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

May 4, 2023

- Two phase 1 clinical trials recruiting patients at 14 sites across the US; nine sites for LYL797, a ROR-1-targeted chimeric antigen receptor T cell (CAR-T) product candidate, and five sites for LYL845, a tumor infiltrating lymphocyte (TIL) product candidate
- Cash, cash equivalents and marketable securities of $668.0 million as of March 31, 2023 support advancing robust pipeline into 2026, through multiple clinical milestones

SOUTH SAN FRANCISCO, Calif., May 04, 2023 (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, 2023.

“We remain focused on accumulating data in the two Phase 1 clinical trials of our wholly owned CAR T cell and TIL product candidates,” said Lynn Seely, M.D., Lyell’s President and CEO. “With more than a dozen sites now open and actively screening and enrolling patients across these two trials, I am pleased with the progress we are making. We are paving the way for two initial clinical data readouts in 2024 that we expect will provide important insights on the potential of our T cell reprogramming technologies to benefit patients with solid tumors. Our strong financial position with cash runway into 2026 positions us to focus on execution, while also advancing new technologies being deployed in our pipeline of novel product candidates.”

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 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^{TM} manufacturing protocol, designed for differentiated potency and durability

- Enrollment in the Phase 1 clinical trial of LYL797 is ongoing at nine sites in the US. The study is enrolling patients with relapsed or refractory triple-negative breast cancer or non-small cell lung cancer. Initial clinical data from the Phase 1 trial of LYL797 are expected in the first half of 2024.

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 at five sites in the US. The study is enrolling patients with relapsed and/or refractory metastatic or locally advanced melanoma, non-small cell lung cancer and colorectal cancer. Initial clinical data from the Phase 1 trial of LYL845 are expected in 2024.

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

- An IND for LYL119 is expected to be submitted in the first half of 2024.
- An abstract highlighting preclinical development of LYL119 has been selected for presentation at the American Society for Gene and Cell Therapy (ASGCT) 26th Annual Meeting taking place in Los Angeles, CA May 16-20, 2023.

First Quarter Financial Results

Lyell reported a net loss of $67.0 million for the first quarter ended March 31, 2023, compared to a net loss of $68.1 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 gains and charges, was $44.8 million for the first quarter ended March 31, 2023, compared to $50.0 million for the same period in 2022.

Revenue

- Revenue was $0.1 million for the first quarter ended March 31, 2023 compared to $0.6 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 first quarter of 2023 due to the termination of the GSK Agreement in December 2022, which drove the $0.5 million decrease in revenue.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $44.6 million for the first quarter ended March 31, 2023, compared to $35.8 million for the same period in 2022. The increase in first quarter 2023 R&D expenses was primarily driven by non-cash expenses related to the change in the estimated fair value of success payment liabilities and an increase in personnel-related expenses, primarily related to an increase in headcount to expand 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 first quarter ended March 31, 2023, were $40.6 million compared to $35.9 million for the same period in 2022. The increase in first 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 $19.3 million for the first quarter ended March 31, 2023, compared to $34.4 million for the same period in 2022. The decrease in first 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 first quarter ended March 31, 2023, were $10.0 million, compared to $16.2 million for the same period in 2022. The decrease in first quarter 2023 non-GAAP G&A expenses was driven by a decrease in legal 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 March 31, 2023 were $668.0 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 advancement of its pipeline or 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 support advancement of its pipeline; 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 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 March 31, 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 March 31,	
	2023	**2022**
Revenue	$ 65	$ 553
Operating expenses:		
Research and development[(1)]	44,630	35,830

General and administrative	19,279	34,421
Other operating income, net	(1,288)	(1,122)
Total operating expenses	62,621	69,129
Loss from operations	(62,556)	(68,576)
Interest income, net	4,497	397
Other income, net[(1)]	1,100	35
Impairment of other investments	(10,000)	—
Total other (loss) income, net	(4,403)	432
Net loss	$ (66,959)	$ (68,144)

(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 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 for Q1 2022 was recognized within research and development expenses in the unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss.

Balance Sheet Data:

	As of March 31, 2023	As of December 31, 2022
Cash, cash equivalents and marketable securities	$ 668,024	$ 710,269
Property and equipment, net	$ 118,600	$ 123,023
Total assets	$ 880,450	$ 937,561
Total stockholders' equity	$ 783,826	$ 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 months ended March 31, 2023 and future periods, the change in the Fred Hutch success payment liability fair value is recognized in other 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 March 31,	
	2023	2022
Net loss - GAAP	$ (66,959)	$ (68,144)
Adjustments:		
Stock-based compensation expense	13,882	22,028
Change in the estimated fair value of success payment liabilities	(1,708)	(3,851)
Impairment of other investments	10,000	—
Net loss - Non-GAAP[(1)]	$ (44,785)	$ (49,967)

(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.

Unaudited Reconciliation of GAAP to Non-GAAP Research and Development Expenses

(in thousands)

	Three Months Ended March 31,	
	2023	2022
Research and development expense - GAAP	$ 44,630	$ 35,830
Adjustments:		
Stock-based compensation expense	(4,612)	(3,764)
Change in the estimated fair value of success payment liabilities[(1)]	608	3,851
Research and development expense - Non-GAAP	$ 40,626	$ 35,917

(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 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 for Q1 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 March 31,	
	2023	2022
General and administrative expense - GAAP	$ 19,279	$ 34,421
Adjustments:		
Stock-based compensation expense	(9,270)	(18,264)
General and administrative expense - Non-GAAP	$ 10,009	$ 16,157

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