

**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 12, 2021

Lyell Immunopharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40502
(Commission File Number)

83-3006753
(IRS Employer
Identification No.)

**400 EAST JAMIE COURT, SUITE 301
SOUTH SAN FRANCISCO, California**
(Address of Principal Executive Offices)

94080
(Zip Code)

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

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 12, 2021, Lyell Immunopharma, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2021. 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release Dated August 12, 2021
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 12, 2021

By: _____
/s/ Charles Newton
Chief Financial Officer



Lyell Immunopharma Reports Second Quarter 2021 Financial Results and Business Highlights

- Achieved operational readiness of state-of-the-art LyFE manufacturing facility to support multiple clinical trials
- Cash, cash equivalents and marketable securities of \$974.8 million as of June 30, 2021 includes \$391.8 million in net proceeds from initial public offering

SOUTH SAN FRANCISCO, Calif., August 12, 2021 -- Lyell Immunopharma, Inc. (Lyell), (Nasdaq: LYEL), a T cell reprogramming company dedicated to the mastery of T cells to cure patients with solid tumors, today reported financial results for the second quarter and first six months of 2021 and provided business highlights.

“Lyell is steadily progressing our two T cell reprogramming platforms, Gen-R and Epi-R, to address what we believe are the primary barriers that limit consistent, reliable and curative responses to cell therapy in solid tumors,” said Liz Homans, Chief Executive Officer of Lyell. “Over the past six months we have expanded our development and executive teams and achieved important operational advances that keep us on track to submit four INDs and begin generating clinical data in 2022. With the completion of our initial public offering in June, we have a strong capital position to execute our vision of curing patients with solid tumors.”

Recent Business Highlights

- **Achieved operational readiness of state-of-the-art manufacturing capabilities** to produce cell products for multiple upcoming planned clinical trials. The LyFE Manufacturing Center integrates innovations that enable real-time monitoring and analysis of data and insights into the manufacturing processes. LyFE is operational and the Company has successfully completed engineering runs at scale to supply product for its upcoming planned clinical trials.
- **Expanded Board of Directors with industry and medical leaders** Otis Brawley, M.D., Elizabeth Nabel, M.D. and Lynn Seely, M.D.

Dr. Brawley is a Bloomberg Distinguished Professor of Oncology and Epidemiology at Johns Hopkins University and is a member of the board of directors of PDS Biotechnology Corporation. He was formerly the Chief Medical and Scientific Officer of American Cancer Society and director of the Georgia Cancer Center at Grady Memorial Hospital.

Dr. Nabel is Executive Vice President for Strategy at ModeX Therapeutics and a member of the board of directors of Moderna, Inc., Medtronic, and Accolade. She is the former President of Brigham Health, which includes Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, and the Brigham and Women's Physician Organization. Dr. Nabel was also a Professor of Medicine at Harvard Medical School.

Dr. Seely is a member of the board of directors of Blueprint Medicines, Corp. She previously served as President, Chief Executive Officer and member of the board of directors of Myovant Sciences and Senior Vice President and Chief Medical Officer of Medivation.

- **Further strengthened its balance sheet with net proceeds of \$391.8 million** from the sale of 25 million shares of common stock in the Company's initial public offering, bringing cash, cash equivalents and marketable securities to \$974.8 million as of June 30, 2021.

Second Quarter and First Six Months of 2021 Financial Results

GAAP Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$974.8 million as of June 30, 2021 compared to \$692.6 million as of December 31, 2020, an increase of \$282.2 million. Lyell successfully completed its initial public offering in June 2021 in which it issued 25 million shares of common stock, at a price of \$17.00 per share, for net proceeds of \$391.8 million, after deducting underwriting discounts and commissions and offering expenses.
- **Research and Development (R&D) Expenses:** R&D expenses, were \$46.4 million and \$88.0 million for the three and six months ended June 30, 2021, respectively, as compared to \$97.2 million and \$122.7 million for the three and six months ended June 30, 2020, respectively. The decrease in R&D expense for the three and six months ended June 30, 2021, compared to the same periods in the prior year was primarily due to a decrease in collaborations and licensing costs, offset by an increase in success payments expenses.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$19.1 million and \$35.9 million for the three and six months ended June 30, 2021, respectively, as compared to \$9.6 million and \$18.4 million for the three and six months ended June 30, 2020, respectively. The increase in G&A expense for the three and six months ended June 30, 2021 compared to the same periods in the prior year was primarily due to an increase in stock-based compensation expense.
- **Net Loss:** Net loss was \$62.6 million and \$117.6 million for the three and six months ended June 30, 2021, respectively, as compared to \$100.7 million and \$129.9 million for the three and six months ended June 30, 2020, respectively.

Non-GAAP Measures

- **Non-GAAP R&D Expenses:** Non-GAAP R&D Expenses were \$32.1 million and \$58.8 million for the three and six months ended June 30, 2021, respectively, as compared to \$91.6 million and \$113.0 million for the three and six months ended June 30, 2020, respectively. Non-GAAP R&D expenses excludes non-cash stock-based compensation expense and non-cash expenses related to the change in the estimated fair value of success payment liabilities.
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- **Non-GAAP G&A Expenses:** Non-GAAP G&A Expenses were \$9.0 million and \$17.9 million for the three and six months ended June 30, 2021, respectively, as compared to \$7.3 million and \$15.0 million for the three and six months ended June 30, 2020, respectively. Non-GAAP G&A expenses exclude non-cash stock-based compensation expense.

- **Non-GAAP Net Loss:** Non-GAAP Net loss was \$38.1 million and \$70.4 million for the three and six months ended June 30, 2021, respectively, as compared to \$92.9 million and \$116.8 million for the three and six months ended June 30, 2020, respectively. Non-GAAP net loss excludes non-cash stock-based compensation expense and non-cash expenses related to the change in the estimated fair value of success payment liabilities.

A discussion of these non-GAAP financial measures, including reconciliations of GAAP to non-GAAP financial measures, is presented below under “Non-GAAP Financial Measures.”

About Lyell Immunopharma, Inc.

Lyell is a T cell reprogramming company dedicated to the mastery of T cells to cure patients with solid tumors. The Company focuses on addressing what it believes are the primary barriers that limit consistent, reliable and curative responses to adoptive T cell therapy: T cell exhaustion and lack of durable stemness, which includes proliferative capacity, ability to self-renew and ability to differentiate and eliminate solid tumors. Lyell is applying its proprietary *ex vivo* genetic and epigenetic reprogramming technology platforms, Gen-R and Epi-R, to address these barriers in order to develop new medicines with improved, durable, and potentially curative clinical outcomes. Lyell is based in South San Francisco, California and 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 progress, business plans, business strategy, product candidates, progress towards completion of the LyFE manufacturing center, manufacturing, and planned clinical trials; Lyell’s vision of curing patients with solid tumors; Lyell’s plans to submit four INDs and begin generating clinical data, and the timing thereof; the 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: the effects of the evolving COVID-19 pandemic; Lyell’s ability to submit planned INDs on the anticipated timing or at all; initiation of planned clinical trials and enrollment of patients in its future clinical trials; Lyell’s ability to manufacture and supply its product candidates for its future clinical trials; the preclinical profiles of Lyell’s product candidates not translating in clinical trials; the potential for results from clinical trials to differ from preclinical, 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 prospectus filed with the Securities and Exchange Commission (SEC) on June 21, 2021 and in Lyell’s future reports to be filed with the SEC, including Lyell’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2021. 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 Balance Sheets Data
(In thousands)

	June 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	\$ 974,784	\$ 692,614
Property and equipment, net	109,637	77,045
Total assets	1,229,867	908,280
Success payment liabilities	25,006	5,773
Total liabilities	207,912	189,840
Convertible preferred stock	-	1,010,968
Total stockholders' equity (deficit)	1,021,955	(292,528)

Lyell Immunopharma, Inc.
Unaudited Selected Consolidated Statements of Operations
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	\$ 2,628	\$ 3,118	\$ 5,073	\$ 4,374
Operating expenses (income):				
Research and development	46,446	97,152	87,975	122,652
General and administrative	19,112	9,562	35,943	18,442
Other operating income, net	(223)	(1,030)	(768)	(1,150)
Total operating expenses	65,335	105,684	123,150	139,944
Loss from operations	(62,707)	(102,566)	(118,077)	(135,570)
Interest income	218	1,881	572	4,222
Other (expense) income, net	(106)	29	(133)	1,452
Net loss	\$ (62,595)	\$ (100,656)	\$ (117,638)	\$ (129,896)

Non-GAAP Financial Measures

To supplement our financial results and guidance presented in accordance with GAAP, we present non-GAAP R&D expenses, non-GAAP G&A expenses and non-GAAP net loss. Non-GAAP R&D expenses and non-GAAP net loss 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 R&D expenses and GAAP net loss, respectively. Non-GAAP net loss further adjusts 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 and non-cash expenses related to the change in the estimated fair value of success payment liabilities from our non-GAAP financial measures because they are non-cash expenses 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, 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 Research and Development Expense
(In thousands)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	2021	2020	2021	2020
Research and development - GAAP	\$ 46,446	\$ 97,152	\$ 87,975	\$ 122,652
Adjustments:				
Stock-based compensation expense	(5,091)	(5,021)	(9,942)	(7,068)
Change in the estimated fair value of success payment liabilities	(9,266)	(488)	(19,233)	(2,558)
Research and development - Non-GAAP	<u>\$ 32,089</u>	<u>\$ 91,643</u>	<u>\$ 58,800</u>	<u>\$ 113,026</u>

Lyell Immunopharma, Inc.
Unaudited Reconciliation of GAAP to Non-GAAP General and Administrative Expense
(In thousands)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	2021	2020	2021	2020
General and administrative - GAAP	\$ 19,112	\$ 9,562	\$ 35,943	\$ 18,442
Adjustments:				
Stock-based compensation expense	(10,158)	(2,247)	(18,039)	(3,474)
General and administrative - Non-GAAP	<u>\$ 8,954</u>	<u>\$ 7,315</u>	<u>\$ 17,904</u>	<u>\$ 14,968</u>

Lyell Immunopharma, Inc.
Unaudited Reconciliation of GAAP to Non-GAAP Net Loss
(In thousands)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	2021	2020	2021	2020
Net loss - GAAP	\$ (62,595)	\$ (100,656)	\$ (117,638)	\$ (129,896)
Adjustments:				
Stock-based compensation expense	15,249	7,268	27,981	10,542
Change in the estimated fair value of success payment liabilities	9,266	488	19,233	2,558
Income tax effect of above adjustments ⁽¹⁾	-	-	-	-
Net loss - Non-GAAP	<u>\$ (38,080)</u>	<u>\$ (92,900)</u>	<u>\$ (70,424)</u>	<u>\$ (116,796)</u>

(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.

Contact:

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