



Lyell Immunopharma Reports Business Highlights and Financial Results for the Fourth Quarter and Full Year 2024

March 11, 2025

- Acquired ImmPACT Bio and strengthened clinical pipeline with the addition of IMPT-314, a next-generation dual-targeting CD19/CD20 CAR T-cell product candidate for the treatment of aggressive large B-cell lymphoma (LBCL)
- Presented positive initial data from Phase 1 multi-center clinical trial of IMPT-314 in patients with aggressive LBCL in the 3rd line and later setting at the American Society of Hematology 2024 Annual Meeting
- Acceleration of development of IMPT-314 in LBCL; remain on track to initiate a pivotal trial in the 3rd line and later setting in mid-2025 and expect to initiate a pivotal trial in the 2nd line setting by early 2026
- Advancing next-generation CAR T-cell product candidates with new targets and technologies; first IND for fully-armed solid tumor product candidate expected in 2026
- Cash, cash equivalents and marketable securities of \$383.5 million as of December 31, 2024, support advancing pipeline into 2027 through multiple clinical milestones

SOUTH SAN FRANCISCO, Calif., March 11, 2025 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a clinical-stage company advancing a pipeline of next-generation CAR T-cell therapies for patients with cancer, today reported financial results and business highlights for the fourth quarter and year ended December 31, 2024.

"Last year was transformative for Lyell and now, based on promising emerging clinical data, we are poised to initiate pivotal development of IMPT-314, our next-generation dual-targeting CD19/CD20 CAR T-cell product candidate for patients with aggressive large B-cell lymphoma," said Lynn Seely, M.D., Lyell's President and CEO. "We believe IMPT-314 has the potential to deliver improved outcomes for patients by increasing complete response rates and prolonging the duration of response over approved CD19 CAR T-cell therapies, and this year we expect to share more mature data from the ongoing Phase 1/2 trial of IMPT-314. We also plan to initiate two pivotal programs for IMPT-314: one for patients in the 3rd line and later setting by the middle of this year and a second program for patients in the 2nd line setting by early 2026. In addition, we expect to submit a new IND in 2026 for a next-generation solid tumor CAR T-cell product candidate with a new target that is fully-armed with a suite of technologies, including our proprietary clinically-validated anti-exhaustion technology. Our strong cash position enables us to advance our pipeline through important clinical milestones and fund operations into 2027."

Fourth Quarter Updates and Recent Business Highlights

Lyell is advancing a pipeline of next-generation CAR T-cell product candidates. Its lead program, IMPT-314, is in Phase 1/2 clinical development for relapsed or refractory aggressive large B-cell lymphoma (LBCL) and its preclinical programs target solid tumor indications. Lyell's programs target cancers with large unmet need with substantial patient populations.

IMPT-314: 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 the approved CD19-targeted CAR T-cell therapies for the treatment of LBCL

IMPT-314 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+ cells to generate more naïve and central memory CAR T cells with enhanced stemlike features and antitumor activity. The ongoing Phase 1/2 clinical trial is a multi-center, open-label study designed to evaluate the tolerability and clinical benefit of IMPT-314 in patients with relapsed/refractory LBCL and determine a recommended Phase 2 dose. IMPT-314 has received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of relapsed/refractory aggressive B-cell lymphoma in the 3rd line and later (3rd line+) setting.

- A Phase 1/2 clinical trial is ongoing and currently enrolling patients in the 3rd line+ and 2nd line settings who have not previously received CAR T-cell therapy.
- Initial data from the Phase 1/2 trial was presented at the American Society for Hematology 2024 Annual Meeting on

December 9, 2024. Data from 23 patients with relapsed or refractory, CAR T-naive LBCL who received IMPT-314 were reported. The efficacy evaluable population consisted of 17 patients. The overall response rate was 94% (16/17 patients), with 71% (12/17 patients) achieving a complete response by three months. The median follow up was 6.3 months (range 1.2 – 12.5 months) and 71% of patients were experiencing a response at last follow-up. In the safety evaluable population of 23 patients, no Grade 3+ CRS was reported. Grade 3 ICANS was reported in 13% (3/23) of patients with a median time to ICANS resolution of 5 days, and rapid improvement to Grade 2 or lower with standard therapy.

- More mature data from the ongoing Phase 1/2 trial in the 3rd line+ setting and initial data from patients in the 2nd line setting are expected to be presented in mid-2025.
- Pivotal trial in the 3rd line+ setting is expected to be initiated in mid-2025 in patients with relapsed/refractory aggressive LBCL who have not previously received CAR T-cell therapy.
- Pivotal trial in the 2nd line setting expected to be initiated by early 2026 in patients with relapsed/refractory aggressive LBCL who have not previously received CAR T-cell therapy.

Preclinical Pipeline, Technologies and Manufacturing Protocols

- The first IND for a fully-armed CAR T-cell product candidate with an undisclosed target for solid tumors is expected in 2026. Lyell is advancing next-generation fully-armed CAR T-cell product candidates, meaning they are armed with multiple technologies, each designed to address different barriers to effective cell therapies, including T-cell exhaustion, lack of durable stemness, as well as immune suppression within the hostile tumor microenvironment.
- Presented nonclinical and clinical data from cell therapy product candidates incorporating anti-exhaustion and manufacturing technologies that demonstrated the potential of Lyell's technologies to improve T-cell function in solid tumors. These presentations, from multiple scientific conferences throughout the year, can be found on the Lyell website [here](#).

Corporate Updates

- Streamlined expenses and expect net cash use in 2025 to be between \$175 million - \$185 million. The disciplined expense management will be accomplished by focusing clinical development efforts on the pivotal trials of IMPT-314 and research efforts on developing next-generation fully-armed CAR T-cell programs for solid tumors.

Fourth Quarter and Full Year 2024 Financial Results

Lyell reported a net loss of \$191.9 million and \$343.0 million for the fourth quarter and year ended December 31, 2024, respectively, compared to a net loss of \$52.9 million and \$234.6 million for the same periods in 2023. Net loss for the fourth quarter and year ended December 31, 2024 included \$87.2 million in acquired in-process research and development (IPR&D) expense as part of our acquisition of ImmPACT Bio USA Inc (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, acquired IPR&D expense, long-lived asset impairment expense and certain non-cash investment gains and charges, was \$45.9 million and \$159.5 million for the fourth quarter and year ended December 31, 2024, respectively, compared to \$43.9 million and \$177.4 million for the same periods in 2023.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were \$48.7 million and \$171.6 million for the fourth quarter and year ended December 31, 2024, respectively, compared to \$47.0 million and \$182.9 million for the same periods in 2023. The increase in fourth quarter 2024 R&D expenses of \$1.7 million was primarily due to increased facilities costs. The decrease in annual 2024 R&D expenses of \$11.3 million was primarily driven by a \$14.0 million decrease in personnel-related expenses mainly due to lower headcount following the Company's November 2023 reduction in workforce, partially offset by a \$3.2 million increase in research activities primarily driven by clinical trial activity. 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 and year ended December 31, 2024 were \$45.4 million and \$157.3 million, respectively, compared to \$42.9 million and \$165.7 million for the same periods in 2023. The \$2.5 million increase in fourth quarter 2024 non-GAAP R&D expenses was primarily driven by increased facilities costs. The \$8.3 million decrease in annual 2024 non-GAAP R&D expenses was primarily driven by the decrease in personnel-related expenses mainly due to lower headcount following the Company's November 2023 reduction in workforce.
- General and administrative (G&A) expenses were \$14.5 million and \$52.0 million for the fourth quarter and year ended December 31, 2024, respectively, compared to \$13.2 million and \$67.0 million for the same periods in 2023. The decrease in annual 2024 G&A expenses of \$14.9 million was primarily driven by a decrease in non-cash stock-based compensation. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the fourth quarter and year ended December 31, 2024 were \$9.7 million and \$33.5 million, respectively, compared to \$8.5 million and \$38.1 million for the same periods in 2023. The \$1.3 million increase in fourth quarter 2024 non-GAAP G&A expenses was primarily driven by acquisition-related personnel expenses. The \$4.6 million decrease in annual 2024 non-GAAP G&A expenses was primarily driven by the decrease in personnel-related expenses mainly due to lower headcount following the Company's November 2023 reduction in workforce.

- Operating expenses for the fourth quarter and year ended December 31, 2024, include \$87.2 million of acquired IPR&D expenses recognized as a part of the acquisition of ImmPACT Bio. Additionally, operating expenses for the fourth quarter and year ended December 31, 2024, include an impairment charge of \$51.3 million for long-lived assets, resulting from the continued decline in our stock price and related market capitalization.

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 December 31, 2024 were \$383.5 million compared to \$562.7 million as of December 31, 2023. Lyell believes that its cash, 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 clinical-stage 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 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. Lyell is based in South San Francisco, California with facilities in West Hills, California and Seattle and Bothell, Washington. To learn more, please visit www.lyell.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements regarding: the anticipated benefits of Lyell's acquisition of ImmPACT Bio; Lyell's ability to accelerate the development of IMPT-314 and deliver improved outcomes for patients by increasing complete response rates and prolonging the duration of response over approved CD19 CAR T-cell therapies; Lyell's initiation of pivotal trials in 2025 and 2026 for IMPT-314; timing of Lyell's submission of a new IND in 2026 for a next-generation solid tumor CAR T-cell product candidate; the ability of Lyell's technology to enable and generate T cells that resist exhaustion and have qualities of durable stemness in order to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical response; Lyell's anticipated progress, business plans, business strategy and clinical trials; Lyell's advancement of its pipeline and its research, development and clinical capabilities; the potential clinical benefits and therapeutic potential of Lyell's product candidates; the advancement of Lyell's technology platform; Lyell's expectation that its financial position and cash runway will support advancement of its pipeline through multiple clinical milestones and fund operations into 2027; expectations around enrollment and the timing of initial and updated clinical data from Lyell's Phase 1/2 trial for IMPT-314; and other statements that are not historical fact. These statements are based on Lyell's current plans, objectives, estimates, expectations and intentions, are not guarantees of future performance and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, but are not limited to, risks and uncertainties related to: the inability to recognize the anticipated benefits of acquiring ImmPACT Bio and successful integration of ImmPACT Bio's business with Lyell's, including a successful manufacturing technology transfer of IMPT-314 to Lyell's LyFE manufacturing facility; the effects of macroeconomic conditions, including any geopolitical instability and actual or perceived changes in interest rates and economic inflation; 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; Lyell's ability to manufacture and supply its product candidates for its 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; the significant uncertainty associated with Lyell's product candidates ever receiving any regulatory approvals; Lyell's ability to obtain, maintain or protect intellectual property rights related to its product candidates; implementation of Lyell's strategic plans for its business and product candidates; the sufficiency of Lyell's capital resources and need for additional capital to achieve its goals; and other risks, including those described under the heading “Risk Factors” in Lyell's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the Securities and Exchange Commission (SEC) on November 7, 2024, and its Annual Report on Form 10-K for the year ended December 31, 2024, being filed with the SEC later 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,

	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Revenue	\$ 11	\$ 13	\$ 61	\$ 130
Operating expenses:				
Research and development ⁽¹⁾	48,668	46,995	171,603	182,945
General and administrative	14,522	13,167	52,041	66,983
Other operating income, net	(513)	(641)	(3,309)	(2,790)
Acquired in-process research and development	87,184	—	87,184	—
Impairment of long-lived assets	51,297	—	51,297	—
Total operating expenses	<u>201,158</u>	<u>59,521</u>	<u>358,816</u>	<u>247,138</u>
Loss from operations	(201,147)	(59,508)	(358,755)	(247,008)
Interest income, net	4,920	7,084	24,068	23,453
Other income (loss), net ⁽¹⁾	4,292	(506)	4,694	1,846
Impairment of other investments	—	—	(13,001)	(12,923)
Total other income, net	<u>9,212</u>	<u>6,578</u>	<u>15,761</u>	<u>12,376</u>
Net loss	<u>\$ (191,935)</u>	<u>\$ (52,930)</u>	<u>\$ (342,994)</u>	<u>\$ (234,632)</u>

- (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 income (loss), net in the Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities in 2023 and 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 income (loss), net in the Consolidated Statements of Operations and Comprehensive Loss.

Balance Sheet Data:

	<u>As of December 31,</u>	
	<u>2024</u>	<u>2023</u>
Cash, cash equivalents and marketable securities	\$ 383,541	\$ 562,729
Property and equipment, net	\$ 48,200	\$ 102,654
Total assets	\$ 490,859	\$ 750,029
Total stockholders' equity	\$ 382,824	\$ 654,952

Non-GAAP Financial Measures

To supplement our financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), we present non-GAAP net loss, non-GAAP R&D expenses and non-GAAP G&A expenses. Non-GAAP net loss and non-GAAP R&D expenses exclude non-cash stock-based compensation expense and non-cash expenses related to the change in the estimated fair value of success payment liabilities from GAAP net loss and GAAP R&D expenses. Non-GAAP net loss further adjusts non-cash acquired IPR&D expense, non-cash long-lived asset impairment expense and 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, acquired IPR&D expense, long-lived asset impairment expense 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.

Unaudited Reconciliation of GAAP to Non-GAAP Net Loss
(in thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Net loss - GAAP	\$ (191,935)	\$ (52,930)	\$ (342,994)	\$ (234,632)
Adjustments:				
Stock-based compensation expense	8,083	8,463	33,144	47,084
Change in the estimated fair value of success payment liabilities	(496)	529	(1,165)	(2,780)
Impairment of other investments	—	—	13,001	12,923
Acquired in-process research and development expense	87,184	—	87,184	—
Impairment of long-lived assets	51,297	—	51,297	—
Net loss - Non-GAAP ⁽¹⁾	\$ (45,867)	\$ (43,938)	\$ (159,533)	\$ (177,405)

- (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 December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Research and development - GAAP	\$ 48,668	\$ 46,995	\$ 171,603	\$ 182,945
Adjustments:				
Stock-based compensation expense	(3,295)	(3,768)	(14,577)	(18,207)
Change in the estimated fair value of success payment liabilities ⁽¹⁾	—	(319)	308	930
Research and development - Non-GAAP	\$ 45,373	\$ 42,908	\$ 157,334	\$ 165,668

- (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 income (loss), net in the Consolidated Statements of Operations and Comprehensive Loss. The changes in the estimated fair value of Stanford success payment liabilities in 2023 and 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 income (loss), 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,	
	2024	2023	2024	2023
General and administrative - GAAP	\$ 14,522	\$ 13,167	\$ 52,041	\$ 66,983
Adjustments:				
Stock-based compensation expense	(4,788)	(4,695)	(18,567)	(28,877)
General and administrative - Non-GAAP	\$ 9,734	\$ 8,472	\$ 33,474	\$ 38,106

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