Lyell Immunopharma Reports First Quarter Financial Results and Business Highlights

May 10, 2022

- Cash, cash equivalents and marketable securities of $838 million as of March 31, 2022 supports advancing a robust cell therapy pipeline
- Research highlighting novel reprogramming technologies designed to overcome barriers to successful adoptive cell therapy in solid tumors presented at multiple scientific conferences

SOUTH SAN FRANCISCO, Calif., May 10, 2022 (GLOBE NEWSWIRE) -- 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 provided business highlights and reported financial results for the first quarter of 2022.

“We continue to progress our mission to develop T-cell therapies that can outlast and eradicate solid tumors,” said Liz Homans, CEO of Lyell Immunopharma. “Our multi-modal pipeline has advanced two products into Phase 1 clinical development, and we remain on track to submit an IND in the second half of this year for LYL845, our wholly owned TIL product candidate, and with our collaborators at GSK we remain on track to submit an IND for LYL331, a next-generation NY-ESO-1 T-cell receptor product candidate in late 2022 – early 2023. We remain focused on executing towards clinical data, and our strong financial position enables us to see our current pipeline through key milestones in evaluating T-cell exhaustion and lack of durable stemness as key barriers to successful cell therapy in patients with solid tumor cancers.”

Recent Business Highlights

- Announced two upcoming abstract presentations at the 25th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT), scheduled for May 16 - 19, 2022, in Washington, DC. The presentations will highlight preclinical data characterizing two investigational products in Phase 1 clinical development, LYL797 and LYL132, that incorporate Lyell reprogramming technologies designed to address major barriers to successful adoptive cell therapy.
- Presented preclinical data characterizing LYL797 at the Association for Cancer Research (AACR) 2022 Annual Meeting. LYL797 is a receptor tyrosine kinase-like orphan receptor 1 (ROR1)-targeted CAR T-cell therapy that incorporates Lyell’s genetic and epigenetic reprogramming technologies, Gen-R™ and Epi-R™, designed to overcome T-cell exhaustion and promote durable stemness.
- Initiated screening for the Phase 1 clinical trial for LYL797. The trial is designed to be an open label dose escalation and expansion trial that initially enrolls patients with relapsed/refractory triple-negative breast cancer or non-small cell lung cancer who have failed at least two lines of therapy. Initial data is expected in 2023.
- Announced FDA clearance of the IND for LYL132, a next-generation T-cell receptor (TCR) therapy for patients with solid tumors expressing New York esophageal squamous cell carcinoma 1 (NY-ESO-1) that incorporates Epi-R.
- Expanded executive management team with the appointment of veteran biotech leader Gary Lee, Ph.D. as Chief Scientific Officer. With more than a decade of experience heading translational cell and gene therapy programs, Dr. Lee sets and oversees the company’s research strategy and pipeline.

First Quarter 2022 Financial Results

GAAP and Non-GAAP Operating Results

- Lyell reported a net loss of $68.1 million for the first quarter ended March 31, 2022, compared to a net loss of $55.0 million for the same period in 2021. 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 $50.0 million for the first quarter ended March 31, 2022 compared to $32.3 million for the same period in 2021.
- Research and development (R&D) expenses were $35.8 million for the first quarter ended March 31, 2022, compared to $41.5 million for the same period in 2021. The decrease in R&D expense was primarily driven by a reduction in the success payment liability balance, which offset increases in infrastructure and personnel 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 first quarter ended March 31, 2022, were $35.9 million, compared to $26.7 million for the same period in 2021.

- General and administrative (G&A) expenses were $34.4 million for the first quarter ended March 31, 2022, compared to $16.8 million for the same period in 2021. The increase in G&A expense was primarily due to a $10.4 million increase in stock-based compensation expense, primarily related to award modifications and new awards granted. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the first quarter ended March 31, 2022 were $16.2 million, compared to $9.0 million for the same period in 2021. The increase in non-GAAP G&A expenses was driven by litigation-related expenses and public company operating costs.

A discussion of these 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, 2022 were $838.0 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 2025.

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 the ability to proliferate, persist and self-renew, as well as generate differentiated effector cell progenies to provide durable anti-tumor functionality. 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 clinical trials; Lyell’s plans to submit INDs and the timing thereof; the progress of Lyell’s clinical trials; the potential clinical benefits and therapeutic potential of Lyell’s product candidates; Lyell’s estimated cash runway and the timing of use of its capital resources; the timing of initial data from Lyell’s Phase 1 open label dose escalation and expansion trial for LYL797; statements regarding GSK’s plans to submit an IND and the timing thereof; 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; geopolitical instability; Lyell’s ability to submit planned INDs or initiate clinical trials on the anticipated timelines; Lyell’s ability to manufacture and supply its product candidates for its 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 Annual Report on Form 10-K for the year ended December 31, 2021 and in Lyell’s future reports to be filed with the SEC, including Lyell’s Quarterly Report on Form 10 -Q for the second quarter ended June 30, 2022. 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,	
	2022	**2021**
Revenue	$ 553	$ 2,445
Operating expenses:		
Research and development	35,830	41,529
General and administrative	34,421	16,831
Other operating income, net	(1,122)	(545)
Total operating expenses	69,129	57,815
Loss from operations	(68,576)	(55,370)
Interest income, net	397	354
Other income (expense), net	35	(27)

Total other income, net	432	327
Net loss	$ (68,144)	$ (55,043)

Balance Sheet Data:

	March 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 838,030	$ 898,325
Property and equipment, net	$ 125,707	$ 120,098
Total assets	$ 1,072,103	$ 1,127,406
Total stockholders' equity	$ 881,249	$ 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, 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 Net Loss

(in thousands)

	Three Months Ended March 31,	
	2022	2021
Net loss - GAAP	$ (68,144)	$ (55,043)
Adjustments:		
Stock-based compensation expense	22,028	12,732
Change in the estimated fair value of success payment liabilities	(3,851)	9,967
Net loss - Non-GAAP[(1)]	$ (49,967)	$ (32,344)

(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 Expense

(in thousands)

	Three Months Ended March 31,	
	2022	2021
Research and development - GAAP	$ 35,830	$ 41,529
Adjustments:		
Stock-based compensation expense	(3,764)	(4,851)
Change in the estimated fair value of success payment liabilities	3,851	(9,967)
Research and development - Non-GAAP	$ 35,917	$ 26,711

Lyell Immunopharma, Inc.

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

(in thousands)

	Three Months Ended March 31,	
	2022	2021

General and administrative - GAAP	$ 34,421	$ 16,831
Adjustments:		
Stock-based compensation expense	(18,264)	(7,881)
General and administrative - Non-GAAP	$ 16,157	$ 8,950

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