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

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- Expect to share initial clinical and translational data from the Phase 1 trial of LYL797, a ROR1-targeted CAR T-cell product candidate, this quarter
- On track to report initial clinical data from the Phase 1 trial of LYL845, an epigenetically enhanced TIL product candidate, in the second half of 2024
- IND for second generation ROR1-targeted CAR T-cell product candidate on track for submission this quarter
- Cash, cash equivalents and marketable securities of $526.3 million as of March 31, 2024 supports advancing diverse pipeline through multiple clinical milestones into 2027

SOUTH SAN FRANCISCO, Calif., May 06, 2024 (GLOBE NEWSWIRE) -- 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 first quarter ended March 31, 2024.

“The initial clinical and translational data from the Phase 1 trial of LYL797, our lead CAR T-cell product candidate, will provide the first insights into our ability to reprogram ROR1 CAR T cells that can expand, infiltrate solid tumors and kill cancer cells in patients,” said Lynn Seely, M.D., Lyell’s President and CEO. “Our strong cash position is expected to fund operations through multiple milestones into 2027, including initial clinical data from our lead TIL program in the second half of this year, and to the continued advancement of multiple product candidates with potential to offer better options for patients with cancer.”

First 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. Two additional product candidates, LYL119, a ROR1-targeted Chimeric Antigen Receptor (CAR) T-cell product candidate and a second-generation tumor infiltrating lymphocyte (TIL) product candidate, are in preclinical development.

LYL797 – A ROR1-targeted 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 (TNBC) or non-small cell lung cancer (NSCLC).
- Initial data from at least 20 patients from the Phase 1 clinical trial of LYL797 are expected this quarter.

LYL845 – A TIL product candidate epigenetically reprogrammed using Lyell’s proprietary Epi-R manufacturing protocol, designed for differentiated potency and durability

- Enrollment in the Phase 1 clinical trial of LYL845 is ongoing. The study includes patients with relapsed or refractory metastatic or locally advanced melanoma, NSCLC and colorectal cancer.
- Initial clinical and translational data from the Phase 1 trial of LYL845 are expected in the second half of 2024.

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

- LYL119 is a ROR1-targeted CAR T-cell product enhanced with Lyell’s four novel 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 this quarter.
- Presented a poster with new nonclinical data on LYL119 at the American Association for Cancer Research (AACR) Annual Meeting 2024. In this study, LYL119, compared to ROR1 CAR T cells reprogrammed with only two or three technologies, demonstrated reduced CAR T-cell exhaustion, enhanced CAR T-cell function, enhanced proliferation capacity and sustained antitumor activity in a mouse xenograft tumor model across a 10-fold dose range, including at very low cell doses. In addition, following repeated rounds of tumor cell killing, LYL119 displayed reduced expression of exhaustion-related gene signatures and retained unique cell subsets characterized by upregulation of memory and effector-associated gene signatures.

First Quarter Financial Results

Lyell reported a net loss of $60.7 million for the first quarter ended March 31, 2024, compared to a net loss of $67.0 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 $37.5 million for the first quarter ended March 31, 2024, compared to $44.8 million for the same period in 2023.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $43.2 million for the first quarter ended March 31, 2024, compared to $44.6 million for the same period in 2023. The decrease in first quarter 2024 R&D expenses of $1.5 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 first quarter ended March 31, 2024, were $38.9 million, compared to $40.6 million for the same period in 2023. The decrease in first quarter 2024 non-GAAP R&D expenses was primarily driven by a decrease in personnel-related expenses.
- General and administrative (G&A) expenses were $13.5 million for the first quarter ended March 31, 2024, compared to $19.3 million for the same period in 2023. The decrease in first 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 first quarter ended March 31, 2024, were $8.1 million, compared to $10.0 million for the same period in 2023. The decrease in 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 March 31, 2024, were $526.3 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 T-cell reprogramming company advancing a diverse pipeline of cell therapies for patients with solid tumors. Lyell is currently enrolling a Phase 1 clinical trial evaluating a ROR1-targeted CAR T-cell therapy in patients with relapsed refractory triple-negative breast cancer and non-small cell lung cancer (NSCLC) and a second Phase 1 clinical trial evaluating reprogrammed tumor infiltrating lymphocytes (TIL) in patients with advanced melanoma, NSCLC and colorectal cancer. 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 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; Lyell's plans to submit an IND for LYL119 and the timing thereof; expectations around enrollment and the timing of initial clinical and translational 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, including 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; anticipated benefits and financial impact of Lyell's workforce restructuring; 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 March 31, 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 March 31,	
	2024	2023
Revenue	$ 3	$ 65
Operating expenses:		
Research and development[(1)]	43,174	44,630
General and administrative	13,494	19,279
Other operating income, net	(1,090)	(1,288)
Total operating expenses	55,578	62,621
Loss from operations	(55,575)	(62,556)
Interest income, net	6,819	4,497
Other income, net[(1)]	1,090	1,100
Impairment of other investments	(13,001)	(10,000)
Total other loss, net	(5,092)	(4,403)
Net loss	$ (60,667)	$ (66,959)

(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 income, net in the unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss.

Balance Sheet Data:

	As of March 31, 2024	As of December 31, 2023
Cash, cash equivalents and marketable securities	$ 526,300	$ 562,729
Property and equipment, net	$ 97,836	$ 102,654
Total assets	$ 694,220	$ 750,029
Total stockholders' equity	$ 603,157	$ 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 March 31,	
	2024	2023
Net loss - GAAP	$ (60,667)	$ (66,959)
Adjustments:		
Impairment of other investments	13,001	10,000
Stock-based compensation expense	9,155	13,882
Change in the estimated fair value of success payment liabilities	968	(1,708)
Net loss - Non-GAAP[(1)]	$ (37,543)	$ (44,785)

(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 March 31,	
	2024	**2023**
Research and development - GAAP	$ 43,174	$ 44,630
Adjustments:		
Stock-based compensation expense	(3,792)	(4,612)
Change in the estimated fair value of success payment liabilities[(1)]	(525)	608
Research and development - Non-GAAP	$ 38,857	$ 40,626

(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 income, net 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 March 31,	
	2024	**2023**
General and administrative - GAAP	$ 13,494	$ 19,279
Adjustments:		
Stock-based compensation expense	(5,363)	(9,270)
General and administrative - Non-GAAP	$ 8,131	$ 10,009

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