

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 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.)

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 12, 2021, Lyell Immunopharma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021. A copy of the press release is attached hereto as Exhibit 99.1.



Lyell Immunopharma Reports Third Quarter 2021 Financial Results and Business Highlights

- Cash and investments of \$936.4 million as of September 30, 2021 supports advancing multi-modality cell therapy pipeline

SOUTH SAN FRANCISCO, Calif., Nov 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 third quarter 2021 financial results and provided business highlights.

“We continue to advance our multi-modality pipeline and remain on track to submit four INDs by the end of 2022 and are expanding our organizational capabilities across research, development and manufacturing to support our pipeline.” said Liz Homans, Chief Executive Officer of Lyell. “Our team is preparing to initiate multiple clinical trials incorporating our two platforms that enable T cells to overcome exhaustion and maintain durable stemness in the solid tumor microenvironment, and we look forward to elucidating the potential clinical benefits of these technologies.”

Third Quarter 2021 Financial Results

GAAP and Non-GAAP Operating Results

- Research and Development (R&D) Expenses were \$31.4 million for the three months ended September 30, 2021, compared to \$24.5 million for the same period in 2020. The increase in R&D expense on a GAAP basis was primarily due to increases in facilities and technology costs and personnel-related expenses, partially offset by a decrease in success payments expenses. 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, 2021 were \$28.7 million, compared to \$21.3 million for the same period in 2020.
 - General and Administrative (G&A) Expenses were \$21.2 million for the three months ended September 30, 2021, compared to \$13.6 million for the same period in 2020. The increase in G&A expense on a GAAP basis was primarily due to an increase in personnel-related expenses, including stock-based compensation expense. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the third quarter ended September 30, 2021 were \$10.9 million, compared to \$5.8 million for the same period in 2020.
 - Net loss was \$48.9 million for the three months ended September 30, 2021, compared to \$35.7 million for the same period in 2020. Non-GAAP net loss, which excludes non-cash stock-based compensation and non-cash expenses related to the change in the estimated fair value of success payment liabilities, was \$35.7 million for the third quarter ended September 2021, compared to \$24.7 million for the same period in 2020.
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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.”

Cash, cash equivalents and marketable securities

Cash, cash equivalents and marketable securities as of September 30, 2021 were \$936.4 million, compared to \$692.6 million as of December 31, 2020, an increase of \$243.8 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.

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 anticipated progress, business plans, business strategy and planned clinical trials; Lyell’s plans to submit four INDs and the timing thereof; 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: 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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 September 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)

	<u>September 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Cash, cash equivalents and marketable securities	\$ 936,432	\$ 692,614
Property and equipment, net	115,857	77,045
Total assets	1,198,334	908,280
Success payment liabilities	25,116	5,773
Total liabilities	211,860	189,840
Convertible preferred stock	-	1,010,968
Total stockholders' equity (deficit)	986,474	(292,528)

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Revenue	\$ 2,755	\$ 1,070	\$ 7,828	\$ 5,444
Operating expenses (income):				
Research and development	31,433	24,501	119,408	147,153
General and administrative	21,241	13,570	57,184	32,012
Other operating income, net	(758)	(158)	(1,526)	(1,308)
Total operating expenses	51,916	37,913	175,066	177,857
Loss from operations	(49,161)	(36,843)	(167,238)	(172,413)
Interest income	270	1,096	842	5,318
Other income (expense), net	16	28	(117)	1,480
Net loss	\$ (48,875)	\$ (35,719)	\$ (166,513)	\$ (165,615)

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 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, 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 Research and Development Expense

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development - GAAP	\$ 31,433	\$ 24,501	\$ 119,408	\$ 147,153
Adjustments:				
Stock-based compensation expense	(2,673)	(1,965)	(12,615)	(9,033)
Change in the estimated fair value of success payment liabilities	(110)	(1,235)	(19,343)	(3,793)
Research and development - Non-GAAP	<u>\$ 28,650</u>	<u>\$ 21,301</u>	<u>\$ 87,450</u>	<u>\$ 134,327</u>

Lyell Immunopharma, Inc.

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

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
General and administrative - GAAP	\$ 21,241	\$ 13,570	\$ 57,184	\$ 32,012
Adjustments:				
Stock-based compensation expense	(10,369)	(7,783)	(28,408)	(11,257)
General and administrative - Non-GAAP	<u>\$ 10,872</u>	<u>\$ 5,787</u>	<u>\$ 28,776</u>	<u>\$ 20,755</u>

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net loss - GAAP	\$ (48,875)	\$ (35,719)	\$ (166,513)	\$ (165,615)
Adjustments:				
Stock-based compensation expense	13,042	9,748	41,023	20,290
Change in the estimated fair value of success payment liabilities	110	1,235	19,343	3,793
Income tax effect of above adjustments ⁽¹⁾	-	-	-	-
Net loss - Non-GAAP	<u>\$ (35,723)</u>	<u>\$ (24,736)</u>	<u>\$ (106,147)</u>	<u>\$ (141,532)</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.

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