Lyell Immunopharma Reports Second Quarter Financial Results and Business Highlights

August 4, 2022

- Cash, cash equivalents and marketable securities of $787.0 million as of June 30, 2022 provides funding into 2025 and supports advancement of multiple product candidates through key clinical milestones

SOUTH SAN FRANCISCO, Calif., Aug. 04, 2022 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Lyell) (Nasdaq: LYEL), a clinical-stage T-cell reprogramming company dedicated to developing curative cell therapies for patients with solid tumors, today provided business highlights and reported financial results for the second quarter of 2022.

“As a clinical stage company, we continue to make progress advancing our pipeline and growing our capabilities,” said Liz Homans, CEO of Lyell Immunopharma. “Our strong financial position enables us to see our current pipeline through important milestones in evaluating T-cell exhaustion and lack of durable stemness as key barriers to successful cell therapy in patients with solid tumor cancers while also advancing next generation technologies such as T-cell rejuvenation. We have recently presented new preclinical data that further elucidate the potential of our reprogramming technologies to endow T cells with the ability to resist exhaustion and maintain properties of durable stemness, and we remain on track to announce initial clinical data in 2023 from our lead program, LYL797.”

Recent Business Highlights

- Presented preclinical data for LYL797, Lyell’s CAR T-cell therapy targeting ROR1+ solid tumors that incorporates Gen-R and Epi-R, at the American Society of Gene & Cell Therapy (ASGCT) demonstrating that Gen-R and Epi-R reprogramming technologies can enhance and prolong anti-tumor functions of ROR1-targeting CAR T-cell therapy in solid tumor model systems.
- Presented preclinical data for LYL132, a TCR therapy targeting NY-ESO-1+ solid tumors that incorporates Epi-R and is being developed in collaboration with GSK, at ASGCT demonstrating that Epi-R reprogramming technology creates populations of stemlike NY-ESO-1-targeting TCR T cells that lead to products with increased proliferative capacity and prolonged functional activity in the presence of persistent antigen exposure.
- Presented preclinical data at the International Society for Stem Cell Research 2022 Annual Meeting (ISSCR) demonstrating the application of Lyell’s rejuvenation technology yielded improvements in antitumor properties of engineered adoptive T-cell products as compared to non-rejuvenated T-cell controls.

Second Quarter 2022 Financial Results

Revenue

- Revenue was $35.7 million and $2.6 million for the three months ended June 30, 2022 and 2021, respectively, primarily related to the recognized portion of the upfront license fee of Lyell’s Collaboration and License Agreement entered into in 2019 and amended in June 2020 and December 2021 (GSK Agreement) with GlaxoSmithKline Intellectual Property (No. 5) Limited and Glaxo Group Limited (together, GSK). The increase of $33.1 million was primarily related to recognizing $35.3 million in revenue due to a mutual agreement with GSK to conclude research activities on an undisclosed target for hematological cancers.

GAAP and Non-GAAP Operating Expenses

- Lyell reported a net loss of $36.3 million for the second quarter ended June 30, 2022, compared to a net loss of $62.6 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 $10.3 million for the second quarter ended June 30, 2022 compared to $38.1 million for the same period in 2021.
- Research and development (R&D) expenses were $43.7 million for the second quarter ended June 30, 2022, compared to $46.4 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 facilities and technology 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 second quarter ended June 30, 2022, were $35.9 million, compared to $32.1 million for the same period in 2021.
- General and administrative (G&A) expenses were $30.5 million for the second quarter ended June 30, 2022, compared to

$19.1 million for the same period in 2021. The increase in G&A expense was primarily due to an $8.1 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 second quarter ended June 30, 2022 were $12.2 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 June 30, 2022 were $787.0 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 clinical-stage T-cell reprogramming company dedicated to developing curative cell therapies for patients with solid tumors. The Company is advancing a pipeline of therapies designed to address 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 advancing its pipeline or growing its capabilities; the potential clinical benefits and therapeutic potential of Lyell’s product candidates; the sufficiency of Lyell’s cash resources to advance multiple product candidates through key milestones; Lyell’s belief that its cash resources will be sufficient to meet working capital and capital expenditure needs into 2025; the timing of initial clinical data from Lyell’s Phase 1 trial for LYL797; the potential of Lyell reprogramming technologies to help resist cell-exhaustion; our expectations regarding GSK’s plans for the NY-ESO-1 programs; 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, if at all; 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; Lyell’s reliance on GSK to advance the development of its NY-ESO-1 programs; 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 most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings with the SEC. 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 35,741	$ 2,628	$ 36,294	$ 5,073
Operating expenses:				
Research and development	43,719	46,446	79,549	87,975
General and administrative	30,454	19,112	64,875	35,943
Other operating income, net	(1,171)	(223)	(2,293)	(768)
Total operating expenses	73,002	65,335	142,131	123,150
Loss from operations	(37,261)	(62,707)	(105,837)	(118,077)
Interest income, net	952	218	1,349	572
Other (expense) income, net	(14)	(106)	21	(133)
Total other income, net	938	112	1,370	439

Net loss	$ (36,323)	$ (62,595)	$ (104,467)	$ (117,638)

Balance Sheet Data:

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 787,002	$ 898,325
Property and equipment, net	$ 127,559	$ 120,098
Total assets	$ 1,021,674	$ 1,127,406
Total stockholders' equity	$ 868,042	$ 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss - GAAP	$ (36,323)	$ (62,595)	$ (104,467)	$ (117,638)
Adjustments:				
Stock-based compensation expense	22,410	15,249	44,438	27,981
Change in the estimated fair value of success payment liabilities	3,587	9,266	(264)	19,233
Net loss - Non-GAAP[(1)]	$ (10,326)	$ (38,080)	$ (60,293)	$ (70,424)

(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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development - GAAP	$ 43,719	$ 46,446	$ 79,549	$ 87,975
Adjustments:				
Stock-based compensation expense	(4,195)	(5,091)	(7,959)	(9,942)
Change in the estimated fair value of success payment liabilities	(3,587)	(9,266)	264	(19,233)
Research and development - Non-GAAP	$ 35,937	$ 32,089	$ 71,854	$ 58,800

Lyell Immunopharma, Inc.

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

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
General and administrative - GAAP	$ 30,454	$ 19,112	$ 64,875	$ 35,943
Adjustments:				
Stock-based compensation expense	(18,215)	(10,158)	(36,479)	(18,039)
General and administrative - Non-GAAP	$ 12,239	$ 8,954	$ 28,396	$ 17,904

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