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 8, 2023

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

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Item 2.02 Results of Operations and Financial Condition.

On August 8, 2023, Lyell Immunopharma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2023. 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 8, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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 8, 2023

By: /s/ CHARLES NEWTON

Charles Newton
Chief Financial Officer

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Exhibit 99.1

Lyell Immunopharma Reports Business Highlights and Financial Results for the Second Quarter 2023

- Cash, cash equivalents and marketable securities of $632.7 million as of June 30, 2023 support advancing multiple product candidates through key clinical milestones
- Remain on track for initial clinical data from two lead product candidates in 2024
- Further strengthened executive leadership with appointment of Matt Lang, J.D., as Chief Business Officer

SOUTH SAN FRANCISCO, Calif., August 8, 2023 -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a clinical-stage T-cell reprogramming company advancing a diverse pipeline of cell therapies for patients with solid tumors, today reported financial results and business highlights for the second quarter ended June 30, 2023.

“Lyell continues to execute on our two Phase 1 clinical trials assessing resistance to T-cell exhaustion and enhanced durable stemness as key success factors to effective cell therapy for solid tumors and we look forward to presenting initial data from both our CAR T-cell and our TIL product candidates in 2024,” said Lynn Seely, M.D., Lyell’s President and CEO. “Our research team continues to advance innovative technologies to generate more potent and long-lasting T cells, and we are on track to submit our next investigational new drug application for our third clinical program in the first half of 2024. We continue to diligently manage our expenses and maintain a cash runway through multiple milestones into 2026.”

Second Quarter Updates and Recent Business Highlights

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

LYL797 – A ROR1 Chimeric Antigen Receptor (CAR) T-cell product candidate genetically reprogrammed to overexpress c-Jun and epigenetically reprogrammed using Lyell’s proprietary Epi-R™ manufacturing protocol, designed for differentiated potency and durability

- Enrollment in the Phase 1 clinical trial of LYL797 is ongoing. The study includes patients with relapsed or refractory triple-negative breast cancer or non-small cell lung cancer and is now open at 14 sites.
- Initial clinical data from the Phase 1 trial of LYL797 are expected in the first half of 2024.
- The Lyell START (Study of Tumor target Analysis for Referrals to Trials) ROR1-biomarker screening protocol was initiated in June 2023 to support the ongoing LYL797 Phase 1 trial, as well as potential future clinical trials with LYL797 and our next-generation ROR1-targeted product candidate, LYL119. START provides a decentralized mechanism for patients anywhere in the United States to have their collected tumor tissue screened for ROR1 expression and, for ROR1 positive patients, to be referred to clinical study sites.

LYL845 – A novel epigenetically reprogrammed TIL product candidate designed for differentiated potency and durability

- Enrollment in the Phase 1 clinical trial for LYL845 is ongoing. The study includes patients with relapsed and/or refractory metastatic or locally advanced melanoma, non-small cell lung cancer and colorectal cancer and is now open at nine sites.
- Initial clinical data from the Phase 1 trial of LYL845 are expected in 2024.

LYL119 – A ROR1 CAR T-cell product candidate incorporating Lyell’s four stackable reprogramming technologies for enhanced cytotoxicity

- LYL119 is a ROR1-targeted CAR T-cell product enhanced with Lyell’s four novel, stackable genetic and epigenetic reprogramming technologies: c-Jun overexpression, NR4A3 knockout, Epi-R manufacturing protocol and Stim-R™ T-cell activation technology.

- An investigational new drug (IND) application for LYL119 is expected to be submitted in the first half of 2024.

Rejuvenation – Novel partial reprogramming technology designed to maintain T-cell identity while reducing cells' epigenetic age

- Data demonstrating that T cells rejuvenated with Lyell's technology have improved expansion capacity and increased expression of biomarkers associated with T-cell stemness, and also exhibit improved antitumor properties compared with non-rejuvenated T-cell controls in sequential cell-killing assays, were presented at the International Society for Stem Cell Research (ISSCR) 2023 Annual Meeting on June 14th in Boston, MA.

Corporate and Operational Updates

- Matt Lang, J.D., was appointed Chief Business Officer in July. He also serves as Lyell's Chief Legal Officer and Corporate Secretary. Mr. Lang is an experienced company builder who has successfully led growth in complex organizations. Mr. Lang is responsible for Lyell's legal, compliance, human resources, alliance management and early commercialization teams.

Second Quarter Financial Results

Lyell reported a net loss of $63.9 million for the second quarter ended June 30, 2023, compared to a net loss of $36.3 million for the same period in 2022. 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 charges, was $45.6 million for the second quarter ended June 30, 2023, compared to $10.3 million for the same period in 2022.

Revenue

- Revenue was approximately zero for the second quarter ended June 30, 2023, compared to $35.7 million for the same period in 2022. No research and development pursuant to our collaboration and license agreement with GlaxoSmithKline (GSK Agreement) was performed in the second quarter of 2023 due to the termination of the GSK Agreement in December 2022, which drove the $35.7 million decrease in revenue.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $47.5 million for the second quarter ended June 30, 2023, compared to $43.7 million for the same period in 2022. The increase in second quarter 2023 R&D expenses was primarily driven by personnel-related expenses, principally related to an increase in headcount to expand our research, development and manufacturing capabilities to support increases in clinical trial enrollment, and an increase in research and laboratory costs primarily associated with clinical trials. 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, 2023, were $41.6 million, compared to $35.9 million for the same period in 2022. The increase in second quarter 2023 non-GAAP R&D expenses was driven by increased personnel-related expenses, primarily related to an increase in headcount to expand our clinical development and manufacturing capabilities in support of our ongoing clinical trials.
- General and administrative (G&A) expenses were $19.0 million for the second quarter ended June 30, 2023, compared to $30.5 million for the same period in 2022. The decrease in second quarter 2023 G&A expenses was primarily driven by changes 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, 2023, were $10.1 million, compared to $12.2 million for the same period in 2022. The decrease in second quarter 2023 non-GAAP G&A expenses was driven by a decrease in legal, consulting and other administrative expenses.

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, 2023 were $632.7 million, compared to $710.3 million as of December 31, 2022. Lyell believes that its cash, cash equivalents and marketable securities balances will be sufficient to meet working capital and capital expenditure needs into 2026.

About Lyell Immunopharma, Inc.

Lyell is a clinical-stage T-cell reprogramming company advancing a diverse pipeline of cell therapies for patients with solid tumors. The technologies powering its product candidates are 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 is applying its proprietary ex vivo genetic and epigenetic reprogramming technologies to address these barriers in order 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: Lyell's anticipated progress, business plans, business strategy and clinical trials; Lyell's advancement of its pipeline or 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 into 2026; Lyell's plans to submit an IND for LYL119 and the timing thereof; expectations around patient profiles, enrollment and timing of initial clinical data from Lyell's Phase 1 trials for LYL797 and LYL845; 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 geopolitical instability; macroeconomic conditions and the lingering effects of the COVID-19 pandemic; 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 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 its Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (SEC) on February 28, 2023, and the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, 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,	
	2023	**2022**	**2023**	**2022**
Revenue	$ 27	$ 35,741	$ 92	$ 36,294
Operating expenses:				
Research and development[(1)]	47,471	43,719	92,101	79,549
General and administrative	19,030	30,454	38,309	64,875
Other operating income, net	(569)	(1,171)	(1,857)	(2,293)
Total operating expenses	65,932	73,002	128,553	142,131
Loss from operations	(65,905)	(37,261)	(128,461)	(105,837)
Interest income, net	5,264	952	9,761	1,349
Other (expense) income, net[(1)]	(326)	(14)	774	21
Impairment of other investments	(2,923)	—	(12,923)	—
Total other income (loss), net	2,015	938	(2,388)	1,370
Net loss	$ (63,890)	$ (36,323)	$ (130,849)	$ (104,467)

(1) As of December 31, 2022, the Company's success payment liability was recognized at fair value as Fred Hutchinson Cancer Center (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 Fred Hutch success payment liabilities in 2022 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, 2023	**As of December 31, 2022**
Cash, cash equivalents and marketable securities	$ 632,700	$ 710,269
Property and equipment, net	$ 113,677	$ 123,023
Total assets	$ 835,354	$ 937,561
Total stockholders' equity	$ 736,855	$ 833,252

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. As of December 31, 2022, our Fred Hutch 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. For the three and six months ended June 30, 2023 and future periods, the change in the Fred Hutch success payment liability fair value is recognized in other (expense) income, net, as the requisite service obligation had been met, whereas it was previously recognized within research and development expenses. Non-GAAP net loss further adjusts non-cash investment gains and charges, as applicable, and for the income tax effect, if any, of the non-GAAP adjustments. 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, non-cash expenses related to the change 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,	
	2023	2022	2023	2022
Net loss - GAAP	$ (63,890)	$ (36,323)	$ (130,849)	$ (104,467)
Adjustments:				
Stock-based compensation expense	14,223	22,410	28,105	44,438
Change in the estimated fair value of success payment liabilities	1,105	3,587	(603)	(264)
Impairment of other investments	2,923	—	12,923	—
Net loss - Non-GAAP[(1)]	$ (45,639)	$ (10,326)	$ (90,424)	$ (60,293)

(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,	
	2023	2022	2023	2022
Research and development expense - GAAP	$ 47,471	$ 43,719	$ 92,101	$ 79,549
Adjustments:				
Stock-based compensation expense	(5,279)	(4,195)	(9,891)	(7,959)
Change in the estimated fair value of success payment liabilities[(1)]	(605)	(3,587)	3	264
Research and development expense - Non-GAAP	$ 41,587	$ 35,937	$ 82,213	$ 71,854

(1) As of December 31, 2022, the Company'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 Fred Hutch success payment liabilities in 2022 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,	
	2023	2022	2023	2022
General and administrative expense - GAAP	$ 19,030	$ 30,454	$ 38,309	$ 64,875
Adjustments:				
Stock-based compensation expense	(8,944)	(18,215)	(18,214)	(36,479)
General and administrative expense - Non-GAAP	$ 10,086	$ 12,239	$ 20,095	$ 28,396

Contact:

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