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

November 12, 2025

- Acquired exclusive global rights to LYL273, a novel GCC-targeted CAR T-cell product candidate that has demonstrated a 67% overall response rate, an 83% disease control rate and a manageable safety profile at the highest dose level studied to date in patients with refractory metastatic colorectal cancer in an ongoing U.S. Phase 1 clinical trial
- Received RMAT designation from the U.S. FDA for ronde-cel for the treatment of patients with relapsed or refractory LBCL receiving treatment in the second-line (2L) setting
- Announced that two abstracts highlighting new clinical and translational data from the Phase 1/2 clinical trial of ronde-cel for the treatment of aggressive large B-cell lymphoma have been accepted for oral presentation at the ASH 67th Annual Meeting and Exposition in December
- Announced the initiation of PiNACLE - H2H, a Phase 3 head-to-head CAR T-cell therapy clinical trial in aggressive large B-cell lymphoma in the 2L setting
- Formed a PiNACLE – H2H Steering Committee comprised of a distinguished group of lymphoma and cell therapy experts
- Cash of approximately $320 million at the end of the third quarter of 2025; current cash is expected to support advancing pipeline into 2027 through key clinical milestones

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2025 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a late-stage clinical company advancing next-generation chimeric antigen receptor (CAR) T-cell therapies for patients with cancer, today reported financial results and business highlights for the third quarter ended September 30, 2025.

Lyell's lead clinical program, rondecabtagene autoleucel (ronde-cel, or LYL314), is an autologous dual-targeting CD19/CD20 chimeric antigen receptor (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 third- or later-line (3L+) setting and in a Phase 1/2 trial in the 2L setting. A second pivotal trial, PiNACLE – H2H, which is a Phase 3 head-to-head CAR T-cell therapy randomized controlled trial of ronde-cel for LBCL in the 2L, is expected to begin by early 2026. The U.S. Food and Drug Administration (FDA) granted ronde-cel Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of patients with R/R LBCL receiving treatment in the 2L setting in November 2025 to complement the RMAT designation received for ronde-cel in the 3L+ setting in April 2025.

Lyell recently acquired exclusive global rights (outside of mainland China, Hong Kong, Macau and Taiwan) to LYL273, a novel autologous guanylyl cyclase-C (GCC)-targeted CAR T-cell product candidate in development for patients with refractory metastatic colorectal cancer (mCRC) and other GCC-expressing cancers from Innovative Cellular Therapeutics. At the highest dose level studied to date, patients with mCRC treated with LYL273 in a Phase 1 clinical trial conducted in the United States achieved a 67% confirmed overall response rate (ORR) and an 83% disease control rate per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 based on local site review, with a manageable safety profile. LYL273 is a GCC-targeted CAR T-cell product candidate enhanced with CD19 CAR expression and controlled cytokine release designed to improve cell expansion, immune cell infiltration and cell killing in the hostile tumor microenvironment.

"Lyell is well positioned with two next-generation CAR T-cell product candidates, each with promising clinical data. We look forward to effectively executing on both clinical programs taking full advantage of our expertise in CAR T-cell clinical development and our wholly-owned manufacturing facility capable of commercial launch," said Lynn Seely, MD, President and CEO of Lyell. "We will be presenting new ronde-cel clinical and translational data at the upcoming ASH meeting and exposition and are focused on rapidly advancing the pivotal development of ronde-cel through our two pivotal programs: PiNACLE – H2H, which is expected to begin enrolling patients receiving treatment in the 2L setting by early 2026, and PiNACLE, our ongoing single-arm pivotal trial for patients receiving treatment in the 3L+ setting."

Third 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. Ronde-cel is in pivotal development for patients with R/R LBCL and LYL273 is in Phase 1 clinical development for refractory mCRC. Lyell's pipeline also includes additional preclinical programs targeting undisclosed solid tumor indications.

Ronde-cel: 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

Ronde-cel 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. It 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 successful End-of-Phase 1 meetings with the U.S. Food and Drug Administration (FDA), Lyell announced the initiation of two pivotal trials – PiNACLE and PiNACLE – H2H. PiNACLE is a single-arm pivotal trial that is currently underway. It is a seamless expansion of the 3L+ cohort of the Phase 1/2 trial of patients with R/R LBCL. PiNACLE – H2H is a Phase 3 head-to-head CAR T-cell therapy randomized controlled trial for LBCL in the 2L. Enrollment in PiNACLE – H2H is expected to begin by early 2026 and until then the Phase 1/2 trial continues to enroll patients with R/R LBCL receiving treatment in the 2L setting.

The FDA has granted ronde-cel 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 ronde-cel.

- PiNACLE is a single-arm pivotal trial evaluating ronde-cel 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 LBCL. Patients may be treated with ronde-cel 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.
- Two abstracts highlighting new clinical and translational data from the Phase 1/2 trial of ronde-cel for the treatment of aggressive LBCL have been accepted for oral presentation at the ASH 67th Annual Meeting and Exposition in December 2025.
- Updated data from the PiNACLE trial will be presented at ASH. Data from this trial are 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.
- The FDA has granted ronde-cel RMAT designation for the treatment of patients with relapsed or refractory LBCL receiving treatment in the 2L setting. RMAT designation recognizes the potential of ronde-cel to address significant unmet needs of patients with LBCL and enables an increased frequency of communications with the FDA on the development of ronde-cel.
- PiNACLE – H2H is a Phase 3 head-to-head CAR T-cell therapy trial, which will evaluate ronde-cel versus an investigator's choice of approved CD19 CAR T-cell therapies (lisocabtagene maraleucel or axicabtagene ciloleucel) in patients with aggressive LBCL receiving treatment in the 2L setting. Patients randomized to ronde-cel will be treated with a dose of 100 x 10^6 CAR T cells. The primary endpoint of the trial is event-free survival. The trial is expected to enroll approximately 400 patients with R/R LBCL (200 per arm). Patients may be treated with ronde-cel in either the inpatient or outpatient setting.
- Clinical site initiation is underway for PiNACLE – H2H in the United States, Canada and Australia, and the first patient is expected to be enrolled by early 2026.
- Lyell recently announced the formation of an expert steering committee comprised of a distinguished group of lymphoma and cell therapy experts who will collaborate with the Company on the design and conduct of PiNACLE – H2H.

LYL273: A next-generation GCC-targeted CAR T-cell product candidate enhanced with CD19 CAR expression and controlled cytokine release designed to improve outcomes for patients with mCRC

LYL273 is a GCC-targeted CAR T-cell therapy enhanced with CD19 CAR expression and controlled cytokine release to increase cell expansion, immune cell infiltration and cancer cell killing in the hostile tumor microenvironment. LYL273 was granted Fast Track designation for the treatment of mCRC by the FDA.

- Dose-dependent clinical activity was observed in patients with refractory mCRC in a U.S. Phase 1 clinical trial.
- Across both dose levels, the overall response rate was 50% (6 of 12 patients), and the disease control rate was 83%. At Dose Level 2, the highest dose tested to-date, the overall response rate was 67%, including one patient with a pathological complete response, one patient with complete reduction in tumor volume of the target lesions (100% partial response) and two additional patients with confirmed partial responses. For patients treated at Dose Level 2, the disease control rate was 83%, and the median progression-free survival was 7.8 months.
- The incidence and severity of treatment-related adverse events were highest at Dose Level 2, where the most common treatment-related adverse events were cytokine release syndrome in 83% (5/6) of patients (Grade 1, 67%; Grade 2, 17%) and diarrhea in 83% (5/6) of patients (Grade 1, 33%; Grade 2, 33%; Grade 3, 17%). The median duration of diarrhea was 11 days. Immune effector cell-associated neurotoxicity syndrome occurred in 33% (2/6) of patients (Grade 2, 17%; Grade

3, 17%) and resolved rapidly with treatment. One patient experienced a dose-limiting toxicity at Dose Level 2, including Grade 3 diarrhea, Grade 4 enterocolitis and death from fungal sepsis 48 days post-infusion. No Grade 3 or higher diarrhea occurred in the last three patients treated since establishing an optimized management protocol for diarrhea, including prophylaxis.

- The U.S. Phase 1 clinical trial is continuing to enroll patients to determine the recommended Phase 2 dose.
- The next data update from this Phase 1 clinical trial is expected in the first half of 2026.

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 the 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.

Third Quarter 2025 Financial Results

Lyell reported a net loss of $38.8 million for the third quarter ended September 30, 2025, compared to a net loss of $44.6 million for the same period in 2024. The $5.7 million decrease in net loss was primarily due to decreased personnel expenses, including a $2.4 million reduction in stock-based compensation expense attributable to lower headcount and the reduced value of new equity awards granted. The decrease was partially offset by a $4.0 million loss related to the put/call asset issued to certain institutional and other accredited investors as part of our July 2025 securities purchase agreement. 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 $29.1 million for the third quarter ended September 30, 2025, compared to $37.1 million for the same period in 2024, primarily due to decreased personnel expenses resulting from lower headcount and 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 $28.2 million for the third quarter ended September 30, 2025, compared to $39.5 million for the same period in 2024. The decrease in third quarter 2025 R&D expenses of $11.3 million was primarily due to a $4.4 million reduction in research activities, collaborations and outside services due primarily to a reduction in costs associated with research and laboratory supplies, collaboration agreement expenses and consulting expenses and a $4.2 million decrease in personnel-related expenses primarily due to lower headcount. 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, 2025, were $26.2 million, compared to $35.9 million for the same period in 2024.
- General and administrative (G&A) expenses were $10.7 million for the third quarter ended September 30, 2025, compared to $11.8 million for the same period in 2024. The decrease in third quarter 2025 G&A expenses of $1.1 million was primarily due to a $0.8 million decrease in stock-based compensation expense primarily related to a decrease in the value of new awards granted and a $0.2 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 third quarter ended September 30, 2025 were $7.5 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 U.S. generally accepted accounting principles (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, 2025 were approximately $320 million, compared to approximately $384 million as of December 31, 2024. Lyell believes that its current cash, after the $40 million payment related to the acquisition of the license to LYL273, cash equivalents and marketable securities balances will be sufficient to meet working capital and capital expenditure needs into 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 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 the progress of the PiNACLE H2H trial in patients with aggressive LBCL receiving treatment in the 2L setting, including Lyell's initiation by early 2026 of the trial and its expectations around enrollment; Lyell's expectations around the progress of the U.S. Phase 1 trial for LYL273, including the timing of its data update in the first half of 2026; the anticipated benefits of RMAT and Fast Track designations for ronde-cel and Fast Track designation for LYL273; Lyell's expectations around presenting new clinical and translational data at the upcoming ASH meeting; 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 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 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; 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 limited experience as a company in enrolling and conducting clinical trials, and lack of experience in completing clinical trials; 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; Lyell's ability to submit planned INDs or initiate or progress clinical trials on the anticipated timelines, if at all; RMAT and Fast Track designations may not actually lead to faster development, regulatory review or approval process, and do not assure ultimate FDA approval; 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; the complexity of manufacturing cellular therapies and Lyell's ability to manufacture and supply its product candidates for its clinical trials; implementation of Lyell's strategic plans for its business and product candidates; Lyell's realization of the expected benefits of its strategic plans for its business and product candidates, including the license of LYL273; the potential reduction of Lyell's cash resources and fluctuations in Lyell's operating results and financial condition as a result of Lyell's milestone, royalty and success payment obligations; 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; other risks, including general economic conditions and regulatory developments, not within our control; and other risks, including those described under the heading "Risk Factors" in Lyell's Annual Report on Form 10 -K for the fiscal year ended December 31, 2024, filed with the Securities Exchange Commission (SEC) on March 11, 2025, and Lyell's Quarterly Report on Form 10-Q for the quarter ended September 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue	$ 15	$ 34	$ 30	$ 50
Operating expenses:				
Research and development[1]	28,172	39,500	106,476	122,935
General and administrative	10,687	11,769	34,519	37,519
Other operating income, net	(1,591)	(730)	(648)	(2,796)
Impairment of long-lived assets	—	—	1,443	—
Total operating expenses	37,268	50,539	141,790	157,658
Loss from operations	(37,253)	(50,505)	(141,760)	(157,608)
Interest income, net	3,266	5,965	10,404	19,148
Other (expense) income, net[1]	(4,859)	(43)	(2,369)	402
Impairment of other investments	—	—	—	(13,001)

Total other (loss) income, net	(1,593)	5,922	8,035	6,549
Net loss	$ (38,846)	$ (44,583)	$ (133,725)	$ (151,059)

(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 for the three and nine months ended September 30, 2025 was recognized within other (expense) income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities for the three and nine months ended September 30, 2024 was recognized within research and development expenses in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Balance Sheet Data:

	As of September 30, 2025	As of December 31, 2024
Cash, cash equivalents and marketable securities	$ 319,624	$ 383,541
Property and equipment, net	$ 36,722	$ 48,200
Total assets	$ 407,965	$ 490,859
Total stockholders' equity	$ 329,121	$ 382,824

Non-GAAP Financial Measures

To supplement our financial results and guidance presented in accordance with 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 and change in the estimated fair value of our securities purchase agreement put/call, 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, non-cash investment gains and charges and change in the estimated fair value of our securities purchase agreement put/call 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net loss - GAAP	$ (38,846)	$ (44,583)	$ (133,725)	$ (151,059)
Adjustments:				
Stock-based compensation expense	5,232	7,622	16,260	25,061
Change in the estimated fair value of success payment liabilities	461	(103)	221	(669)
Change in the estimated fair value of securities purchase agreement put/call asset	4,029	—	4,029	—
Impairment of other investments	—	—	—	13,001
Net loss - Non-GAAP[(1)]	$ (29,124)	$ (37,064)	$ (113,215)	$ (113,666)

(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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development - GAAP	$ 28,172	$ 39,500	$ 106,476	$ 122,935
Adjustments:				
Stock-based compensation expense	(2,004)	(3,625)	(6,687)	(11,282)
Change in the estimated fair value of success payment liabilities[(1)]	—	40	—	308
Research and development - Non-GAAP	$ 26,168	$ 35,915	$ 99,789	$ 111,961

(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 for the three and nine months ended September 30, 2025 was recognized within other (expense) income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities for the three and nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
General and administrative - GAAP	$ 10,687	$ 11,769	$ 34,519	$ 37,519
Adjustments:				
Stock-based compensation expense	(3,228)	(3,997)	(9,573)	(13,779)
General and administrative - Non-GAAP	$ 7,459	$ 7,772	$ 24,946	$ 23,740

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