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): February 28, 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

Item 2.02 Results of Operations and Financial Condition.

On February 28, 2023, Lyell Immunopharma, Inc. (the "Company") issued a press release announcing its financial results for the quarter and full year ended December 31, 2022. 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 February 28, 2023
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: February 28, 2023

By: /s/ CHARLES NEWTON

Charles Newton
Chief Financial Officer

Exhibit 99.1

Lyell Immunopharma Reports Business Highlights and Financial Results for the Fourth Quarter and Full Year 2022

- Cash, cash equivalents and marketable securities of $710.3 million as of December 31, 2022 supports advancing robust pipeline into 2026, through multiple clinical milestones
- Phase 1 clinical trials initiated for two wholly-owned product candidates for the treatment of solid tumors
- Nonclinical data highlighting CAR T cell and TIL product candidates designed for differentiated potency and durability presented at multiple scientific conferences

SOUTH SAN FRANCISCO, Calif., Feb. 28, 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 fourth quarter and year ended December 31, 2022.

“Lyell continued to gain momentum in 2022 with the initiation of two Phase 1 clinical trials for our wholly-owned CAR T cell and TIL product candidates, and we head into 2023 with a goal of accelerating this momentum to generate clinical data from these trials as rapidly as possible,” said Lynn Seely, M.D., Lyell’s President and CEO. “We continued to invest in our innovative reprogramming technologies and recently announced two product candidates in preclinical development that incorporate new stackable technologies designed to further enhance T-cell potency and cytotoxicity to defeat solid tumors. Our strong financial position with cash runway into 2026 positions us to demonstrate the value of our two lead clinical programs that target solid tumors with large unmet needs while continuing to invest in and develop our innovative pipeline.”

Fourth 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 two additional product candidates, LYL119 and a TIL product candidate incorporating novel genetic and epigenetic reprogramming technologies, are in preclinical development.

LYL797 – A ROR1 CAR T-cell product candidate genetically reprogrammed using 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. Initial clinical data from the Phase 1 trial of LYL797 are expected in the first half of 2024.
- Presented nonclinical data at the American Association of Cancer Research 2022 Annual Meeting characterizing LYL797 and demonstrating that Lyell’s c-Jun overexpression and Epi-R reprogramming technologies can overcome barriers of T-cell exhaustion and lack of durable stemness in engineered T cells using a set of *in vitro* and *in vivo* models, including an aggressive syngeneic mouse tumor model and a xenograft lung cancer model.
- Presented nonclinical data demonstrating LYL797 showed improved expansion and anti-tumor activity and prolonged survival compared to conventional ROR1 CAR T cells in an established human ROR1-positive H1975 mouse xenograft model at the American Society of Gene and Cell Therapy Annual Meeting.

LYL119 – An innovative ROR1 CAR T-cell product designed for enhanced cytotoxicity

- LYL119 incorporates four of Lyell’s stackable reprogramming technologies, including two novel technologies – a genetic knockout of NR4A3 (NR4A3-KO) and Stim-R™. These technologies, which are complementary to c-Jun and Epi-R, are designed to further improve the anti-tumor potency and durability of T-cells.
- An IND for LYL119 is expected to be submitted in the first half of 2024.

- Presented nonclinical data demonstrating that the combination of two genetic reprogramming technologies, NR4A3 gene knockout and c-Jun overexpression, enhances the functional activity of ROR1 CAR T cells as shown by higher levels of cytokine production, increased CAR T-cell persistence and reduced surface expression of inhibitory receptors after repetitive antigen stimulation, as well as significant improvement in tumor control *in vivo* at The Society for Immunotherapy of Cancer 2022 Annual Meeting (SITC 2022).
- Presented nonclinical data at SITC 2022 demonstrating that Lyell's proprietary Stim-R epigenetic reprogramming technology, which enables precise control and optimized delivery of activation molecules during T-cell production, generates potent CAR T-cell product candidates with increased cell proliferation and persistence, as well as improved tumor control *in vivo*.

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

- Announced clearance of the IND for LYL845 in October 2022; enrollment in the Phase 1 clinical trial for LYL845 is ongoing. Initial clinical data from the Phase 1 trial of LYL845 are expected in 2024.
- Presented nonclinical data at SITC 2022 demonstrating the ability of Lyell's Epi-R technology to successfully expand TIL in both hot and cold tumors and to retain qualities linked with anti-tumor functionality and improved outcomes in previous TIL clinical trials. These qualities present in Lyell's Epi-R TIL include a greater proportion of CD8+ T cells, enrichment for T cells with stem-like profiles, better metabolic fitness and preserved polyclonality compared to control TIL preparations.
- Presented bioinformatic analyses, including comprehensive analyses of transcriptomic profiles, polyclonality and prediction of tumor-reactive T cell clones in Lyell's LYL845 product candidate, at SITC 2022. These analyses demonstrated that LYL845 expanded at clinical scale using Epi-R technology remained highly polyclonal and preserved approximately 94% of the predicted tumor reactive clones. Further, the preserved predicted tumor reactive clones in LYL845 have increased stemness and reduced exhaustion-associated genes compared to TIL products derived from the standard process.

Corporate and Operational Updates

- In December, Lynn Seely, M.D., a member of the company's board since May 2021 and former President and CEO of Myovant Sciences, was named President and CEO. Dr. Seely has extensive biopharmaceutical leadership experience with a track record of success building companies and developing new medicines in oncology and women's health.
- In September, Rahsaan W. Thompson was named Chief Legal Officer. Mr. Thompson is a biopharmaceutical industry veteran with more than 20 years of experience with development stage and commercial companies.
- In January, Gary Lee, Ph.D. was named Chief Scientific Officer. Dr. Lee is a veteran biotech leader with more than a decade of experience heading translational cell and gene therapy programs.

Fourth Quarter and Full Year 2022 Financial Results

Lyell reported a net loss of $8.4 million and $183.1 million for the fourth quarter and year ended December 31, 2022, respectively, compared to a net loss of $83.7 million and $250.2 million for the same periods in 2021. 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 $0.3 million and $104.2 million for the fourth quarter and year ended December 31, 2022, respectively, compared to $41.7 million and $147.9 million for the same periods in 2021.

Revenue

- Revenue was $48.4 million and $84.7 million for the fourth quarter and year ended December 31, 2022, respectively, compared to $2.8 million and $10.7 million for the same periods in 2021. The increase in revenue was driven primarily by recognizing the remaining deferred revenue from the GSK collaboration agreement.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $38.0 million and $159.2 million for the fourth quarter and year ended December 31, 2022, respectively, compared to $19.3 million and $138.7 million for the same periods in 2021. The increase in fourth quarter 2022 R&D expenses was primarily driven by non-cash expenses related to the change in the estimated fair value of success payment liabilities. The increase in annual 2022 R&D expenses was due primarily to increases in personnel and infrastructure costs to support the expansion of our R&D and manufacturing capabilities. 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 fourth quarter and year ended December 31, 2022, were $41.0 million and $147.6 million, respectively, compared to $32.2 million and $119.7 million for the same periods in 2021.
- General and administrative (G&A) expenses were $26.3 million and $117.3 million for the fourth quarter and year ended December 31, 2022, respectively, compared to $31.9 million and $89.1 million for the same periods in 2021. The decrease in fourth quarter 2022 and increase in annual 2022 G&A expenses were both primarily driven by changes in non-cash stock-based compensation. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the fourth quarter and year ended December 31, 2022 were $12.3 million and $52.1 million, respectively, compared to $13.4 million and $42.2 million for the same periods in 2021. The increase in annual 2022 non-GAAP G&A expenses was driven by increased legal and corporate expenses and public company operating costs.

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 December 31, 2022 were $710.3 million, compared to $898.3 million as of December 31, 2021. 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 advancing its pipeline or growing its capabilities; the potential clinical benefits and therapeutic potential of Lyell's product candidates; Lyell's expectation that its strong financial position with cash runway into 2026 will enable it to demonstrate the value of its two lead clinical programs and continue to invest in and develop its pipeline; expected milestones; enrollment expectations for the Phase 1 clinical trials of LYL797 and LYL845; the timing of initial clinical data from Lyell's planned 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 ongoing 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 lack of experience as a company in enrolling, conducting or 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 Lyell's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the Securities and Exchange Commission (SEC) on November 8, 2022, and its Annual Report on Form 10-K for the year ended December 31, 2022, 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 December 31, 2022		Year Ended December 31,	
	2022	2021	2022	2021
Revenue	$ 48,386	$ 2,822	$ 84,683	$ 10,650
Operating expenses:				
Research and development	38,032	19,285	159,188	138,693
General and administrative	26,348	31,873	117,307	89,057
Other operating income, net	(1,210)	(798)	(4,754)	(2,324)
Total operating expenses	63,170	50,360	271,741	225,426
Loss from operations	(14,784)	(47,538)	(187,058)	(214,776)
Interest income, net	3,453	323	7,053	1,165
Other income (expense), net	2,934	(44)	1,887	(161)
Impairment of other investments	—	(36,447)	(5,000)	(36,447)
Total other income (loss), net	6,387	(36,168)	3,940	(35,443)
Net loss	$ (8,397)	$ (83,706)	$ (183,118)	$ (250,219)

Balance Sheet Data:

	As of December 31,	
	2022	2021
Cash, cash equivalents and marketable securities	$ 710,269	$ 898,325
Property and equipment, net	$ 123,023	$ 120,098
Total assets	$ 937,561	$ 1,127,406
Total stockholders’ equity	$ 833,252	$ 929,787

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, 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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Net loss - GAAP	$ (8,397)	$ (83,706)	$ (183,118)	$ (250,219)
Adjustments:				
Stock-based compensation expense	18,363	21,178	81,924	62,201
Change in the estimated fair value of success payment liabilities	(7,307)	(15,630)	(5,130)	3,713
Impairment of other investments	—	36,447	5,000	36,447
Gain on other investments	(2,923)	—	(2,923)	—
Net loss - Non-GAAP[(1)]	$ (264)	$ (41,711)	$ (104,247)	$ (147,858)

(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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Research and development - GAAP	$ 38,032	$ 19,285	$ 159,188	$ 138,693
Adjustments:				
Stock-based compensation expense	(4,320)	(2,713)	(16,721)	(15,328)
Change in the estimated fair value of success payment liabilities	7,307	15,630	5,130	(3,713)
Research and development - Non-GAAP	$ 41,019	$ 32,202	$ 147,597	$ 119,652

Lyell Immunopharma, Inc.

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

(in thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
General and administrative - GAAP	$ 26,348	$ 31,873	$ 117,307	$ 89,057
Adjustments:				
Stock-based compensation expense	(14,043)	(18,465)	(65,203)	(46,873)
General and administrative - Non-GAAP	$ 12,305	$ 13,408	$ 52,104	$ 42,184

Contact:

Ellen Rose

Senior Vice President, Communications and Investor Relations

erose@lyell.com