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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November **5, 2026**

Gyre Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-51173**	**56-2020050**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12730 High Bluff Drive **Suite 250** **San Diego, CA**	**92130**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (**858) 284-0115**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities 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	GYRE	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 5, 2026, Gyre Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended September 30, 2026 and other matters described therein. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

As provided in General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 incorporated herein shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information or Exhibit 99.1 be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01. Regulation FD

On November 5, 2026, the Company made available an updated corporate presentation on the Company's website.

A copy of the corporate presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act or the Exchange Act, regardless of any general incorporate language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibits are being furnished herewith:

Exhibit Number	Exhibit Title or Description
99.1	Press Release, dated November 5, 2026
99.2	Corporate Presentation, dated November 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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 hereunto duly authorized.

GYRE THERAPEUTICS, INC.

Date: November 5, 2026

By: /s/ Ying Luo
Name: Ying Luo
Title: Chief Executive Officer and President

Exhibit 99.1

Gyre Therapeutics Reports Third Quarter 2026 and Year-to-Date Financial Results with Business Updates

Q3 2026 revenue of $32.9 million; GAAP basic EPS: $(0.04)

Full year 2026 revenue guidance of $100.5 to $111.0 million affirmed

SAN DIEGO, November 5, 2026 -- Gyre Therapeutics, Inc. (Gyre, Gyre Therapeutics or the Company) (Nasdaq: GYRE), a U.S. biopharmaceutical company with research operations and commercial business in China to advance global development of protein degrader therapeutics, today announced financial results for the third quarter ended September 30, 2026, and provided a business update.

Dr. Ying Luo, President and Chief Executive Officer of Gyre Therapeutics, commented, “I am pleased with our execution in the third quarter, our first full quarter incorporating Cullgen's operations within Gyre Therapeutics. We are advancing our protein degrader pipeline toward first-in-human data and initiating new clinical programs next year. Meanwhile, after recently completing an onsite inspection by China’s National Medical Products Administration, or NMPA, we continue to prepare for the China NMPA decision on F351 for CHB-induced liver fibrosis, which we anticipate launching, if approved, sometime in the first half of 2027. Together, these programs are expected to drive our next phase of growth and demonstrate the strength of our unique business model, combining U.S. innovation with capital-efficient operations in China.”

Third Quarter Business Highlights and Upcoming Milestones

Pipeline Development Updates

F351 (hydronidone)

In May 2026, Gyre announced that the Center for Drug Evaluation (CDE) of the NMPA accepted its New Drug Application (NDA) for F351 (hydronidone) as a treatment for chronic hepatitis B (CHB)-induced liver fibrosis. The acceptance came after Gyre submitted the NDA through its majority-owned subsidiary Gyre Pharmaceuticals Co., Ltd. (Gyre Pharmaceuticals) following the priority review status for F351 granted by the NMPA in March 2026. During the third quarter, Gyre Pharmaceuticals completed an on-site inspection conducted by the NMPA of its manufacturing plants and clinical centers. Gyre believes a decision from the NMPA could occur by the end of 2026 or in the first quarter of 2027.

CG001419 for cancer pain and solid tumors

Following the successful completion of a Phase 1 study in Australia of 78 healthy volunteers in December 2025, Gyre is now planning a Phase 2 study to further evaluate CG001419 in cancer-induced bone pain (CIBP) and other metastatic cancer pain syndromes in China to initiate in the first half of 2027.

CG001419 continues to separately be evaluated in a Phase 1 trial in China for the treatment of solid tumors.

CG009301 for AML

CG009301 is a GSPT1 degrader for acute myeloid leukemia (AML), a fast-growing cancer of the blood and bone marrow. This candidate continues to be studied in a Phase 1 dose-escalation trial being conducted in China in patients with high-risk hematologic malignancies. We anticipate Phase 1 dose-escalation data to be available in the second half of 2027.

Dual-degrader programs (next-generation targeted protein degraders)

Gyre expects to submit Investigational New Drug (IND) applications and initiate Phase 1 clinical trials, upon regulatory approval of IND applications, in the United States and/or China around mid-2027 for CG923308, a CDK2-Cyclin E dual degrader for solid tumor indications, and CG620953, a TYK2-JAK1 dual degrader for autoimmune diseases.

DACs, next-generation ADCs

Additional developments from our in-house R&D efforts include discovery/preclinical stage degrader antibody conjugate (DAC) candidates for solid tumors and hematological malignancies, which are considered the next generation of antibody drug conjugates (ADCs). These DACs consist of distinct protein degraders paired with tumor-specific antibodies. We continue to make progress as we screen to identify leads and look to provide more details on our first IND-ready DAC candidate(s) in 2027.

Pirfenidone for Pneumoconiosis

A Phase 3 trial of pirfenidone for the treatment of pneumoconiosis in China completed enrollment in 2025. A total of 272 patients were enrolled evaluating the efficacy and safety of 52 weeks of pirfenidone capsule treatment in patients with pneumoconiosis versus placebo. The potential for additional patient enrollment is currently being evaluated to replace patients that have dropped out of the study.

Pirfenidone for Radiation-Induced Lung Injury (RILI)

In April 2026, Gyre Pharmaceuticals initiated its adaptive Phase 2/3 clinical trial in oncology-related pulmonary complications, with the first patient enrolled. The trial is evaluating pirfenidone for RILI, including cases complicated by immune-related pneumonitis, at leading oncology centers.

Commercial Products:

ETUARY™ (pirfenidone for IPF), Etorel™ and Contiva™

ETUARY (pirfenidone), the Company's primary product approved in China for idiopathic pulmonary fibrosis (IPF), generated $31.4 million in sales for the quarter ended September 30, 2026, compared to $27.7 million for the same period in 2025. Etorel (nintedanib ethanesulfonate soft capsules), which was launched in June 2025 and is indicated for systemic sclerosis-associated interstitial lung disease (SSc-ILD) and progressive pulmonary fibrosis (PPF) and IPF, generated $1.0 million in sales for the quarter ended September 30, 2026, compared to $1.5 million for the same period in 2025. Contiva (avatrombopag maleate tablets), which was launched in China in March 2025 and is indicated for thrombocytopenia in adults with chronic liver disease and immune thrombocytopenic purpura, generated $0.1 million in sales for the quarter ended September 30, 2026, compared to $1.2 million for the same period in 2025. Contiva and Etorel product revenues were slightly lower due to the implementation of China's national centralized procurement program.

Financial Results

Cash Position

As of September 30, 2026, Gyre held $41.6 million in cash and cash equivalents, $15.8 million in short-term bank deposits, $12.6 million in short-term investment, and $28.8 million in long-term certificates of deposit, totaling $98.8 million. Compared to $116.1 million as of December 31, 2025, total cash decreased by $17.3 million, or 15%, primarily driven by a decrease in short-term investment of $15.5 million.

Financial Results for the Three Months Ended September 30, 2026

- Revenues: Revenues for the three months ended September 30, 2026 were $32.9 million, compared to $32.7 million for the same period in 2025, representing a $0.2 million, or 1%, increase. 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: For the three months ended September 30, 2026, cost of revenues was $1.9 million, compared to $1.6 million for the same period in 2025. 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 Expense: For the three months ended September 30, 2026, selling and marketing expense was $15.0 million compared to $15.3 million for the same period in 2025. The $0.3 million, or 2%, 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.
- Research and Development Expense: For the three months ended September 30, 2026, research and development expense was $8.5 million, compared to $7.8 million for the same period in 2025. The $0.7 million, or 9%, 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 Expense: For the three months ended September 30, 2026, general and administrative expense was $8.9 million, compared to $6.4 million for the same period in 2025. The $2.5 million, or 39%, 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.
- (Loss) Income from Operations: For the three months ended September 30, 2026, loss from operations was $1.5 million, compared to income from operations of $1.5 million for the same period in 2025. The $3.0 million change was primarily driven by an increase in total operating expenses including increased stock-based compensation, and Phase 3C and other clinical trial and pre-clinical activities.

- Net (Loss) Income: For the three months ended September 30, 2026, net loss was $2.5 million, compared to net income of $1.9 million for the same period in 2025. The $4.4 million increase in net loss was primarily driven by an increase in operating expenses of $3.2 million, and other expenses of $1.2 million.

Financial Results for the Nine Months Ended September 30, 2026

- Revenues: Revenues for the nine months ended September 30, 2026, were $86.5 million, compared to $93.0 million for the same period in 2025, resulting in a $6.5 million decrease. 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 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: For the nine months ended September 30, 2026, cost of revenues was $5.4 million, compared to $3.7 million for the same period in 2025. The $1.7 million increase was primarily driven by higher Etorel product costs.
- Selling and Marketing Expense: For the nine months ended September 30, 2026, selling and marketing expense was $43.0 million, compared to $41.4 million for the same period in 2025. The $1.6 million 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 Expense: For the nine months ended September 30, 2026, research and development expense including related parties was $39.1 million, compared to $24.2 million for the same period in 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 Expense: For the nine months ended September 30, 2026, general and administrative expense was $27.0 million, compared to $21.9 million for the same period in 2025. The $5.0 million 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 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.
- (Loss) Income from Operations: For the nine months ended September 30, 2026, loss from operations was $34.9 million, compared to $1.8 million income from operations for the same period in 2025. The $36.7 million decrease was primarily driven by an increase in total operating expense including transaction costs, increased stock-based compensation, and Phase 3C and other clinical trial and pre-clinical activities.
- Net (Loss) Income: For the nine months ended September 30, 2026, net loss was $35.3 million, compared to $4.6 million net income for the same period in 2025. The $40.0 million increase in net loss was primarily driven by an increase in operating expenses of $30.1 million, an increase in other expenses of $1.1 million, and a decrease in revenue of $6.5 million, a decrease in fair value of warrant liabilities of $2.5 million, partially offset by a decrease in income tax expense of $1.0 million.

Use of Non-GAAP Financial Measures by Gyre Therapeutics, Inc.

Gyre reports financial results in accordance with accounting principles generally accepted in the United States (GAAP). This release presents the financial measure "adjusted net income," which is not calculated in accordance with GAAP. The most directly comparable GAAP measure for this non-GAAP financial measure is "net income." Adjusted net income presents Gyre's results of operations after excluding gain from change in fair value of warrants, stock-based compensation, provision for income taxes, transaction costs and loss on disposal of assets, net. This is meant to supplement, and not substitute, Gyre's financial information presented in accordance with GAAP. Adjusted net income as defined by Gyre may not be comparable to similar non-GAAP measures presented by other companies. Management believes that presenting adjusted net income provides investors with additional useful information in evaluating Gyre's performance and valuation. See the reconciliation of adjusted net income to net income in the section titled "Reconciliation of GAAP to Non-GAAP Financial Measures" below.

About F351

F351 is Gyre's lead development candidate for the treatment of liver fibrosis that is being developed for two different indications. It is a structurally modified derivative of pirfenidone designed to optimize metabolic properties while targeting the TGF-β1 signaling pathway, a key mediator of fibrogenesis. Gyre is developing F351 for two primary indications: CHB-associated liver fibrosis in the PRC and MASH-associated liver fibrosis for global markets.

Gyre has completed a Phase 1 U.S. clinical trial in healthy volunteers evaluating F351's safety, tolerability, and pharmacokinetics (PK). Gyre is further analyzing Phase 3 study results generated in China, together with new pre-clinical results to determine an optimal regulatory path for global Phase 2 studies in MASH fibrosis.

About Gyre Pharmaceuticals

Gyre Pharmaceuticals Co., Ltd., a subsidiary of Gyre Therapeutics, Inc., is a commercial-stage biopharmaceutical company committed to the research, development, manufacturing, and commercialization of innovative drugs for organ fibrosis. Its flagship product, ETUARY™ (pirfenidone capsule), was the first approved treatment in 2011 for idiopathic pulmonary fibrosis (IPF) in the PRC. Gyre Pharmaceuticals' pipeline includes F351 (hydronidone), a structural analogue of pirfenidone, which has received Breakthrough Therapy designation by the CDE of the NMPA in March 2021 and is currently under review by the NMPA for a New Drug Application (NDA) for the treatment of CHB-induced liver fibrosis, which is liver damage resulting from the infection of the hepatitis B virus (HBV). Gyre Pharmaceuticals is leveraging the pirfenidone-platform to develop treatments for pneumoconiosis and RILI with or without immune-related pneumonitis. Our expertise in pirfenidone compounds has allowed us to expand development programs with F528 for the treatment of chronic obstructive pulmonary disease (COPD), F230 in development for the treatment of pulmonary arterial hypertension (PAH), and F573 in development for the treatment of acute/acute-on-chronic liver failure (ALF/ACLF). As of September 30, 2026, Gyre Therapeutics owns a 69.7% equity interest in Gyre Pharmaceuticals.

About Gyre Therapeutics

Gyre Therapeutics is a U.S. biopharmaceutical company with research operations and commercial business in China, focused on generating cashflows with marketed therapeutics for fibrosis and leveraging capital efficiencies to advance the pipeline of next-generation protein degrader therapeutics for global markets.

Gyre's wholly owned subsidiary, Cullgen Inc., is a clinical-stage biopharmaceutical company focused on the discovery and development of targeted protein degrader and DAC therapies for critical conditions, including cancer and inflammatory diseases. Cullgen has created a portfolio of highly selective targeted protein degrader and DAC product candidates designed to eliminate therapeutically relevant proteins in patients.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, are forward-looking statements, including statements concerning: the development and commercial potential and potential benefits of F351 and Gyre's other product candidates; the timing and progression of commercial approval of F351; and the timing of the NMPA's decision on Gyre’s NDA, and, if the NDA is approved, the anticipated commercial launch of F351; the regulatory path for, and time of, any global Phase 2 clinical trials of F351; initiation of Phase 2 clinical trial of CG001419; the timing of Phase 1 dose-escalation data for CG009301; and the timing of IND applications for CG923308 and CG620953. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “design,” “estimate,” “predict,” “potential,” “plan,” “anticipate,” “continue” or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: unexpected costs, charges or expenses resulting from Gyre's acquisition of Cullgen; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the acquisition; the risk that the combined company may not be able to successfully integrate the businesses and realize the expected benefits of the acquisition in a timely manner or at all; the uncertainties associated with Gyre’s and Cullgen’s product candidates, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; risks related to the inability of the combined entity to obtain sufficient additional capital to continue to advance these product candidates and its pre-clinical programs; uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; risks related to the failure to realize any value from product candidates and pre-clinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; risks associated with the possible failure to realize certain anticipated benefits of the acquisition, including with respect to future financial and operating results. Additional risks and factors are identified under “Risk Factors” in Gyre’s Annual Report on Form 10-K for the year ended December 31, 2025, filed on March 13, 2026, and in other filings with the Securities and Exchange Commission.

Gyre expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Contact:

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Investors

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

	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
Change in fair value of warrant liability	(315)	(23)	(95)	2,444
Other (expense) income, net	(498)	95	(1,328)	(206)
(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 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

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

	September 30, 2026 (Unaudited)	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		
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

Gyre Therapeutics, Inc.
Unaudited Reconciliation of GAAP to Non-GAAP Financial Measures
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025 (As Recast)	2026	2025 (As Recast)
Net (loss) income	$ (2,478)	$ 1,927	$ (35,327)	$ 4,629
Gain (Loss) from change in fair value of warrant liability [(1)]	315	23	95	(2,444)
Stock-based compensation	1,734	1,334	6,392	3,277
Provision for income taxes	733	593	1,118	2,156
Transaction costs [(2)]	50	—	6,936	—
Loss on disposal of assets, net [(3)]	—	1	18	2
Non-GAAP adjusted net (loss) income	$ 354	$ 3,878	$ (20,768)	$ 7,620

(1) Reflects adjustments for fair value of warrants based on the Black-Scholes option pricing model.
(2) Reflects non-recurring expenses related to the transaction costs related to the merger with Cullgen Inc. and the proposed merger transaction between Cullgen Inc. and Pulmatrix, Inc. that was terminated in February 2026.
(3) Reflects non-recurring losses from the disposal of assets that are not part of the Company's ongoing operations.

A Global Innovator Expanding And Reinventing Protein Degrader Therapeutics

Gyre THERAPEUTICS

November 2026

Forward-looking Statements

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Gyre Is A Global Development Engine Fueled by its China Discovery and Commercialization Platform

Value Drivers	Details	Key Features
Growth Opportunities	• Diversified R&D programs spanning across multiple indications • Both early- and late-stage pipeline assets provide near- and long-term catalysts	Degrader platform for the development of TPDs & DACs
Established Innovation Engine	• Supports next-generation TPD and DAC platform development • Fully-integrated R&D capabilities	Dual degraders for oncology/I&I DACs in pre-IND studies
Global Infrastructure	• Leveraging cost-efficient China operations for accelerated discovery, preclinical validation, and early clinical-stage development	San Diego: Headquarters Shanghai: Discovery Beijing: Manufacturing & Sales
Commercial Footprint	• ETUARY™ has been the market-leading pirfenidone brand in China for treatment of idiopathic pulmonary fibrosis (IPF) • F351 adds a near-term revenue growth catalyst for the China commercial portfolio	ETUARY™ FY26 Total Revenue Guidance $100.5M-$111M F351 potential launch in 1H27

A Commercial Foundation and Integrated U.S. – China R&D Engine Support Capital-Efficient Advancement of a Diversified Pipeline

*TPDs = targeted protein degraders; DACs = degrader antibody conjugates

Gyre's Flexible, Capital-Efficient Global Development Strategy

China Revenue Builds & De-Risks the Early Pipeline

- Cash-flow Generation: Established commercial operations in China to help offset cash burn.
- Reinvestment to R&D Engine: China-generated cash funds preclinical development quickly, at scale, and cost-efficiently, leveraging Gyre's already-established China infrastructure.
- Translational De-risking: Conduct broader preclinical and translational studies to select strongest candidates and build IND-enabling packages.



U.S. Capital Advances Priority Assets Globally

- Focused Capital Allocation: U.S.-raised capital invests into the highest-priority U.S. and global clinical programs.
- Flexible Clinical Routing: Initiate studies in the U.S., China or both based on the most efficient development path.
- Pivotal Development and Launch: Advance selected assets through U.S. and global clinical studies, pivotal trials, regulatory approvals and launch.



Global Development Programs and Upcoming Catalysts

Program and Description	Indication	Pre-IND Studies	Phase 1	Phase 2	Phase 3	NDA Submitted	Catalyst
DAC Platform / Next-Gen Degrader Technologies	Oncology / Inflammatory Disease Discovery Platform	Discovery & lead selection in China					Lead DAC selection ongoing / IND-enabling advancement
CDK2 / Cyclin E Degrader CG923308	CDK4/6i-resistant Breast Cancer and Other Solid Tumors	IND-enabling development in China; Phase 1 in U.S. and/or China					Anticipate IND-application submission in U.S. and/or China and Phase 1 initiation around mid-2027
TYK2 / JAK1 Degrader CG620953	Systemic Lupus Erythematosus (SLE) & Rheumatoid Arthritis (RA)	IND-enabling development in China; Phase 1 in U.S. and/or China					Anticipate IND-application submission in U.S. and/or China and Phase 1 initiation around mid-2027
GSPT1 Degrader CG009301	R/R AML, HR-MDS, R/R ALL; Solid Tumor Cancers	Phase 1 dose escalation ongoing in China					Phase 1 dose-escalation data in patients with high-risk hematologic malignancies in 2H27
TRK Degrader CG001419	Cancer-induced Bone Pain (CIBP)	Phase 1 in healthy volunteers completed in Australia; Phase 2 in China					Planning Phase 2 initiation in China 1H27
Hydronidone F351	Chronic Hepatitis B (CHB)-induced Liver Fibrosis						Decision expected from NMPA by YE26/1Q27 & potential launch in 1H27

Cancer Inflammation / Fibrosis Degrader DAC

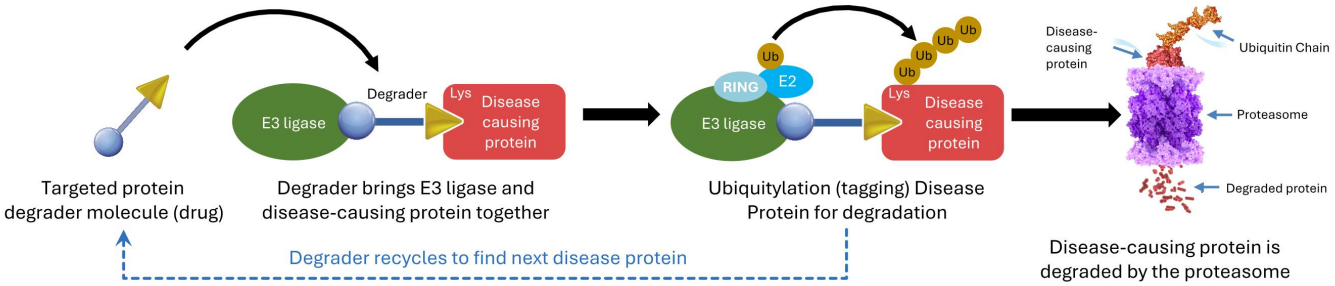
China R&D incubator provides new promising clinical assets for global development in cancer, immunology & inflammatory (I&I) diseases, and pain

Gyre THERAPEUTICS

Targeted Protein Degraders (TPDs)

A Modular Degrader Platform: From Discovery to Clinic

Ubiquitin Proteasome System (UPS) – Our Engine for Targeted Protein Degradation



Targeted protein degrader molecule (drug)

Degrader brings E3 ligase and disease-causing protein together

Ubiquitylation (tagging) Disease Protein for degradation

Disease-causing protein is degraded by the proteasome

Degrader recycles to find next disease protein

Gyre's Proprietary Targeted Protein Degraders' Enables:

- **Drugging 'undruggable' disease-causing proteins**
- **Catalytic high potency**
- **High target selectivity**
- **Overcome drug resistance**
- **Sustained target depletion**

Our expertise also translates well into implementing TPD technology in combination with Antibody-drug conjugates (ADCs) to make next-gen ADCs, called Degrader Antibody Conjugates (DACs).

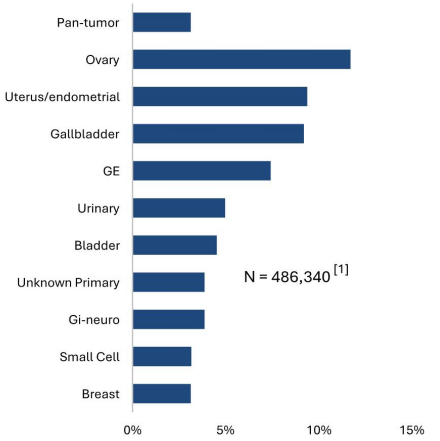


One Platform. Multiple Degraders. Built for Broad Impact Across Oncology and Immunology.

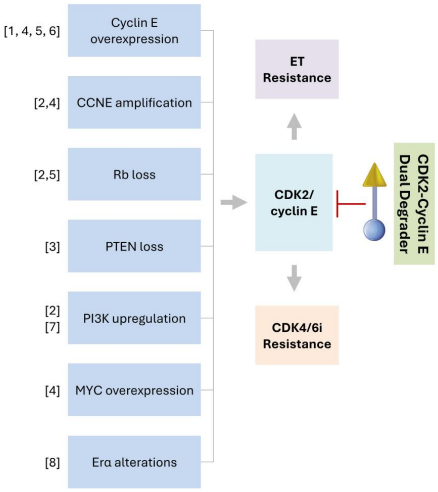
CDK2-Cyclin E Dual Degrader: Novel Strategy for Multiple Solid Cancer Types

Cyclin E Is Functionally Amplified or Overexpressed Across Multiple Cancer Types

CCNE1 Amplification Prevalence (%)



Diverse CDK4/6i or Endocrine Therapy Resistance Converge on Activation of CDK2/Cyclin E



Market Opportunity & Unmet Medical Need

- Verzenio, Kisqali, and Ibrance
- ~$14.6B Total Global Revenues in 2025 [9]
- Projected total global revenues between $25.8B - $35.7B by early 2030s[9]
- ~50% of patients develop resistance to CDK4/6 inhibitors within 2 years of starting therapy

:[1] Lee et al (2026) Clin Cancer Res. PMID:41870274

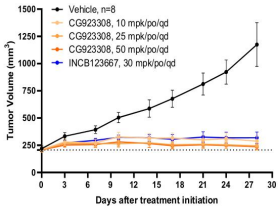
[1] Turner NC (2019) J Clin Oncol. PMID: 30807234; [2] Herrera-Abreu MT (2016) Cancer Res. PMID: 27020857; [3] Costa C (2020) Cancer Discov. PMID: 31594766
[4] Freeman-Cook (2021) Cancer Cell. PMID: 34520734; [5] Wander SA (2020) Cancer Discov. PMID: 32404308; [6] Al-Qasem AJ(2022) NPJ Precis Oncol. 2022 PMID: 36153348
[7] Josefine B (2012) Breast Cancer Res Treat. PMID: 23242584; [8] Caldon CE (2012) Mol. Cancer Ther. PMID: 22564725

[9] Strategic Market Research, July 2026

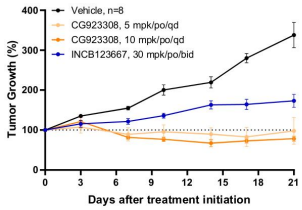
Gyre THERAPEUTICS

CG923308 Demonstrates Anti-Cancer Efficacy in Resistant Preclinical Models

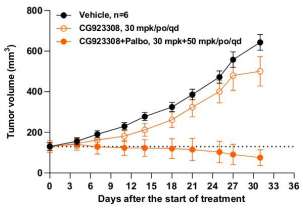
A. Ovarian Cancer CDX



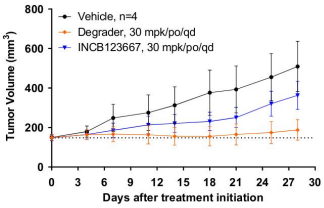
C. Gastric Cancer CDX



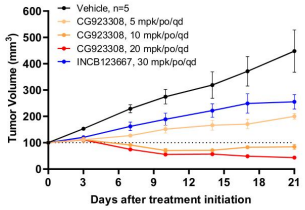
E. CDK4/6i-resistant breast cancer CDX



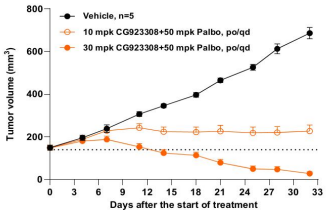
B. Chemo-resistant TNBC PDX



D. TNBC CDX



F. CDK4/6i-resistant breast cancer PDX

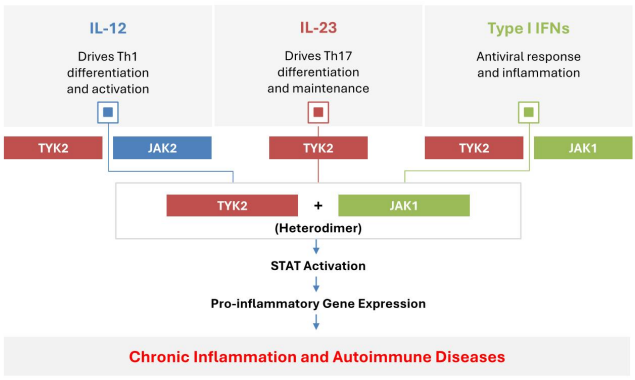


CG923308 produces meaningful anti-cancer efficacy in multiple solid tumor preclinical mouse models, including CDK4/6i-resistant models

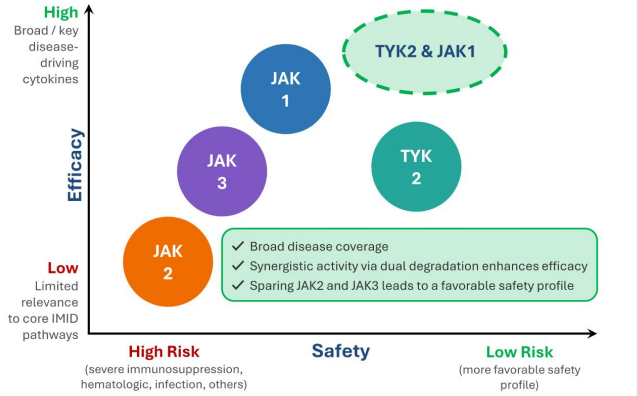
INCB123667: A phase 2/3 CDK2 inhibitor by Incyte; **Palbo**: Palbociclib (Ibrance), CDK4/6 inhibitor developed by Pfizer; **TQB3616**: CDK2/4/6 inhibitor developed by Chia Tai Tianqing; **TNBC**: triple-negative breast cancer

TYK2-JAK1 Dual Degrader: Next-Generation Therapy for Autoimmune Diseases

Cytokine signaling mediated by TYK2 and JAK1



Sweet Spot of TYK2/JAK1 Dual Targeting



Significant Unmet Need and Market Opportunity Across Autoimmune Diseases

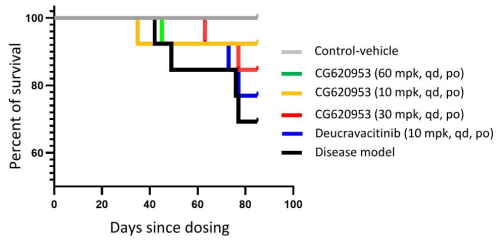
- 125MM+ Patients Worldwide[1] — Psoriasis
- 18MM Patients Worldwide[2] — Rheumatoid Arthritis
- 204K+ Patients U.S.[3] — Systemic Lupus Erythematosus
- Other Inflammatory and Autoimmune Indications

Notes:
1. https://www.psoriasis.org/psoriasis-statistics/
2. https://www.who.int/news-room/fact-sheets/detail/rheumatoid-arthritis;
3. https://www.niams.nih.gov/health-topics/lupus/basics/symptoms-causes;

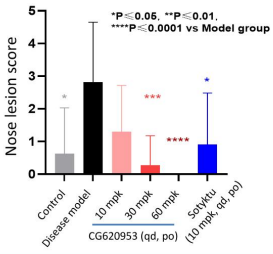
CG620953 Demonstrates Efficacy in Lupus and RA Preclinical Models

Lupus

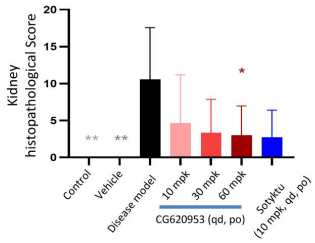
Survival rate



Doral skin lesion score

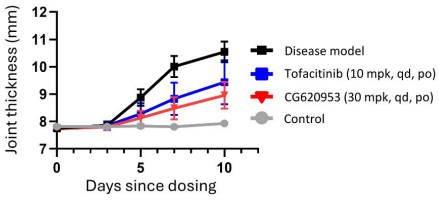


Kidney injury histopathology

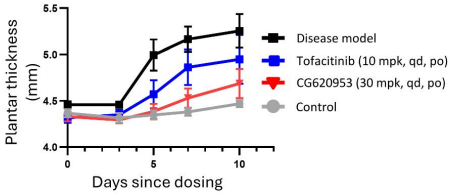


RA

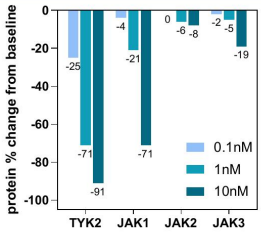
Joint inflammation & cartilage destruction



Hind paw edema



TYK2/JAK1 degradation & JAK2/3 sparing



CG620953 exhibit enhanced efficacy signals in preclinical models

Gyre THERAPEUTICS

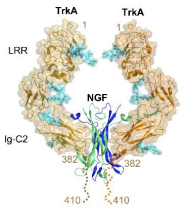
Pan-TRK Degrader: Potential First-in-Class, Non-Opioid Therapeutic Degrader for Cancer-Induced Bone Pain

Nerve growth factor (NGF) stimulates the TRKA signaling pathway to transmit pain to the central nervous system



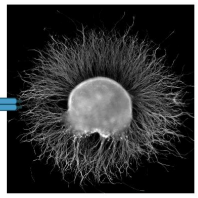
Injury / Inflammation

NGF



NGF-TRKA complex

TrkA



Dorsal root ganglion (DRG)



Brain

Cancer-Induced Bone Pain U.S. Market Opportunity

280K – 330K

New cases of malignant bone metastasis in the U.S. annually [1,2]

Significant Unmet Need

70-90% develop symptomatic pain with limited current treatment options [3]

193-225 Days

Average treatment duration for cancer-induced bone pain [4,5]

Our Differentiated Approach

CG001419 Oral Pan-TRK Degrader

Mechanism

- Degrades TrkA & TrkB proteins to achieve high potency.
- Non-brain-penetrance to avoid CNS side effects.

Early Validation

- Phase 1a target engagement in high single-digit / low double-digit nanomolar ranges.
- Well-tolerated up to highest dose tested.[6]

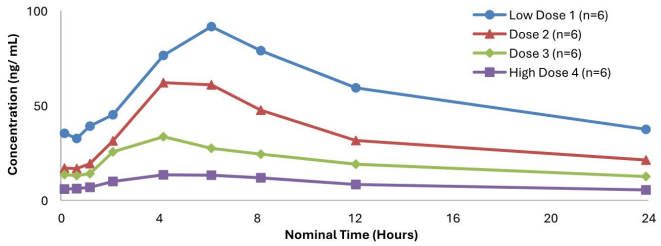
Speed Advantage

U.S.□China clinical development enables parallel execution and faster timelines.

1. https://pubmed.ncbi.nlm.nih.gov/22570568; 2. https://pubmed.ncbi.nlm.nih.gov/26229504; 3. https://pubmed.ncbi.nlm.nih.gov/23344095; 4.https://pubmed.ncbi.nlm.nih.gov/25919474; 5. https://pubmed.ncbi.nlm.nih.gov/37343145; 6. Company data; CG001419-101 (NCT06636500).

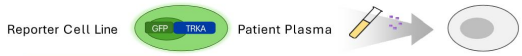
CG001419 Phase 1 Results: PD Target Engagement and Safety

Multiple Ascending Dose (MAD) PK – Day 7



Pharmacodynamics: Potential Target Engagement

Surrogate PD Assay Demonstrated Degradation Potency in the Low-nM Range.



DC50 = 2.1 ng/mL
DC90 = 16 ng/mL

Safety / Tolerability from Phase 1

Pharmacodynamics: potential target engagement demonstrated

- Plasma-to-reporter cell assay showed **TRKA degradation**, supporting potential target engagement
- Potent surrogate PD activity observed: **DC50 = 2.1 ng/mL; DC90 = 16 ng/mL**

Favorable safety / tolerability profile

- Single and multiple oral doses were well tolerated up to the highest tested dose levels
- Most TEAEs were **mild or moderate; no Grade 4 TEAEs** reported
- Common TEAEs were largely general / administration-site events, likely related to blood collection procedures

Predictable exposure profile supports continued development

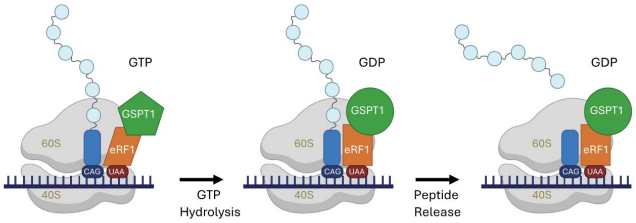
- Single-dose CG001419 exposure increased **dose-proportionally**
- Fed condition increased systemic exposure; 7-day MAD exposure increased **less than dose-proportionally** for CG001419 and metabolites M2/M8

Completed Phase 1 studies in healthy volunteers; currently planning Phase 2 for cancer-induced bone pain to commence in U.S. or China

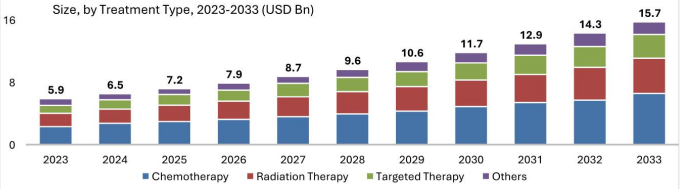
Source: Company data; CG001419-101 (NCT06636500).

CG009301: Targeting GSPT1 for AML and Solid Tumor Cancers

- GSPT1 controls protein translation termination and plays important function for leukemia stem cells and tumor cells with MYC overproduction
- GSPT1 lacks an active site and is often considered “undruggable”
- Other programs targeting GSPT1 show insufficient therapeutic index. CG009301 demonstrate encouraging safety profile in our preclinical studies and early clinical development.



Global Blood Cancer Treatment Market



The Market will Grow At the CAGR of:	10.3%	The Forecasted Market size for 2033 in US$:	15.7Bn

market.us

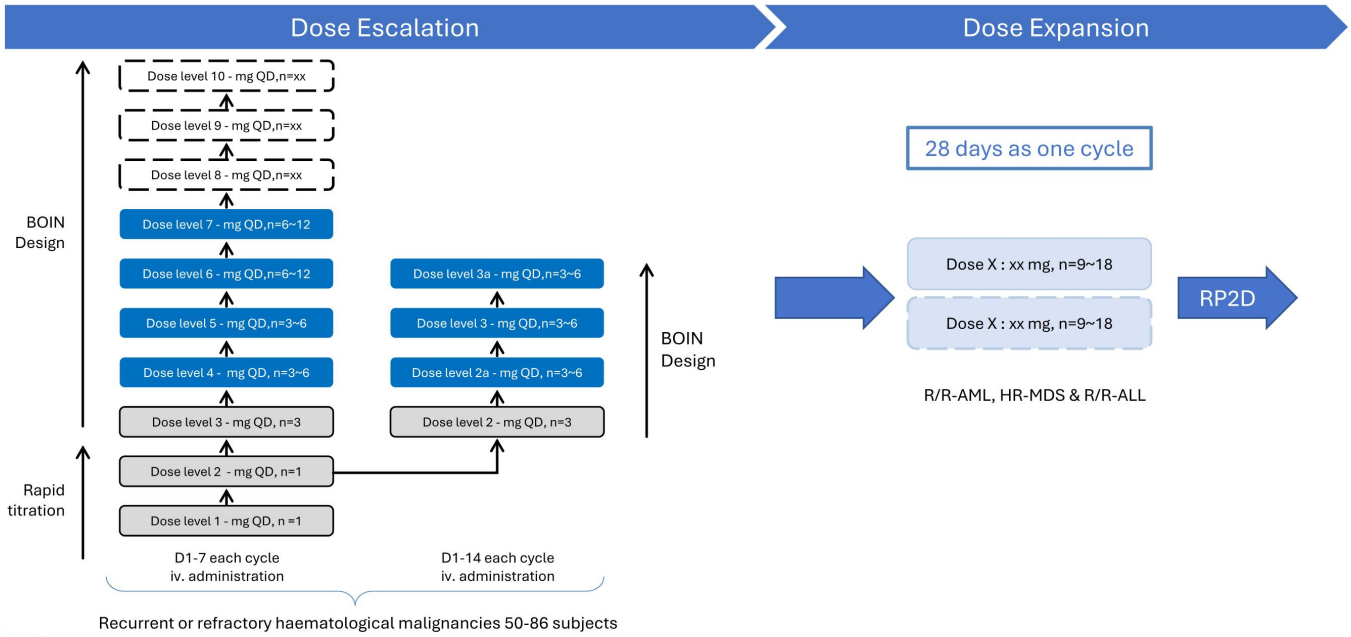
U.S. Patient Population

AML [1]	MDS [1]	ALL [1]	MYC-amplified Solid Tumors [2],[3]
~20,800 new cases	~10,000 new cases	~6,500 new cases	28%
11,220 mortality	30-40% MDS progress to AML [4]	1,330 mortality	

Notes:
1. 2024 by American Cancer Society estimates
2. The Cancer Genome Atlas (TCGA) estimates
3. Schaub et al (2018) *Cell Syst* PMID: 29596783O
4. Volpe et al. (2022) *Clin Lymphoa Myelom Leuk*, PMID: 34544674

Gyre THERAPEUTICS

CG009301: Ongoing Phase 1 in China for Patients with High-risk Heme Malignancies

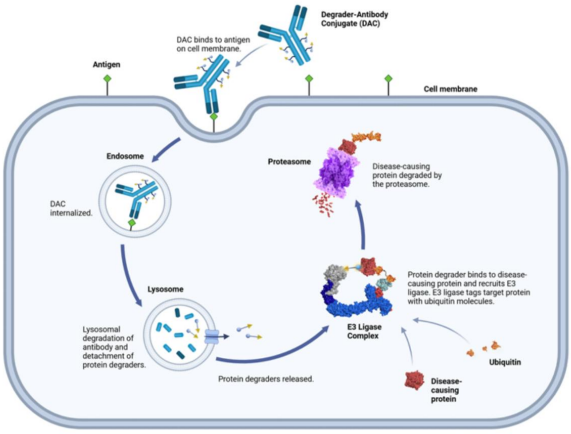


Gyre THERAPEUTICS

Degrader-Antibody Conjugates (DACs)

Leveraging Expertise in TPDs and China ADC Platform to Develop Degrader-Antibody Conjugates (DACs)

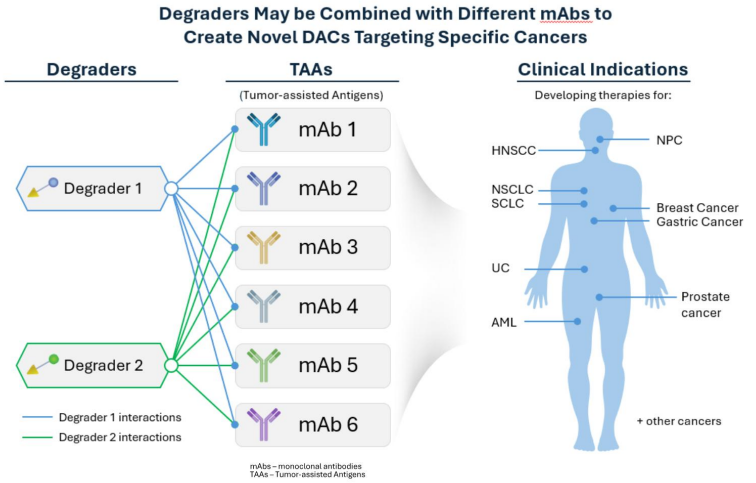
Gyre's DAC Mechanism of Action & Benefits



HIGH POTENCY | **IMPROVED PK**

TWO LAYERS OF SELECTIVITY

Gyre's DAC Platform for Multiple Cancer Types

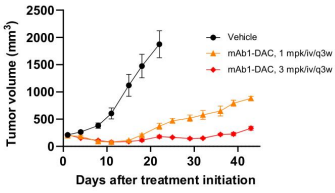


Gyre's Degrader Molecule 1-DAC Demonstrates Durable Prostate Tumor Growth Inhibition

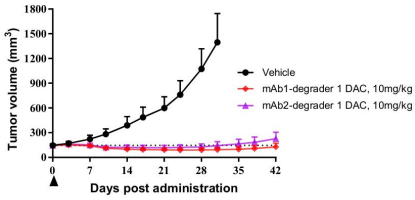
- Prostate cancer causes 35,000 – 36,500 deaths each year and is the second-leading cause of cancer death in American men.[1]
- Degrader 1 targets epigenetic factors that are frequently mutated across human malignancies and drive oncogenic signaling, including AR-mediated transcription in prostate cancer.
- Prior developments targeting the epigenetic factors for prostate cancer has been limited by the toxicity.

[1] American Cancer Society estimates as of August 2026

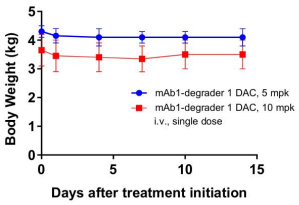
A. Prostate cancer CDX model



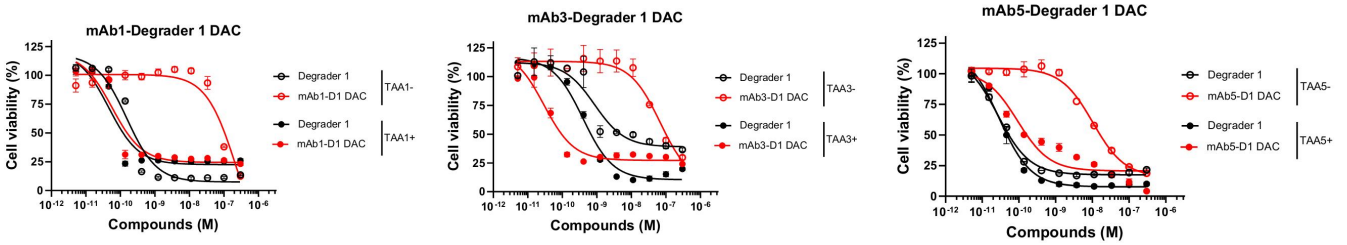
B. Enzalutamide-resistant CRPC PDX model



C. Non-human primate pilot toxicity

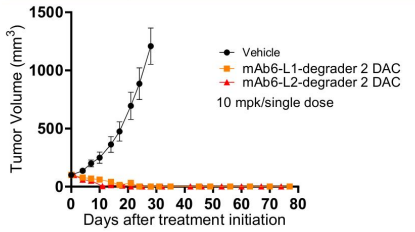


D. Degrader Molecule 1-Targeting DACs Demonstrate Demonstrates TAA-Dependent Cell Killing Activity When Conjugated to Additional Antibodies

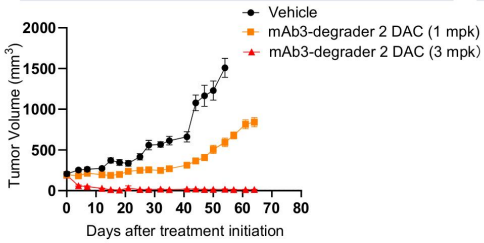


Gyre's Degrader Molecule 2-DAC Demonstrate Broad Efficacy Across Diverse Tumor Types

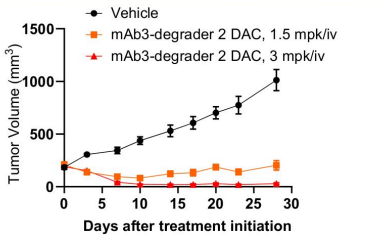
A. AML CDX model



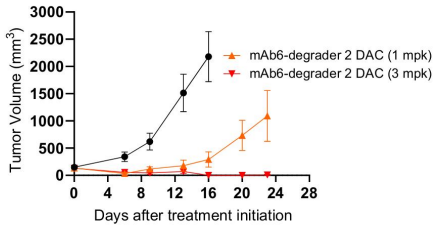
C. Breast Cancer model



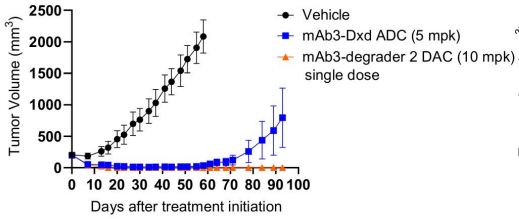
E. Gastric Cancer CDX model



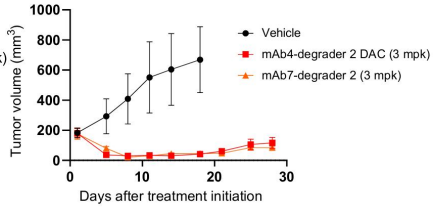
B. AML CDX model



D. Breast Cancer model



F. NSCLC CDX model



mAb: monoclonal antibody recognizing a specific antigen; **DXd-ADC**: HER2-DXd ADC (Enhertu) Developed by Daiichi Sankyo and AstraZeneca

Commercial Foundation and Growth Opportunities with F351 (Hydronidone)

ETUARY™: The Commercial Anchor of Our Fibrosis Franchise Since 2011

A Durable Revenue Base that Funds Innovation and Supports Our Next-generation Degrader / DAC Platform

Established Leadership

ETUARY™ has anchored our IPF franchise in China through consistent execution and broad physician reach, supported by ~370 commercial personnel across 3,000+ hospitals and pharmacies.

Durable Market Position

ETUARY™ was approved by China's National Medical Products Administration (NMPA) in 2011 before Esbriet approval by US FDA. GYRE Pharmaceuticals has maintained market leadership positions in China since then, which demonstrated GYRE's capability to manage the drug life cycle.

Funds the Innovation Pipeline

ETUARY™'s recurring commercial revenue supports our next-generation degrader / DAC platform without dilution dependence.

1 ETUARY™ (Pirfenidone) (1)



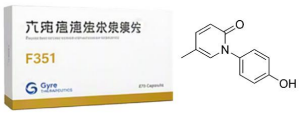
China's Leading Pirfenidone Brand
For the Treatment of IPF (1)

2 Etorel ™ – Launched in 2025



Complementary PF option that extends the fibrosis toolkit alongside ETUARY™.

3 F351 (Hydronidone)



New Drug Application (NDA) accepted for priority review by NMPA in May 2026.

A One-stop Shop for Fibrosis – Building Physician Reach Ahead of F351

Notes:
1. ETUARY market position based on IQVIA CHPA data for pirfenidone in China [2014-2026]; legal review required. Financial data inclusive of pro forma data prior to GNI Group and Catalyst Biosciences business combination. 2017 sales in audited China GAAP; 2025 in audited U.S. GAAP

F351 Phase 3 Results in CHB-associated Liver Fibrosis Supports Regulatory Filing

F351 poised to be the next-generation of fibrosis therapy

Breakthrough Therapy Designation
Priority Review of NDA
(China NMPA, 2021, 2026)

NDA accepted by NMPA in May 2026

Primary Endpoint Met with High Statistical Significance

≥1-stage fibrosis regression at Week 52:

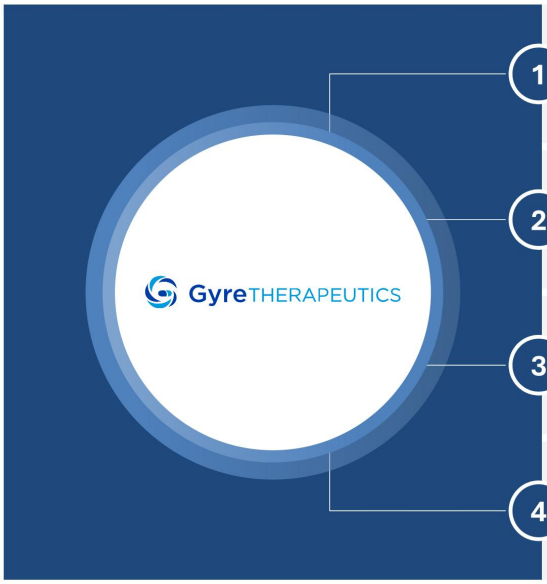
- F351: 52.85% (n=123) vs.
- Placebo: 29.84% (n=124)
- **Delta: 23.01%**
- **p = 0.0002** (ITT[1] analysis with central blinded pathology review)
- Consistent with fibrosis regression rates observed in Phase 2

Key Secondary Endpoint Reduction in Liver Inflammation

≥1-grade inflammation improvement without fibrosis progression at Week 52:

- F351: 49.57% (n=123) vs.
- Placebo: 34.82% (n=124)
- **Delta: 14.75%**
- **p = 0.0246**
- Reinforces anti-inflammatory activity

Key Value Drivers



Lead TPD Assets

- Opportunities in cancer and autoimmune diseases with dual degraders
- TPD portfolio highly validated for large unmet need indications

TPD / DAC R&D Engine

- Multiple shots on goal
- DACs paint a promising picture as the next-gen to ADCs / TPDs alone

Global Exposure

- Lean operations to de-risk assets
- U.S. headquarters and integrated U.S. and China R&D operations

Revenues to Support Operations

- ETUARY™ and anticipated F351 sales in China expected to cover operation expenses to support early-stage R&D and proof-of-concepts studies

U.S. Management Team with Cross-Culture Operational Experience



Ying Luo, Ph.D.
Chief Executive Officer



Thomas Eastling
Chief Financial Officer



Weiguo Ye
Chief Operating Officer



Yue Xiong, Ph.D.
Chief Scientific Officer



Ruoyu Chen
Chief Information Officer



Jialiang Wang, Ph.D.
Executive Vice President,
General Manager



Joshua Bergmann, J.D.
General Counsel and
Corporate Secretary



Seth Goldblum, MBA
Senior Vice President –
Corporate Development



Mark Marino, M.D.
Senior Vice President –
Clinical Development



Michael Plewe, Ph.D.
Senior Vice President -
Medicinal Chemistry



Jing Liu, Ph.D.
Senior Vice President –
Platform Chemistry



Chuck Monahan
Senior Vice President –
Regulatory Affairs



Leslie Robinson, Ph.D., J.D.
Vice President - Intellectual
Property and Licensing



Sudan Loganathan, Ph.D.
Vice President – Investor
Relations & Finance Strategy



Liang Zhao
Vice President –
Corporate Controller

Gyre
THERAPEUTICS

Thank You!

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