Lyell Immunopharma Reports Q4 and Full Year 2025 Business and Financial Results

March 12, 2026

- Patient dosing has commenced in first-of-its-kind Phase 3 head-to-head CAR T-cell 2L randomized controlled clinical trial (PiNACLE-H2H) in patients with large B-cell lymphoma, and the 3L+ pivotal trial (PiNACLE) evaluating ronde-cel is ongoing
- Phase 1 trial is ongoing for LYL273, an enhanced GCC-targeted CAR T-cell candidate for metastatic colorectal cancer; seven new patients treated without dose-limiting toxicity and including dose escalation to Dose Level 3
- Smital Shah was appointed Chief Financial and Business Officer in March 2026
- Second $50 million tranche of $100 million equity private placement closed in March 2026 after achievement of clinical milestone for ronde-cel
- Cash of approximately $247.2 million at the end of 2025 excluding the $50 million tranche; current cash expected to advance pipeline into the second quarter of 2027, including through multiple key clinical milestones

SOUTH SAN FRANCISCO, Calif., March 12, 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 fourth quarter and year ended December 31, 2025. Lyell has since commenced patient dosing in the first-of-its-kind Phase 3 head-to-head CAR T-cell randomized controlled clinical trial of rondecabtagene autoleucel (ronde-cel) versus investigator's choice of axicabtagene ciloleucel (axi-cel) or lisocabtagene maraleucel (liso-cel) in patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) with disease progression on at least one prior line of therapy (PiNACLE-H2H). Lyell has dosed seven new patients with metastatic colorectal cancer (mCRC) with LYL273, an enhanced guanylyl cyclase C (GCC)-targeted CAR T-cell product candidate, since its November 2025 acquisition, without dose-limiting toxicity and including dose escalation to Dose Level 3.

Lyell also recently announced it has closed the sale of an additional $50 million of shares of its common stock to investors from its July 2025 equity private placement of up to $100 million, following achievement of a clinical milestone within its PiNACLE pivotal trial evaluating ronde-cel in patients with R/R LBCL in the third- or later-line setting (3L+), and the appointment of Smital Shah as its Chief Financial and Business Officer.

"Lyell is on track to achieve multiple clinical milestones in the next 12 to 18 months. We have now advanced ronde-cel into two pivotal clinical trials, with the pivotal data supporting BLA submission from the PiNACLE trial expected to be reported mid-next year," said Lynn Seely, M.D., President and Chief Executive Officer of Lyell. "With the encouraging emerging safety profile and clinical activity observed with LYL273 in patients with metastatic colorectal cancer, we believe Lyell is well-positioned with two next-generation CAR T-cell product candidates."

Fourth Quarter Updates and Recent Business Highlights

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 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. Ronde-cel has received from the U.S. Food and Drug Administration (FDA) Regenerative Medicine Advanced Therapy (RMAT) designation as well as Fast Track designation for the treatment of adults with R/R LBCL.

- The pivotal PiNACLE single-arm trial is a seamless expansion of the 3L+ cohort in the Phase 1/2 multi-cohort trial and is evaluating ronde-cel at a dose of 100 x 10^6 CAR T cells in patients with R/R LBCL. The trial is expected to enroll

approximately 120 patients in 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.

- Patient dosing commenced in February 2026 in PiNACLE-H2H, the Phase 3 randomized controlled trial evaluating ronde-cel versus investigator's choice of axi-cel or liso-cel in patients with R/R LBCL in the 2L setting. The trial is expected to enroll approximately 400 patients (200 per arm) at sites in the US, Canada and Australia. Patients may be treated in either the inpatient or outpatient setting. The trial's primary endpoint is event-free survival.
- Updated data from the ongoing Phase 1/2 clinical trial were presented at the December 2025 American Society of Hematology Annual Meeting and Exposition (ASH 2025):
    - A best overall response rate of 93% and a complete response rate of 76% in 29 efficacy-evaluable patients with R/R LBCL in the 3L+ setting. The median progression-free survival was 18 months as of the data cutoff date of September 5, 2025.
    - Data were also presented from the 2L cohort in the Phase 1/2 multi-cohort clinical trial, including an efficacy-evaluable population of 18 patients (94% with high-risk primary refractory disease) and demonstrated an 83% best overall response rate and a 61% complete response rate.
    - The safety profile was appropriate for outpatient administration. Data from 25 patients treated with ronde-cel who received dexamethasone prophylaxis in the 3L+ and 2L settings revealed no events of ≥ Grade 3 cytokine release syndrome and a 4% rate of ≥ Grade 3 immune cell-associated neurotoxicity syndrome.

LYL273 (formerly known as GCC19CART): A next-generation GCC-targeted CAR T-cell product candidate for the treatment of 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 tumor microenvironment. In November 2025, we acquired global rights (excluding mainland China, Hong Kong, Macau and Taiwan) to LYL273, which has shown promising dose-dependent clinical activity in patients with advanced mCRC in a Phase 1 trial conducted in the U.S. LYL273 received from the FDA Fast Track designation for the treatment of mCRC.

- The U.S. Phase 1 clinical trial is continuing to enroll patients to determine the recommended Phase 2 dose. Seven additional patients with mCRC have been treated with LYL273 since the November 2025 acquisition without dose-limiting toxicity and including dose escalation to Dose Level 3.
- A 67% best overall response rate, an 83% disease control rate and an 8-month median progression-free survival with a manageable safety profile have been reported at the highest dose level tested as of the data cutoff date of October 28, 2025 (Dose Level 2) in patients with refractory mCRC in the U.S. Phase 1 clinical trial.

Fourth Quarter and Full Year 2025 Financial Results

Lyell reported a net loss of $140.7 million and $274.4 million for the fourth quarter and year ended December 31, 2025, respectively, compared to a net loss of $191.9 million and $343.0 million for the same periods in 2024. Net loss for the fourth quarter and year ended December 31, 2025 included $66.3 million in acquired in-process research and development (IPR&D) expense as part of the acquisition of our rights to LYL273, and $19.7 million in stock-based compensation expense for an equity milestone deemed probable related to the LYL273 license acquisition. Net loss for the fourth quarter and year ended December 31, 2024 included $87.2 million in acquired IPR&D expense as part of our acquisition of ImmPACT Bio and $51.3 million of long-lived asset impairment expense. 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 securities purchase agreement put/call liability, long-lived asset impairment expense and certain non-cash investment gains and charges, was $33.1 million and $144.8 million for the fourth quarter and year ended December 31, 2025, respectively, compared to $45.9 million and $159.5 million for the same periods in 2024.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $52.2 million for the fourth quarter ended December 31, 2025, compared to $48.7 million for the same period in 2024. The increase in fourth quarter 2025 R&D expenses of $3.5 million was primarily due to $19.7 million in stock-based compensation expense for an equity milestone deemed probable related to the LYL273 license acquisition. The increase in fourth quarter 2025 R&D expenses was partially offset by an $8.9 million reduction in personnel costs and a $4.7 million reduction in additional facilities and technology costs primarily due to reduced headcount following the successful technology transfer of ronde-cel to our LyFE Manufacturing Center™ (LyFE) and associated workforce reduction in the first half of 2025. 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 fourth quarter ended December 31, 2025, were $30.1 million compared to $45.4 million for the same period in 2024 due to the workforce reduction related to the successful technology transfer of ronde-cel.
- General and administrative (G&A) expenses were $10.6 million for the fourth quarter ended December 31, 2025, compared

to $14.5 million for the same period in 2024. The decrease in fourth quarter 2025 G&A expenses of $3.9 million was primarily due to a $4.1 million decrease in personnel costs associated with the workforce reduction related to the successful ronde-cel technology transfer, partially offset by a $0.8 million increase in collaborations and licenses expenses.

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 December 31, 2025 were approximately $247.2 million (excluding the $50 million tranche received in March 2026), compared to approximately $383.5 million as of December 31, 2024. Lyell believes that its current cash, cash equivalents and marketable securities balances will be sufficient to meet working capital and capital expenditure needs into the second quarter of 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 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 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 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 the second quarter of 2027 through multiple key clinical milestones; Lyell’s expectation around the timing of the achievement of clinical milestones in the next 12 to 18 months; Lyell’s expectations around the progress of the PiNACLE trial, including expectations around enrollment, and using pivotal data from the trial to support a Biologics License Application (BLA) submission to the FDA in mid-2027; Lyell’s belief that it is well-positioned with two next generation CAR T-cell product candidates; Lyell’s expectations around the progress of the PiNACLE-H2H trial, including its expectations around enrollment; Lyell’s expectations around the progress of the U.S. Phase 1 trial for LYL273; the anticipated benefits of RMAT and Fast Track designations for ronde-cel and Fast Track designation for LYL273; Lyell’s advancement of its pipeline and its research, development and clinical capabilities; 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 of its business plans, 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 make planned regulatory submissions 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 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 Annual Report on Form 10-K for the year ended December 31, 2025, 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 December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Revenue	$ 6	$ 11	$ 36	$ 61
Operating expenses:				
Research and development[1]	52,199	48,668	158,675	171,603
General and administrative	10,616	14,522	45,135	52,041
Other operating income, net	(1,497)	(513)	(2,145)	(3,309)
Acquired in-process research and development	66,332	87,184	66,332	87,184
Impairment of long-lived assets	—	51,297	1,443	51,297
Total operating expenses	127,650	201,158	269,440	358,816
Loss from operations	(127,644)	(201,147)	(269,404)	(358,755)
Interest income, net	2,676	4,920	13,080	24,068
Other (expense) income, net[1]	(15,755)	4,292	(18,124)	4,694
Impairment of other investments	—	—	—	(13,001)
Total other (loss) income, net	(13,079)	9,212	(5,044)	15,761
Net loss	$ (140,723)	$ (191,935)	$ (274,448)	$ (342,994)

(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 beginning in Q4 2024 was recognized within other (expense) income, net in the Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities in the first nine months of 2024 were recognized within research and development expenses in the Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Fred Hutch success payment liabilities was recognized within other (expense) income, net in the Consolidated Statements of Operations and Comprehensive Loss.

Balance Sheet Data:

	As of December 31,	
	2025	2024
Cash, cash equivalents and marketable securities	$ 247,220	$ 383,541
Property and equipment, net	$ 34,771	$ 48,200
Total assets	$ 340,052	$ 490,859
Total stockholders' equity	$ 248,202	$ 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. Non-GAAP net loss is further adjusted by acquired IPR&D expense, non-cash long-lived asset impairment expense, non-cash investment gains and charges and the 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, acquired IPR&D expense, long-lived asset impairment expense, non-cash investment gains and charges and the change in the estimated fair value of our securities purchase agreement put/call 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 December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Net loss - GAAP	$ (140,723)	$ (191,935)	$ (274,448)	$ (342,994)
Adjustments:				
Stock-based compensation expense[1]	25,569	8,083	41,829	33,144
Change in the estimated fair value of success payment liabilities	610	(496)	831	(1,165)
Acquired in-process research and development	66,332	87,184	66,332	87,184
Change in the estimated fair value of securities purchase agreement put/call liability	15,157	—	19,186	—
Impairment of long-lived assets	—	51,297	1,443	51,297
Impairment of other investments	—	—	—	13,001
Net loss - Non-GAAP[2]	$ (33,055)	$ (45,867)	$ (144,827)	$ (159,533)

(1) Stock-based compensation expense for the year ended December 31, 2025 reflects the expense associated with an ICT equity milestone deemed probable of achievement of $19.7 million.

(2) 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 December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Research and development - GAAP	$ 52,199	$ 48,668	$ 158,675	$ 171,603
Adjustments:				
Stock-based compensation expense[1]	(22,056)	(3,295)	(28,743)	(14,577)
Change in the estimated fair value of success payment liabilities[2]	—	—	—	308
Research and development - Non-GAAP	$ 30,143	$ 45,373	$ 129,932	$ 157,334

(1) Research and development stock-based compensation expense for the year ended December 31, 2025 reflects the expense associated with an ICT equity milestone deemed probable of achievement of $19.7 million.

(2) 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 beginning in Q4 2024 was recognized within other (expense) income, net in the Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities in the first nine months of 2024 were recognized within research and development expenses in the Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Fred Hutch success payment liabilities was recognized within other (expense) income, net in the 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 December 31,		Year Ended December 31,	
	2025	2024	2025	2024
General and administrative - GAAP	$ 10,616	$ 14,522	$ 45,135	$ 52,041
Adjustments:				
Stock-based compensation expense	(3,513)	(4,788)	(13,086)	(18,567)
General and administrative - Non-GAAP	$ 7,103	$ 9,734	$ 32,049	$ 33,474

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