

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): August 6, 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	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 2.02 Results of Operations and Financial Condition.

On August 6, 2026, Lyell Immunopharma, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2026. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed “filed” for the 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 into any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release Dated August 6, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 6, 2026

By: /s/ MARK MELTZ
Mark Meltz
General Counsel and Corporate Secretary



Lyell Immunopharma Reports Business Highlights and Financial Results for the Second Quarter 2026

- PiNACLE pivotal clinical trial evaluating ronde-cel in 3L+ patients with LBCL on track to report additional data in second half of 2026, with pivotal data expected mid-2027 and BLA submission expected to follow in the second half of 2027
- Presented updated ronde-cel data in more than 100 patients with relapsed/refractory LBCL at the EHA 2026 Congress, with Phase 1/2 safety data showing no Grade ≥ 3 CRS and low rates of Grade ≥ 3 ICANS supporting potential outpatient administration
- Reported updated LYL273 safety data in relapsed/refractory mCRC, with gastrointestinal prophylaxis regimen and standardized safety management plan reducing Grade ≥ 2 diarrhea or colitis from 55% to 10%; amended ongoing U.S. Phase 1 trial to a Phase 1/2 design to enable seamless expansion into a potential pivotal single-arm Phase 2 trial pending regulatory alignment
- Additional data from the U.S. Phase 1 trial of LYL273 in 3L+ patients with relapsed/refractory mCRC and End-of-Phase 1 FDA meeting are expected in the second half of 2026
- Approximately \$228.0 million in cash, cash equivalents and marketable securities as of June 30, 2026, expected to provide runway into Q3 2027

SOUTH SAN FRANCISCO, Calif., August 6, 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 reported financial results and business highlights for the second quarter ended June 30, 2026.

Second Quarter Updates and Recent Business Highlights

Rondecabtagene Autoleucel (Ronde-cel): A next-generation dual-targeting CD19/CD20 CAR T-cell product candidate designed to increase complete response rates and prolong the duration of response as compared to approved CD19-targeted CAR T-cell therapies for the treatment of large B-cell lymphoma (LBCL)

Ronde-cel is an autologous CAR T-cell product candidate under evaluation in two pivotal trials in patients with relapsed/refractory (R/R) LBCL in the third- or later-line (3L+) setting (PiNACLE) and the second-line (2L) setting (PiNACLE-H2H). Rondecel targets B cells that express either CD19 or CD20 with a true 'OR' logic gate to achieve full potency at either target and is manufactured with a process that enriches for CD62L-positive cells to generate more naïve and central memory CAR T cells with enhanced stemlike features and antitumor activity. The U.S. Food and Drug Administration (FDA) has granted ronde-cel Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations for the treatment of adults with R/R diffuse large B-cell lymphoma (DLBCL) in the 3L+ setting and also RMAT designation for the treatment of large B-cell lymphoma (LBCL) in the 2L setting. The FDA has also granted ronde-cel Orphan Drug Designation for the treatment of DLBCL/HGBCL with MYC and BCL2 rearrangements.

- In June 2026, Lyell presented updated safety data and translational insights for ronde-cel in two presentations at the European Hematology Association (EHA) 2026 Congress in Stockholm, Sweden.
 - Safety data from more than 100 patients with R/R LBCL treated with ronde-cel (65 in the 3L+ setting and 43 in the 2L setting) were presented. There were no Grade ≥ 3 CRS events and low rates of Grade ≥ 3 ICANS reported in the Phase 1/2 trial as of the data cutoff date of May 5, 2026, supporting the potential for outpatient administration. The manufacturing success rate was 97%.
 - Translational analyses were presented providing a biological basis for ronde-cel's durable responses, including enhanced memory potential of cytotoxic effector cells from CD62L+ enrichment and CD19/CD20 dual-targeting to overcome low antigen expression.
- The PiNACLE pivotal single-arm trial, a seamless expansion of the 3L+ cohort in the Phase 1/2 multi-cohort trial, is ongoing. Additional data from this trial are expected in the second half of 2026, and pivotal data are expected in mid-2027 with submission of a Biologics License Application (BLA) to the FDA expected to follow in the second

half of 2027. The primary endpoint of the trial is overall response rate, including an evaluation of duration of response.

- PiNACLE-H2H, the first-of-its-kind Phase 3 randomized controlled trial evaluating ronde-cel versus investigator's choice of axicabtagene ciloleucel or lisocabtagene maraleucel in patients with R/R LBCL in the 2L setting continues to enroll patients. A progress update for this trial is expected in the second half of 2026. The trial's primary endpoint is event-free survival.

LYL273: A next-generation guanylyl cyclase C (GCC)-targeted CAR T-cell product candidate for the treatment of relapsed/refractory metastatic colorectal cancer (mCRC) and other GCC-expressing cancers

LYL273 is a 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. In November 2025, Lyell acquired global rights (excluding mainland China, Hong Kong, Macau and Taiwan) to LYL273, which has shown promising dose-dependent clinical activity in patients with advanced R/R mCRC in a Phase 1 trial conducted in the U.S. following proof of concept in 15 patients in China. The FDA granted LYL273 Fast Track designation for the treatment of mCRC.

- In June 2026, Lyell reported updated safety data from patients with 3L+ R/R mCRC in the ongoing U.S. Phase 1 trial, including 19 patients, of which 10 were treated with gastrointestinal (GI) prophylaxis and a new safety management protocol and 9 were treated without GI prophylaxis across Dose Levels 1 and 2 (1 and 2 x 10⁶ CAR+ cells/kg, respectively) as of the data cutoff date of May 5, 2026. The GI prophylaxis regimen included treatment with infliximab, vedolizumab and budesonide prior to the development of symptoms.
 - The rate of Grade $\geq$ 2 diarrhea or colitis was reduced from 55% to 10%, and there were no reported cases of Grade $\geq$ 3 diarrhea or colitis in patients treated with GI prophylaxis.
 - No patients treated with GI prophylaxis experienced Grade $\geq$ 3 CRS or ICANS.
 - GCC CAR T-cell expansion kinetics were similar in patients treated with and without GI prophylaxis.
 - Dose escalation continues, and the maximum tolerated dose has not been determined.
- Based on the new safety data, Lyell amended the ongoing U.S. Phase 1 trial to a Phase 1/2 design, enabling seamless expansion into a potential pivotal single-arm Phase 2 trial once the recommended Phase 2 dose is determined and subject to discussions with the FDA. The amendment adds new cohorts, including a 2L cohort and a cohort evaluating a combination strategy with radiotherapy.
- Additional U.S. Phase 1 clinical data in patients with R/R mCRC in the 3L+ setting and an End-of-Phase 1 meeting with the FDA are expected in the second half of 2026.

Second Quarter 2026 Financial Results

Lyell reported a net loss of \$44.8 million for the second quarter ended June 30, 2026, compared to a net loss of \$42.7 million for the same period in 2025. The \$2.1 million increase in net loss was primarily due to a \$4.7 million increase in research and development expenses driven by increased clinical trial activity and lower interest income, partially offset by lower property and equipment disposal losses, and a \$1.4 million long-lived asset impairment charge that did not recur. Non-GAAP net loss, which excludes non-cash stock-based compensation, non-cash expenses related to the change in the estimated fair value of the Securities Purchase Agreement put/call asset relating to the Company's July 2025 private placement transaction and success payment liabilities, increased by \$2.8 million to \$40.6 million for the second quarter ended June 30, 2026, compared to \$37.8 million for the same period in 2025, primarily due to increased clinical trial activity and lower interest income.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were \$39.5 million for the second quarter ended June 30, 2026, compared to \$34.9 million for the same period in 2025. The \$4.7 million increase was primarily due to an \$8.8 million increase in research activities, collaborations and outside services due to increased clinical trial activity, partially offset by a \$4.2 million decrease in facilities and personnel expenses. Non-GAAP R&D expenses, which exclude non-cash stock-based compensation, for the second quarter ended June 30, 2026 were \$37.4 million compared to \$32.6 million for the same period in 2025.
- General and administrative (G&A) expenses were \$9.6 million for the second quarter ended June 30, 2026 compared to \$9.8 million for the same period in 2025, primarily due to lower professional services expenses. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the second quarter ended June 30, 2026 were \$7.2 million compared to \$7.1 million for the same period in 2025.

A discussion of non-GAAP financial measures, including reconciliations of the most comparable U.S. generally accepted accounting principles (GAAP) measures to non-GAAP financial measures, is presented below under “Non-GAAP Financial Measures.”

Cash, cash equivalents and marketable securities

Cash, cash equivalents and marketable securities as of June 30, 2026 were \$228.0 million compared to \$247.2 million as of December 31, 2025. Lyell believes that its current cash, cash equivalents and marketable securities balances will be sufficient to meet working capital and capital expenditure needs into the third quarter of 2027.

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. LyFE 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 plans for its existing cash, cash equivalents and marketable securities, and its expectation that its financial position and cash runway will be sufficient to meet working capital and capital expenditure needs into the third quarter of 2027; Lyell’s expectations around the progress of the PiNACLE and PiNACLE-H2H trials, including the expected timing for release of additional and pivotal data from the PiNACLE trial; the use of pivotal data from the PiNACLE trial to support a BLA submission to the FDA in 2027 and other expectations around enrollment and regulatory submissions; Lyell’s expectations around the progress of the U.S. Phase 1 trial for LYL273, including the expected timing for release of additional clinical data from this trial and an End-of-Phase 1 FDA meeting; the anticipated benefits of Orphan Drug, RMAT and Fast Track designations for ronde-cel and Fast Track designation for LYL273; the capability of LyFE to manufacture drug supply through potential commercial launch and its expected manufacturing capacity; the potential clinical benefits and therapeutic potential of Lyell’s product candidates; 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, being filed with the Securities and Exchange Commission today. 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.

Lyell Immunopharma, Inc.
Unaudited Selected Consolidated Financial Data
(in thousands)

Statement of Operations Data:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Revenue	\$ 4	\$ 8	\$ 6	\$ 15
Operating expenses:				
Research and development	39,524	34,857	76,128	78,304
General and administrative	9,576	9,786	19,131	23,832
Other operating (income) loss, net	(1,759)	1,062	(3,655)	943
Impairment of long-lived assets	—	1,443	—	1,443
Total operating expenses	47,341	47,148	91,604	104,522
Loss from operations	(47,337)	(47,140)	(91,598)	(104,507)
Interest income, net	2,184	3,276	4,378	7,138
Other income, net	398	1,180	18,312	2,490
Total other income, net	2,582	4,456	22,690	9,628
Net loss	<u>\$ (44,755)</u>	<u>\$ (42,684)</u>	<u>\$ (68,908)</u>	<u>\$ (94,879)</u>

Balance Sheet Data:

	As of June 30, 2026	As of December 31, 2025
Cash, cash equivalents and marketable securities	\$ 227,998	\$ 247,220
Property and equipment, net	\$ 30,507	\$ 34,771
Total assets	\$ 311,153	\$ 340,052
Total stockholders’ equity	\$ 233,815	\$ 248,202

Non-GAAP Financial Measures

To supplement our financial results and guidance presented in accordance with GAAP, we present non-GAAP net loss, non-GAAP R&D expenses and non-GAAP G&A expenses. Non-GAAP net loss excludes non-cash stock-based compensation expense, non-cash expenses related to the change in the estimated fair value of success payment liabilities and the change in the estimated fair value of our securities purchase agreement put/call asset. Non-GAAP R&D and G&A expenses exclude non-cash stock-based compensation expense from GAAP R&D and G&A expenses. We believe that these non-GAAP financial measures, when considered together with our financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare our results from period to period, and to identify operating trends in our business. We have excluded stock-based compensation expense, changes in the estimated fair value of success payment liabilities and the change in the estimated fair value of our securities purchase agreement put/call asset from our non-GAAP financial measures because they are gains and charges that may vary significantly from period to period as a result of changes not directly or immediately related to the operational performance for the periods presented. We also regularly use these non-GAAP financial measures internally to understand, manage and evaluate our business and to make operating decisions. These non-GAAP financial measures are in addition to, and not a substitute for or superior to, measures of financial performance prepared in accordance with GAAP. In addition, these non-GAAP financial measures have no standardized meaning prescribed by GAAP and are not prepared under any comprehensive set of accounting rules or principles and, therefore, have limits in their usefulness to investors. We encourage investors to carefully consider our results under GAAP, as well as our supplemental non-GAAP financial information, to more fully understand our business.

Lyell Immunopharma, Inc.

Unaudited Reconciliation of GAAP to Non-GAAP Net Loss

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Net loss - GAAP	\$ (44,755)	\$ (42,684)	\$ (68,908)	\$ (94,879)
Adjustments:				
Change in the estimated fair value of securities purchase agreement put/call asset	—	—	(17,561)	—
Stock-based compensation expense	4,532	5,004	8,827	11,028
Change in the estimated fair value of success payment liabilities	(399)	(115)	(752)	(240)
Net loss - Non-GAAP ⁽¹⁾	\$ (40,622)	\$ (37,795)	\$ (78,394)	\$ (84,091)

(1) There was no income tax effect related to the adjustments made to calculate non-GAAP net loss because of the full valuation allowance on our net deferred tax assets for all periods presented.

Lyell Immunopharma, Inc.

Unaudited Reconciliation of GAAP to Non-GAAP Research and Development Expenses

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development - GAAP	\$ 39,524	\$ 34,857	\$ 76,128	\$ 78,304
Adjustments:				
Stock-based compensation expense	(2,174)	(2,295)	(4,375)	(4,683)
Research and development - Non-GAAP	\$ 37,350	\$ 32,562	\$ 71,753	\$ 73,621

Lyell Immunopharma, Inc.

Unaudited Reconciliation of GAAP to Non-GAAP General and Administrative Expenses

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
General and administrative - GAAP	\$ 9,576	\$ 9,786	\$ 19,131	\$ 23,832
Adjustments:				
Stock-based compensation expense	(2,358)	(2,709)	(4,452)	(6,345)
General and administrative - Non-GAAP	<u>\$ 7,218</u>	<u>\$ 7,077</u>	<u>\$ 14,679</u>	<u>\$ 17,487</u>

Contact:

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