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 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 November 7, 2024, Lyell Immunopharma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 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 November 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: November 7, 2024

By: /s/ MATTHEW LANG

Matthew Lang
Chief Business Officer

Exhibit 99.1

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

- Acquired ImmPACT Bio and strengthened clinical pipeline with the addition of IMPT-314, a dual-targeting CD19/CD20 CAR T-cell product candidate with strong Phase 1 clinical data in patients with aggressive relapsed/refractory B-cell non-Hodgkin's lymphoma
- Presenting initial data from Phase 1 multi-center clinical trial of IMPT-314 at the American Society of Hematology 2024 (ASH) Annual Meeting
- Presenting three abstracts at the Society for Immunotherapy of Cancer (SITC) 2024 Annual Meeting highlighting anti-exhaustion technology and product candidates being advanced in Lyell's pipeline
- Cash, cash equivalents and marketable securities of $460.7 million as of September 30, 2024 funds the Company through multiple clinical milestones into 2027

SOUTH SAN FRANCISCO, Calif., Nov. 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 third quarter ended September 30, 2024.

"With our acquisition of ImmPACT now complete, we plan to accelerate the development of IMPT-314, a dual-targeting CD19/CD20 CAR T-cell product candidate we believe has the potential to deliver increased complete response rates with longer duration of response over approved CD19 CAR T-cell therapies for patients with aggressive B-cell non-Hodgkin's lymphoma," said Lynn Seely, M.D., Lyell's President and CEO. "We look forward to presenting the initial data from the Phase 1 trial of IMPT-314 at ASH next month and expect to initiate a pivotal clinical trial in 2025. In addition, site selection and initiation is progressing well for our Phase 1 trial of LYL119, our next-generation ROR1-targeted CAR T-cell product candidate designed with four technologies to generate T cells with even greater capacity to resist exhaustion. Our strong cash position enables us to advance our pipeline through important clinical milestones and fund operations into 2027."

Third Quarter Updates and Recent Business Highlights

Lyell is advancing two wholly-owned product candidates: IMPT-314 is in Phase 1-2 clinical development and LYL119 is entering Phase 1 clinical development. Lyell is also advancing next-generation CAR T-cell product candidates for solid tumors, which are in preclinical development.

IMPT-314 – A next-generation dual-targeting CD19/CD20 CAR T-cell product candidate designed for improved response rates with enhanced durability for the treatment of large B-cell lymphoma (LBCL)

- IMPT-314 is an autologous CAR T-cell product candidate enriched with naïve and central memory T cells during the manufacturing process. The Phase 1-2 clinical trial is a multi-center, open-label clinical trial designed to evaluate the tolerability and clinical benefit of IMPT-314 in patients with relapsed/refractory LBCL and determine a recommended Phase 2 dose. The trial is enrolling three cohorts of patients including CAR T-naïve patients in the third-line setting, CAR T-naïve patients in the second-line setting and CAR T-experienced patients. IMPT-314 has received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of relapsed/refractory aggressive B-cell lymphoma.
- Initial data from Phase 1-2 trial will be presented at the ASH 2024 Annual Meeting on December 9, 2024.
- Expect to initiate a pivotal trial in 2025 in patients with relapsed/refractory large B-cell lymphoma in the third-line setting who have not yet been exposed to CAR T-cell therapy.

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

- LYL119 is an autologous ROR1-targeted CAR T-cell product candidate enhanced with four novel technologies: c-Jun overexpression, NR4A3 knockout, Epi-R manufacturing protocol and Stim-R^{TM} T-cell activation technology designed to enable T cells to resist exhaustion and to enhance their stem-like qualities.

- 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.
- Presenting a poster at the SITC 2024 Annual Meeting titled “Multiomic profiling of LYL119: A Reprogrammed ROR1 CAR T Product Generates T cells with Reduced Exhaustion and Enhanced Memory Characteristics Associated with Increased AP-1 and Reduced NR4A Bindings.” In a validated preclinical xenograft model of non-small cell lung cancer, LYL119 achieves complete tumor control and prolonged survival even at very low doses compared to LYL797, Lyell’s first generation ROR1-targeted CAR T-cell product candidate. The study presents potential molecular mechanisms underlying the functional reduction of T-cell exhaustion and enhancement of memory-related characteristics of LYL119 CAR T cells after antigen encounter in vitro and in vivo.
- Initial clinical data are expected in the second half of 2025.

Third Quarter Financial Results

Lyell reported a net loss of $44.6 million for the third quarter ended September 30, 2024, compared to a net loss of $50.9 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 $37.1 million for the third quarter ended September 30, 2024, compared to $43.0 million for the same period in 2023.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $39.5 million for the third quarter ended September 30, 2024, compared to $43.8 million for the same period in 2023. The decrease in third quarter 2024 R&D expenses of $4.3 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 third quarter ended September 30, 2024, were $35.9 million, compared to $40.5 million for the same period in 2023. The decrease in third quarter 2024 non-GAAP R&D expenses was primarily driven by a decrease in personnel-related expenses.
- General and administrative (G&A) expenses were $11.8 million for the third quarter ended September 30, 2024, compared to $15.5 million for the same period in 2023. The decrease in third 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 third quarter ended September 30, 2024, were $7.8 million, compared to $9.5 million for the same period in 2023. The decrease in third 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 September 30, 2024, were $460.7 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 company advancing a pipeline of next-generation CAR T-cell therapies for patients with solid tumors or hematologic malignancies. Lyell’s product candidates are enhanced with novel technology designed to generate T cells that resist exhaustion and have qualities of durable stemness in order to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical response. 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 anticipated benefits of Lyell's acquisition of ImmPACT Bio; Lyell's ability to accelerate the development of IMPT-314 and deliver increased complete response rates; Lyell's initiation of a pivotal trial in 2025 for IMPT-314; Lyell's development plans for LYL119 and the effectiveness of any technologies incorporated into LYL119; the ability of Lyell's technology to enable and generate T cells that resist exhaustion and have qualities of durable stemness in order to drive durable tumor toxicity and achieve consistent and long-lasting clinical response; 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 data from Lyell's Phase 1-2 trial for IMPT-314 and Phase 1 trial for 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 inability to recognize the anticipated benefits of acquiring ImmPACT Bio and successful integration of ImmPACT Bio's business with Lyell's, including manufacturing IMPT-314 in Lyell's LyFE manufacturing facility; 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 September 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue	$ 34	$ 25	$ 50	$ 117
Operating expenses:				
Research and development[(1)]	39,500	43,849	122,935	135,950
General and administrative	11,769	15,507	37,519	53,816
Other operating income, net	(730)	(292)	(2,796)	(2,149)
Total operating expenses	50,539	59,064	157,658	187,617
Loss from operations	(50,505)	(59,039)	(157,608)	(187,500)
Interest income, net	5,965	6,608	19,148	16,369
Other (expense) income, net[(1)]	(43)	1,578	402	2,352
Impairment of other investments	—	—	(13,001)	(12,923)
Total other income, net	5,922	8,186	6,549	5,798
Net loss	$ (44,583)	$ (50,853)	$ (151,059)	$ (181,702)

(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 September 30, 2024	**As of December 31, 2023**
Cash, cash equivalents and marketable securities	$ 460,659	$ 562,729
Property and equipment, net	$ 88,047	$ 102,654
Total assets	$ 619,215	$ 750,029
Total stockholders' equity	$ 530,697	$ 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss - GAAP	$ (44,583)	$ (50,853)	$ (151,059)	$ (181,702)
Adjustments:				
Stock-based compensation expense	7,622	10,516	25,061	38,621
Change in the estimated fair value of success payment liabilities	(103)	(2,706)	(669)	(3,309)
Impairment of other investments	—	—	13,001	12,923
Net loss - Non-GAAP[(1)]	$ (37,064)	$ (43,043)	$ (113,666)	$ (133,467)

(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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development - GAAP	$ 39,500	$ 43,849	$ 122,935	$ 135,950
Adjustments:				
Stock-based compensation expense	(3,625)	(4,548)	(11,282)	(14,439)
Change in the estimated fair value of success payment liabilities[(1)]	40	1,246	308	1,249
Research and development - Non-GAAP	$ 35,915	$ 40,547	$ 111,961	$ 122,760

(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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
General and administrative - GAAP	$ 11,769	$ 15,507	$ 37,519	$ 53,816
Adjustments:				
Stock-based compensation expense	(3,997)	(5,968)	(13,779)	(24,182)
General and administrative - Non-GAAP	$ 7,772	$ 9,539	$ 23,740	$ 29,634

Contact:

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