251	$ 219,763

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025 (As Recast)	2026	2025 (As Recast)
Revenues	$ 32,934	$ 32,694	$ 86,469	$ 92,999
Operating expenses:				
Cost of revenues	1,947	1,628	5,383	3,673
Selling and marketing	15,028	15,328	42,918	41,363
Research and development	8,484	7,797	34,265	24,239
Research and development-related parties	24	—	4,860	—
General and administrative	8,921	6,447	26,964	21,928
Transaction costs	50	—	6,936	—
Total operating expenses	34,454	31,200	121,326	91,203
(Loss) income from operations	(1,520)	1,494	(34,857)	1,796
Other (loss) income, net:				
Interest income	588	954	2,071	2,751
Other (expense) income, net	(498)	95	(1,328)	(206)
Change in fair value of warrant liability	(315)	(23)	(95)	2,444
(Loss) income before income taxes	(1,745)	2,520	(34,209)	6,785
Provision for income taxes	(733)	(593)	(1,118)	(2,156)
Net (loss) income	(2,478)	1,927	(35,327)	4,629
Accretion of Cullgen redeemable convertible preferred stock	—	(2,707)	(3,905)	(7,927)
Net income (loss) attributable to noncontrolling interest	1,575	(1,805)	(10,370)	(4,449)
Net (loss) income attributable to common stockholders	$ (4,053)	$ 1,025	$ (28,862)	$ 1,151
Net (loss) income per share attributable to common stockholders:				
Basic	$ (0.04)	$ 0.01	$ (0.29)	$ 0.01
Diluted	$ (0.04)	$ 0.01	$ (0.29)	$ (0.01)
Weighted average shares used in calculating net (loss) income per share attributable to common stockholders:				
Basic	106,302,559	90,850,040	99,473,991	88,812,863
Diluted	106,302,559	103,955,878	99,473,991	88,913,503
Other comprehensive income (loss) :				
Reclassification adjustment for (loss) gain included in net (loss) income	(11)	18	(19)	26
Unrealized gain (loss) on short-term investments	258	(1)	(79)	(5)
Foreign currency translation adjustments	1,413	1,010	5,551	1,557
Other comprehensive (loss) income attributable to noncontrolling interest:				
Reclassification adjustment for loss included in net loss attributable to noncontrolling interest	—	(8)	(5)	(3)
Unrealized gain (loss) on short-term investments attributable to noncontrolling interest	—	18	(299)	16
Foreign currency translation adjustments attributable to noncontrolling interest	427	357	1,748	567
Comprehensive income (loss) attributable to noncontrolling interest	2,002	(1,438)	(8,926)	(3,869)
Comprehensive (loss) income attributable to common stockholders	$ (2,820)	$ 1,685	$ (24,853)	$ 2,149

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

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

	Series B Convertible Preferred Stock		Redeemable convertible preferred stock		Redeemable Noncontrolling Interests		Common Stock		Additional Paid-In Capital	Statutory Reserve	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Gyre Stockholders' Equity	Non-controlling Interest	Total Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount							
Balance at December 31, 2025, as recast	—	$ —	2,601,826	$ 15,784	1,095,409	$ 0	91,314,007	91	$ 172,819	$ 3,098	$ (112,603)	$ (908)	$ 62,497	$ (2,952)	$ 59,545
Appropriation of statutory reserve	—	—	—	—	—	—	—	—	—	550	(550)	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	2,583	—	—	—	2,583	242	2,825
Stock options exercised	—	—	—	—	—	—	23,114	—	21	—	—	—	21	—	21
Accretion of Cullgen redeemable convertible preferred stock	—	—	—	—	—	2,847	—	—	—	—	(1,096)	—	(1,096)	(1,751)	(2,847)
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	—	—	—	(20)	(20)	(31)	(51)
Reclassification adjustment for loss included in net loss	—	—	—	—	—	—	—	—	—	—	—	(3)	(3)	(5)	(8)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	1,451	1,451	728	2,179
Net loss	—	—	—	—	—	—	—	—	—	—	(12,050)	—	(12,050)	(6,529)	(18,579)
Balance at March 31, 2026, as recast	—	$ —	2,601,826	$ 15,784	1,095,409	$ 115,877	91,337,121	$ 91	$ 175,423	$ 3,648	$ (126,299)	$ 520	$ 53,383	$ (10,298)	$ 43,085
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,833	—	—	—	1,833	—	1,833
Stock options exercised	—	—	—	—	—	—	246,115	—	188	—	—	—	188	—	188
Shares issued upon common control merger with Cullgen	3,697,235	22,430	(2,601,826)	(15,784)	(1,095,409)	(116,935)	14,450,527	15	63,200	—	—	(376)	62,839	48,199	111,038
Accretion of Cullgen redeemable convertible preferred stock	—	—	—	—	—	1,058	—	—	—	—	(407)	—	(407)	(651)	(1,058)
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	—	—	—	(18)	(18)	(268)	(286)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	—	—	1,366	1,366	593	1,959
Net loss	—	—	—	—	—	—	—	—	—	—	(11,256)	—	(11,256)	(3,014)	(14,270)
Balance at June 30, 2026	3,697,235	$ 22,430	—	$ -	$ -	$ -	106,033,763	$ 106	$ 240,644	$ 3,648	$ (137,962)	$ 1,492	$ 107,928	$ 34,561	$ 142,489
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,734	—	—	—	1,734	—	1,734
Stock options exercised	—	—	—	—	—	—	310,817	—	233	—	—	—	233	—	233
Conversion of Series B Preferred Shares to Common Shares	(144,808)	(879)	—	—	—	—	724,045	1	878	—	—	—	879	—	879
Unrealized gain on short-term investments	—	—	—	—	—	—	—	—	—	—	—	258	258	—	258
Reclassification adjustment for loss included in net loss	—	—	—	—	—	—	—	—	—	—	—	(11)	(11)	—	(11)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	—	—	986	986	427	1,413
Net loss (income)	—	—	—	—	—	—	—	—	—	—	(4,053)	—	(4,053)	1,575	(2,478)
Balance at September 30, 2026	3,552,427	$ 21,551	—	$ -	$ -	$ -	107,068,625	$ 107	$ 243,489	$ 3,648	$ (142,015)	$ 2,725	$ 107,954	$ 36,563	$ 144,517

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

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

	Redeemable convertible preferred stock		Redeemable Noncontrolling Interests		Common Stock		Additional Paid-In Capital	Statutory Reserve	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Gyre Stockholders' Equity	Non-controlling Interest	Total Equity
	Shares	Amount	Shares	Amount	Shares	Amount							
Balance at December 31, 2024, as recast	2,601,826	$ 15,784	1,095,409	$ 25	102,344,086	$ 86	$ 136,954	$ 3,098	$ (109,348)	$ (2,898)	$ 27,892	$ 7,898	$ 35,790
Stock-based compensation expense	—	—	—	—	—	—	507	—	—	—	507	316	823
Stock options exercised	—	—	—	—	1,273,931	1	955	—	—	—	956	—	956
Accretion of Cullgen redeemable convertible preferred stock	—	—	—	2,578	—	—	—	—	(993)	—	(993)	(1,585)	(2,578)
Issuance of Common Stock upon ATM program	—	—	—	—	54,734	—	509	—	—	—	509	—	509
CVR liability settlement	—	—	—	—	—	—	25	—	—	—	25	—	25
Deferred financing costs amortization	—	—	—	—	—	—	(2)	—	—	—	(2)	—	(2)
Unrealized gain on short-term investments	—	—	—	—	—	—	—	—	—	7	7	11	18
Reclassification adjustment for gains included in net loss	—	—	—	—	—	—	—	—	—	(2)	(2)	(2)	(4)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	122	122	77	199
Net income	—	—	—	—	—	—	—	—	3,163	—	3,163	1,776	4,939
Balance at March 31, 2025, as recast	2,601,826	$ 15,784	1,095,409	$ 103	87,636,209	$ 87	$ 138,948	$ 3,098	$ (107,178)	$ (2,771)	$ 32,184	$ 8,491	$ 40,675
Stock-based compensation expense	—	—	—	—	—	—	906	—	—	—	906	214	1,120
Stock options exercised	—	—	—	—	631,064	1	1,031	—	—	—	1,032	—	1,032
Accretion of Cullgen redeemable convertible preferred stock	—	—	—	2,642	—	—	—	—	(1,017)	—	(1,017)	(1,625)	(2,642)
Issuance of common stock	—	—	—	—	2,555,555	3	22,997	—	—	—	23,000	—	23,000
Deferred financing costs amortization	—	—	—	—	—	—	(1,676)	—	—	—	(1,676)	—	(1,676)
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	—	(9)	(9)	(13)	(22)
Reclassification adjustment for gains included in net loss	—	—	—	—	—	—	—	—	—	5	5	7	12
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	215	215	133	348
Net loss	—	—	—	—	—	—	—	—	(1,027)	—	(1,027)	(1,210)	(2,237)
Balance at June 30, 2025, as recast	2,601,826	$ 15,784	1,095,409	$ 45	90,822,828	$ 91	$ 162,206	$ 3,098	$ (109,222)	$ (2,560)	$ 53,613	$ 5,997	$ 59,610
Stock-based compensation expense	—	—	—	—	—	—	1,147	—	—	—	1,147	187	1,334
Stock options exercised	—	—	—	—	67,553	—	50	—	—	—	50	—	50
Accretion of Cullgen redeemable convertible preferred stock	—	—	—	2,707	—	—	—	—	(1,042)	—	(1,042)	(1,665)	(2,707)
Deferred financing costs amortization	—	—	—	—	—	—	(3)	—	—	—	(3)	—	(3)
Unrealized (loss) gain on short-term investments	—	—	—	—	—	—	—	—	—	(19)	(19)	18	(1)
Reclassification adjustment for gains included in net loss	—	—	—	—	—	—	—	—	—	26	26	(8)	18
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	653	653	357	1,010
Capital injection in a subsidiary	—	—	—	—	—	—	4,503	—	—	—	4,503	(4,503)	—
Net income (loss)	—	—	—	—	—	—	—	—	2,067	—	2,067	(140)	1,927
Balance at September 30, 2025, as recast	2,601,826	$ 15,784	1,095,409	$ 52	90,890,381	$ 91	$ 167,903	$ 3,098	$ (108,197)	$ (1,900)	$ 60,995	$ 243	$ 61,238

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

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

	Nine Months Ended September 30,	
	2026	2025 (As Recast)
Operating Activities		
Net (loss) income	$ (35,327)	$ 4,629
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Stock-based compensation	6,392	3,277
Equity in loss of unconsolidated affiliate	65	57
Depreciation and amortization	2,622	2,372
Noncash lease expense	1,539	1,234
Deferred income taxes, net	(2,905)	(1,022)
Bad debt expense and other non-cash items	175	(29)
Accrued interest on short-term and long-term certificates of deposit	600	(78)
Accretion of premium or discount on short-term investments	(18)	(67)
Change in fair value of financial liabilities, net	95	(2,439)
Foreign currency exchange loss	—	165
Loss on disposal of property and equipment	18	2
Changes in operating assets and liabilities:		
Notes receivable	4,858	3,701
Accounts receivable	(403)	(5,981)
Inventories	(1,577)	(2,423)
Prepaid and other assets	2,355	(1,451)
Income tax payable	(234)	(217)
Accounts payable	1,296	423
Deferred revenue	—	(9,270)
Due to related parties	4,620	—
Accrued expenses and other liabilities	(456)	(2,130)
Operating lease liabilities	(1,245)	(963)
Net proceeds from CVR liability settlement	—	25
Net cash used in operating activities	(17,530)	(10,185)
Investing Activities		
Purchase of short-term investments	—	(564)
Acquisition of intangible assets	(1,125)	(737)
Purchase of certificates of deposit	(18,823)	(19,184)
Purchase of available-for-sale securities	(2,004)	(16,466)
Proceeds from available-for-sale securities	17,270	17,449
Purchase of property and equipment	(1,419)	(1,197)
Proceeds from sale of equipment	61	19
Proceeds from maturity of certificates of deposit	14,471	27,190
Net cash provided by investing activities	8,431	6,510
Financing Activities		
Payments of listing expense	(208)	(2,496)
Deferred financing costs paid	—	(1,487)
Proceeds from the exercise of stock options	442	2,038
Proceeds from the issuance of common stock	—	23,000
Proceeds from the issuance of common stock in ATM program	—	509
Net cash provided by financing activities	234	21,564
Effect of exchange rate changes on cash	1,316	149
Net (decrease) increase in cash	(7,549)	18,038
Cash at beginning of the period	49,192	39,048
Cash at end of period	$ 41,643	$ 57,086
Supplement disclosure of non-cash operating activities:		
Right-of-use asset obtained in exchange for operating lease liabilities	587	1,603
Supplemental Disclosure of Non-Cash Financing and Investing Activities:		
Accretion of redeemable convertible preferred stock	3,905	7,927
Purchase of property and equipment and intangible assets included in accrued expenses and other liabilities	75	15
Unpaid listing expense included in accrued expenses	—	257
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	4,328	5,993

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

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

1. Organization and Basis of Presentation

The Company

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

As of September 30, 2026, the Company holds a 69.7% indirect interest in Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals Co., Ltd., "Gyre Pharmaceuticals"), a commercial-stage biopharmaceutical company registered and established in the People's Republic of China ("PRC") in 2002. The majority shareholder of Gyre is GNI USA, Inc. ("GNI USA"), which is indirectly wholly owned by GNI Group Ltd. ("GNI Japan"). Gyre is a commercial-stage biotechnology company with a proven track record of success in developing and commercializing small-molecule anti-inflammatory and anti-fibrotic drugs targeting organ diseases, focusing specifically on organ fibrosis. Fibrotic diseases represent a large patient population with significant unmet medical needs.

On May 4, 2026 (the "Merger Closing Date"), the Company completed the merger (the "Merger") with Cullgen Inc. ("Cullgen") pursuant to the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated March 2, 2026, by and among Gyre, Cullgen, and Helix Merger Sub Corp. ("Merger Sub"). Upon consummation of the Merger, Cullgen became a wholly owned subsidiary of Gyre. Cullgen, a biopharmaceutical company dedicated to the development of medicines for the treatment of diseases lacking effective therapeutic approaches, was incorporated in the state of Delaware on January 12, 2018.

Liquidity

For the nine months ended September 30, 2026, the Company had a net loss of $35.3 million, while net cash used in operating activities was $17.5 million. As of September 30, 2026, the Company had an accumulated deficit of $142.0 million and cash and cash equivalents of $41.6 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 twelve months following the issuance of these condensed consolidated financial statements.

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its controlled subsidiaries after elimination of all intercompany accounts and transactions among consolidated entities. On May 4, 2026, the Company completed the Merger with Cullgen, an entity under common control with the Company through GNI Japan. The Merger has been accounted for as a transaction between entities under common control. Accordingly, the accompanying unaudited condensed consolidated financial statements have been retrospectively recast for all periods presented during which the Company and Cullgen were under common control to reflect the combined financial position, results of operations, changes in stockholders' equity, and cash flows of the Company and Cullgen as if the common-control transfer had occurred at the beginning of the earliest period presented.

For periods prior to the Merger Closing Date, the retrospective recast reflects the common-control transfer of Cullgen to the Company but does not give effect to the Company's acquisition or exchange of Cullgen ownership interests held by parties other than GNI Japan before the date such interests were acquired or exchanged. Accordingly, Cullgen's historical equity, net income or loss, and comprehensive income or loss attributable to ownership interests held by parties other than GNI Japan have been presented as noncontrolling interests for periods prior to the Merger Closing Date. Upon completion of the Merger, Cullgen became a wholly owned subsidiary of the Company and the related Cullgen noncontrolling interests were eliminated within equity, with no gain or loss recognized in the condensed consolidated statements of operations or comprehensive income.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and the requirements of the Securities and Exchange Commission (the "SEC") for interim reporting. The December 31, 2025 consolidated balance sheet has been derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2025, as filed with the SEC, and has been retrospectively recast to reflect the Merger, which was accounted for as a transaction between entities under common control (see Note 2, Summary of Significant Accounting Policies). The retrospective recast reflects a change in reporting entity resulting from a combination of entities under common control and does not represent the correction of an error in previously issued financial statements. As permitted under the SEC's interim reporting rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements after giving effect to the retrospective recast described above, 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 unaudited condensed consolidated results of operations and cash flows for any interim period are not necessarily indicative of the results to be expected for the year ending December 31, 2026, or for any other future annual or interim period.

The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the consolidated financial statements filed with the Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 13, 2026 (the "Annual Report"), together with the disclosures included herein regarding the retrospective recast resulting from the Merger.

2. Summary of Significant Accounting Policies

Common Control Merger and Retrospective Recast

The Company acquired Cullgen in an all-stock transaction pursuant to which all outstanding shares of Cullgen capital stock were exchanged for shares of the Company's common stock or Series B Convertible Preferred Stock in accordance with the exchange terms set forth in the Merger Agreement. The Company evaluated the Merger under ASC 805-50 and determined that the Merger is a combination of entities under common control because both the Company and Cullgen were controlled by GNI Japan before and after the Merger and such control was not transitory. The net assets transferred in the Merger were determined to represent a business, as defined under ASC 805-10-55-4, and the Merger resulted in a change in reporting entity, as defined under ASC 250-10-20. The Company was identified as the receiving entity and Cullgen as the transferring entity for accounting purposes. The assets and liabilities transferred were recognized at their historical carrying amounts on the Merger Closing Date. No new basis of accounting or goodwill was recognized in accordance with ASC 805-50.

In accordance with ASC 805-50 and applicable SEC rules and regulations, the historical periods included in the accompanying interim financial statements have been retrospectively recast to reflect the common control transaction. As such, the financial statements for periods prior to the Merger reflect the combined results of the Company and Cullgen as if Cullgen had been part of the Company during the historical periods presented during which the entities were under common control.

The Merger also resulted in the Company acquiring or exchanging Cullgen ownership interests held by parties other than GNI Japan. The Company accounts for the acquisition or exchange of those non-GNI interests as an equity transaction as of the Merger Closing Date. Accordingly, the retrospective recast of historical periods prior to the Merger Closing Date does not give effect to the acquisition or exchange of such non-GNI interests before the date those interests were acquired or exchanged. For those pre-Merger periods, the Company retained and attributed Cullgen's historical non-GNI ownership interests as noncontrolling interests, including redeemable preferred stock interests classified outside permanent equity when applicable.

The historical financial data of Cullgen included in the historical recast periods has been derived from the historical financial statements and accounting records of Cullgen, which were prepared on a standalone basis in accordance with GAAP using the historical accounting policies applied by Cullgen. Management reviewed GNI Japan's historical carrying-basis information for Cullgen and did not identify acquisition-accounting basis differences, pushdown accounting adjustments, or goodwill associated with Cullgen that would require adjustment to Cullgen's standalone historical financial information for purposes of the retrospective recast.

Use of Estimates

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

Noncontrolling Interest

The Company reports noncontrolling interest ("NCI") in a subsidiary as a separate component of equity in the condensed consolidated balance sheets. The Company also reports the portion of net income or loss and comprehensive income or loss attributable to the Company and NCI separately in the condensed consolidated statements of operations and comprehensive income.

In connection with the retrospective recast of the Merger, for periods prior to the Merger Closing Date, the Company attributes Cullgen's historical equity, net income or loss, and comprehensive income or loss between the controlling interest and NCI based on the applicable ownership interests and contractual or economic rights. Cullgen interests held by GNI Japan or its controlled affiliates are attributed to the controlling interest and eliminated in consolidation. Cullgen interests held by parties other than GNI Japan are presented as NCI. The non-GNI portion of Cullgen's redeemable convertible preferred stock principal and cumulative accretion is presented as redeemable noncontrolling interests outside permanent equity until the Merger Closing Date when such interests were acquired or exchanged in the Merger.

For pre-Merger periods, accretion of Cullgen redeemable convertible preferred stock held by non-GNI holders is retained in the recast financial statements and considered in the attribution of income or loss between the controlling interest and NCI. The residual Cullgen income or loss after the effect of such preferred stock accretion is attributed between the controlling interest and NCI based on the applicable common ownership interests. On the Merger Closing Date, Cullgen became a wholly owned subsidiary of the Company and the related Cullgen NCI was eliminated within equity, with no gain or loss recognized in net income or comprehensive income.

Series B Convertible Preferred Stock

The Company accounts for its Series B Preferred Stock in accordance with ASC Topic 480, Distinguishing Liabilities from Equity ("ASC 480"), and other applicable GAAP. The Series B Preferred Stock was issued by the Company in connection with the Merger and was initially recognized at the carryover-basis amount determined in the common-control transaction. The Company evaluates the instrument's redemption, conversion, and other substantive terms at each reporting date to determine whether classification as a liability, temporary equity, or permanent equity is required. Preferred stock that is mandatorily redeemable is classified as a liability and measured at the present value of the redemption amount. Preferred stock that is redeemable upon the occurrence of events not solely within the Company's control is classified as temporary equity. At all other times, preferred stock is classified within stockholders' equity. The Company records accretion to redemption value when required by applicable accounting guidance. The Company concluded that the Series B Preferred Stock was classified as temporary equity (mezzanine equity) as of September 30, 2026 under ASC 480-10-S99.

Stockholder approval for conversion of the Series B Preferred Stock was obtained on June 10, 2026, which eliminated the stockholder-approval contingency that had restricted conversion and could have resulted in cash settlement if conversion shares were not deliverable. However, stockholder approval did not eliminate a separate fundamental transaction feature that may require settlement upon events not solely within the Company's control. Accordingly, while any Series B Preferred Stock remains outstanding, the Company will continue to classify the instrument in temporary equity unless the shares are converted into common stock, the fundamental transaction feature is removed or amended such that temporary equity classification is no longer required, or the Company otherwise concludes that permanent equity classification is appropriate under applicable accounting guidance. Because the Series B Preferred Stock does not have an ultimate redemption amount or earliest redemption date to which the carrying amount should be accreted and was not currently redeemable or probable of becoming redeemable as of September 30, 2026, the Company did not record periodic accretion to redemption value.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The CODM uses segment net income or loss generated from segment assets in monitoring budget versus actual results in assessing the performance of the segment.

Following the Merger with Cullgen, the Company's CODM changed from a previous group consisting of (i) the Executive Chairman of Gyre's Board of Directors, who also served as Gyre's Interim Chief Executive Officer, and (ii) Gyre's Chief Operating Officer, who also served as Gyre Pharmaceuticals' General Manager, to the Company's Chief Executive Officer. The Company has determined that it has two reportable segments.

Risks and Uncertainties

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

Concentration of Credit Risk

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

The Company is exposed to United States credit risk in the event of default by the United States institutions holding cash to the extent beyond the amount insured by the United States Federal Depository Insurance Corporation ("FDIC"). In the United States, the FDIC insures deposits at federally insured financial institutions up to a limit of $250,000 per depositor, per insured bank, for each account ownership category. The Securities Investor Protection Corporation ("SIPC") protects customer assets held by registered broker-dealers, with a standard limit of $500,000 per customer. The Company maintains cash and deposits in excess of the amount protected by FDIC and SIPC insurance. In the event of failure or insolvency of one of these financial institutions, the Company may be unable to recover its deposits in full. Management believes that these financial institutions are of high credit quality and continually monitors the creditworthiness of these financial institutions. As of September 30, 2026 and December 31, 2025, the Company had cash and cash equivalents held in U.S. financial institutions of $23.7 million and $25.9 million, respectively. Of the 2026 balance, $8.0 million represented general bank deposits and $15.7 million represented investment related cash. At September 30, 2026, the Company's U.S. cash balances exceeded FDIC insurance coverage by $7.0 million and exceeded SIPC coverage by $15.2 million.

In May 2015, a new Deposit Insurance System ("DIS") managed by the People's Bank of China was implemented by the Chinese government. Deposits in the licensed banks in mainland China are protected by DIS, up to a limit of Chinese Renminbi ("RMB") 5,000,000, or approximately $742,379, based on the September 30, 2026 spot exchange rate. The Company maintains cash and deposits in excess of the amount protected by DIS and in the event of bankruptcy of one of these financial institutions, the Company may be unable to claim its deposits back in full. Management believes that these financial institutions are of high credit quality and continually monitors the creditworthiness of these financial institutions. The following table presents the Company's cash balances maintained in mainland China by investment type and the amount (in millions) that exceeded applicable deposit insurance coverage as of September 30, 2026 and December 31, 2025:

	September 30, 2026	**December 31, 2025 (As Recast)**
Cash and cash equivalents	17.9	15.3
Long-term certificates of deposit	28.8	23.5
Short-term bank deposits	15.8	15.4
Total cash, cash equivalents and bank deposits	62.5	54.2
Amount exceeding PRC DIS coverage	61.8	53.5

Accounts receivable are typically unsecured and are derived from product sales. The Company manages credit risk related to the accounts receivable through ongoing monitoring of outstanding balances and limiting the amount of credit extended based upon payment history and creditworthiness. Historically, the Company has collected receivables from customers within the credit terms with no significant credit losses incurred. Note receivable is also subject to credit risk. The Company monitors the creditworthiness and repayment performance of the borrower on an ongoing basis and has not experienced significant credit losses related to such receivable.

The Company's short-term investments include marketable securities. The Company classifies its marketable securities as available-for-sale securities, which include commercial paper, corporate debt securities and U.S. government agency securities. These securities are recorded at fair value with the related unrealized gains and losses included in accumulated other comprehensive loss. Premiums or discounts from par value are amortized to investment income over the life of the underlying investment and are included in 'interest income' within the consolidated statements of comprehensive loss. All the Company's available-for-sale securities are available to the Company for use in current operations. As a result, the Company classified all these securities as current assets even though the stated maturity of some individual securities may be one year or more beyond the balance sheet date. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in 'Net loss' within the consolidated statements of comprehensive loss. If any adjustment is required to reflect a decline in the value of the investment that the Company considers to be "other than temporary", the Company recognizes a charge to the consolidated statements of comprehensive loss.

Concentration of Customer Risk

For the three months ended September 30, 2026, following the completion of the Merger with Cullgen, the Company's revenue consists of (i) pharmaceutical product sales primarily generated through its legacy business and (ii) collaboration-based revenue generated by Cullgen's operations.

Pharmaceutical Product Sales

For the three months ended September 30, 2026, the Company had two customers, Sinopharm Group Co., Ltd. ("Sinopharm"), and China Resources Pharmaceutical Group Ltd ("Resources Pharmaceutical"), who accounted for approximately 51.4% and 11.8% of total revenue, respectively. For the three months ended September 30, 2025, the Company had three customers, Sinopharm, Resources Pharmaceutical, and Shanghai Pharmaceuticals Holding Co., Ltd. ("Shanghai Pharmaceuticals"), who accounted for approximately 47.3%, 11.4% and 10.7% of total revenue, respectively. All customers are located in mainland China.

For the nine months ended September 30, 2026, the Company had three customers, Sinopharm, Resources Pharmaceutical and Shanghai Pharmaceuticals, who accounted for approximately 47.5%, 12.3% and 10.4% of total revenue, respectively. For the nine months ended September 30, 2025, the Company had three customers, Sinopharm, Resources Pharmaceutical, and Shanghai Pharmaceuticals, who accounted for approximately 44.1%, 11.4% and 10.6% of total revenue, respectively. All customers are located in mainland China.

Collaboration-Based Revenue

Cullgen's collaboration-based revenue is generated pursuant to collaboration agreements with customers. For the three months ended September 30, 2026, all of Cullgen's revenue was from a single customer. For the nine months ended September 30, 2026, the majority of Cullgen's revenues were from another customer, which also made up all of Cullgen's revenues for the three and nine months ended September 30, 2025, as further described in Note 6 to the consolidated financial statements.

Accounts Receivable Concentration

As of September 30, 2026 and December 31, 2025, the Company had one customer, Sinopharm, who accounted for approximately 49.0% and 53.3% of accounts receivable, respectively.

Foreign Currency Risk

Transactions in subsidiaries are recorded in the functional currency of the respective subsidiary. The determination of functional currency is based on the criteria of Accounting Standard Codification ("ASC") 830, *Foreign Currency Matters.*

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. 42.9% of the Company's cash and cash equivalents, 100.0% of the Company's short-term bank deposits and 100% of the Company's long-term certificates of deposit as of September 30, 2026 in the amount of $17.9 million, $15.8 million and $28.8 million, respectively, were denominated in RMB.

Accounting Pronouncements – Recently Adopted

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

New Accounting Pronouncements Issued and Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative* ("ASU 2023-06"). ASU 2023-06 modifies the disclosure or presentation requirements of a variety of Topics in the Financial Accounting Standards Codification (the "Codification"). Certain of the amendments represent clarifications to or technical corrections of the current requirements. Because of the variety of Topics amended, a broad range of entities may be affected by one or more of those amendments. Many of the amendments allow users to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the SEC's requirements. Also, the amendments align the requirements in the Codification with the SEC's regulations. For entities subject to the SEC's existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all other entities, the amendments will be effective two years later. The amendments in this update should be applied prospectively. For all entities, if by June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the related amendment will be removed from the Codification and will not become effective for any entity. The Company is currently evaluating the potential impact this standard will have on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses (Subtopic 220-40)* ("ASU 2024-03"). The ASU requires the disaggregated disclosure of specific expense categories, including purchases of inventory, employee compensation, depreciation, and amortization, within relevant income statement captions. This ASU also requires disclosure of the total amount of selling expenses along with the definition of selling expenses. The ASU is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. In January 2025, the FASB issued ASU 2025-01, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40) - Clarifying the Effective Date* to clarify the effective date of ASU 2024-03 for non-calendar year-end entities. ASU 2024-03 is effective for the Company's fiscal year 2027, and interim periods starting in fiscal year 2028. Early adoption is permitted. The amendments in this ASU are to be applied retrospectively to any or all prior periods presented in the consolidated financial statements. Early adoption is also permitted. This ASU will likely result in the required additional disclosures being included in the Company's consolidated financial statements, once adopted. The Company has elected not to early adopt ASU 2024-03. The Company is currently assessing the impact of the disclosure requirements on its consolidated financial statements.

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

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

Subsequent Events

The Company accounts for subsequent events in accordance with ASC 855, *Subsequent Events,* which defines subsequent events as events or transactions that occur after the balance sheet date but before the financial statements are issued. Management has evaluated subsequent events through the date the financial statements were issued and filed with the SEC.

3. Fair Value Measurements and Financial Instruments

For a description of the fair value hierarchy and the fair value methodology, see Note 2 — *Summary of Significant Accounting Policies* in the Annual Report. There were no significant changes in these methodologies during the nine months ended September 30, 2026. As of September 30, 2026, the Company's highly liquid money market funds are included within cash equivalents.

The following tables present the fair value hierarchy for financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents				
Money market funds[1]	$ 20,178	$ —	$ —	$ 20,178
Short-term investments				
Available-for-sale securities				
US government agency securities	—	2,002	—	2,002
Corporate debt securities	—	9,632	—	9,632
Commercial paper	—	995	—	995
Total financial assets	$ 20,178	$ 12,629	$ —	$ 32,807
Financial liabilities:				
Warrant liability, noncurrent	$ —	$ —	$ 3,056	$ 3,056
Total financial liabilities	$ —	$ —	$ 3,056	$ 3,056

	December 31, 2025 (As Recast)			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents				
Money market funds[1]	$ 25,043	$ —	$ —	$ 25,043
Short-term investments				
Available-for-sale securities				
US government agency securities	—	2,000	—	2,000
Corporate debt securities	—	23,146	—	23,146
Commercial paper	—	2,939	—	2,939
Total financial assets	$ 25,043	$ 28,085	$ —	$ 53,128
Financial liabilities:				
Warrant liability, noncurrent	$ —	$ —	$ 2,961	$ 2,961
Total financial liabilities	$ —	$ —	$ 2,961	$ 2,961

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

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

Money market funds are valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. U.S. Treasury securities, commercial paper, corporate debt securities and U.S. government agency securities are valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

During the nine months ended September 30, 2026 and the year ended December 31, 2025, there were no transfers of fair value measurement between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and liabilities.

Warrant Liability

In October 2023, Catalyst entered into a Securities Purchase Agreement for a private placement with GNI USA (the "Private Placement"). Upon closing of the Private Placement, the Company issued 811 shares of Series X Convertible Preferred Stock, par value $0.001 per share (the "Series X Preferred Stock"), and 811 warrants to purchase Series X Preferred Stock (the "Preferred Stock Warrants") to GNI USA for an aggregate purchase price of approximately $5.0 million. The Preferred Stock Warrants are immediately exercisable at an exercise price of $4,915.00 per share of Series X Preferred Stock and expire on October 30, 2033. The number of shares of Common Stock, par value $0.001 per share ("common stock"), issuable upon exercise and conversion of the Preferred Stock Warrants is 540,666. No warrants were exercised as of September 30, 2026. The Company accounted for the Private Placement as a non-arm's length transaction. The Preferred Stock Warrants were initially recognized at fair value upon issuance and the remaining proceeds from the Private Placement were allocated to the Series X Preferred Stock.

The Preferred Stock Warrants are freestanding financial instruments classified as a warrant liability on the Company's condensed consolidated balance sheet. The fair value of the Preferred Stock Warrants is subject to uncertainty due to unobservable inputs, including the expected volatility of the Company's stock price, the likelihood of warrant exercise, and the estimated term of the warrants. Since there is limited market activity for the Preferred Stock Warrants, their fair value is determined using an option pricing model, which incorporates subjective inputs such as the Company's stock price volatility, derived from historical and peer company data, as well as management's expectations regarding future performance. As these assumptions evolve due to market conditions or company specific factors, the warrant liability may experience fluctuations. The Preferred Stock Warrants are revalued each reporting period with the change in fair value recorded as change in fair value of warrant liability in other income, net on the consolidated statement of operations and comprehensive income.

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

	September 30, 2026	December 31, 2025 (As Recast)
Share price	$ 7.33	$ 7.06
Exercise price	$ 4,915.00	$ 4,915.00
Dividend yield	—%	—%
Risk-free interest	5.06%	3.93%
Term (years)	7.08	7.83
Expected volatility	82.00%	81.00%

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

	Warrant liability
Balance at December 31, 2025 (As Recast)	$ 2,961
Changes in fair value	95
Balance at September 30, 2026	$ 3,056

Financial Instruments

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

September 30, 2026	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Money market funds (cash equivalents)	$ 20,178	$ —	$ —	$ 20,178
Short-term bank deposits	15,772	—	—	15,772
Long-term certificates of deposit	28,775	—		28,775
Short-term investments (available-for-sale securities)				—
US government agency securities	2,000	2	—	2,002
Corporate debt securities	9,562	70	—	9,632
Commercial paper	995	—	—	995
Total financial assets	$ 77,282	$ 72	$ —	$ 77,354
Classified as:				
Cash and cash equivalents				$ 20,178
Short-term bank deposits				15,772
Long-term certificates of deposit				28,775
Short-term investments				12,629
Total financial assets				$ 77,354

December 31, 2025 (As Recast)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Money market funds (cash equivalents)	$ 25,043	$ —	$ —	$ 25,043
Short-term bank deposits	15,355	—	—	15,355
Long-term certificates of deposit	23,516	—	—	23,516
Short-term investments (available-for-sale securities)				
US government agency securities	2,000	—	—	2,000
Corporate debt securities	22,866	280	—	23,146
Commercial paper	2,939	—	—	2,939
Total financial assets	$ 91,719	$ 280	$ —	$ 91,999
Classified as:				
Cash and cash equivalents				$ 25,043
Short-term bank deposits				15,355
Long-term certificates of deposit				23,516
Short-term investments				28,085
Total financial assets				$ 91,999

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

	September 30, 2026	
	Amortized Cost	Fair Value
Due in one year	$ 15,772	$ 15,772
Due in one to five years	28,775	28,775
Total	$ 44,547	$ 44,547

Interest income from the short-term bank deposits is recognized on an accrual basis over the term of the deposits. The accrued interest income for the three months ended September 30, 2026 and 2025 was $0.1 million and $0.1 million, respectively. The accrued interest income for the nine months ended September 30, 2026 and 2025 was $0.3 million and $0.4 million, respectively.

Interest income from the long-term certificates of deposit is recognized on an accrual basis over the term of the deposits. The accrued interest income for the three months ended September 30, 2026 and 2025 was $0.1 million and $0.1 million, respectively. The accrued interest income for the nine months ended September 30, 2026 and 2025 was $0.5 million and $0.4 million, respectively.

4. Balance Sheet Components

Inventories

Inventories as of September 30, 2026 and December 31, 2025, consisted of the following components (in thousands):

	September 30, 2026	December 31, 2025 (As Recast)
Raw materials	$ 1,984	$ 970
Work in progress	7,484	6,307
Finished goods	2,751	2,894
Inventories	$ 12,219	$ 10,171

Accrued Expenses and Other Current Liabilities

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

	September 30, 2026	December 31, 2025 (As Recast)
Accrued payroll and other personnel-related expenses	$ 6,512	$ 8,965
Accrued expenses - research and development	2,917	2,161
Payable to property and equipment & intangible asset suppliers	2,647	1,115
Accrued sales rebates	1,716	1,382
Accrued expenses - selling, general and administrative	1,660	2,066
Other accrued liabilities	588	839
Contract liabilities	460	352
Accrued professional services	443	1,184
Deferred government grants	101	97
Accrued expenses and other current liabilities	$ 17,044	$ 18,161

Accounts and Note Receivables, Net

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

	September 30, 2026	December 31, 2025 (As Recast)
Accounts receivable	$ 33,000	$ 31,229
Note receivable	793	5,638
Allowance for credit losses	(337)	(151)
Accounts and note receivables, net	$ 33,456	$ 36,716

Property and Equipment, Net

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

	September 30, 2026	December 31, 2025 (As Recast)
Buildings	$ 20,527	$ 19,568
Construction in progress	565	765
Machinery and electronic devices	10,859	9,895
Furniture and fixtures	856	823
Motor vehicles	197	189
Equipment	5,157	5,073
Leasehold improvements	2,432	2,238
Property and equipment, gross	40,593	38,551
Less: Accumulated depreciation	(13,582)	(11,002)
Property and equipment, net	$ 27,011	$ 27,549

Depreciation expense was $0.3 million and $0.7 million for the three months ended September 30, 2026 and 2025, respectively. Depreciation expense was $2.1 million and $2.0 million for the nine months ended September 30, 2026 and 2025, respectively.

Prepaid Assets and Other Current Assets

Prepaid assets and other current assets consisted of the following (in thousands):

	September 30, 2026	December 31, 2025 (As Recast)
Advances to suppliers	$ 5,271	$ 3,354
Other tax recoverable	1,293	1,949
Prepaid VAT	766	262
Other deposits	86	203
Interest Receivable	3	14
Deferred transaction cost	—	3,831
Prepaid Assets and Other Current Assets	$ 7,419	$ 9,613

Other Assets, Noncurrent

Other assets, noncurrent consisted of the following (in thousands):

	September 30, 2026	December 31, 2025 (As Recast)
Right-of-use assets	$ 2,886	$ 3,609
Land use rights, net	1,456	1,425
Long-term investment	1,595	1,591
Other assets, noncurrent	852	999
Other assets, noncurrent	$ 6,789	$ 7,624

Long-Term Investment Measured Under Equity Method

On June 28, 2024, Gyre Pharmaceuticals entered into a partnership agreement as a limited partner with other investors and is obligated to pay $4.5 million for an 18.93% equity interest in the partnership. In April 2025, a new investor joined the partnership agreement, and as a result, Gyre Pharmaceuticals' equity interest was adjusted to 18.35%. Pursuant to the partnership agreement, Gyre Pharmaceuticals, as a limited partner, shall not participate in any activities related to the management of the investment business. However, Gyre Pharmaceuticals may appoint a member to the advisory committee of the partnership.

As of September 30, 2026 and December 31, 2025, the Company's total investment in the partnership was $1.8 million and $1.7 million, respectively, and the carrying value of the Company's long-term investment in this affiliate, which was included in "Other assets, noncurrent" on the balance sheet, was $1.6 million and $1.6 million, respectively.

5. Intangible Assets

Intangible assets with finite lives consist primarily of patents, technological know-how, computer software, and technology rights. Technology rights refer to the intellectual property ("IP") associated with Etorel™ (nintedanib, ethanesulfonate soft capsules) (the "Etorel™ IP Rights"), which were obtained upon the successful transfer of the marketing authorization holder following approval by the PRC National Medical Products Administration (the "NMPA") in March 2025, and the commercial sales of Etorel™ commenced in June 2025. As of September 30, 2026, the Company recognized the total consideration for the Etorel™ technology rights in the amount of RMB 35.0 million, or approximately $5.2 million, based on the September 30, 2026 spot exchange rate.

The gross carrying amounts and accumulated amortization of the Company's intangible assets with determinable lives as of September 30, 2026 and December 31, 2025 were as follows (in thousands):

	September 30, 2026		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	$ 452	$ (356)	$ 96
Computer software	367	(226)	141
Technology rights	5,197	(1,030)	4,167
Total intangible assets	$ 6,016	$ (1,612)	$ 4,404

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

Intangible assets are carried at cost less accumulated amortization and impairment, if applicable, and the amortization expense is recorded in operating expenses. The weighted average amortization period for the intangible assets was 6.2 years as of September 30, 2026, compared to 7.0 years as of December 31, 2025.

Amortization expense was $0.2 million and $0.2 million for the three months ended September 30, 2026 and 2025, respectively. Amortization expense was $0.5 million and $0.4 million for the nine months ended September 30, 2026 and 2025, respectively. Based on finite-lived intangible assets recorded as of September 30, 2026, the estimated future amortization expense is as follows (in thousands):

	Estimated amortization expense
2026	$ 182
2027	723
2028	692
2029	691
2030	680
Thereafter	1,436
Total	$ 4,404

6. Revenue

The Company's product revenues were mainly generated from the sale of ETUARY™. The Company launched two new products: Contiva™ (avatrombopag maleate tablets), which commenced commercialization in March 2025, and Etorel™, which commenced commercialization in June 2025. The Company also generated collaboration revenue from collaboration agreements with strategic partners. Collaboration revenue consists primarily of upfront nonrefundable payments and reimbursements for research and development services performed under this arrangement. The following table summarizes the composition of the Company's revenues for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Revenue Composition	2026		2025 (As Recast)		2026		2025 (As Recast)	
ETUARY™	$ 31,384	95.3%	$ 27,694	84.8%	$ 80,310	92.9%	$ 72,916	78.4%
Contiva™	59	0.2%	1,245	3.8%	1,791	2.1%	3,024	3.3%
Etorel™	983	3.0%	1,544	4.7%	1,910	2.2%	3,140	3.4%
Other Products	—	0.0%	81	0.2%	31	0.0%	313	0.3%
Collaborations	508	1.5%	2,130	6.5%	2,427	2.8%	13,606	14.6%
Total	$ 32,934	100%	$ 32,694	100%	$ 86,469	100%	$ 92,999	100%

Sales of Pharmaceutical Products

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

Product returns to date have not been significant and the Company has not considered it necessary to record a reserve for product returns. The Company's product revenues were recognized at a point in time when the underlying product was delivered to the customer, which was when the customer obtained control of the product. Revenue from sales of pharmaceutical products was $32.4 million and $30.6 million for the three months ended September 30, 2026 and 2025, respectively. Revenue from sales of pharmaceutical products was $84.0 million and $79.4 million for the nine months ended September 30, 2026 and 2025, respectively. All sales are generated in the PRC. Contract liabilities recognized for the three and nine months ended September 30, 2026 were immaterial.

Collaborations

In June 2023, Cullgen entered into a Collaboration, Option and License Agreement (the "Astellas Agreement") with Astellas Pharma Inc. to discover multiple innovative protein degraders, including cell cycle and DNA repair degraders. Upon execution of the agreement, Cullgen received a nonrefundable upfront payment and is entitled to reimbursement for research and development services performed under the agreement. The Astellas Agreement ended in March 2026.

The Company determined that the Astellas Agreement is within the scope of ASC 606 and identified two performance obligations related to the pre-exercise research activities for the cell cycle and DNA repair programs. The upfront payment was allocated to the performance obligations based on their relative standalone selling prices. Revenue associated with the upfront payment and research reimbursements is recognized over time using a cost-based measure of progress.

Contract liabilities primarily consist of the unrecognized portion of the upfront payment received under the Astellas Agreement and are recognized as revenue as the related performance obligations are satisfied. No contract liabilities associated with Astellas Agreement existed as of September 30, 2026 as the agreement ended in March 2026. Contract liabilities were $1.0 million as of December 31, 2025, and the Company recognized $1.0 million in revenue from the contract liabilities during the nine months ended September 30, 2026.

7. Leases

Operating Leases

As of September 30, 2026, Gyre Pharmaceuticals maintained leases for office spaces in the following locations: in Beijing, comprising approximately 2,130 square meters with a lease expiration in June 2027; in Zhengzhou, comprising approximately 180 square meters with a lease expiration in August 2027; in Shanghai, comprising approximately 224 square meters with a lease expiration in December 2026; in Nanjing, comprising approximately 70 square meters with a lease expiration in February 2027; and in Beijing, for a staff dormitory comprising approximately 249 square meters with a lease expiration in March 2028. Cullgen maintained leases for research and office facilities in Shanghai, China, comprising multiple buildings and floors with lease expirations ranging from February 2029 to February 2037; in San Diego for office facility with lease expiration in July 2028. In connection with the Merger, the Company early terminated the lease for its U.S. headquarters in San Diego, California, and relocated its U.S. headquarters to Cullgen's leased facility in San Diego, California, with a lease expiration in July 2028.

The Company also has multiple short-term leased properties used as offices and employee dormitories. The Company recorded a total of $22 thousand and $17 thousand in short-term rent expenses during the three months ended September 30, 2026 and 2025, respectively. The Company recorded a total of $57 thousand and $49 thousand in short-term rent expenses during the nine months ended September 30, 2026 and 2025, respectively. The short-term rent expense amounts are recorded in operating expenses in the accompanying condensed consolidated statements of operations and comprehensive income.

As of September 30, 2026, the Company recorded an aggregate right-of-use asset of $4.3 million, and an aggregate lease liability of $3.0 million in the accompanying condensed consolidated balance sheets.

For the three months ended September 30, 2026 and 2025, the Company’s operating lease expense was $0.4 million and $0.3 million, respectively. For the nine months ended September 30, 2026 and 2025, the Company's operating lease expense was $1.3 million and $1.2 million, respectively. Variable lease payments for the three and nine months ended September 30, 2026 and 2025 were immaterial.

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

	Nine Months Ended September 30,	
	2026	2025 (As Recast)
Cash paid for amounts included in the measurement of lease liabilities	$ 1,006	$ 1,274

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

	September 30, 2026	December 31, 2025 (As Recast)
Weighted-average remaining lease term	5.4 years	5.4 years
Weighted-average discount rate	7.61%	7.81%

As of September 30, 2026, undiscounted future minimum payments under the Company's operating leases were as follows (in thousands):

	Amount
Remaining in 2026	$ 365
2027	1,152
2028	694
2029	224
2030	198
Thereafter	1,202
Total undiscounted lease payments	3,835
Less: imputed interest	(825)
Total lease liabilities	3,010
Less: current portion of lease liabilities	(1,143)
Lease liabilities, net of current portion	$ 1,867

The Company is required to maintain security deposits of $0.5 million in connection with various leases, which amounts are included in other assets, noncurrent on the Company's condensed consolidated balance sheets.

Land Use Rights

As of September 30, 2026, the Company held land use rights for two land parcels in Beijing's Shunyi District, expiring in 2053, and in Cangzhou, Hebei Province, expiring from 2067 to 2070. These parcels, with a combined area of approximately 66,559 square meters, are utilized as manufacturing facilities. As of September 30, 2026, the aggregate carrying amount of the land use rights, net assets for these parcels was $1.5 million.

8. Stockholders' Equity

Merger With Cullgen

On May 4, 2026, the Company completed its merger with Cullgen. Pursuant to the Merger Agreement, all outstanding shares of Cullgen common stock and redeemable convertible preferred stock were converted into shares of the Company's common stock or Series B Preferred Stock based on the exchange ratios specified in the Merger Agreement. 57,821,355 shares of Cullgen redeemable convertible preferred stock and 10,023,615 shares of Cullgen common stock were converted into an aggregate of 3,697,235 shares of the Company's Series B Preferred Stock and 14,450,527 shares of the Company's common stock. Upon completion of the Merger, no shares of Cullgen common stock or redeemable convertible preferred stock remained outstanding. Cullgen redeemable convertible preferred stock carrying amount was adjusted to the redemption amount as of the balance sheet date and immediately before the Merger Closing Date in accordance with ASC 480-10-S99. The redeemable convertible preferred stock that was held by shareholders other than GNI Japan was separately disclosed as Redeemable noncontrolling interests — Cullgen redeemable convertible preferred stock on the unaudited condensed consolidated balance sheet as of December 31, 2025.

Common Stock

Common stock reserved for future issuance is as follows:

	September 30, 2026		December 31, 2025 (As Recast)
Options issued and outstanding	23,404,916	(1)	23,580,270
Preferred Stock Warrants issued and outstanding	540,666		540,666
Series B Preferred Stock issued and outstanding as converted	17,762,135	(2)	—
Total common stock reserved	41,707,717		24,120,936

(1) Includes 5,869,446 options exercisable for shares of common stock, which underlying shares of common stock were transferred in the name of the Company to Futu Network Technology Limited, the stock plan administrator of the 2023 Omnibus Incentive Sub-Plan for Chinese Participants.
(2) Includes 3,552,427 Series B preferred stock convertible for shares of common stock with a conversion ratio of 5.0.

2024 ATM Program

On November 27, 2024, the Company entered into an Open Market Sale Agreement (the "ATM Agreement") with Jefferies LLC (the "Sales Agent") as sales agent, pursuant to which the Company may offer and sell, from time to time, through the Sales Agent, shares of common stock with aggregate gross sales proceeds of up to $50.0 million through an at-the-market offering program (the "ATM Program"). The Company will pay the Sales Agent a commission of up to 3% of the gross proceeds of any shares sold. The Company also agreed to reimburse the Sales Agent for certain expenses incurred in connection with its services under the ATM Agreement, including up to $135,000 for legal expenses in connection with the establishment of the ATM Program. During the nine months ended September 30, 2025, the Company sold 54,734 shares of common stock under the ATM Program and received net proceeds of $0.5 million, after deducting commissions and offering costs of $8.6 thousand. During the nine months ended September 30, 2026, there were no sales under the ATM Program.

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

May 2025 Underwritten Public Offering

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

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

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

Conversion of Series B Preferred Stock

During the nine months ended September 30, 2026, the Company issued 724,045 shares of common stock upon the conversion of 144,808 shares of Series B Preferred Stock. The carrying value of the converted Series B Preferred Stock was reclassified from temporary equity to permanent stockholders' equity and recorded as common stock and additional paid-in capital. As of September 30, 2026, 3,552,427 shares of Series B Preferred Stock remained outstanding.

Subsequent to September 30, 2026, on October 22, 2026, 475,300 shares of Series B Preferred Stock were converted into 2,376,500 shares of the Company's common stock pursuant to the conversion provisions of the Series B Preferred Stock.

Restricted Net Assets

Under PRC laws and regulations, Gyre Pharmaceuticals and Cullgen Shanghai are subject to restrictions on foreign exchange and cross-border cash transfers, including to parent companies and U.S. stockholders. The ability to distribute earnings to the parent companies and U.S. stockholders is also limited. Current PRC regulations permit Gyre Pharmaceuticals to pay dividends to BJContinent Pharmaceuticals Limited ("BJC") only out of its accumulated profits as determined in accordance with PRC accounting standards and regulations. Amounts restricted include paid-in capital and the statutory reserves of Gyre Pharmaceuticals. The aggregate amounts of restricted capital and statutory reserves, which represented the amount of net assets of the relevant subsidiaries not available for distribution were $132.3 million and $128.1 million as of September 30, 2026 and December 31, 2025, respectively.

Statutory Reserve

Gyre Pharmaceuticals is required to set aside at least 10% of its after-tax profits as the statutory reserve fund until the cumulative amount of the statutory reserve fund reaches 50% or more of its registered capital, if any, to fund its statutory reserves, which are not available for distribution as cash dividends. At the Company's discretion, the Company may allocate a portion of after-tax profits based on PRC accounting standards to a discretionary reserve fund. Appropriations to these reserves were $0.6 million and $0.0 million for the nine months ended September 30, 2026 and 2025, respectively.

Noncontrolling Interest

The noncontrolling interests in the Company's consolidated financial statements represent the economic interests in Gyre Pharmaceuticals held by shareholders other than BJC and four other holding company subsidiaries of the Company. As of September 30, 2026, the Company's indirect ownership in Gyre Pharmaceuticals is 69.7%.

In accordance with ASC 810-10, the noncontrolling interests also reflected Cullgen's net income or loss, accretion of Cullgen redeemable convertible preferred stock, and comprehensive income or loss that are attributable to the 61.5% ownership of Cullgen held by parties other than GNI Japan prior to the Merger Closing Date. The Company acquired all the Cullgen ownership interests upon the Merger.

9. Stock Based Compensation

2023 Omnibus Incentive Plan

The Gyre Therapeutics, Inc. 2023 Omnibus Incentive Plan (the "2023 Omnibus Incentive Plan") was approved by Catalyst's stockholders in August 2023 and ratified by Gyre's Board in October 2023. The 2023 Omnibus Incentive Plan became effective on October 30, 2023. The 2023 Omnibus Incentive Plan permits the Company to issue up to 17,845,496 shares of common stock and will automatically increase by the lesser of (i) 5% of the total number of outstanding shares of common stock on December 31st of the preceding calendar year and (ii) such smaller number of shares of common stock as determined by Gyre's Board on the first day of each fiscal year beginning on January 1, 2024. On January 1, 2024, January 1, 2025 and January 1, 2026, an additional 3,829,780, 4,315,377 and 4,565,700 shares of common stock, respectively, were reserved for issuance under the 2023 Omnibus Incentive Plan. During the nine months ended September 30, 2025, certain members of senior management were granted both awards subject solely to time-based vesting requirements and awards that are subject to the achievement of certain levels of specific performance, in addition to time-based vesting requirements (the "Performance-Based Awards"). These Performance-Based Awards are subject to the achievement of certain sales metrics and approval of Hydronidone for commercialization and may vest in full after two or three years. The awards become eligible to vest only if the goals are achieved and will vest only if the grantee remains employed by the Company through each applicable vesting date.

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

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

The following table summarizes 2023 Omnibus Incentive Plan activity for the nine months ended September 30, 2026:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Outstanding — December 31, 2025	19,483,378	$ 3.27	5.9
Options granted	700,000	6.40	
Options exercised	(580,046)	0.76	
Options forfeited and cancelled	(325,625)	9.61	
Outstanding — September 30, 2026	19,277,707	$ 3.35	5.3
Exercisable — September 30, 2026	16,172,586	$ 2.20	4.6

Valuation Assumptions

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

The Company also granted performance-based stock options that vest under two types of independent performance conditions. One condition is tied to a certain sales target that is deemed not probable as of September 30, 2026. The other condition is tied to the approval in the PRC of a New Drug Application ("NDA") for Hydronidone. The grant-date fair value of these awards was determined using the Black-Scholes Option Pricing Model, which incorporates key inputs such as stock price, exercise price, expected volatility, risk-free interest rate, time to expiration, and a zero-dividend yield.

The following table shows the weighted-average grant date fair value of options and the assumptions used to estimate the fair value for time-based awards, and for performance-based awards during the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Time-based and performance-based awards	2026	2025	2026	2025
Weighted-average grant-date fair value	$ 4.37	$ 5.09	$ 4.53	$ 7.25
Risk-free interest rate (%)	4.41%	3.84% - 3.91%	3.78% - 4.41%	3.84% - 4.40%
Expected option life (in years)	5.77	5.81-6.08	5.27 - 6.08	5.27 - 6.41
Expected dividend yield (%)	—%	—%	—%	—%
Volatility (%)	82.0%	81.5%	79.3% - 82.0%	81.5% - 84.3%

Amended and Restated 2018 Cullgen Stock Incentive Plan (the "Cullgen Plan")

The Cullgen Plan provides for the issuance of stock-based awards, including stock options, restricted stock awards, restricted stock units, and other equity-based awards, to officers, directors, employees, and consultants of Cullgen. The plan authorized issuance of up to 9,000,000 shares of Cullgen common stock. Stock options granted under the plan generally vest over four years, are exercisable at prices determined by the board of directors at the date of grant, and expire no later than ten years from issuance or five years for incentive stock options granted to a 10% stockholder.

In connection with the Merger, the Company assumed and amended and restated the 2018 Cullgen Stock Incentive Plan and all outstanding stock options and other equity awards granted thereunder. Each outstanding Cullgen equity award was converted into the right to receive 0.4753 shares (the "Exchange Ratio") with respect to the Company's common stock, with corresponding adjustments to the number of shares subject to each award and the exercise price, as applicable (hereinafter the "Assumed Awards"). The Assumed Awards have the same terms and conditions including any vesting provisions and any provisions providing for accelerated vesting upon certain events as were applicable under such incentive plan as of immediately prior to the Merger.

As of the Merger Closing Date, 4,156,800 shares of the Company's common stock were reserved for issuance upon the exercise or vesting of the Assumed Awards. The Company accounts for the Assumed Awards in accordance with ASC 718, Compensation—Stock Compensation.

The following table summarizes Cullgen stock option activity for the nine months ended September 30, 2026 on a post conversion basis:

	Number of Shares Underlying Outstanding Options		Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Outstanding — December 31, 2025	4,096,892		$ 2.02	5.0
Options granted	71,295		8.09	
Options exercised	(7,228)	(1)	3.12	
Options forfeited and cancelled	(33,750)		5.06	
Outstanding — September 30, 2026	4,127,209		$ 2.10	4.9
Exercisable — September 30, 2026	3,734,069		$ 1.59	3.6

(1) Certain options were exercised for Cullgen common stock prior to the merger, and the resulting shares were subsequently converted into Gyre common shares upon consummation of the merger.

Valuation Assumptions

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

The following table shows the weighted-average grant date fair value of options and the assumptions used to estimate the fair value for time-based awards, and for performance-based awards during the three and nine months ended September 30, 2026:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Time-based awards	2026	2025	2026	2025
Weighted-average grant-date fair value	n/a	n/a	$ 7.22	n/a
Risk-free interest rate (%)	n/a	n/a	3.58%	n/a
Expected option life (in years)	n/a	n/a	7.0	n/a
Expected dividend yield (%)	n/a	n/a	—%	n/a
Volatility (%)	n/a	n/a	130.3%	n/a

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025 (As Recast)	2026	2025 (As Recast)
Cost of revenues	$ 55	$ 38	$ 355	$ 85
Selling and marketing	279	24	1,925	53
Research and development	263	59	681	202
General and administrative	1,137	1,213	3,431	2,937
Total stock-based compensation expense	$ 1,734	$ 1,334	$ 6,392	$ 3,277

As of September 30, 2026, the Company had an unrecognized stock-based compensation expense of $11.0 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 1.9 years.

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

The dilutive effect of outstanding stock options and warrants is calculated using the treasury stock method. Stock options and warrants are excluded from the diluted EPS attributable to common stock calculation if they have an anti-dilutive effect. If there is a net loss for the period, all options are excluded from the diluted EPS calculation.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025 (As Recast)	2026	2025 (As Recast)
Numerator:				
Net (loss) income	$ (2,478)	$ 1,927	$ (35,327)	$ 4,629
Add: Accretion of Cullgen redeemable convertible preferred stock	—	(2,707)	(3,905)	(7,927)
Less: Allocation of undistributed loss to noncontrolling interest	1,575	(1,805)	(10,370)	(4,449)
Net (loss) income attributable to common stockholders - basic	$ (4,053)	$ 1,025	$ (28,862)	$ 1,151
Less: Change in fair value of warrant liability	—	—	—	2,444
Net (loss) income attributable to common stockholders - diluted	$ (4,053)	$ 1,025	$ (28,862)	$ (1,293)
Denominator:				
Basic common shares outstanding:				
Weighted average common shares outstanding	106,302,559	90,850,040	99,473,991	88,812,863
Weighted average shares used in calculating net (loss) income per share attributable to common stockholders, basic	106,302,559	90,850,040	99,473,991	88,812,863
Dilutive potential common shares:				
Weighted average of common stock options	—	13,105,838	—	—
Weighted average of preferred stock warrants (as converted)	—	—	—	100,640
Weighted average shares used in calculating net loss per share attributable to common stockholders, diluted	106,302,559	103,955,878	99,473,991	88,913,503
Net (loss) income per share attributable to common stockholders:				
Basic	$ (0.04)	$ 0.01	$ (0.29)	$ 0.01
Diluted	$ (0.04)	$ 0.01	$ (0.29)	$ (0.01)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025 (As Recast)	2026	2025 (As Recast)
Options to purchase common stock	32,485,349	257,464	33,323,986	15,695,867
Series B preferred stock (as converted)	17,762,135	—	17,762,135	—
Redeemable convertible preferred stock (as converted)	—	27,482,490	—	27,482,490
Warrants to purchase preferred stock (as converted)	540,666	540,666	540,666	—
Total	50,788,150	28,280,620	51,626,787	43,178,357

11. Commitments and Contingencies

Litigation and Legal Matters

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

Purchasing Commitments

Property and Equipment

The Company's commitments related to purchase of property and equipment contracted but not yet reflected in the condensed consolidated financial statements were $4.9 million as of September 30, 2026 and are expected to be incurred within one year.

Etorel™ IP Rights

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

According to the agreement, except for RMB 35.0 million, or approximately $5.2 million based on the September 30, 2026 spot exchange rate, the Company is committed to additional annual payments over eight years following the commencement of commercial sales in June 2025, which will be contingent consideration based on actual annual sales in future years. For each of the first two years starting from June 2025, the minimum annual commission is RMB 10 million, or approximately $1.5 million, based on the September 30, 2026 spot exchange rate, which has already been included in the IP cost. If the sales-based commission calculated at 5% of annual sales in the first year exceeds RMB 10 million (approximately $1.5 million, based on the September 30, 2026 spot exchange rate) or the commission calculated at 4% of annual sales in the second year exceeds RMB 10 million (approximately $1.5 million, based on the September 30, 2026 spot exchange rate), the excess amount for each year will be recognized as contingent consideration. For the third year through the eighth year, the contingent payments will be calculated at 3%, 2%, 2%, 1%, 1%, and 1% of sales in each year, respectively.

As of September 30, 2026, the Company assessed the possibility that annual sales commissions in the second year would exceed RMB 10 million, or approximately $1.5 million, based on the September 30, 2026 spot exchange rate, as remote and did not accrue any contingent consideration.

As of September 30, 2026, the total accrued contract consideration was $1.8 million, which was recorded under accrued expenses and other current liabilities.

Hydronidone (F351)

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

Under the Hydronidone Transfer Agreement, in exchange for the Hydronidone IP Rights, Gyre Pharmaceuticals is obligated to pay RMB 8.3 million, or approximately $1.2 million, based on the September 30, 2026 spot exchange rate, after the NDA passes the NMPA's Center for Food and Drug Review and Inspection's on-site registration inspection for the Hydronidone product; and RMB 49.6 million, or approximately $7.4 million, based on the September 30, 2026 spot exchange rate upon the NMPA's approval of the NDA. As of September 30, 2026, the next payment conditions have not been met; as such, no payments have been accrued.

Upon Hydronidone product achieving commercialization, the Company will be required to make annual royalty payments based on future product sales. These contingent payments are structured as twelve annual royalties equal to 10%, 14%, 16%, 16%, 16%, 16%, 16%, 15%, 14%, 12%, 10%, and 8% of annual sales. As of September 30, 2026, commercialization has not yet been achieved, and no royalty payments have been incurred or accrued.

SDM Service

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

Under the SDM Clinical Trial Agreement, the Company is obligated to make payments based on the achievement of specified clinical and operational milestones and the performance of clinical trial–related services, including trial preparation, patient enrollment and follow-up, site management, interim analyses, data management–related activities, and preparation of the clinical study report. The aggregate contractual amount under the agreement is approximately RMB 114.0 million, or approximately $16.9 million, based on the September 30, 2026 spot exchange rate.

As of September 30, 2026, the Company recognized $2.8 million in research and development expenses and made payments of $4.9 million under the SDM Clinical Trial Agreement.

Research and Development Programs

In addition to the $8.6 million commitment to GNI Group for the Hydronidone program, as of September 30, 2026, Gyre Pharmaceuticals has committed to allocate $37.3 million toward future research and development activities for various programs. Gyre Therapeutics has not committed to allocate any amount toward research and development activities.

Indemnification Agreements

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

12. Income Taxes

During the three and nine months ended September 30, 2026 and 2025, the Company recorded the following income tax provision (in thousands) and effective tax rate:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025 (As Recast)	2026	2025 (As Recast)
(Benefit) provision for income tax	$ 733	$ 593	$ 1,118	$ 2,156
Effective tax rate	-42.01%	23.53%	-3.27%	31.78%

The change in effective tax rate for the three and nine months ended September 30, 2026 and 2025 was primarily due to the business combination with Cullgen and the increase of research and development expenditures. The Company expects to incur income tax expense for the current period as a result of the impact of valuation allowance. Accordingly, the effective tax rate for the nine months ended September 30, 2026 was negative. The Company's income tax provision reflects the retrospective presentation of the common-control combination with Cullgen.

As of September 30, 2026, after consideration of certain limitations (see below), the Company had approximately $200.4 million federal and $39.8 million state net operating loss ("NOL") carryforwards for U.S. tax purposes available to reduce future taxable income which, if unused, will begin to expire in 2037 for federal and 2034 for state tax purposes. The federal net operating loss carryforward includes $199.0 million that has an indefinite life.

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

13. Related Party Transactions

Research and Development with GNI Group

Research and development expenses for the services received from Shanghai Genomics, Inc. ("Shanghai Genomics"), a wholly owned subsidiary of GNI Group, were $0.2 million and $0.1 million for the three months ended September 30, 2026 and 2025, respectively. Research and development expenses for the related services received from Shanghai Genomics were $5.3 million and $0.3 million for the nine months ended September 30, 2026 and 2025, respectively. The amount for the nine months ended September 30, 2026 included a milestone payment of RMB 33.1 million (approximately $4.9 million, based on the September 30, 2026 spot exchange rate) recognized under the Hydronidone Transfer Agreement upon the submission and acceptance of the Hydronidone NDA by the Center for Drug Evaluation ("CDE") of the National Medical Products Administration ("NMPA"). As of September 30, 2026, the related payment has been accrued under due to related parties in the condensed consolidated balance sheets. No payments for such services were made to entities controlled by GNI Group during the three and nine months ended September 30, 2026 and 2025. As of September 30, 2026 and December 31, 2025, the Company had related parties payables of $4.9 million primarily due to an affiliate of GNI Group and $0.2 million due to GNI Group, respectively.

Other Receivables from GNI

As of September 30, 2026 and December 31, 2025, the Company had recorded $0.3 million and $0.2 million in other receivables from GNI Group, all of which related to Continent Pharmaceuticals Inc.'s ("CPI") restructuring transaction.

Operating Lease with Shanghai Genomics, Inc.

As of September 30, 2026 and December 31, 2025, operating lease ROU assets and operating lease liabilities recognized for leases were as follows (in thousands):

	September 30, 2026	December 31, 2025 (As Recast)
Operating lease right-of-use assets	$ 1,283	$ 1,296
Operating lease liabilities, current	(70)	(96)
Operating lease liabilities, non-current	(1,229)	(1,227)

The related lease expense recognized from related parties included in "Research and development expenses" and "General and administrative expenses" in the condensed consolidated statements of operations and comprehensive (loss) income was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025 (As Recast)	2026	2025 (As Recast)
Research and development expenses	$ 293	$ 514	$ 396	$ 663
General and administrative expenses	-	49	60	49
Total	$ 293	$ 563	$ 456	$ 712

14. Employee Benefit Plans

Mainland China Contribution Plan

Pursuant to relevant PRC regulations, the Company is required to make contributions to various defined contribution plans organized by municipal and provincial PRC governments. The contribution for each employee is based on a percentage of the employee's current compensation as required by the local government. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme. The total contributions for such employee benefits were $1.9 million and $1.8 million for the three months ended September 30, 2026 and 2025, respectively. The total contributions for such employee benefits were $5.5 million and $5.2 million for the nine months ended September 30, 2026 and 2025, respectively.

Defined-Contribution Savings Plan

In the U.S., the Company maintains a defined-contribution savings plan pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan is available to employees who meet the minimum age and length of service requirements. The contributions made during the three months ended September 30, 2026 and 2025 were $36.7 thousand and $36.6 thousand, respectively. The contributions made during the nine months ended September 30, 2026 and 2025 were $107.5 thousand and $107.4 thousand, respectively.

15. Segment Information

The Company is a consolidated entity comprised of two reporting segments: Gyre Pharmaceuticals, and Gyre. The Company's reportable segments are based upon internal organizational structure, the manner in which operations are managed, the criteria used by the CODM to evaluate segment performance, the availability of separate financial information, and overall materiality considerations. Gyre's operations are primarily located in the United States and Shanghai, China, and Gyre Pharmaceuticals' operations are primarily located in mainland China.

Gyre Pharmaceuticals

Gyre Pharmaceuticals has three major commercial drug products ETUARY™, Etorel™, and Contiva™—as well as several product candidates in pre-clinical and clinical development. Gyre Pharmaceuticals' product revenues are mainly generated from the sale of ETUARY™, Etorel™, Contiva™ and certain generic drugs. Gyre Pharmaceuticals primarily sells its pharmaceutical products to distributors in the PRC, who ultimately sell the products to hospitals, other medical institutions and pharmacies.

Gyre

Gyre is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of innovative therapies for the treatment of cancer, inflammatory diseases and organ fibrosis. The Company's pipeline includes F351 for the treatment of MASH-associated liver fibrosis in the United States, as well as targeted protein degrader and degrader-antibody conjugate therapies under development including CG001419 for pain and solid tumors and CG009301 for acute myeloid leukemia ("AML") in China. The Company is primarily engaged in research and development activities and does not currently generate commercial product revenue.

Segment information for the three and nine months ended September 30, 2026 and 2025 is as follows (in thousands):

	Three Months Ended September 30, 2026		
	Gyre Pharmaceuticals	Gyre	Total
Revenues	$ 32,426	$ 508	$ 32,934
Operating expenses			
Cost of revenues	1,947	—	1,947
Selling and marketing	15,028	—	15,028
Research and development	5,117	3,367	8,484
Research and development - related parties	24	—	24
General and administrative	4,323	4,624	8,947
Transaction costs	—	50	50
Total segment operating expenses	26,439	8,041	34,480
Income (loss) from segment operations	5,987	(7,533)	(1,546)
Other segment income (loss), net:			
Interest income	243	345	588
Other expense, net	(312)	(186)	(498)
Change in fair value of warrant liability	—	(315)	(315)
Provision for income taxes	(732)	(1)	(733)
Net segment income (loss)	$ 5,186	$ (7,690)	$ (2,504)
Reconciliation of profit or loss			
Other general and administrative expenses			(26)
Total consolidated net loss			$ (2,478)
Supplemental disclosure of stock-based compensation expense:			
Cost of revenue	$ 55	$ —	$ 55
Selling and marketing	279	—	279
Research and development	202	61	263
General and administrative	230	907	1,137
Stock-based compensation total	$ 766	$ 968	$ 1,734

	Nine Months Ended September 30, 2026		
	Gyre Pharmaceuticals	Gyre	Total
Revenues	$ 84,042	$ 2,427	$ 86,469
Operating expenses			
Cost of revenues	5,383	—	5,383
Selling and marketing	42,918	—	42,918
Research and development	20,280	13,985	34,265
Research and development - related parties	4,860	—	4,860
General and administrative	13,348	13,631	26,979
Transaction costs	—	6,936	6,936
Total segment operating expenses	86,789	34,552	121,341
Loss from segment operations	(2,747)	(32,125)	(34,872)
Other segment income (loss), net:			
Interest income	760	1,311	2,071
Other expense, net	(1,130)	(198)	(1,328)
Change in fair value of warrant liability	—	(95)	(95)
(Provision) benefit for income taxes	(1,188)	70	(1,118)
Net segment loss	$ (4,305)	$ (31,037)	$ (35,342)
Reconciliation of profit or loss			
Other general and administrative expenses			(15)
Total consolidated net loss			$ (35,327)
Supplemental disclosure of stock-based compensation expense:			
Cost of revenue	$ 355	$ —	$ 355
Selling and marketing	1,925	—	1,925
Research and development	396	285	681
General and administrative	1,009	2,422	3,431
Stock-based compensation total	$ 3,685	$ 2,707	$ 6,392

	Three Months Ended September 30, 2025 (As Recast)		
	Gyre Pharmaceuticals	Gyre	Total
Revenues	$ 30,564	$ 2,130	$ 32,694
Operating expenses:			
Cost of revenues	1,628	—	1,628
Selling and marketing	15,328	—	15,328
Research and development	2,145	5,652	7,797
General and administrative	2,594	3,846	6,440
Total segment operating expenses	21,695	9,498	31,193
Income (loss) from segment operations	8,869	(7,368)	1,501
Other segment income (loss), net:			
Interest income	295	659	954
Other income (expense), net	213	(118)	95
Change in fair value of warrant liability	-	(23)	(23)
Provision for income taxes	(1,691)	1,098	(593)
Net segment income (loss)	$ 7,686	$ (5,752)	$ 1,934
Reconciliation of profit or loss			
Other general and administrative expenses			7
Total consolidated net income			$ 1,927
Supplemental disclosure of stock-based compensation expense:			
Cost of revenue	$ 38	$ —	$ 38
Selling and marketing	24	—	24
General and administrative	277	936	1,213
Research and development	—	59	59
Stock-based compensation total	$ 339	$ 995	$ 1,334

	Nine Months Ended September 30, 2025 (As Recast)		
	Gyre Pharmaceuticals	Gyre	Total
Revenues	$ 79,393	$ 13,606	$ 92,999
Operating expenses:			
Cost of revenues	3,673	—	3,673
Selling and marketing	41,363	—	41,363
Research and development	8,511	15,728	24,239
General and administrative	9,008	12,908	21,916
Total segment operating expenses	62,555	28,636	91,191
Income (loss) from segment operations	16,838	(15,030)	1,808
Other segment income (loss), net:			
Interest income	850	1,901	2,751
Other (expense) income, net	(516)	310	(206)
Change in fair value of warrant liability	—	2,444	2,444
(Provision) benefit for income taxes	(3,254)	1,098	(2,156)
Net segment income (loss)	$ 13,918	$ (9,277)	$ 4,641
Reconciliation of profit or loss			
Other general and administrative expenses			12
Total consolidated net income			$ 4,629
Supplemental disclosure of stock-based compensation expense:			
Cost of revenue	$ 85	$ —	$ 85
Selling and marketing	53	—	53
General and administrative	628	2,309	2,937
Research and development	—	202	202
Stock-based compensation total	$ 766	$ 2,511	$ 3,277

The table below presents total assets as of September 30, 2026 and December 31, 2025.

	September 30, 2026			
	Gyre Pharmaceuticals	Gyre	Other Unallocated Amount	Consolidated
Total assets	$ 147,171	$ 53,723	$ 357	$ 201,251

	December 31, 2025 (As Recast)			
	Gyre Pharmaceuticals	Gyre	Other Unallocated Amount	Consolidated
Total assets	$ 138,407	$ 81,000	$ 356	$ 219,763

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

	Nine Months Ended September 30, 2026		
	Gyre Pharmaceuticals	Gyre	Consolidated
Purchase of property and equipment	$ 1,293	$ 126	$ 1,419

	Nine Months Ended September 30, 2025 (As Recast)		
	Gyre Pharmaceuticals	Gyre	Consolidated
Purchase of property and equipment	$ 1,046	$ 151	$ 1,197

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

In this Quarterly Report on Form 10-Q (this "Quarterly Report"), unless otherwise specified, references to "we," "our," "us" and "our company" refer to Gyre Therapeutics, Inc. ("Gyre"), its directly owned subsidiary, Cullgen Inc. ("Cullgen"), and our majority indirectly owned subsidiary, Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals Co., Ltd.) ("Gyre Pharmaceuticals"). The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and related notes that appear in this Quarterly Report and with the audited consolidated financial statements and related notes that are included as part of our Annual Report on Form 10-K for the year ended December 31, 2025 (the "Annual Report").

In addition to historical information, this Quarterly 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 Quarterly 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 Quarterly Report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

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

In May 2026, we acquired Cullgen in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated March 2, 2026 (the "Merger Agreement"), by and among the Company, Helix Merger Sub Corp., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub"), and Cullgen. Pursuant to the Merger Agreement, among other matters, Merger Sub merged with and into Cullgen, with Cullgen continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the "Merger"). The related transaction costs were expensed as incurred.

Cullgen is a clinical-stage biopharmaceutical company focused on the discovery and development of targeted protein degrader and degrader-antibody conjugate therapies designed to improve the lives of patients suffering from critical conditions such as pain, cancer and inflammatory diseases. Cullgen has created a portfolio of highly selective targeted protein degrader product candidates designed to potently and efficiently eliminate therapeutically relevant proteins in patients. By leveraging its expertise in targeted protein degraders, Cullgen believes its product candidates have many distinct advantages over other therapeutic modalities, including higher selectivity, improved therapeutic profile and avoidance of known toxicities.

As always, we are in the process of reviewing our programs and evaluating our pipeline and clinical development strategy, including in connection with the Cullgen acquisition, to optimize capital allocation and prioritize programs across the organization. As a result of the Cullgen acquisition, we intend to leverage Cullgen's capabilities in the PRC for the development and early-stage clinical trials of various product candidates.

Our Commercial Portfolio

ETUARY™ (pirfenidone)

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

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

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

Etorel™ (nintedanib esilate soft capsules)

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

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

Contiva™ (avatrombopag maleate tablets)

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

Our Product Candidate Pipeline

F351 (hydronidone)

F351 is our lead development candidate for the treatment of liver fibrosis. It is a structurally modified derivative of pirfenidone designed to optimize metabolic properties while targeting the transforming growth factor ("TGF")-β1 signaling pathway, a key mediator of fibrogenesis. We are developing F351 for two primary indications: chronic hepatitis B ("CHB")-associated liver fibrosis in the PRC and metabolic dysfunction-associated steatohepatitis ("MASH")-associated liver fibrosis in the United States. F351 represents our primary liver-focused development program and reflects our commitment to advancing therapies targeting both viral- and metabolic-associated liver fibrosis.

CHB-Associated Liver Fibrosis (PRC)

For CHB-associated liver fibrosis, antiviral therapy may suppress viral infection but is not able to prevent, slow or reverse fibrosis progression, and anti-fibrotic treatment is recommended for intermediate and advanced liver fibrosis and early-stage cirrhosis. As of December 31, 2025, no small molecule or biologic drugs treating CHB-associated liver fibrosis have been approved globally. In recognition of the severity of the disease, lack of current therapies and the preliminary clinical evidence generated to date, the Center for Drug Evaluation ("CDE") of the NMPA granted F351 Breakthrough Therapy designation in March 2021.

We conducted a Phase 3 randomized, double-blind, placebo controlled, entecavir-based, multi-center trial in the PRC assessing F351 in CHB-associated liver fibrosis. This trial was designed to randomize 248 patients, with a primary endpoint of ≥1-stage reduction in Ishak fibrosis score at Week 52 for F351 in combination with entecavir.

In May 2025, we reported that in the pivotal Phase 3 trial, F351 met its primary endpoint and also met a key secondary endpoint with statistically significant inflammation improvement without fibrosis progression at Week 52 versus placebo. F351 was well tolerated in the study, with a comparable incidence of serious adverse events and no patient discontinuations due to adverse events in the F351 group.

The CDE of the NMPA granted priority review status to the New Drug Application ("NDA") for F351 in March 2026. On March 22, 2026, Gyre Pharmaceuticals submitted its NDA to the CDE of the NMPA to seek conditional approval for F351, the Company's lead product candidate, for the treatment of CHB-induced liver fibrosis. On May 12, 2026, the Company announced that the NMPA accepted its NDA. The Company believes a decision from the CDE of the NMPA could occur by the end of 2026 or in the first quarter of 2027.

MASH-Associated Liver Fibrosis (United States)

In the United States, we have completed a Phase 1 clinical trial in healthy volunteers evaluating F351's safety, tolerability, and pharmacokinetics ("PK"). We continue to engage with the U.S. Food and Drug Administration regarding investigational new drug ("IND") requirements for a Phase 2 clinical trial in MASH-associated liver fibrosis.

Pipeline Assets Following Cullgen Acquisition

On May 4, 2026, Gyre Therapeutics acquired Cullgen Inc. in an all-stock transaction valued at approximately $300 million, and Cullgen became a wholly owned subsidiary of Gyre. Upon the closing of this transaction, Cullgen's former Chief Executive Officer ("CEO"), Dr. Ying Luo, was appointed President and CEO of Gyre and joined Gyre's Board. Additionally, Yue Xiong, former Chief Scientific Officer ("CSO") of Cullgen, was appointed CSO of Gyre, Thomas Eastling, former Chief Financial Officer ("CFO") of Cullgen, was appointed CFO of Gyre, and Ping Zhang was named Chairman. The combined company remains headquartered in San Diego with subsidiaries in Beijing and Shanghai, roughly 740 employees, and numerous announced therapeutic programs spanning inflammation/pain and cancer.

TRKA Degrader for Pain (CG001419)

Gyre acquired Cullgen's most advanced legacy product candidate, CG001419, an oral tropomyosin receptor kinase A ("TRKA") degrader. CG001419 has been in development as a non-opioid alternative for pain management and, separately, as a treatment for various indications within oncology.

In December 2025, Cullgen completed a Phase 1 study (NCT06636500) that was a single-center, randomized, placebo-controlled, double-blind, single-ascending-dose/food-effect (with or without food) and multiple-ascending-dose trial that evaluated the safety, tolerability and PK characteristics of CG001419 in 78 healthy volunteers. The study was conducted in Australia after receiving ethics committee approval in early 2025. Results from the study showed that all doses were well-tolerated with no drug-related serious adverse events observed. We are now planning a Phase 2 study to further evaluate CG001419 in cancer-induced bone pain (CIBP) or other metastatic cancer pain syndromes in China, which is expected to initiate in the first half of 2027.

TRKA Degrader for Solid Tumors (CG001419)

CG001419 is also currently being studied in a Phase 1 trial for the treatment of solid tumors. TRK proteins also act as oncogenic drivers when mutated or rearranged, leading to uncontrolled cell growth and tumor development. Cullgen's TRK degrader for cancer is being developed as a selective, clinically active oral TRK degrader for the treatment of adult cancer patients with neurotrophic TRK gene abnormalities. For this indication, CG001419 is being evaluated in a Phase 1 clinical trial in China.

GSPT1 Degrader for AML (CG009301)

Gyre acquired Cullgen's second product candidate, CG009301, a highly selective degrader targeting the GSPT1 protein for the treatment of cancer, with development initially focused on hematologic malignancies. GSPT1 is a protein translation termination factor and plays a vital role in cancer cell survival and proliferation. Rapidly dividing hematologic cancer cells such as leukemia, including AML and acute lymphoblastic leukemia, high-risk myelodysplastic syndrome ("MDS") and leukemia stem cells rely on GSPT1 to maintain protein synthesis during oncogenesis. These tumor cells are highly sensitive to GSPT1 depletion, which leads to impaired protein translation, activation of the integrated stress response and TP53-independent cell death. Cullgen initiated a Phase 1, dose-escalation trial in China of CG009301 in patients with high-risk hematologic malignancies in April 2025. We anticipate Phase 1 dose-escalation data to be available in the second half of 2027.

CDK2-Cyclin E Dual Degrader for Solid Tumors (CG923308)

We are developing CG923308, a highly potent and selective dual degrader of both the cyclin dependent kinase 2 ("CDK2") and cyclin E proteins. In preclinical models of breast cancer resistant to endocrine therapies alone or in combination with a CDK4/6 inhibitor or other solid tumors characterized by cyclin E amplification, CG923308 demonstrated precise target degradation and outperformed the leading, late-stage clinical CDK2 inhibitors in development in blocking cell proliferation and achieving durable tumor suppression. Furthermore, CG923308 exhibits a favorable PK and safety profile. We plan to develop CG923308 for the treatment of solid tumors with CCNE1 amplification or HR+ / HER2- advanced breast cancer with resistance to current therapies. We intend to submit an IND application for CG923308 in the first quarter of 2027.

TYK2-JAK1 Degrader for Autoimmune Diseases (CG620953)

We are developing CG620953, a highly potent and selective dual degrader of Tyrosine kinase 2 ("TYK2") and Janus kinase 1 ("JAK1") while sparing JAK2. In preclinical studies, CG620953 demonstrated selective target degradation and outperformed commercialized TYK2 selective inhibitors in reducing disease activity. CG620953 also exhibits a favorable PK and safety profile, providing rationale for further evaluation in the clinic. We intend to submit an IND application for CG620953 in the United States or China around mid-2027.

Degrader – Antibody Conjugates ("DACs") as the Next-Generation of Antibody-Drug Conjugates ("ADCs")

We are developing a robust suite of DACs that target both solid tumors and hematological malignancies by pairing distinct protein degraders with tumor-specific antibodies. These preclinical DAC candidates demonstrate tumor associated antigen dependent cytotoxicity *in vitro* and drive potent, durable tumor regression *in vivo*, including success in models resistant to standard therapies.

Other Product Candidates

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

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

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

Etorel™ IP Rights

In May 2024, Gyre Pharmaceuticals entered into an agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. (the "Jiangsu Wangao Agreement"), effective from May 7, 2024 to May 6, 2035. Pursuant to the Jiangsu Wangao Agreement, Gyre Pharmaceuticals obtained the drug registration certificate for and became the marketing authorization holder of Etorel™ (nintedanib, ethanesulfonate soft capsules), a small-molecule drug for the treatment of IPF, SSc-ILD and PPF, within the PRC. The total minimum payments under the Jiangsu Wangao Agreement are Chinese Renminbi ("RMB") 35.0 million, or approximately $5.2 million, based on the September 30, 2026 spot exchange rate. This includes an upfront transfer fee of RMB 15.0 million, or approximately $2.2 million, payable in three installments, and subsequent payments based on annual sales over eight years following the commencement of commercial sales. Additionally, Gyre Pharmaceuticals will bear the costs associated with relocating the production site to a designated location and will cover all expenses related to the manufacturing process. As of September 30, 2026, we had paid four installments totaling RMB 23.0 million, or approximately $3.4 million, based on the September 30, 2026 spot exchange rate.

Long-Term Investment Measured Under Equity Method

On June 28, 2024, Gyre Pharmaceuticals entered into a partnership agreement as a limited partner and is obligated to pay $4.5 million for an 18.93% equity interest in the partnership. In April 2025, a new investor joined the partnership agreement, and as a result, Gyre Pharmaceuticals' equity interest was adjusted to 18.35%. Pursuant to the partnership agreement, Gyre Pharmaceuticals, as a limited partner, shall not participate in any activities related to the management of the investment business. However, Gyre Pharmaceuticals may appoint a member to the advisory committee of the partnership.

As of September 30, 2026 and December 31, 2025, our total investment in the partnership was $1.8 million and $1.7 million, respectively, and the carrying value of our long-term investment in this affiliate was $1.6 million and $1.6 million, respectively.

Financial Operations Overview

During the three months ended September 30, 2026, we had a net loss of $2.5 million and net loss attributable to common stockholders of $4.1 million. For the nine months ended September 30, 2026, we had net loss of $35.3 million and net loss attributable to common stockholders of $28.9 million. During the three months ended September 30, 2025, we had net income of $1.9 million and net income attributable to common stockholders of $1.0 million. For the nine months ended September 30, 2025, we had net income of $4.6 million and net income attributable to common stockholders of $1.2 million. As of September 30, 2026, we had an accumulated deficit of $142.0 million and cash and cash equivalents of $41.6 million. As of December 31, 2025, we had an accumulated deficit of $112.6 million and cash and cash equivalents of $49.2 million.

Components of Results of Operations

Revenues

Sales of Pharmaceutical Products

We generate revenue primarily through sales of ETUARY™, Contiva™, Etorel™ and certain generic drugs in the PRC. Distributors are our direct customers, and sales to distributors accounted for 100% of the revenue. Such distributors sell our pharmaceutical products to certain outlets, including hospitals and other medical institutions, as well as pharmacies.

Collaborations

We also generate revenue through collaboration and license agreements with strategic partners. Revenue consists of upfront nonrefundable payments and reimbursements for research and development services provided under the agreement and is recognized over time as the related research activities are performed.

Operating Expenses

Cost of Revenue

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

Selling and Marketing Expenses

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

Research and Development Expenses

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

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

We record accrued expenses for estimated costs of the research and development activities conducted by third party service providers, which include outsourced research and development expenses, stock-based compensation and professional services. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in current liabilities and within research and development expense.

We manage our research and development expenses by identifying the research and development activities we expect to be performed during a given period and then prioritizing efforts based on anticipated probability of successful technical development and regulatory approval, market potential, available human and capital resources, scientific data and other considerations. We regularly review our research and development activities based on unmet medical need and, as necessary, reallocate resources among our research and development portfolio that we believe will best support the long-term growth of our business. Although we do track and allocate certain operational research and development costs, as described above, we do not fully track and allocate research and development expenses at the individual product candidate level.

General and Administrative Expenses

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

Other Income, Net

Change in Fair Value of Warrant Liability

In connection with a private placement conducted in October 2023 with GNI USA, Inc., we issued (i) 811 shares of our Series X Convertible Preferred Stock, par value $0.001 per share (the "Series X Preferred Stock") and (ii) warrants to purchase up to 811 shares of Series X Preferred Stock (the "Preferred Stock Warrants"), which are freestanding financial instruments classified as warrant liability since the underlying securities are contingently redeemable upon the occurrence of events which are outside of our control. The Preferred Stock Warrants are recorded at fair value upon issuance and are subject to remeasurement at the end of each reporting period, with any change in fair value recognized in our statements of operations as other income.

Other Income, Net

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

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

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

Provision for Income Taxes

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

On July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was enacted into law, which introduced several U.S. income tax provisions that have impacted and may continue to impact our provision for income taxes. The provisions include, but are not limited to, the immediate expensing of domestic research and development expenses beginning in 2025, as well as a modification to the Global Intangible Low-Taxed Income effective in 2026. We have recognized the effects of the OBBBA provisions on our financial results to the extent they are applicable to the nine months ended September 30, 2026. We will continue to evaluate the impact of the OBBBA on our unaudited condensed consolidated financial statements.

Results of Operations

Comparison of the three months ended September 30, 2026 and 2025

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

	Three Months Ended September 30,			
	2026	2025 (As Recast)	Change ($)	Change (%)
Revenues	$ 32,934	$ 32,694	$ 240	1%
Operating expenses				
Cost of revenues	1,947	1,628	319	20%
Selling and marketing	15,028	15,328	(300)	(2)%
Research and development	8,484	7,797	687	9%
Research and development -related parties	24	—	24	*
General and administrative	8,921	6,447	2,474	38%
Transaction costs	50	—	50	*
Total operating expenses	34,454	31,200	3,254	10%
(Loss) income from operations	(1,520)	1,494	(3,014)	(202)%
Other income (loss), net:				
Interest income	588	954	(366)	(38)%
Change in fair value of warrant liability	(315)	(23)	(292)	1270%
Other (expense) income, net	(498)	95	(593)	(624)%
(Loss) income before income taxes	(1,745)	2,520	(4,265)	(169)%
Provision for income taxes	(733)	(593)	(140)	24%
Net (loss) income	(2,478)	1,927	(4,405)	(229)%
Accretion of Cullgen redeemable convertible preferred stock	—	(2,707)	2,707	(100)%
Net income (loss) attributable to noncontrolling interest	1,575	(1,805)	3,380	(187)%
Net (loss) income attributable to common stockholders	$ (4,053)	$ 1,025	$ (5,078)	(495)%

*Not meaningful

Revenues

Revenues for the three months ended September 30, 2026 and 2025 were $32.9 million and $32.7 million, respectively, representing an increase of $0.2 million, or 1%. Gyre Pharmaceuticals revenue increased during the period, primarily driven by higher ETUARY™ sales volumes resulting from ETUARY™ focused marketing efforts, despite lower Contiva™ and Etorel™ product revenues earned following the implementation of China's national centralized procurement program. The increase was offset by a net $1.6 million decrease in collaboration revenue primarily driven by the Collaboration, Option, and License Agreement with Astellas Pharma Inc. (the "Astellas Agreement"), which ended in March 2026.

Cost of Revenues

Cost of revenues for the three months ended September 30, 2026 and 2025 were $1.9 million and $1.6 million, respectively. The $0.3 million, or 20% increase, was primarily driven by a $0.5 million increase in production costs associated with Etorel™ products, partially offset by a $0.1 million decrease in production costs for ETUARY™, and a $0.1 million decrease in tax and related surcharges.

Selling and Marketing Expenses

Selling and marketing expenses decreased $0.3 million, or 2%, for the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The decrease was primarily attributable to a $1.1 million reduction in promotional and conference expenses, as certain promotional objectives were achieved during the first half of 2026, resulting in lower spending during the third quarter. This decrease was partially offset by a $0.4 million increase in personnel-related costs, primarily due to increased sales commissions resulting from higher sales volumes, and a $0.3 million increase in stock-based compensation expenses.

R***esearch and Development Expenses***

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

	Three Months Ended September 30,			
	2026	2025 (As Recast)	Change ($)	Change (%)
External clinical expenses	$ 1,559	$ 1,178	$ 381	32%
Personnel-related expenses	3,225	3,297	(72)	(2)%
Facilities, depreciation and other expenses	1,336	794	542	68%
External pre-clinical expenses	2,278	2,383	(105)	(4)%
Materials and utilities	86	140	(54)	(39)%
Licensing fee – related party	24	5	19	380%
Total research and development expenses	$ 8,508	$ 7,797	$ 711	9%

Research and development expenses increased by $0.7 million, or 9%, for the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The increase was primarily related to a $0.4 million increase in external clinical research expenses, mainly attributable to the F351 Phase 3C experimental review expense in connection with the China NMPA's review of Gyre Pharmaceuticals' NDA for F351, and a $0.5 million increase in facilities, depreciation and other expenses. The increase was partially offset by a $0.2 million decrease in pre-clinical research expenses, utilities, materials, and personnel-related expenses.

General and Administrative Expenses

General and administrative expenses increased by $2.5 million, or 39%, for the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The increase was primarily driven by a $0.9 million increase in personnel costs related to Gyre Pharmaceuticals' internal restructuring, a $1.1 million increase in professional fees, a $0.2 million increase in miscellaneous expenses, and a $0.3 million increase in depreciation and amortization. The increase is partially offset by a $0.1 million decrease in stock-based compensation expenses.

Transaction Costs

For the three months ended September 30, 2026, $0.1 million in transaction costs were incurred in connection with the acquisition of Cullgen which closed in early May 2026.

Change in Fair Value of Warrant Liability

Loss from remeasurement of the preferred stock warrants liability was $315 thousand for the three months ended September 30, 2026 compared with $23 thousand for the three months ended September 30, 2025. The change was related to the remeasurement of the preferred stock warrants liability.

Other (Loss) Income, Net

Interest income decreased by $0.4 million, or 38%, for the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The decrease was related to lower average cash balances maintained in interest-bearing accounts during the three month period, as well as lower interest rates earned on the Company's bank deposits.

Net other expense was $0.5 million for the three months ended September 30, 2026 and net other income was $0.1 million for the three months ended September 30, 2025. The change was resulted from a decrease in government grant income at Gyre Pharmaceuticals and costs associated with the early termination of our San Diego office lease in July 2026.

Provision for Income Taxes

Provision for income taxes was $0.7 million and $0.6 million for the three months ended September 30, 2026 and 2025, respectively. The increase was primarily attributable to a lower income tax benefit recognized by Cullgen due to the decrease in taxable income during the three months ended September 30, 2026.

Comparison of the nine months ended September 30, 2026 and 2025

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

	Nine Months Ended September 30,			
	2026	2025 (As Recast)	Change ($)	Change (%)
Revenues	$ 86,469	$ 92,999	$ (6,530)	(7)%
Operating expenses				
Cost of revenues	5,383	3,673	1,710	47%
Selling and marketing	42,918	41,363	1,555	4%
Research and development	34,265	24,239	10,026	41%
Research and development -related parties	4,860	—	4,860	*
General and administrative	26,964	21,928	5,036	23%
Transaction costs	6,936	—	6,936	*
Total operating expenses	121,326	91,203	30,123	33%
(Loss) income from operations	(34,857)	1,796	(36,653)	(2041)%
Other income (loss), net:				
Interest income	2,071	2,751	(680)	(25)%
Change in fair value of warrant liability	(95)	2,444	(2,539)	(104)%
Other expense, net	(1,328)	(206)	(1,122)	545%
(Loss) income before income taxes	(34,209)	6,785	(40,994)	(604)%
Provision for income taxes	(1,118)	(2,156)	1,038	(48)%
Net (loss) income	(35,327)	4,629	(39,956)	(863)%
Accretion of Cullgen redeemable convertible preferred stock	(3,905)	(7,927)	4,022	(51)%
Net (loss) income attributable to noncontrolling interest	(10,370)	(4,449)	(5,921)	133%
Net (loss) income attributable to common stockholders	$ (28,862)	$ 1,151	$ (30,013)	(2608)%

*Not meaningful

Revenues

Revenues for the nine months ended September 30, 2026 and 2025 were $86.5 million and $93.0 million, respectively, representing a decrease of $6.5 million or 7.0%. Revenue from Gyre Pharmaceuticals increased by net $4.7 million during the period, primarily driven by higher ETUARY™ sales volumes resulting from ETUARY™-focused marketing efforts, despite lower Contiva™ and Etorel™ product revenues following the implementation of China's national centralized procurement program. The overall increase in revenue from Gyre Pharmaceuticals was offset by a net $11.2 million decrease primarily driven by the collaboration revenue under the Astellas Agreement which ended in March 2026.

Cost of Revenues

Cost of revenues for the nine months ended September 30, 2026 and 2025 was $5.4 million and $3.7 million, respectively. The $1.7 million, or 47%, increase was primarily attributable to higher Etorel™ product costs.

Selling and Marketing Expenses

Selling and marketing expenses increased by $1.6 million, or 4%, for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The increase was primarily attributable to a $1.9 million increase in stock-based compensation expense, partially offset by a $0.3 million decrease in promotional and conference and other expenses.

Research and Development Expenses

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

	Nine Months Ended September 30,			
	2026	2025 (As Recast)	Change ($)	Change (%)
External clinical expenses	$ 15,472	$ 6,190	$ 9,282	150%
Personnel-related expenses	9,403	9,166	237	3%
Facilities, depreciation and other expenses	3,112	3,327	(215)	(6)%
External pre-clinical expenses	4,861	4,480	381	9%
Materials and utilities	1,417	1,035	382	37%
Licensing fee – related party	4,860	41	4,819	11754%
Total research and development expenses	$ 39,125	$ 24,239	$ 14,886	61%

Research and development expenses including related parties increased by $14.9 million, or 61%, for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The increase was primarily related to a $9.3 million increase in external clinical research expenses, mainly attributable to the F351 Phase 3C experimental review expense in connection with the China NMPA's review of Gyre pharmaceuticals' NDA for F351; a $4.8 million increase for the milestone payment Gyre Pharmaceuticals owed to an affiliate of GNI Group related to China's NMPA acceptance of the NDA for F351 as a treatment for CHB-induced liver fibrosis; a $0.4 million increase in pre-clinical expenses; a $0.4 million increase in materials and utilities expenses; and a $0.2 million increase in personnel-related expenses including stock-based compensation expenses. The increase was partially offset by a $0.2 million decrease in facilities, depreciation and other expenses.

General and Administrative Expenses

General and administrative expenses increased by $5.0 million, or 23%, for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The increase was primarily driven by a $3.6 million increase in personnel costs related to Gyre Pharmaceuticals' internal restructuring and Gyre's severance expense associated with the acquisition of Cullgen, a $1.1 million increase in miscellaneous expenses, a $0.5 million increase in stock-based compensation expenses and $0.3 million increase in depreciation expenses, partially offset by a $0.4 million decrease in professional fees.

Transaction costs

For the nine months ended September 30, 2026, $3.8 million in transaction costs were incurred in connection with the termination of the proposed merger between Cullgen and Pulmatrix, Inc. in February 2026 and $3.1 million in transaction costs were incurred related to the acquisition of Cullgen, which closed in early May 2026, totaling $6.9 million.

Change in Fair Value of Warrant Liability

Loss from remeasurement of the preferred stock warrants liability was $0.1 million for the nine months ended September 30, 2026 compared with a gain from remeasurement of the preferred stock warrants liability of $2.4 million for the nine months ended September 30, 2025. The change was related to the remeasurement of the preferred stock warrants liability.

Other (Loss) Income, Net

Interest income decreased by $0.7 million, or 25%, for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The decrease was due to lower average cash balances maintained in interest-bearing accounts during the period, as well as lower interest rates earned on the Company's bank deposits.

Net other expense was $1.3 million for the nine months ended September 30, 2026, compared to net other expense was $0.2 million for the nine months ended September 30, 2025. The net increase resulted from a decrease in government grant income at Gyre Pharmaceuticals. In addition, our net other loss increased primarily due to foreign currency revaluation losses recognized in the first quarter of 2026 and costs associated with the early termination of the San Diego office lease in the third quarter of 2026.

Provision for Income Taxes

Provision for income taxes was $1.1 million and $2.2 million for the nine months ended September 30, 2026 and 2025, respectively. The decrease was mainly due to the Company's pre-tax loss incurred since the first fiscal quarter of 2026, partially offset by income tax expense recognized on certain non-deductible items, including donations, and the impact of other permanent and temporary tax differences.

Recent Accounting Pronouncements

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

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2026, we had cash and cash equivalents of $41.6 million, short-term bank deposits of $15.8 million, short-term investments of $12.6 million, and long-term certificates of deposit of $28.8 million, which are available to fund operations, and an accumulated deficit of $142.0 million. Our net loss during the nine months ended September 30, 2026 was $35.3 million, while cash used in operating activities was $17.5 million. We believe that our existing cash and cash equivalents, cash flows from operations, and access to capital markets will be sufficient to fund our operating activities and obligations for at least the next 12 months following the filing date of this Quarterly Report and thereafter for the foreseeable future.

Future Funding Requirements

We expect to use cash provided by operating activities, short-term deposits, and long-term certificates of deposit, as well as potential cash issuances to meet our current and future financial obligations, including funding our operations, research and development activities, clinical pipelines, and capital expenditures. Our ability to make these payments depends on our future performance, which will be affected by financial, business, economic, regulatory, and other factors, many of which we cannot control. In addition, we anticipate that we will incur expenses related to and in connection with the integration between our business and Cullgen. Factors that may affect financing requirements include, but are not limited to:

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

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

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

	Nine Months Ended September 30,	
	2026	2025 (As Recast)
Cash Flow Data:		
Net cash used in operating activities	$ (17,530)	$ (10,185)
Net cash provided by investing activities	8,431	6,510
Net cash provided by financing activities	234	21,564
Effect of exchange rate changes on cash	1,316	149
Net change in cash and cash equivalents	$ (7,549)	$ 18,038

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2026 was $17.5 million, reflecting our net loss of $35.3 million and offset by non-cash items of $8.6 million, which was primarily driven by a $6.4 million in stock-based compensation, $2.6 million of depreciation and amortization, $1.5 million of noncash lease expense, and $0.6 million of accrued interest on short-term and long-term certificates of deposit, partially offset by a $2.9 million deferred income tax benefit. Additionally, $9.2 million of cash provided by changes in net operating assets and liabilities was primarily driven by a $4.9 million decrease in notes receivable, a $4.6 million increase in amounts due to related parties, a $2.4 million decrease in prepaid and other assets, and a $1.3 million increase in accounts payable, partially offset by a $1.6 million increase in inventories, a $1.2 million decrease in operating lease liabilities, a $0.4 million increase in accounts receivable, and a $0.8 million decrease in accrued expenses and other liabilities, including income tax payable..

Cash used in operating activities for the nine months ended September 30, 2025 was $10.2 million, reflecting our net income of $4.6 million and non-cash charges of $3.5 million, which primarily included $3.3 million in stock-based compensation and $2.4 million in depreciation and amortization, partially offset by a $2.4 million change in the fair value of warrant liability and $1.0 million in deferred income taxes. Additionally, $18.3 million cash used in changes in net operating assets and liabilities was primarily driven by a $9.9 million increase in accounts receivable, inventories, prepaid and other assets and a $12.5 million decrease in deferred revenue, and other liabilities, including accrued expenses, income tax payable and operating lease liabilities, partially offset by a $3.7 million decrease in notes receivable and a $0.4 million increase in accounts payable.

The increase in cash used in operating activities for the nine months ended September 30, 2026 compared with cash used in operating activities for the nine months ended September 30, 2025 was primarily attributable to less cash received under the Astellas Agreement that ended in March 2026 combined with the transaction costs associated with the Merger that closed in May 2026, as well as overall higher spending in clinical and other research programs.

Cash Flows from Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2026 was $8.4 million, which consisted primarily of $17.2 million of proceeds from available-for-sale securities, $14.5 million of proceeds from the maturity of certificates of deposit, and $0.1 million of proceeds from sale of equipment, partially offset by $18.8 million in purchases of certificates of deposit, $1.1 million in acquisitions of intangible assets, $2.0 million in purchases of available-for-sale securities, and $1.4 million in purchases of property and equipment.

Cash provided by investing activities for the nine months ended September 30, 2025 was $6.5 million, which consisted primarily of $27.2 million of proceeds from the maturity of certificates of deposit and $17.4 million of proceeds from available-for-sale securities, partially offset by $19.2 million in purchases of certificates of deposit, $16.5 million in purchases of available-for-sale securities, $1.2 million in purchases of property and equipment, $0.7 million in acquisitions of intangible assets, and $0.6 million in purchases of short-term investments.

Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2026 was $0.2 million, primarily due to proceeds from stock options exercised, partially offset by listing expense.

Cash provided by financing activities for the nine months ended September 30, 2025 was $21.6 million, primarily due to $23.0 million in proceeds from the issuance of common stock, $2.0 million in proceeds from the exercise of stock options, and $0.5 million in proceeds from the issuance of common stock under our ATM program with Jefferies LLC, partially offset by $2.5 million in payments of listing expenses and $1.5 million of cash used for deferred financing costs.

Restricted Net Assets

Under PRC laws and regulations, Gyre Pharmaceuticals and Cullgen are 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 $132.3 million and $128.1 million as of September 30, 2026 and December 31, 2025. We do not expect the restrictions described above to have a material impact on our ability to meet our cash obligations.

Contractual Obligations and Other Commitments

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

Leases

We have entered into lease arrangements in (1) San Diego, California for our headquarters and subsidiary, the latest of which expires in July 2028, and (2) the PRC, for office and laboratory spaces through February 2037. As of September 30, 2026, our fixed lease payment obligations were $3.8 million, with $0.4 million payable within the remaining three months.

Research and Development Programs

As of September 30, 2026, we have committed to allocate $45.9 million toward future research and development activities for various programs.

Property and Equipment

Our commitments related to the purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statements were $4.9 million as of September 30, 2026 and are expected to be incurred within one year.

Etorel™ IP Rights

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

Critical Accounting Policies and Estimates

Please refer to our critical accounting policies as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025 and Note 2 — *Summary of Significant Accounting Policies* in the accompanying notes to the unaudited Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report for a description of significant accounting policies.

Smaller Reporting Company and Accelerated Filer Status

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

Based on the aggregate market value of our common stock held by non-affiliates as of June 30, 2026, we remain a smaller reporting company and continue to qualify as an "accelerated filer". As a result of our transition to accelerated filer status, we were required, pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), to include in our Annual Report an attestation report from our independent registered public accounting firm regarding the effectiveness of our internal control over financial reporting, and we have complied with this requirement by including the attestation report in our Annual Report. However, we expect to continue to take advantage of the reduced reporting requirements applicable to smaller reporting companies.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2026, our management, with the participation and supervision of our principal executive officer and our principal financial officer, evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2026 to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except that associated with the Merger, management is in the process of implementing new controls and changes to existing controls over financial reporting including but not limited to certain controls in the areas of financial statement close, consolidation and 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 and in Part II, Item 1A "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 (the "Q2 Quarterly Report), which could materially affect our business, financial position, or future results of operations. The risks described in our Annual Report and our Q2 Quarterly 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 and in Part II, Item 1A "Risk Factors" in our Q2 Quarterly 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

None.

Trading Arrangements

During the three months ended September 30, 2026, no director or executive officer adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, as such terms are defined under Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

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

Exhibit Number	Exhibit Title	Incorporated by reference Form	File No.	Exhibit No.	Filing Date
2.1(a)†#	Asset Purchase Agreement, dated as of December 26, 2022, by and among Catalyst Biosciences, Inc., GNI Group Ltd., and GNI Hong Kong Limited.	8-K	000-51173	2.1	Dec. 27, 2022
2.1(b)	Agreement and Amendment to Asset Purchase Agreement, dated as of March 29, 2023, by and among Catalyst Biosciences, Inc., GNI Group Ltd., and GNI Hong Kong Limited.	8-K	000-51173	2.2	Mar. 30, 2023
2.2(a)#	Business Combination Agreement, dated as of December 26, 2022, by and among Catalyst Biosciences, Inc., GNI USA, Inc., GNI Group Ltd., GNI Hong Kong Limited, Shanghai Genomics, Inc., the individuals listed on Annex A thereto and Continent Pharmaceuticals Inc.	8-K	000-51173	2.2	Dec. 27, 2022
2.2(b)	Amendment to Business Combination Agreement, dated as of March 29, 2023, by and among Catalyst Biosciences, Inc., GNI USA, Inc., GNI Group Ltd., GNI Hong Kong Limited, Shanghai Genomics, Inc., the Minority Holders and Continent Pharmaceuticals Inc.	8-K	000-51173	2.1	Mar. 30, 2023
2.2(c)	Second Amendment to Business Combination Agreement, dated as of August 30, 2023, by and among Catalyst Biosciences, Inc., GNI USA, Inc., GNI Group Ltd., GNI Hong Kong Limited, Shanghai Genomics, Inc. and Continent Pharmaceuticals Inc.	8-K	000-51173	2.1	Aug. 31, 2023
2.3	Agreement and Plan of Merger and Reorganization, dated March 2, 2026, by and among Gyre Therapeutics, Inc., Helix Merger Sub Corp., and Cullgen Inc.	8-K	000-51173	2.1	Mar. 2, 2026
3.1	Restated Certificate of Incorporation of the Company.	10-Q	000-51173	3.1	Nov. 13, 2024
3.2	Amended and Restated Bylaws of the Company.	8-K	000-51173	3.3	Oct. 30, 2023
3.3(a)	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, filed with the Delaware Secretary of State on April 10, 2017.	10-Q	000-51173	3.1	Aug. 3, 2017

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

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

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

SIGNATURES

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

GYRE THERAPEUTICS, INC.

Date: November 6, 2026

/s/ Ying Luo

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

Date: November 6, 2026

/s/ Thomas Eastling

Thomas Eastling
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 31.1

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

I, Ying Luo, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2026

/s/ Ying Luo

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

Exhibit 31.2

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

I, Thomas Eastling, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2026

/s/ Thomas Eastling

Thomas Eastling
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Gyre Therapeutics, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ying Luo, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 6, 2026

/s/ Ying Luo

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

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

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Gyre Therapeutics, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas Eastling, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 6, 2026

/s/ Thomas Eastling
Thomas Eastling
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

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

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