Lyell Immunopharma Reports Business Highlights and Financial Results for the Third Quarter 2026

November 4, 2026

- Announced updated clinical data in more than 80 patients from the ongoing PiNACLE pivotal trial in patients with 3L+ R/R LBCL and from the Phase 1/2 trial 2L cohort of ronde-cel in abstracts accepted for presentation at ASH 2026.
- The overall response rate was 91% and the complete response rate was 77% among 44 efficacy-evaluable patients in the 3L+ PiNACLE trial. The median duration of complete response and median progression-free survival were not reached, with an estimated continued complete response rate of 92% at six months and 75% at 12 months. No Grade ≥ 3 CRS was observed and Grade ≥ 3 ICANS was reported in 9% of patients.
- PiNACLE pivotal data disclosure is on track for mid-2027, with BLA submission expected to follow in the second half of 2027.
- Completed technology transfer of LYL273 to the LyFE Manufacturing Center™ following FDA review of improved manufacturing process and updated analytical methods; additional clinical data and End-of-Phase 1 meeting with FDA expected in 2027.
- Announced private placement financing of $80.0 million with participation from a high-quality syndicate of existing and new investors.
- Approximately $194.0 million in cash, cash equivalents and marketable securities as of September 30, 2026, together with net proceeds from the private placement, expected to fund operations into 2028.

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2026 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a late-stage clinical company advancing a pipeline of 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, 2026.

“The updated ronde-cel data accepted for presentation at ASH further strengthen our conviction in ronde-cel’s potential to meaningfully improve outcomes for patients with large B-cell lymphoma,” said Lynn Seely, M.D., President and Chief Executive Officer of Lyell. “The high rates of very durable complete responses achieved by ronde-cel in both the second- and third- or later-line settings, including in patients with high-risk primary refractory disease, clearly showcase the next-generation potential of ronde-cel. With two pivotal trials underway, including our single-arm pivotal PiNACLE trial expected to complete enrollment by year end and on track for pivotal data and BLA submission in the second half of 2027, we are now focusing on preparation for commercialization. We are also continuing to advance LYL273 following the successful transfer of manufacturing to LyFE, as we work to determine the recommended Phase 2 dose and optimize the safety management plan ahead of our planned End-of-Phase 1 discussions with the FDA in 2027.”

Third Quarter Updates and Recent Business Highlights

Rondecabtagene Autoleucel (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 relapsed/refractory large B-cell lymphoma

Ronde-cel is an autologous CAR T-cell product candidate under evaluation in two pivotal trials in patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) in the third- or later-line (3L+) setting (PiNACLE) and the second-line (2L) setting (PiNACLE-H2H). A multi-cohort dose-escalation, dose-expansion Phase 1/2 trial is also ongoing. Ronde-cel targets B cells that express either CD19 or CD20 with a true ‘OR’ logic gate to achieve full potency at either target and 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. The U.S. Food and Drug Administration (FDA) has granted ronde-cel Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations for the treatment of adults with R/R diffuse LBCL in the 3L+ setting and also RMAT designation for the treatment of LBCL in the 2L setting.

- Lyell announced today updated clinical data from the ongoing PiNACLE pivotal trial in patients with 3L+ R/R LBCL and from the Phase 1/2 trial 2L cohort of ronde-cel in patients with R/R LBCL in two abstracts accepted for presentation at the 68th American Society of Hematology Meeting and Exposition (ASH 2026), taking place December 12–15, 2026.
- The PiNACLE pivotal single-arm trial, a seamless expansion of the 3L+ cohort in the Phase 1/2 multi-cohort trial, is ongoing. Pivotal data are expected in mid-2027 with submission of a Biologics License Application (BLA) to the FDA

expected to follow in the second half of 2027. The primary endpoint of the trial is overall response rate, including an evaluation of duration of response.
- PiNACLE-H2H, the first-of-its-kind Phase 3 randomized controlled trial evaluating ronde-cel versus investigator's choice of axicabtagene ciloleucel or lisocabtagene maraleucel in patients with R/R LBCL in the 2L setting, continues to enroll patients. The trial's primary endpoint is event-free survival.

LYL273: A next-generation guanylyl cyclase C (GCC)-targeted CAR T-cell product candidate for the treatment of relapsed/refractory metastatic colorectal cancer (mCRC) and other GCC-expressing cancers

LYL273 is a GCC-targeted CAR T-cell product candidate enhanced with CD19 CAR expression and controlled cytokine release, designed to improve CAR T-cell expansion, immune cell infiltration and cancer cell killing in the hostile solid tumor microenvironment. The FDA granted LYL273 Fast Track designation for the treatment of mCRC.

- In September 2026, Lyell completed the planned technology transfer for LYL273 to its LyFE Manufacturing Center™ (LyFE) in Bothell, Washington, following FDA review of an improved manufacturing process and updated analytical methods. LyFE is implementing the improved manufacturing process and updated analytical methods to enhance manufacturing performance and increase capacity. The Phase 1/2 clinical trial of LYL273 in patients with R/R mCRC continues to enroll patients, including dosing of patients with LYL273 manufactured using the new process at LyFE, with the goal of determining the recommended Phase 2 dose and optimizing the safety management plan.
- Additional clinical data from the Phase 1/2 trial of LYL273 in patients with 3L+ R/R mCRC and an End-of-Phase 1 meeting with the FDA are expected in 2027.

Corporate Update

- In November 2026, the Company announced a private placement of $80.0 million with participation from a high-quality syndicate of existing and new investors. The proceeds are expected to extend cash runway into 2028, beyond anticipated BLA submission for ronde-cel in the second half of 2027, as well as updated clinical data from the GCC-targeted LYL273 program for patients with mCRC.

Third Quarter 2026 Financial Results

Lyell reported a net loss of $45.5 million for the third quarter ended September 30, 2026, compared to a net loss of $38.8 million for the same period in 2025. The $6.7 million increase in net loss was primarily due to a $12.7 million increase in research and development expenses driven by increased clinical trial activity, partially offset by a $4.0 million prior-year loss on the securities purchase agreement put/call that did not recur. Non-GAAP net loss, which excludes non-cash stock-based compensation, non-cash expenses related to the change in the estimated fair value of the securities purchase agreement put/call relating to the Company's July 2025 private placement transaction and success payment liabilities, increased by $12.2 million to $41.3 million for the third quarter ended September 30, 2026, compared to $29.1 million for the same period in 2025, primarily due to increased clinical trial activity and lower interest income.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $40.9 million for the third quarter ended September 30, 2026, compared to $28.2 million for the same period in 2025. The $12.7 million increase was primarily due to a $12.2 million increase in research activities, collaborations and outside services due to increased clinical trial activity. Non-GAAP R&D expenses, which exclude non-cash stock-based compensation, for the third quarter ended September 30, 2026 were $38.8 million compared to $26.2 million for the same period in 2025.
- General and administrative (G&A) expenses were $9.3 million for the third quarter ended September 30, 2026, compared to $10.7 million for the same period in 2025, primarily due to lower professional services expenses. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the third quarter ended September 30, 2026 were $6.9 million compared to $7.5 million for the same period in 2025.

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, 2026 were $194.0 million compared to $247.2 million as of December 31, 2025. Lyell believes that its current cash, cash equivalents and marketable securities balances, together with the net proceeds from the $80.0 million private placement in November 2026, will be sufficient to meet working capital and capital expenditure needs into 2028.

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 arm CAR T cells with enhancements needed to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical responses, including the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor

microenvironment. LyFE has commercial launch capability and is expected to have the capacity to manufacture more than 3,000 CAR T-cell doses per year. 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 intention to present updated ronde-cel results at ASH 2026; Lyell's belief that its current cash, cash equivalents and marketable securities, together with the net proceeds from the private placement in November 2026, will be sufficient to meet working capital and capital expenditure needs into 2028; Lyell's expectations around the progress of the PiNACLE and PiNACLE-H2H trials, including the expected timing for release of additional and pivotal data from the PiNACLE trial, the use of pivotal data from the PiNACLE trial to support a BLA submission to the FDA in the second half of 2027 and other expectations around enrollment and regulatory submissions; Lyell's planned activities in anticipation of commercialization; Lyell's expectations around the progress of the U.S. Phase 1/2 trial for LYL273, including the expected timing for release of additional clinical data from this trial, determination of the recommended Phase 2 dose, optimization of the safety management plan, implementation of the improved manufacturing process and updated analytical methods and an End-of-Phase 1 FDA meeting; the anticipated benefits of Orphan Drug, RMAT and Fast Track designations for ronde-cel and Fast Track designation for LYL273; the capability of LyFE to manufacture drug supply through potential commercial launch and its expected manufacturing capacity; 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 operates in a rapidly evolving industry and has a limited operating history; Lyell's ability to successfully develop, manufacture and commercialize product candidates or its experiencing significant delays in doing so; Lyell's dependence on the enrollment and retention of patients in its current and planned clinical trials for its product candidates; the potential for results of Lyell's research, nonclinical studies or earlier clinical trials to not be predictive of future results; clinical development involving a lengthy and expensive process with uncertain outcomes; Lyell's product candidates and technologies being based on novel technologies that are unproven and may not result in approvable or marketable products; Lyell facing substantial competition in a rapidly changing industry, which may result in others discovering, developing or commercializing products before or more successfully than it does; Lyell's ability to obtain and maintain sufficient intellectual property protection for its product candidates; the complexity of manufacturing cellular therapies; Lyell's ability to manufacture drug products for its clinical trials itself and any potential delays in further qualifying or in receiving regulatory approvals for any manufacturing facility or product candidates or in expanding its manufacturing capacity; Lyell's reliance on third parties; implementation of Lyell's strategic plans for its business and product candidates and Lyell's realization of the expected benefits of such plans; 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; and other risks, including those described under the heading "Risk Factors" in Lyell's Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, being filed with the Securities and Exchange Commission 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,	
	2026	**2025**	**2026**	**2025**
Revenue	$ 3	$ 15	$ 9	$ 30
Operating expenses:				
Research and development	40,898	28,172	117,026	106,476
General and administrative	9,297	10,687	28,428	34,519
Other operating income, net	(1,897)	(1,591)	(5,552)	(648)
Impairment of long-lived assets	—	—	—	1,443
Total operating expenses	48,298	37,268	139,902	141,790
Loss from operations	(48,295)	(37,253)	(139,893)	(141,760)
Interest income, net	1,905	3,266	6,283	10,404
Other income (expense), net	861	(4,859)	19,173	(2,369)

Total other income (loss), net	2,766	(1,593)	25,456	8,035
Net loss	$ (45,529)	$ (38,846)	$ (114,437)	$ (133,725)

Balance Sheet Data:

	As of September 30, 2026	As of December 31, 2025
Cash, cash equivalents and marketable securities	$ 193,988	$ 247,220
Property and equipment, net	$ 28,531	$ 34,771
Total assets	$ 273,854	$ 340,052
Total stockholders' equity	$ 192,721	$ 248,202

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 excludes non-cash stock-based compensation expense, non-cash expenses related to the change in the estimated fair value of success payment liabilities and the change in the estimated fair value of our securities purchase agreement put/call asset. Non-GAAP R&D and G&A expenses exclude non-cash stock-based compensation expense from GAAP R&D and 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 the change in the estimated fair value of our securities purchase agreement put/call asset from our non-GAAP financial measures because they are 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,	
	2026	2025	2026	2025
Net loss - GAAP	$ (45,529)	$ (38,846)	$ (114,437)	$ (133,725)
Adjustments:				
Change in the estimated fair value of securities purchase agreement put/call	—	4,029	(17,561)	4,029
Stock-based compensation expense	4,514	5,232	13,341	16,260
Change in the estimated fair value of success payment liabilities	(263)	461	(1,015)	221
Net loss - Non-GAAP[(1)]	$ (41,278)	$ (29,124)	$ (119,672)	$ (113,215)

(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,	
	2026	**2025**	**2026**	**2025**
Research and development - GAAP	$ 40,898	$ 28,172	$ 117,026	$ 106,476
Adjustments:				
Stock-based compensation expense	(2,124)	(2,004)	(6,499)	(6,687)
Research and development - Non-GAAP	$ 38,774	$ 26,168	$ 110,527	$ 99,789

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,	
	2026	**2025**	**2026**	**2025**
General and administrative - GAAP	$ 9,297	$ 10,687	$ 28,428	$ 34,519
Adjustments:				
Stock-based compensation expense	(2,390)	(3,228)	(6,842)	(9,573)
General and administrative - Non-GAAP	$ 6,907	$ 7,459	$ 21,586	$ 24,946

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