Lyell Immunopharma Reports Business Highlights and Financial Results for the Second Quarter 2025

August 12, 2025

- Presented positive new clinical data demonstrating high rates of durable complete responses from the Phase 1/2 trial of LYL314 for the treatment of aggressive large B-cell lymphoma
- Initiated the PiNACLE pivotal trial of LYL314 in patients with large B-cell lymphoma receiving treatment in the third- or later-line (3L+) setting; remain on track to initiate a pivotal trial in the second-line (2L) setting by early 2026
- Entered into a securities purchase agreement for a private placement for gross proceeds of up to approximately $100 million
- Pro-forma cash of approximately $347 million inclusive of the initial proceeds from the private placement to support advancing pipeline into mid-2027 through key clinical milestones

SOUTH SAN FRANCISCO, Calif., Aug. 12, 2025 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a late-stage clinical company advancing next-generation CAR T-cell therapies for patients with cancer, today reported financial results and business highlights for the second quarter ended June 30, 2025. Lyell's lead clinical program, LYL314, is a next-generation autologous dual-targeting CD19/CD20 CAR T-cell product candidate under evaluation in PiNACLE, a single-arm pivotal trial enrolling patients with relapsed and/or refractory (R/R) large B-cell lymphoma (LBCL) in the 3L+ setting and in a Phase 1/2 study in the 2L setting.

"Based on the high rate of durable complete responses achieved by LYL314 in patients with aggressive LBCL presented at the International Conference on Malignant Lymphoma in Lugano, Switzerland, in June, we believe that our CD19/CD20 CAR T-cell therapy will disrupt the therapeutic landscape by delivering meaningfully increased complete response rates and improved durability over the currently approved CD19 CAR T-cell therapies," said Lynn Seely, M.D., President and CEO of Lyell. "Our recent private placement with well-respected investors significantly derisks our business, extends our cash runway into mid-2027 and enables us to focus on rapidly advancing the clinical development of LYL314. We have initiated the PiNACLE single-arm pivotal trial for patients with LBCL receiving treatment in the third- or later-line setting and are on track to begin a second pivotal trial of LYL314 for patients with LBCL in the second-line setting by early 2026."

Second Quarter Updates and Recent Business Highlights

Lyell is advancing a pipeline of next-generation CAR T-cell product candidates targeting cancers with large unmet need and substantial patient populations. Its lead program, LYL314, is in pivotal development for patients with R/R LBCL and its preclinical programs target solid tumor indications.

LYL314: A next-generation dual-targeting CD19/CD20 CAR T-cell product candidate designed to increase complete response rates and prolong the duration of response as compared to approved CD19-targeted CAR T-cell therapies for the treatment of LBCL

LYL314 is an autologous CAR T-cell product candidate with a true 'OR' logic gate to target B cells that express either CD19 or CD20 with full potency and that is manufactured with a process that enriches for CD62L-positive cells to generate more naïve and central memory CAR T cells with enhanced stemlike features and antitumor activity. Following a successful End-of-Phase 1 meeting with the U.S. Food and Drug Administration (FDA), LYL314 is currently being evaluated in the pivotal PiNACLE trial, which is a seamless expansion of the 3L+ cohort of the Phase 1/2 trial of patients with R/R LBCL. The Phase 1/2 trial continues to enroll CAR T-cell therapy naïve patients receiving treatment in the 2L setting and a pivotal trial for these 2L patients is expected be initiated by early 2026. The FDA has granted LYL314 Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations for the treatment of R/R diffuse LBCL in the 3L+ setting. RMAT provides all the benefits of the Fast Track and Breakthrough Therapy designation programs and enables increased frequency of communications with the FDA on the development of LYL314.

- PiNACLE is a single-arm pivotal trial evaluating LYL314 at a dose of 100 x 10^6 CAR T cells in patients with LBCL receiving

treatment in the 3L+ setting. The trial is expected to enroll approximately 120 patients with R/R diffuse large B-cell lymphoma, high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, transformed follicular lymphoma or Grade 3B follicular lymphoma who have not previously received CAR T-cell therapy. Patients may be treated with LYL314 in either the inpatient or outpatient setting and there is no upper age limit for eligibility. The primary endpoint of the trial is the overall response rate, including an evaluation of duration of response.

- New clinical data from the Phase 1/2 multi-center clinical trial of LYL314 in patients with R/R LBCL were presented at the 18th International Conference on Malignant Lymphoma in June and included more mature data from patients treated in the 3L+ setting and initial data from patients treated in the 2L setting. The data were presented in an oral presentation titled "LYL314, a CD19/CD20 CAR T -cell candidate enriched for CD62L+ stem-like cells, achieves high rates of durable complete responses in relapsed and/or refractory large B-cell lymphoma". Highlights include:
    - Fifty-one CAR T-naive patients with R/R LBCL received LYL314 as of April 15, 2025 (the data cutoff date for the presentation). The efficacy evaluable population consisted of 36 patients with Day 84 assessments or prior disease progression or death. Patient demographics and baseline disease characteristics were consistent with high-risk patient populations: median ages of 65 and 69 years in the 3L+ and 2L, respectively, 41% of 3L+ and 65% of 2L patients had Stage IV disease at trial entry, and 47% of 3L+ and 82% of 2L patients had primary refractory disease.
    - In efficacy-evaluable 3L+ patients, with a median follow-up of 9 months (N = 25): The overall response rate was 88% (22/25 patients), with 72% (18/25) of patients achieving a complete response. 71% (10/14) of patients with complete response remained in complete response at ≥ 6 months.
    - In initial data from efficacy-evaluable 2L patients, with a median follow-up of 5 months (N = 11): The overall response rate was 91% (10/11 patients), with 64% (7/11) achieving a complete response. 100% (7/7) of patients with complete response were in complete response at their last assessment, including 3/3 patients at ≥ 6 months. In patients with primary refractory disease, a difficult to treat population, 70% (7/10) achieved a complete response.
    - In 51 patients, including patients from both the 3L+ and the 2L cohorts, a manageable safety profile appropriate for outpatient administration was observed. No Grade ≥ 3 and low rates of Grade 1 (22%) or Grade 2 (35%) cytokine release syndrome (CRS) were reported. Immune effector cell-associated neurotoxicity syndrome (ICANS) was reported in 6% (Grade 1), 2% (Grade 2), and 14% (Grade ≥ 3) of patients. The median time to complete resolution of all reports of ICANS was 5 days, with rapid improvement (median of 2 days) to Grade 2 or lower with standard therapy. No deaths were related to LYL314 administration. LYL314 demonstrated robust expansion with a time to peak of 10 days. The final drug product contained the desired CD62L-positive naïve T-cell phenotype (median, 95%). Rapid and durable depletion of B cells was demonstrated through month 6 and up to the month 12 assessment.
- An update on the progress of the PiNACLE trial is planned for late 2025. Data from this trial is expected to form the basis of a Biologics License Application submission to the FDA in 2027 for patients with R/R LBCL receiving treatment in the 3L+ setting.
- More mature data from the ongoing Phase 1/2 trial in the 2L setting are expected to be presented in late 2025.
- A Phase 3 randomized controlled trial of LYL314 is expected to be initiated by early 2026 in patients receiving treatment in the 2L setting with R/R LBCL.

Preclinical Pipeline, Technologies and Manufacturing Protocols

Lyell is advancing next-generation fully-armed CAR T-cell product candidates, each including multiple technologies, designed to overcome T-cell exhaustion and lack of durable stemness, as well as immune suppression within the hostile tumor microenvironment.

- The first IND for a fully-armed CAR T-cell product candidate with an undisclosed target for solid tumors is expected in 2026.

Corporate Updates

- In July, Lyell entered into a securities purchase agreement for a private placement with certain institutional and other accredited investors, for gross proceeds of up to approximately $100 million. The initial closing of approximately $50 million of common stock at a price of $13.32 per share occurred on July 25, 2025.
- After deducting offering expenses, Lyell expects to use net proceeds from the private placement, together with its existing cash, cash equivalents, and marketable securities, to advance two pivotal-stage clinical trials of LYL314 as well as working capital for other general corporate purposes.

Second Quarter 2025 Financial Results

Lyell reported a net loss of $42.7 million for the second quarter ended June 30, 2025, compared to a net loss of $45.8 million for

the same period in 2024. The $3.1 million decrease in net loss was primarily due to a decrease of $3.3 million in stock-based compensation expense resulting from lower headcount and the reduced value of new equity awards. Non-GAAP net loss, which excludes 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, decreased to $37.8 million for the second quarter ended June 30, 2025, compared to $39.1 million for the same period in 2024, primarily due to lower interest income primarily driven by decreased interest rates in 2025 coupled with lower cash equivalent and marketable securities balances.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $34.9 million for the second quarter ended June 30, 2025, compared to $40.3 million for the same period in 2024. The decrease in second quarter 2025 R&D expenses of $5.4 million was primarily due to a $2.9 million reduction in research activities, collaborations and outside services due primarily to a reduction in costs associated with research and laboratory supplies and collaboration agreements and a $2.4 million decrease in personnel-related expenses primarily due to reduced stock-based compensation expense resulting from lower headcount and the reduced value of new equity awards. 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, 2025 were $32.6 million, compared to $37.2 million for the same period in 2024.
- General and administrative (G&A) expenses were $9.8 million for the second quarter ended June 30, 2025, compared to $12.3 million for the same period in 2024. The decrease in second quarter 2025 G&A expenses of $2.5 million was primarily due to a $1.7 million decrease in stock-based compensation expense primarily related to a decrease in the value of new awards granted and a $0.8 million decrease in outside services primarily due to a reduction in legal expenses. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the second quarter ended June 30, 2025 were $7.1 million, compared to $7.8 million for the same period in 2024.

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 June 30, 2025 were approximately $297 million, compared to approximately $384 million as of December 31, 2024. Lyell believes that its cash, cash equivalents and marketable securities balances totaling approximately $347 million inclusive of the initial $50 million of proceeds from its recent private placement, will be sufficient to meet working capital and capital expenditure needs into mid-2027.

About Lyell Immunopharma, Inc.

Lyell is a late-stage clinical company advancing a pipeline of next-generation CAR T-cell therapies for patients with hematologic malignancies and solid tumors. To realize the potential of cell therapy for cancer, Lyell utilizes a suite of technologies to endow CAR T cells with attributes needed to drive durable tumor cytotoxicity and high rates of long-lasting clinical responses, including the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment. The Lyell LyFE Manufacturing Center™ has commercial launch capability and can manufacture more than 1,200 CAR T-cell doses at full capacity. 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 initiation by early 2026 of a pivotal trial for LYL314 for patients with LBCL in the 2L setting; expectations around the potential for CD19/CD20 CAR T-cell therapies to disrupt the therapeutic landscape; the anticipated benefits of RMAT and Fast Track designations for LYL314; Lyell’s expectations around the progress of the PiNACLE trial, including expectations around enrollment and timing of progress update in late 2025, and using data from the trial to form the basis of a Biologics License Application submission to the FDA in 2027 for patients with relapsed and/or refractory LBCL receiving treatment in the 3L+ setting; Lyell’s expectations around continued enrollment for and timing of more mature clinical data from its ongoing Phase 1/2 trial for LYL314 in the 2L setting in late 2025; the advancement of Lyell’s technology platform; Lyell’s advancement of its pipeline and its research, development and clinical capabilities; Lyell’s submission of an IND in 2026 for a CAR T-cell product candidate with an undisclosed target for solid tumors; Lyell’s plans for using the net proceeds from the private placement and its existing cash, cash equivalents and marketable securities, and its expectation that its financial position and cash runway will support advancement of its pipeline into mid-2027 through key clinical milestones; the sufficiency of the capacity of LyFE to manufacture drug supply for Lyell’s ongoing and planned pivotal trials and through potential commercial launch; Lyell’s anticipated progress, business plans, business strategy and clinical trials; the potential clinical benefits and therapeutic potential of Lyell’s product candidates, including meaningful increased complete response rates and prolonged duration of response; 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: 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; the complexity of manufacturing cellular therapies, which subjects us to a multitude of

manufacturing risks, any of which could substantially increase our costs, delay our programs or limit supply of our product candidates; 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; RMAT and Fast Track designations may not actually lead to faster development, regulatory review or approval process, and does not assure ultimate FDA approval; 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; the effects of macroeconomic conditions, including the effects of disruption between the U.S. and its trading partners due to tariffs or other policies, and any geopolitical instability; potential changes to U.S. drug pricing, including the potential for "most-favored nations" pricing limitations; and other risks, including those described under the heading "Risk Factors" in Lyell's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue	$ 8	$ 13	$ 15	$ 16
Operating expenses:				
Research and development[(1)]	34,857	40,261	78,304	83,435
General and administrative	9,786	12,256	23,832	25,750
Other operating loss (income), net	1,062	(976)	943	(2,066)
Impairment of long-lived assets	1,443	—	1,443	—
Total operating expenses	47,148	51,541	104,522	107,119
Loss from operations	(47,140)	(51,528)	(104,507)	(107,103)
Interest income, net	3,276	6,364	7,138	13,183
Other income (expense), net[(1)]	1,180	(645)	2,490	445
Impairment of other investments	—	—	—	(13,001)
Total other income, net	4,456	5,719	9,628	627
Net loss	$ (42,684)	$ (45,809)	$ (94,879)	$ (106,476)

(1) As of October 1, 2024, the Company's success payment liability was recognized at fair value as Stanford had provided the requisite service obligation to earn the potential success payment consideration. The change in the estimated fair value of Stanford success payment liabilities in the first half of 2025 was recognized within other income (expense), net in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities in the first half of 2024 was recognized within research and development expenses in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Balance Sheet Data:

	As of June 30, 2025	As of December 31, 2024
Cash, cash equivalents and marketable securities	$ 296,849	$ 383,541
Property and equipment, net	$ 39,115	$ 48,200
Total assets	$ 385,453	$ 490,859
Total stockholders' equity	$ 298,923	$ 382,824

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 is further adjusted by 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Net loss - GAAP	$ (42,684)	$ (45,809)	$ (94,879)	$ (106,476)
Adjustments:				
Stock-based compensation expense	5,004	8,284	11,028	17,439
Change in the estimated fair value of success payment liabilities	(115)	(1,534)	(240)	(566)
Impairment of other investments	—	—	—	13,001
Net loss - Non-GAAP[(1)]	$ (37,795)	$ (39,059)	$ (84,091)	$ (76,602)

(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 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,	
	2025	2024	2025	2024
Research and development - GAAP	$ 34,857	$ 40,261	$ 78,304	$ 83,435
Adjustments:				
Stock-based compensation expense	(2,295)	(3,865)	(4,683)	(7,657)
Change in the estimated fair value of success payment liabilities[(1)]	—	793	—	268
Research and development - Non-GAAP	$ 32,562	$ 37,189	$ 73,621	$ 76,046

(1) As of October 1, 2024, the Company's success payment liability was recognized at fair value as Stanford had provided the requisite service obligation to earn the potential success payment consideration. The change in the estimated fair value of Stanford success payment liabilities in the first half of 2025 was recognized within other income (expense), net in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities in the first half of 2024 was recognized within research and development expenses in the 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
General and administrative - GAAP	$ 9,786	$ 12,256	$ 23,832	$ 25,750
Adjustments:				
Stock-based compensation expense	(2,709)	(4,419)	(6,345)	(9,782)
General and administrative - Non-GAAP	$ 7,077	$ 7,837	$ 17,487	$ 15,968

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