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 7, 2024

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

Delaware	**001-40502**	**83-1300510**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 7, 2024, Lyell Immunopharma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2024. 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 7, 2024
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 7, 2024

By: /s/ MATTHEW LANG

Matthew Lang
Chief Business Officer

Exhibit 99.1

Lyell Immunopharma Reports Business Highlights and Financial Results for the Second Quarter 2024

- Reported dose-dependent antitumor clinical activity in patients with relapsed/refractory triple-negative breast cancer from the Phase 1 trial of LYL797, a ROR1-targeted Chimeric Antigen Receptor (CAR) T-cell product candidate enhanced with proprietary anti-exhaustion technology; 40% objective response rate and 60% clinical benefit rate at the highest dose cleared at the time of the initial data report (150 x 10^6 CAR T cells)
- Expanded development of LYL797 into four new tumor types, including ROR1+ relapsed/refractory platinum-resistant ovarian cancer, endometrial cancer, multiple myeloma and chronic lymphocytic leukemia
- Received FDA clearance of an IND for LYL119, a next-generation ROR1-targeted CAR T-cell product candidate incorporating four proprietary technologies designed to enhance the anti-exhaustion capability and persistence of T cells
- Cash, cash equivalents and marketable securities of $491.1 million as of June 30, 2024 supports advancing diverse pipeline through multiple clinical milestones into 2027

SOUTH SAN FRANCISCO, Calif., August 7, 2024 -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a clinical-stage T-cell reprogramming company advancing a diverse pipeline of cell therapies for patients with solid tumors or hematologic malignancies, today reported financial results and business highlights for the second quarter ended June 30, 2024.

“We are pleased that initial data from our Phase 1 trial of LYL797 demonstrated dose-dependent clinical activity and that LYL797 CAR T cells expanded, infiltrated solid tumors and killed cancer cells in patients. Based on these promising initial data, we have expanded the cancer indications under evaluation in this trial to include patients with ovarian and endometrial cancers, and we plan to file an IND to initiate a new trial evaluating LYL797 in multiple myeloma and chronic lymphocytic leukemia,” said Lynn Seely, M.D., Lyell’s President and CEO. “In addition, our IND for LYL119, a next generation ROR1-targeted CAR T-cell product candidate designed with four technologies to generate T cells with even greater capacity to resist exhaustion, has been cleared by the FDA, and we expect to report initial clinical data from the Phase 1 trial in the second half of 2025. We remain on track to report initial clinical data from our lead TIL program in the second half of this year. Our strong cash position enables us to advance multiple product candidates through critical clinical milestones and fund operations into 2027.”

Second Quarter Updates and Recent Business Highlights

Lyell is advancing four wholly-owned product candidates. Two product candidates, LYL797 and LYL845, are in Phase 1 clinical development, and LYL119 is entering Phase 1 clinical development. A second-generation tumor infiltrating lymphocyte (TIL) product candidate is in preclinical development.

LYL797 – A ROR1-targeted CAR T-cell product candidate enhanced with anti-exhaustion technology designed for improved tumor infiltration and tumor cell killing

- Enrollment in the Phase 1 clinical trial of LYL797 is ongoing. The study was initiated in patients with relapsed/refractory triple-negative breast cancer (TNBC) or non-small cell lung cancer (NSCLC). Based on the initial clinical data that demonstrated dose-dependent anti-tumor activity, the trial has been expanded to include patients with platinum-resistant ovarian or endometrial cancers and an investigational new drug (IND) application is expected to be submitted in the second half of this year to initiate a second Phase 1 clinical trial of LYL797 in multiple myeloma and chronic lymphocytic leukemia (CLL).
- Initial clinical and translational data from the Phase 1 clinical trial of LYL797 were reported in June 2024. The initial dataset of 20 patients (16 patients with TNBC and four patients with NSCLC) demonstrated dose-dependent antitumor clinical activity and the ability of LYL797 CAR T cells to proliferate, infiltrate tumors and kill cancer cells in patients with relapsed/refractory disease. Patients with TNBC treated with LYL797 had an objective response rate (ORR) of 40% and a clinical benefit rate (CBR) of 60% at the 150 x 10^6 CAR T cell dose level, with a CBR of 38% across all dose levels evaluable at the time data were reported. Common treatment-related adverse

events (TRAE) in patients without lung metastases included Grade 1 and 2 cytokine release syndrome (CRS) and headache, and the expected cytopenia from lymphodepletion. There were no reports of immune effector cell-associated neurotoxicity syndrome (ICANS) attributed to LYL797. Pneumonitis occurred in some patients with lung metastases, including the index patient who experienced Grade 5 respiratory failure on Day 41. All patients are now given dexamethasone prophylaxis and dose escalation is continuing separately and more gradually in patients with lung involvement. No dose-limiting toxicities have been reported in patients without lung involvement.

- Updated data from the ongoing Phase 1 trial in solid tumor indications, including the initiation of dose expansion, are expected in late 2024 – early 2025.

LYL845 – A TIL product candidate epigenetically reprogrammed using Lyell's proprietary Epi-R manufacturing protocol, designed for differentiated potency and durability

- Enrollment in the Phase 1 clinical trial of LYL845 is ongoing. The trial is designed to include patients with relapsed or refractory metastatic or locally advanced melanoma, NSCLC and colorectal cancer.
- Initial clinical and translational data from the Phase 1 trial of LYL845 in patients with advanced melanoma are expected in the second half of 2024.

LYL119 – A next-generation ROR1-targeted CAR T-cell product candidate incorporating four stackable and complementary anti-exhaustion technologies designed for enhanced potency

- LYL119 is a ROR1-targeted CAR T-cell product enhanced with four novel genetic and epigenetic reprogramming technologies: c-Jun overexpression, NR4A3 knockout, Epi-R manufacturing protocol and Stim-R™ T-cell activation technology.
- An IND application for LYL119 has received clearance from the U.S. Food and Drug Administration (FDA).
- The Phase 1 trial is designed as an open-label dose-escalation and -expansion trial in patients with ROR1-positive solid tumors and will initially enroll patients with ROR1-positive platinum-resistant ovarian cancer or endometrial cancer. It is estimated that approximately 50% of patients with ovarian cancer and approximately 50% of patients with endometrial cancer have ROR1-positive tumors.
- Initial clinical data are expected in the second half of 2025.

Second Quarter Financial Results

Lyell reported a net loss of $45.8 million for the second quarter ended June 30, 2024, compared to a net loss of $63.9 million for the same period in 2023. Non-GAAP net loss, which excludes non-cash stock-based compensation, non-cash expenses related to the change in the estimated fair value of success payment liabilities and certain non-cash investment gains and charges, was $39.1 million for the second quarter ended June 30, 2024, compared to $45.6 million for the same period in 2023.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $40.3 million for the second quarter ended June 30, 2024, compared to $47.5 million for the same period in 2023. The decrease in second quarter 2024 R&D expenses of $7.2 million was primarily driven by a decrease in personnel-related expenses associated with Lyell's November 2023 reduction in workforce. Non-GAAP R&D expenses, which exclude non-cash stock-based compensation and non-cash expenses related to the change in the estimated fair value of success payment liabilities for the second quarter ended June 30, 2024, were $37.2 million, compared to $41.6 million for the same period in 2023. The decrease in second quarter 2024 non-GAAP R&D expenses was primarily driven by a decrease in personnel-related expenses.

- General and administrative (G&A) expenses were $12.3 million for the second quarter ended June 30, 2024, compared to $19.0 million for the same period in 2023. The decrease in second quarter 2024 G&A expenses was primarily driven by decreases in non-cash stock-based compensation. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the second quarter ended June 30, 2024, were $7.8 million, compared to $10.1 million for the same period in 2023. The decrease in second quarter 2024 non-GAAP G&A expenses was primarily driven by a decrease in personnel-related expenses associated with Lyell's November 2023 reduction in workforce.

A discussion of non-GAAP financial measures, including reconciliations of the most comparable 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, 2024, were $491.1 million, compared to $562.7 million as of December 31, 2023. Lyell believes that its cash, cash equivalents and marketable securities balances will be sufficient to meet working capital and capital expenditure needs into 2027.

About Lyell Immunopharma, Inc.

Lyell is a clinical-stage T-cell reprogramming company advancing a diverse pipeline of cell therapies, including three product candidates in or entering Phase 1 clinical development for patients with solid tumors or hematologic malignancies. Lyell's product candidates are enhanced with novel anti-exhaustion technology designed to address barriers that limit consistent and long-lasting responses to cell therapy for solid tumors: T-cell exhaustion and lack of durable stemness, which includes the ability to persist and self-renew to drive durable tumor cytotoxicity. Lyell applies its proprietary ex vivo genetic and epigenetic reprogramming technology to address these barriers to develop new medicines with improved durable clinical outcomes. Lyell is based in South San Francisco, California with facilities in Seattle and Bothell, Washington. 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: the continued clinical progress of the LYL797 trials; Lyell's plans to enroll patients with platinum-resistant ovarian cancer and endometrial cancer in the LYL797 trial; Lyell's plans to submit an IND for LYL797 to initiate a new trial evaluating LYL797 in patients with multiple myeloma or chronic lymphocytic leukemia and the timing thereof; Lyell's development plans for LYL119 and the effectiveness of any technologies incorporated into LYL119; the ability of Lyell's anti-exhaustion technology to address barriers that limit consistent and long-lasting responses to cell therapy for solid tumors: T-cell exhaustion and lack of durable stemness, and for its reprogramming technology to address these barriers to develop new medicines with improved durable clinical outcomes; Lyell's anticipated progress, business plans, business strategy and clinical trials; Lyell's advancement of its pipeline and its research, development and clinical capabilities; the potential clinical benefits and therapeutic potential of Lyell's product candidates; the advancement of Lyell's technology platform; Lyell's expectation that its financial position and cash runway will support advancement of its pipeline through multiple clinical milestones into 2027; expectations around enrollment and the timing of initial and updated clinical and translational data from Lyell's Phase 1 trials for LYL797, LYL845 and LYL119; 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: the effects of macroeconomic conditions, including any geopolitical instability and actual or perceived changes in interest rates and economic inflation; Lyell's ability to submit planned INDs or initiate or progress clinical trials on the anticipated timelines, if at all; Lyell's limited experience as a company in enrolling and conducting clinical trials, and lack of experience in completing clinical trials; Lyell's ability to manufacture and supply its product candidates for its clinical trials; the nonclinical profiles of Lyell's product candidates or technology not translating in clinical trials; the potential for results from clinical trials to differ from nonclinical, early clinical, preliminary or expected results; significant adverse events, toxicities or other undesirable side effects associated with Lyell's product candidates; the significant uncertainty associated with Lyell's product candidates ever receiving any regulatory approvals; Lyell's ability to obtain, maintain or protect intellectual property rights related to its product candidates; implementation of Lyell's strategic plans for its business and product candidates; 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 Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission (SEC) on February 28, 2024, and the Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, being filed with the SEC 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,	
	2024	2023	2024	2023
Revenue	$ 13	$ 27	$ 16	$ 92
Operating expenses:				
Research and development[(1)]	40,261	47,471	83,435	92,101
General and administrative	12,256	19,030	25,750	38,309
Other operating income, net	(976)	(569)	(2,066)	(1,857)
Total operating expenses	51,541	65,932	107,119	128,553
Loss from operations	(51,528)	(65,905)	(107,103)	(128,461)
Interest income, net	6,364	5,264	13,183	9,761
Other (expense) income, net	(645)	(326)	445	774
Impairment of other investments	—	(2,923)	(13,001)	(12,923)
Total other income (loss), net	5,719	2,015	627	(2,388)
Net loss	$ (45,809)	$ (63,890)	$ (106,476)	$ (130,849)

(1) Lyell's success payment liability was recognized at fair value as Fred Hutch had provided the requisite service obligation to earn the potential success payment consideration under the continued collaboration. The change in the estimated fair value of Fred Hutch success payment liabilities beginning in Q1 2023 was recognized within other (expense) income, net in the unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities was recognized within research and development expenses in the unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss.

Balance Sheet Data:

	As of June 30, 2024	As of December 31, 2023
Cash, cash equivalents and marketable securities	$ 491,119	$ 562,729
Property and equipment, net	$ 93,096	$ 102,654
Total assets	$ 654,142	$ 750,029
Total stockholders' equity	$ 566,501	$ 654,952

Non-GAAP Financial Measures

To supplement our financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), we present non-GAAP net loss, non-GAAP R&D expenses and non-GAAP G&A expenses. Non-GAAP net loss and non-GAAP R&D expenses exclude non-cash stock-based compensation expense and non-cash expenses related to the change in the estimated fair value of success payment liabilities from GAAP net loss and GAAP R&D expenses. Non-GAAP net loss further adjusts non-cash investment gains and charges, as applicable. Non-GAAP G&A expenses exclude non-cash stock-based compensation expense from GAAP 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 non-cash investment gains and charges from our non-GAAP financial measures because they are non-cash 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,	
	2024	2023	2024	2023
Net loss - GAAP	$ (45,809)	$ (63,890)	$ (106,476)	$ (130,849)
Adjustments:				
Stock-based compensation expense	8,284	14,223	17,439	28,105
Impairment of other investments	—	2,923	13,001	12,923
Change in the estimated fair value of success payment liabilities	(1,534)	1,105	(566)	(603)
Net loss - Non-GAAP[(1)]	$ (39,059)	$ (45,639)	$ (76,602)	$ (90,424)

(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 U.S. 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,	
	2024	2023	2024	2023
Research and development - GAAP	$ 40,261	$ 47,471	$ 83,435	$ 92,101
Adjustments:				
Stock-based compensation expense	(3,865)	(5,279)	(7,657)	(9,891)
Change in the estimated fair value of success payment liabilities[(1)]	793	(605)	268	3
Research and development - Non-GAAP	$ 37,189	$ 41,587	$ 76,046	$ 82,213

(1) Lyell's success payment liability was recognized at fair value as Fred Hutch had provided the requisite service obligation to earn the potential success payment consideration under the continued collaboration. The change in the estimated fair value of Fred Hutch success payment liabilities beginning in Q1 2023 was recognized within other (expense) income, net in the unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities was recognized within research and development expenses in the unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss.

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,	
	2024	2023	2024	2023
General and administrative - GAAP	$ 12,256	$ 19,030	$ 25,750	$ 38,309
Adjustments:				
Stock-based compensation expense	(4,419)	(8,944)	(9,782)	(18,214)
General and administrative - Non-GAAP	$ 7,837	$ 10,086	$ 15,968	$ 20,095

Contact:

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