Lyell Immunopharma Reports Recent Business Highlights and Third Quarter Financial Results

November 8, 2022

- Investigational New Drug (IND) application clearance of LYL845 advances second wholly owned product candidate into clinical development
- Cash, cash equivalents and marketable securities of $750.7 million as of September 30, 2022; extends funding into 2026 and supports advancement of multiple product candidates through key clinical milestones

SOUTH SAN FRANCISCO, Calif., Nov. 08, 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 third quarter of 2022.

“In the past year we have advanced two product candidates into clinical development and have added LYL119, a second-generation CAR T-cell product candidate, to our pipeline of wholly owned novel cell therapies,” said Liz Homans, CEO of Lyell. “As we continue to progress our pipeline, we are grateful for the support of physicians, clinical site staff, patients and their families and our dedicated and talented employees who enable our mission,” said CEO Liz Homans. “Our strong financial position allows us to execute against our long-range plans with a cash runway into 2026, which takes us through important clinical milestones. These expected milestones include initial clinical data from both of our wholly owned product candidates, LYL797 and LYL845.”

Recent Business Highlights

- Announced FDA clearance of the IND for LYL845, a TIL product candidate enhanced with Lyell’s novel epigenetic reprogramming technology for solid tumors. LYL845 is an autologous TIL therapy enhanced with Lyell’s Epi-R™ reprogramming technology designed to create polyclonal T cell populations with properties of durable stemness and improved function.
    - The Phase 1 trial is expected to initially enroll patients with relapsed and/or refractory metastatic or locally advanced melanoma and subsequently expand into non-small cell lung cancer and colorectal cancer.
    - Initial data presentation for LYL845 is expected in 2024.
- Announced the presentation of five abstracts at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting highlighting preclinical data on Lyell’s product candidates and new genetic and epigenetic reprogramming technologies. The abstracts showcase compelling preclinical data underlying Lyell’s lead TIL product candidate, LYL845, as well as preclinical data on new stackable genetic and epigenetic reprogramming technologies being incorporated into LYL119, its second-generation investigational ROR1-targeting CAR T-cell product candidate.
- Presented the first-in-human Phase 1 trial design for LYL797, Lyell’s ROR1-targeted CAR T-cell therapy enhanced with genetic and epigenetic reprogramming for the treatment of solid tumors, at the European Society for Medical Oncology (ESMO) Congress 2022 in Paris, France.
    - Patient screening in the Phase 1 trial of LYL797 was initiated in late March; however, clinical site activation was initially slower than anticipated. Lyell has undertaken several measures to accelerate administrative site activation activities and has also increased the number of sites that will participate in the trial. As a result, although site activations are now progressing well, enrollment has been slower than anticipated.
    - Despite the accelerated pace of site activations, in order to present a meaningful dataset in terms of both the number of patients and duration of response to therapy, the timing of presentation of initial data is now expected to occur in the first half of 2024.
- Announced the appointment of Rahsaan W. Thompson, as Chief Legal Officer. Mr. Thompson is a biopharmaceutical industry veteran, with more than 20 years of experience with development stage and commercial companies.
- Announced that GSK informed Lyell that, as part of a number of strategic actions it is taking, it is discontinuing its development of product candidates targeting NY-ESO-1, including the second-generation product candidates incorporating

our genetic and epigenetic reprogramming technologies (LYL132 and LYL331). The termination of the collaboration agreement with Lyell will be effective December 24, 2022. Given the early stage of these second-generation programs, the decision is not based on any clinical efficacy or safety data from these programs.

Third Quarter 2022 Financial Results

Revenue

- Revenue was approximately zero and $2.8 million for the three months ended September 30, 2022 and 2021, respectively. No additional research and development pursuant to the GSK Agreement was performed in the third quarter of 2022, which drove a decrease in revenue of $2.8 million.

GAAP and Non-GAAP Operating Expenses

- Lyell reported a net loss of $70.3 million for the third quarter ended September 30, 2022, compared to a net loss of $48.9 million for the same period 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 non-cash impairment adjustment of other investments, was $43.7 million for the third quarter ended September 30, 2022 compared to $35.7 million for the same period in 2021.
- Research and development (R&D) expenses were $41.6 million for the third quarter ended September 30, 2022, compared to $31.4 million for the same period in 2021. The increase in R&D expenses was primarily driven by 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 third quarter ended September 30, 2022, were $34.7 million, compared to $28.7 million for the same period in 2021.
- General and administrative (G&A) expenses were $26.1 million for the third quarter ended September 30, 2022, compared to $21.2 million for the same period in 2021. The increase in G&A expenses was primarily due to a $4.3 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 third quarter ended September 30, 2022 were $11.4 million, compared to $10.9 million for the same period in 2021. The increase in non-GAAP G&A expenses was driven by 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 September 30, 2022 were $750.7 million, compared to $898.3 million as of December 31, 2021. Certain clinical trial expenses projected for 2022 are now expected to be incurred in 2023. As a result of expense timing, as well as diligent expense management, 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 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 technologies 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 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; the sufficiency of Lyell’s cash resources to support advancement of multiple product candidates through key clinical milestones and execute against Lyell’s long-range plans; expected milestones; Lyell’s belief that its cash resources will be sufficient to meet working capital and capital expenditure needs into 2026; enrollment expectations for the planned Phase 1 clinical trial of LYL845; the timing of initial clinical data from Lyell’s planned Phase 1 trials for LYL797 and LYL845; the potential of Lyell reprogramming technologies to help resist cell-exhaustion; 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

COVID-19 pandemic; geopolitical instability; macroeconomic conditions; Lyell's ability to submit planned INDs or initiate or progress clinical trials on the anticipated timelines, if at all; our 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 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 most recently filed quarterly report on 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 September 30, 2022		Nine Months Ended September 30, 2022	
	2022	2021	2022	2021
Revenue	$ 3	$ 2,755	$ 36,297	$ 7,828
Operating expenses:				
Research and development	41,607	31,433	121,156	119,408
General and administrative	26,084	21,241	90,959	57,184
Other operating income, net	(1,251)	(758)	(3,544)	(1,526)
Total operating expenses	66,440	51,916	208,571	175,066
Loss from operations	(66,437)	(49,161)	(172,274)	(167,238)
Interest income, net	2,251	270	3,600	842
Other (expense) income, net	(1,068)	16	(1,047)	(117)
Impairment of other investments	(5,000)	—	(5,000)	—
Total other (loss) income, net	(3,817)	286	(2,447)	725
Net loss	$ (70,254)	$ (48,875)	$ (174,721)	$ (166,513)

Balance Sheet Data:

	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 750,651	$ 898,325
Property and equipment, net	$ 125,727	$ 120,098
Total assets	$ 977,269	$ 1,127,406
Total stockholders' equity	$ 820,026	$ 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 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss - GAAP	$ (70,254)	$ (48,875)	$ (174,721)	$ (166,513)
Adjustments:				
Stock-based compensation expense	19,123	13,042	63,561	41,023
Change in the estimated fair value of success payment liabilities	2,441	110	2,177	19,343
Impairment of other investments	5,000	—	5,000	—
Net loss - Non-GAAP[(1)]	$ (43,690)	$ (35,723)	$ (103,983)	$ (106,147)

(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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development - GAAP	$ 41,607	$ 31,433	$ 121,156	$ 119,408
Adjustments:				
Stock-based compensation expense	(4,442)	(2,673)	(12,401)	(12,615)
Change in the estimated fair value of success payment liabilities	(2,441)	(110)	(2,177)	(19,343)
Research and development - Non-GAAP	$ 34,724	$ 28,650	$ 106,578	$ 87,450

Lyell Immunopharma, Inc.

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

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
General and administrative - GAAP	$ 26,084	$ 21,241	$ 90,959	$ 57,184
Adjustments:				
Stock-based compensation expense	(14,681)	(10,369)	(51,160)	(28,408)
General and administrative - Non-GAAP	$ 11,403	$ 10,872	$ 39,799	$ 28,776

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