

**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 10, 2026

Lyell Immunopharma, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40502
(Commission
File Number)

83-1300510
(IRS Employer
Identification No.)

201 Haskins Way
South San Francisco, California
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's Telephone Number, Including Area Code: 650 695-0677

(Former Name or Former Address, if Changed Since Last Report)
Not Applicable

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:

- ☐ 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, \$0.0001 par value per share	LYEL	The Nasdaq Global Select 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 8.01. Other Events.

On September 10, 2026, Lyell Immunopharma, Inc. (the “Company”) issued a press release (the “LYL273 Press Release”) regarding the completion of the technology transfer for LYL273 to the Company’s LyFE Manufacturing Facility™ in Bothell, Washington and an updated timeline on the Phase 1/2 trial evaluating LYL273 in metastatic colorectal cancer. LYL273 is the Company’s next-generation guanylyl cyclase C (GCC)-targeted CAR T-cell product candidate for the treatment of relapsed/refractory metastatic colorectal cancer and other GCC-expressing cancers.

A copy of the LYL273 Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit
No

- | | |
|-------|---|
| 99.1 | <u>Press Release, dated September 10, 2026, titled “Lyell Immunopharma Completes Manufacturing Transfer for LYL273 and Provides Updated Timeline on Phase 1/2 Trial in Metastatic Colorectal Cancer.”</u> |
| 104.1 | Cover Page Interactive Data File, formatted in inline XBRL. |

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.

Lyell Immunopharma, Inc.

Date: September 10, 2026

By: /s/ Mark Meltz

Mark Meltz

General Counsel



Lyell Immunopharma Completes Manufacturing Transfer for LYL273 and Provides Updated Timeline on Phase 1/2 Trial in Metastatic Colorectal Cancer

- Technology transfer to LyFE Manufacturing Center™ completed following FDA review of improved manufacturing process and updated analytical methods
- Dosing of additional patients with the new process at LyFE continues with the goal of determining the recommended Phase 2 dose and optimized safety management plan to support End-of-Phase 1 discussions with the FDA
- Additional clinical data from the Phase 1/2 trial of LYL273 in patients with third- or later-line relapsed/refractory metastatic colorectal cancer and End-of-Phase 1 meeting with FDA expected in 2027

SOUTH SAN FRANCISCO, Calif., Sept. 10, 2026 — Lyell Immunopharma, Inc. (Nasdaq: LYEL), a late-stage clinical company advancing a pipeline of next-generation chimeric antigen receptor (CAR) T-cell therapies for patients with cancer, today announced successful completion of the planned technology transfer for LYL273, a guanylyl cyclase C (GCC)-targeted CAR T-cell product candidate, to its LyFE Manufacturing Center™ (LyFE) in Bothell, Washington, following review by the U.S. Food and Drug Administration (FDA). LyFE is implementing an improved manufacturing process and updated analytical methods to enhance manufacturing performance and increase capacity. The Phase 1/2 clinical trial of LYL273 in patients with relapsed/refractory metastatic colorectal cancer (R/R mCRC) continues to enroll patients with the goal of determining the recommended Phase 2 dose and optimized safety management plan. Additional clinical data from the trial and a planned End-of-Phase 1 meeting with the FDA are now expected in 2027.

“The LYL273 Phase 1/2 clinical trial continues to build momentum. We are activating additional clinical sites for the expansion phase of the trial, with strong interest in the study across our group of highly experienced investigators,” said Lynn Seely, MD, President and Chief Executive Officer of Lyell. “LYL273 has already generated encouraging clinical activity data in patients with metastatic colorectal cancer. We are now focused on determining the recommended Phase 2 dose and optimizing the safety management plan, including with results from patients treated with LYL273 manufactured at LyFE. We look forward to sharing additional clinical data and bringing a more complete data package to the FDA as we plan for our End-of-Phase 1 meeting in 2027.”

About LYL273

LYL273 is a guanylyl cyclase C (GCC)-targeted CAR T-cell product candidate enhanced with CD19 CAR expression and controlled cytokine release, designed to improve CAR T-cell expansion, immune cell infiltration and cancer cell killing in the hostile solid tumor microenvironment. CARABiNER (NCT05319314) is an ongoing Phase 1/2 dose-escalation, dose-expansion trial of LYL273 in the United States in patients with R/R mCRC. Lyell announced in June 2026 safety data from the trial demonstrating that gastrointestinal prophylaxis consisting of infliximab, vedolizumab and budesonide reduced Grade ≥ 2 diarrhea/colitis from 55%

without prophylaxis to 10% with prophylaxis. Enrollment in the trial is continuing with dose escalation to determine the recommended Phase 2 dose, including with data from the improved LyFE manufacturing process and analytical methods, as well as to optimize the prophylaxis and safety management plan to calibrate immune suppression.

About Lyell Immunopharma, Inc.

Lyell is a late-stage clinical company advancing a pipeline of next-generation CAR T-cell therapies for patients with hematologic malignancies and solid tumors. To realize the potential of cell therapy for cancer, Lyell utilizes a suite of technologies to arm CAR T cells with enhancements needed to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical responses, including the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment. Lyell's proprietary LyFE Manufacturing Center™ has commercial launch capability and is expected to have the capacity to manufacture more than 1,200 CAR T-cell doses per year. To learn more, please visit www.lyell.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements regarding: Lyell's expectations around the progress of the U.S. Phase 1/2 trial for LYL273, including expectations around patient enrollment and site activation, activities to determine a recommended Phase 2 dose and optimized safety plan and the timing for release of additional clinical data from this trial and a planned End-of-Phase 1 FDA meeting; the potential clinical benefits and therapeutic potential of LYL273; manufacturing activities at LyFE and the capability of LyFE to manufacture drug supply through potential commercial launch and its expected manufacturing capacity; and other statements that are not historical fact. These statements are based on Lyell's current plans, objectives, estimates, expectations and intentions, are not guarantees of future performance and inherently involve significant risks and uncertainties. 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, but are not limited to, risks and uncertainties related to: Lyell operates in a rapidly evolving industry and has a limited operating history; Lyell's ability to successfully develop, manufacture and commercialize product candidates or its experiencing significant delays in doing so; Lyell's dependence on the enrollment and retention of patients in its current and planned clinical trials for its product candidates; the potential for results of Lyell's research, nonclinical studies or earlier clinical trials to not be predictive of future results; clinical development involving a lengthy and expensive process with uncertain outcomes; Lyell's product candidates and technologies being based on novel technologies that are unproven and may not result in approvable or marketable products; Lyell facing substantial competition in a rapidly changing industry, which may result in others discovering, developing or commercializing products before or more successfully than it does; Lyell's ability to obtain and maintain sufficient intellectual property protection for its product candidates; the complexity of manufacturing cellular therapies; Lyell's ability to manufacture drug products for its clinical trials itself and any potential delays in further qualifying or in receiving regulatory approvals for any manufacturing facility or product candidates or in expanding its manufacturing capacity; Lyell's reliance on third parties; implementation of Lyell's strategic plans for its business and product candidates and Lyell's realization of the expected benefits of such plans; the potential reduction of Lyell's cash resources and fluctuations in Lyell's operating results and financial condition as a result of Lyell's milestone, royalty and success payment obligations; the sufficiency of Lyell's capital resources and need for additional capital to achieve its goals; and other risks, including those described under the heading "Risk Factors" in Lyell's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, filed with the U.S. Securities and Exchange Commission on August 6, 2026. Forward-looking statements contained in this press release are made as of this date, and Lyell undertakes no duty to update such information except as required under applicable law.

Contact:

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