

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): September 1, 2026

Gyre Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

000-51173
(Commission File Number)

56-2020050
(IRS Employer Identification No.)

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

92130
(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 7.01 Regulation FD Disclosure.

On September 1, 2026, Gyre Therapeutics, Inc. (the “Company”) made available an updated corporate presentation on the Company’s website.

A copy of the corporate presentation is furnished as Exhibit 99.1 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 Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

<u>Exhibit Number</u>	<u>Exhibit Title or Description</u>
99.1	Corporate Presentation, dated September 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: September 1, 2026

By: /s/ Thomas Eastling
Name: Thomas Eastling
Title: Chief Financial Officer

A Global Innovator Expanding And Reinventing Protein Degradar Therapeutics



September 2026

Forward-looking Statements

This presentation contains "forward-looking statements" within the meaning of the federal securities laws, including Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, regarding the current plans, expectations and strategies of Gyre Therapeutics, Inc. and its subsidiaries ("Gyre"), which statements are subject to substantial risks and uncertainties and are based on management's estimates and assumptions. All statements, other than statements of historical facts included in this presentation, are forward-looking statements, including Gyre's ability to leverage China operations for discovery, validation and development of therapeutics, clinical development plans, anticipated timelines and milestones of Gyre's degrader antibody-conjugate platform, CG923308, CG620953, CG009301, CG001419, F351 and ETUARY™, including the geographic location and timing of anticipated regulatory submissions and approvals, and the potential therapeutic benefits, efficacy, safety and differentiation of such product candidates, and market size and commercial opportunity estimates, Gyre's plans, objectives, goals, strategies, future events, or intentions relating to Gyre's products and markets, the safety, efficacy and clinical benefits of Gyre's product candidates, the anticipated timing and design of any planned and ongoing preclinical studies and clinical trials, Gyre's research and development efforts, plans and objectives of management for future operations and future results of anticipated product development efforts, potential addressable market size and Gyre's liquidity and capital resources and business trends. In some cases, you can identify forward-looking statements by terms such as "believe," "can," "could," "anticipate," "design," "estimate," "expect," "forecast," "intend," "may," "might," "plan," "target," "seek," "goal," "assume," "milestones," "potential," "predict," "objective," "should," "strategy," "will," "would," "forthcoming," or the negative of these terms, and similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements may include express or implied statements relating to: the estimated future financial performance and financial position of Gyre; the therapeutic potential and utility, efficacy and clinical benefits of the product candidates of Gyre; the risk/benefit profile of Gyre's product candidates; expectations regarding Gyre's research and development efforts, including geographic location and timing of initiation of clinical trials for Gyre's product candidates; Gyre's expectations regarding the advancement of product candidates into IND-enabling studies; and Gyre's expectations, hopes, beliefs, intentions and strategies; and other statements that are not historical fact. These statements involve known and unknown risks, uncertainties and other factors that could cause Gyre's actual results to differ materially from the forward-looking statements expressed or implied in this presentation, in addition to those risks and uncertainties, such as the uncertainties inherent in the clinical drug development process, the regulatory approval process, the timing of any regulatory filings, the potential for substantial delays, the risk that earlier study results may not be predictive of future study results, manufacturing risks, competition from other therapies or products and the impacts of current macroeconomic and geopolitical risks. A discussion of these and other factors, is set forth in Gyre's Annual Report on Form 10-K for the year ended December 31, 2025 filed with the Securities and Exchange Commission (the "SEC") on March 13, 2026 and elsewhere in such other filings and in Gyre's periodic reports and subsequent disclosure documents filed with the SEC. Gyre cannot assure you that it will realize the results, benefits or developments that it expects or anticipates or, even if substantially realized, that they will result in the consequences or affect Gyre or its business in the way expected. Forward-looking statements are not historical facts and reflect management's current views with respect to future events. Given the significant uncertainties, you should evaluate all forward-looking statements in the context of these risks and uncertainties and not place undue reliance on these forward-looking statements as predictions of future events. All forward-looking statements in this presentation apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this presentation. Gyre has no intention to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances, except as required by law.

Certain information contained in this presentation and statements made orally during this presentation relate to or is based on studies, publications, surveys and other data obtained from third-party sources and Gyre's own internal estimates and research. While Gyre believes these third-party studies, publications, surveys and other data to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, no independent sources have evaluated the reasonableness or accuracy of Gyre's internal estimates or research, and no reliance should be made on any information or statements made in this presentation relating to or based on such internal estimates and research. This presentation contains trademarks, trade names and service marks of other companies which are the property of their respective owners. This presentation concerns a discussion of investigational drugs that are under preclinical and/or clinical investigation, and which have not yet been approved for marketing by the U.S. Food and Drug Administration. They are currently limited by Federal law to investigational use, and no representations are made as to their safety or effectiveness for the purposes for which they are being investigated.

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 early 27*
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 Degradator Technologies	Oncology / Inflammatory Disease Discovery Platform	 Discovery & lead selection in China					Lead DAC selection / IND-enabling advancement
 CDK2 / Cyclin E Degradator CG923308	CDK4/6i-resistant Breast Cancer and Other Solid Tumors	 IND-enabling development in China; Phase 1 in U.S. and/or China					Q1'27 IND-application submission in U.S. and/or China; Phase 1 start in 2027
 TYK2 / JAK 1 Degradator CG620953	Systemic Lupus Erythematosus (SLE) & Rheumatoid Arthritis (RA)	 IND-enabling development in China; Phase 1 in U.S. and/or China					Q1'27 IND-application submission in U.S. and/or China; Phase 1 start in 2027
 GSPT1 Degradator CG009301	R/R AML, HR-MDS, R/R ALL; Solid Tumor Cancers	 Phase 1 dose escalation ongoing in China					Phase 1 data in patients with high-risk hematologic malignancies expected at trial completion
 TRK Degradator CG001419	Cancer-induced Bone Pain (CIBP)	 Phase 1 in healthy volunteers completed in Australia; Phase 2 in U.S. or China					Planning Phase 2 initiation in U.S. or China
 Hydronidone F351	Chronic Hepatitis B (CHB)-induced Liver Fibrosis	 NDA-filing accepted by China NMPA in May 2026; Potential launch post-NMPA decision in early 2027					

 Cancer
  Inflammation / Fibrosis
  Degradator
  DAC

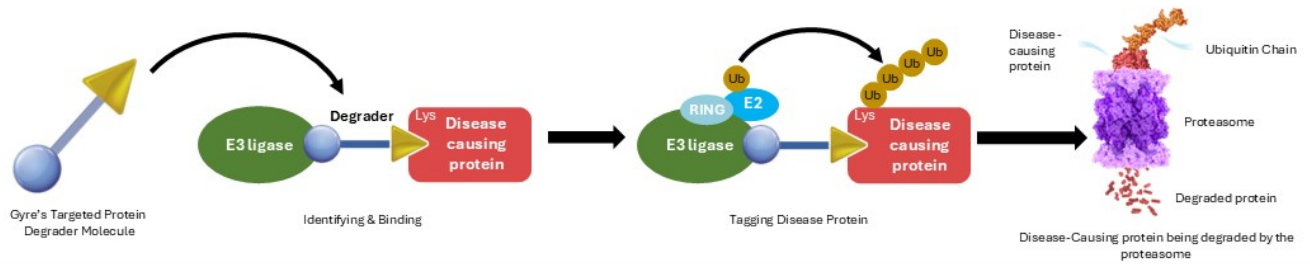
China R&D incubator provides new promising clinical assets for global development in cancer, immunology & inflammatory (I&I) diseases, and pain



Targeted Protein Degradors (TPDs)

A Modular Degradator Platform: From Discovery to Clinic

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



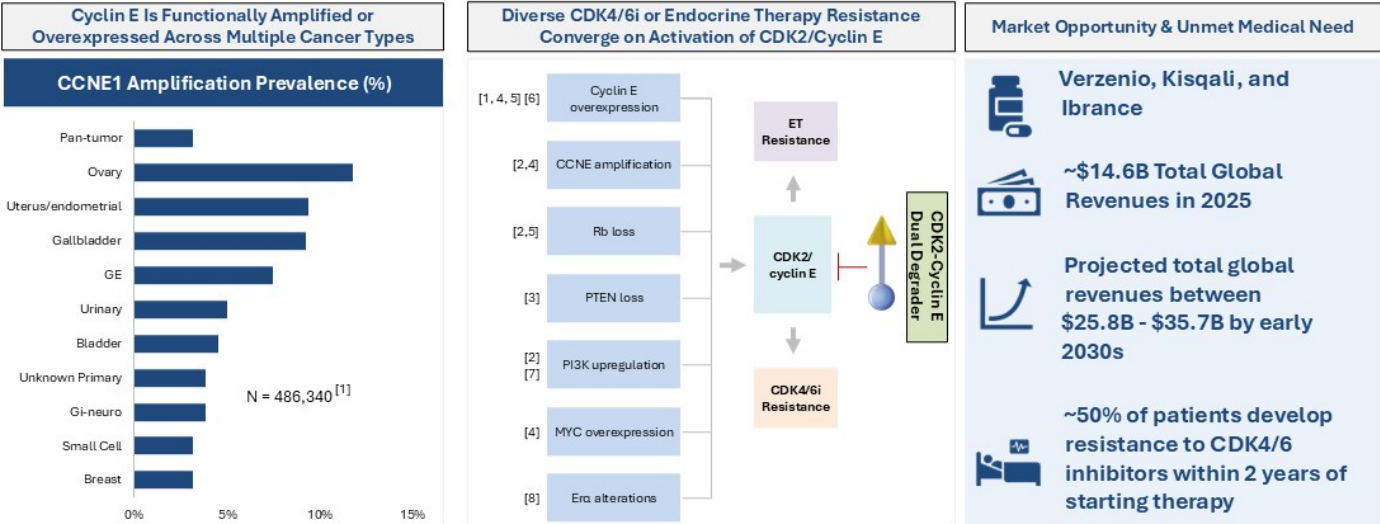
Gyre's Proprietary Targeted Protein Degraders' Catalytic Mechanism of Action Enables:

- High Potency
- Access to Undruggable Targets
- Modular Design to Create Multiple Degraders

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

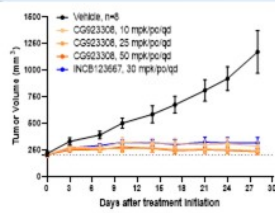
One Platform. Multiple Degraders. Built for Broad Impact Across Oncology and Immunology.

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

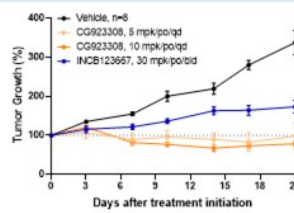


CG923308 Demonstrates Anti-Cancer Efficacy in Resistant Preclinical Models

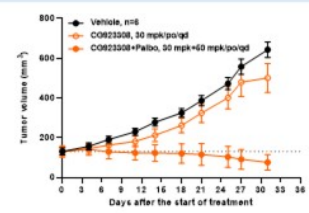
A. Ovarian Cancer CDX



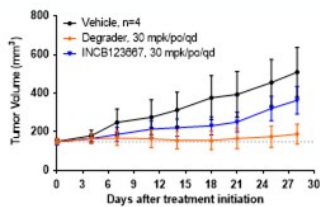
C. Gastric Cancer CDX



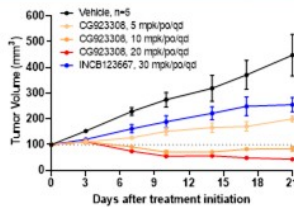
E. CDK4/6i-resistant breast cancer CDX



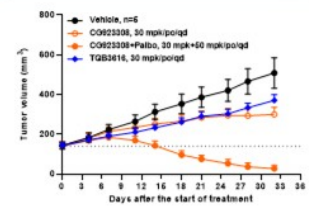
B. Chemo-resistant TNBC PDX



D. TNBC CDX



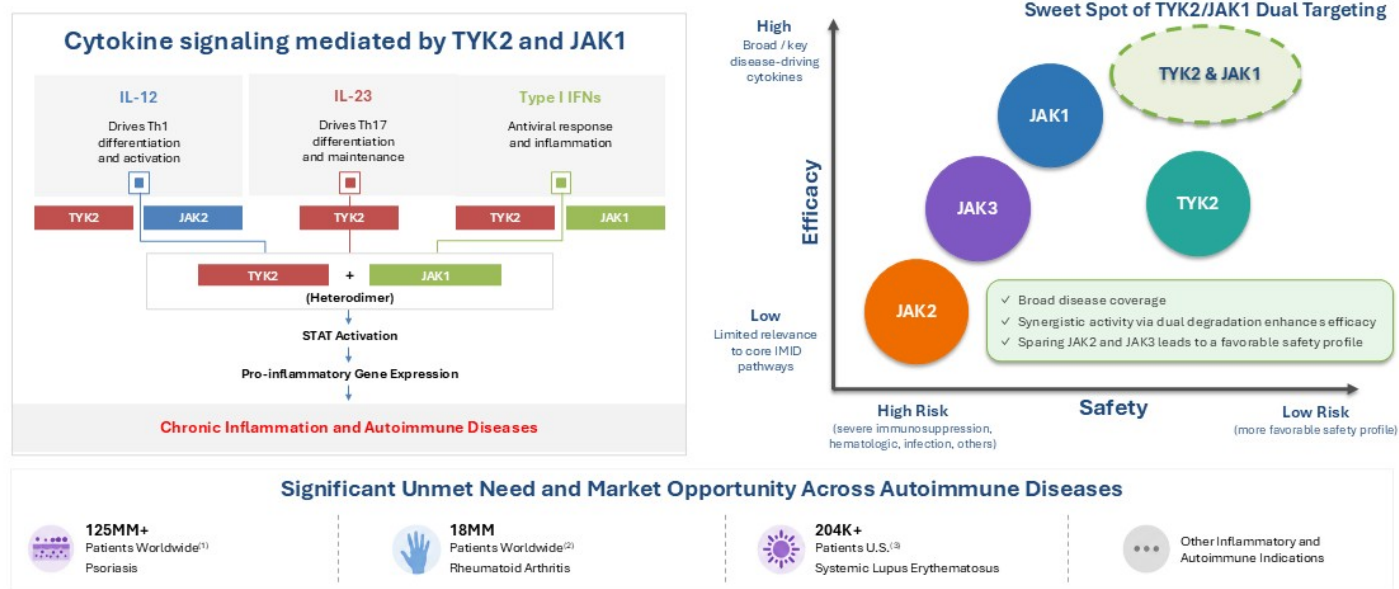
F. CDK4/6i-resistant breast cancer PDX



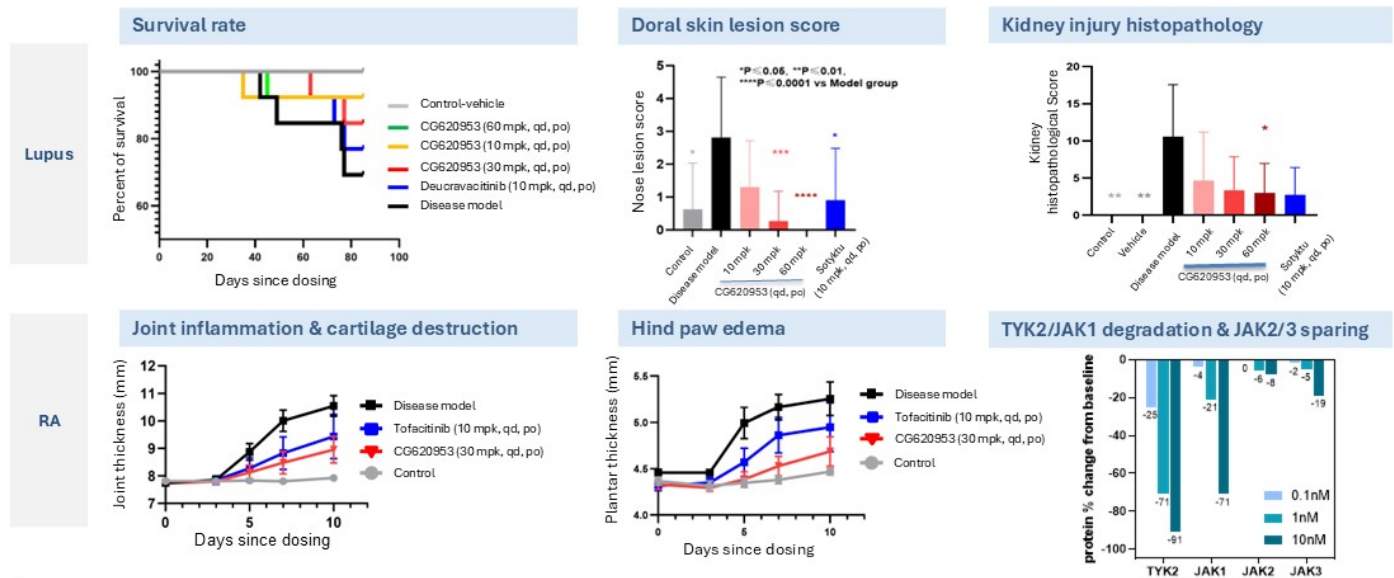
INCB123667: A phase 2/3 CDK2 inhibitor by Incyte; Palbo: Palbociclib (Ibrance), CDK4/6 inhibitor developed by Pfizer; TQB3816: CDK2/4/6 inhibitor developed by Chia Tai Tianqing; TNBC: triple-negative breast cancer

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

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



CG620953 Demonstrates Efficacy in Lupus and RA Preclinical Models



CG620953 exhibit enhanced efficacy signals in preclinical models

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

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}

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/37943145>

Our Differentiated Approach

CG001419

Oral Pan-TRK Degradar

Differentiated Mechanism

Degrades TrkA at the source

Early Clinical Validation

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

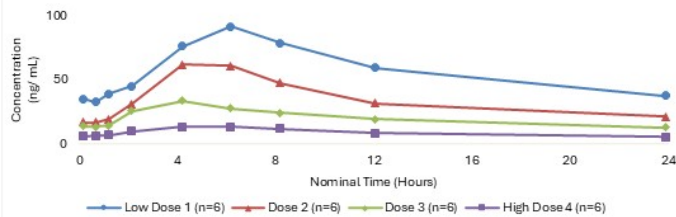
Speed Advantage

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

6. Company data; CG001419-101 (NCT06696500).

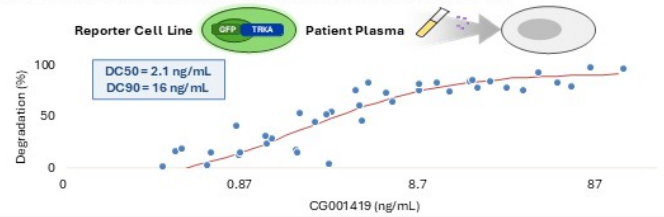
CG001419 Phase 1 Results: PD Target Engagement and Safety

Multiple Ascending Dose (MAD) PK – Day 7



Pharmacodynamics: Potential Target Engagement

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



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

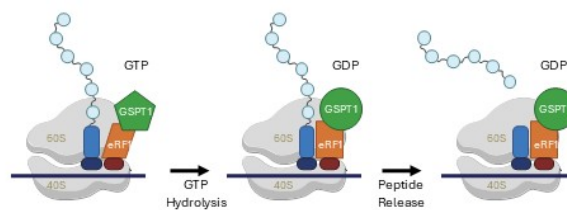
- Single-dose CG001419 exposure increased **dose-proportionally**
- Fed condition increased systemic exposure; 7-day MAD exposure increased **less than dose-proportionally** for CG001419 and metabolites M2/M8

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).

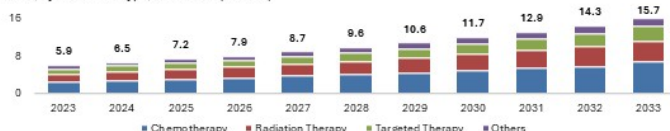
CG009301: Targeting GSPT1 for AML and Solid Tumor Cancers

- 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

Size, by Treatment Type, 2023-2033 (USD Bn)



The Market will Grow
At the CAGR of:

10.3%

The Forecasted Market
size for 2033 in US\$:

15.7Bn

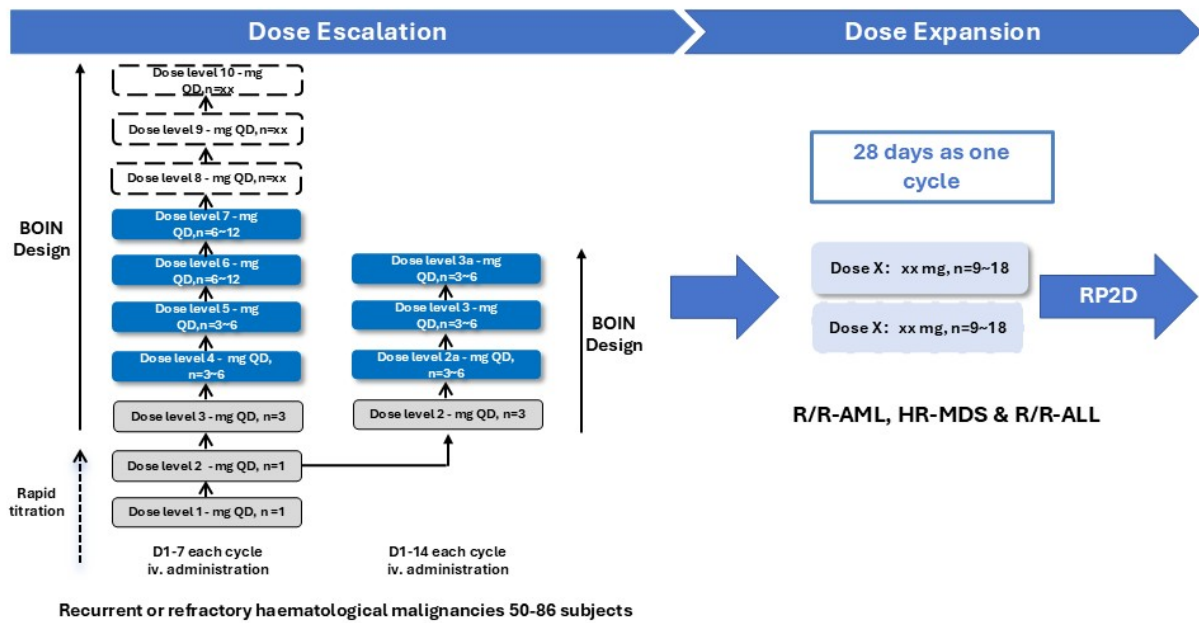
market.us

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: 295967830
4. Volpe et al. (2022) Clin Lymphoma Myelom Leuk, PMID: 34544674

CG009301: Ongoing Phase 1 in China for patients with high-risk heme malignancies

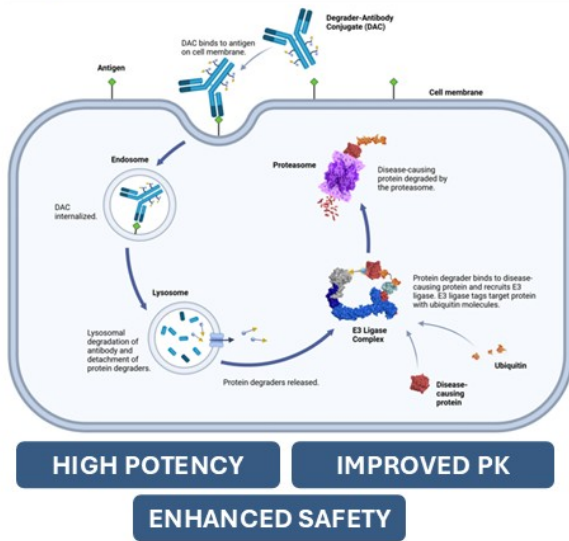




Degrader-Antibody Conjugates (DACs)

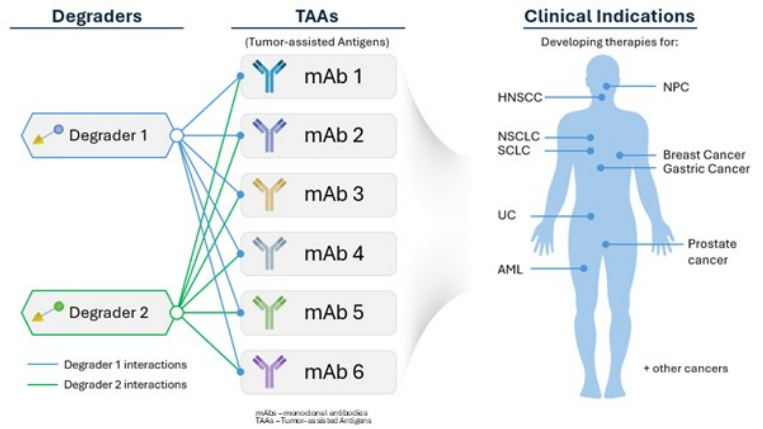
Leveraging Expertise in TPDs and China ADC Platform to Develop Degradar-Antibody Conjugates (DACs)

Gyre's DAC Mechanism of Action & Benefits



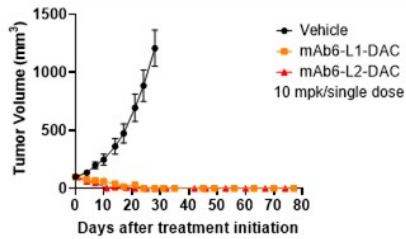
Gyre's DAC Platform for Multiple Cancer Types

Degraders May be Combined with Different mAbs to Create Novel DACs Targeting Specific Cancers

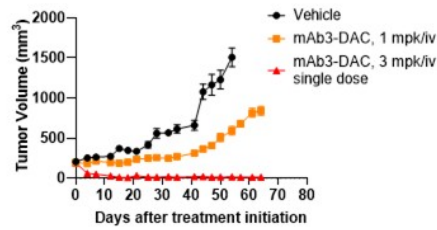


Gyre's DACs Demonstrate Broad Efficacy Across Diverse Tumor Types

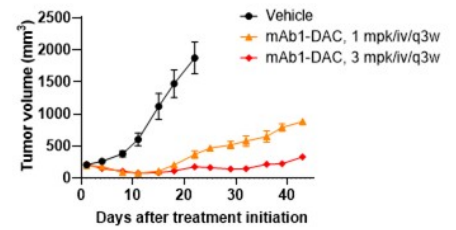
A. AML CDX model



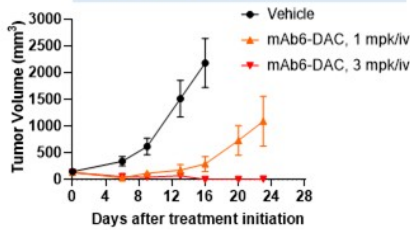
C. Breast Cancer model



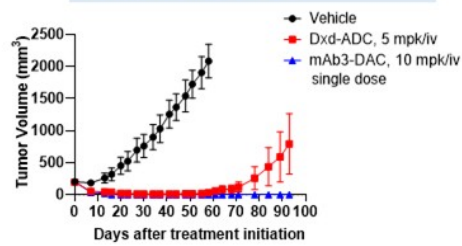
E. Prostate Cancer CDX model



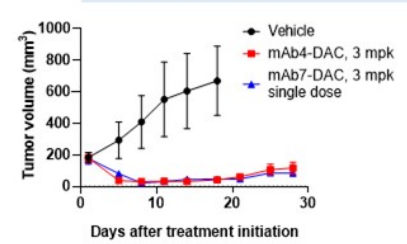
B. AML CDX model



D. Breast Cancer model



F. NSCLC CDX model



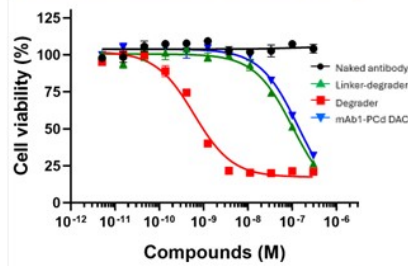
mAb: monoclonal antibody recognizing a specific antigen; Dxd-ADC: HER2-DXd ADC (Enhertu) Developed by DaiichiSankyo and AstraZeneca

DAC for Prostate Cancer and Solid Tumors With An Epigenetic-Targeting Payload

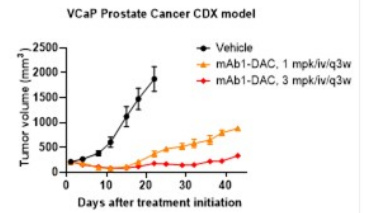
- » Prostate cancer causes 35,000 – 36,500 deaths each year and is the second-leading cause of cancer death in the US.¹
- » Epigenetic factors are frequently mutated across human malignancies, including prostate cancer.
- » Prior developments targeting epigenetic factors for prostate cancer has been limited by the toxicity.

1. American Cancer Society estimates as of August 2026

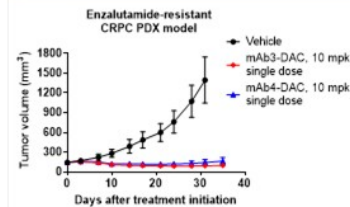
Protein degradation & cytotoxicity



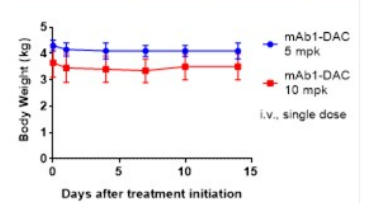
Prostate cancer CDX model



Therapeutic-resistant PDX model



Non-human primate pilot toxicity



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 Degradator / 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 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 degradator / DAC platform without dilution dependence.



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 [2014-2025]; 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 analysis with central blinded pathology review)
- Consistent with fibrosis regression rates observed in Phase 2

Key Secondary Endpoint Reduction in Liver Inflammation

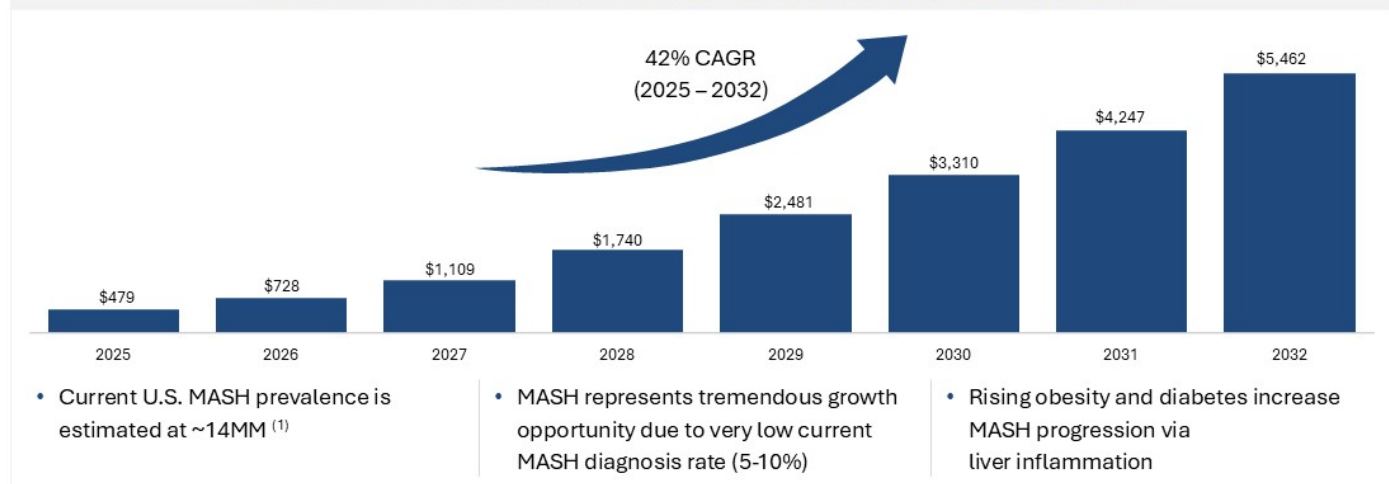
≥1-grade inflammation improvement without fibrosis progression at Week 52:

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

MASH Fibrosis Market Provides Significant Upside Opportunity For F351

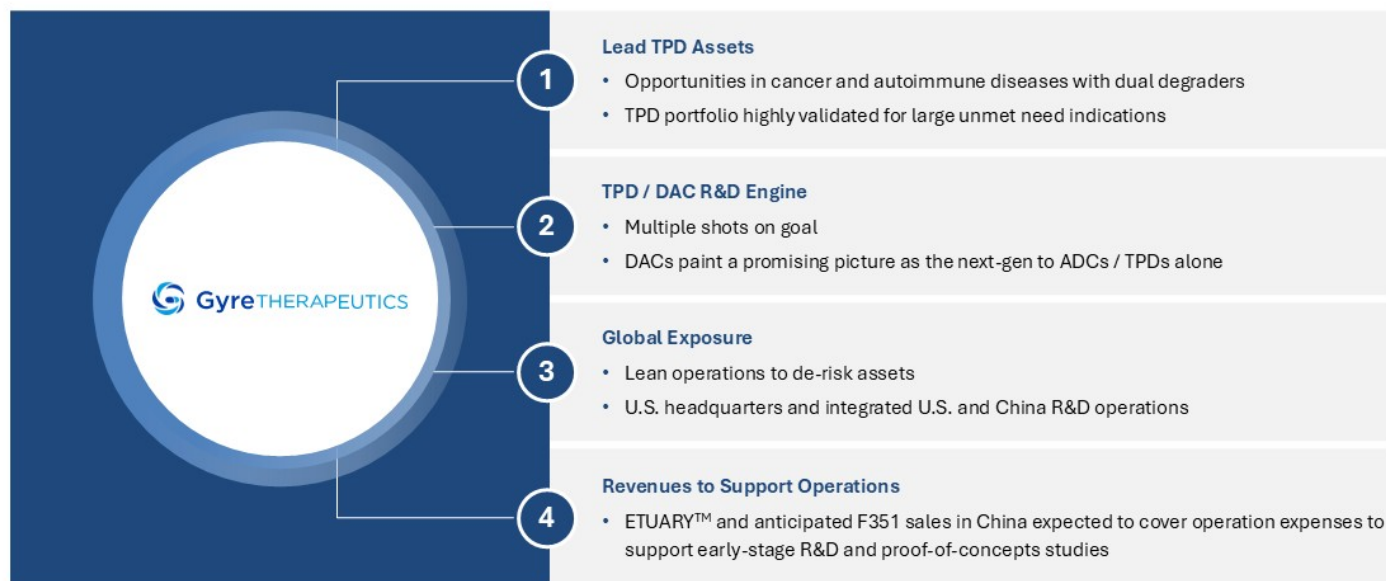
China-First Strategy Provides Accelerated POC

Forecasted Market Size of MASH Fibrosis Therapies in the USA (\$MM USD)



USA MASH Therapeutics Sales forecast from Evaluate Pharma as of 5-13-2026
Assumes 50% of all MASH patients progress to MASH fibrosis (Stage >F2) based on Luthra & Sheth (2025).
Note:
1. Le et al. (2025) JAMA; AJMC; MASH Awareness; Estes et al. (2018) AASLD; L.E.K., interviews

Key Value Drivers



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

Thank You!

