Lyell Immunopharma Reports Fourth Quarter and Full Year 2021 Financial Results and Business Highlights

March 29, 2022

- Cash, cash equivalents and marketable securities of $898 million as of December 31, 2021 supports advancing multi-modality cell therapy pipeline
- Clinical development commencing for two programs that incorporate Lyell's novel reprogramming technologies

SOUTH SAN FRANCISCO, Calif., March 29, 2022 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc., (Nasdaq: LYEL), a T-cell reprogramming company dedicated to the mastery of T cells to cure patients with solid tumors, today reported fourth quarter and full year 2021 financial results and provided business highlights.

"With the recent FDA clearance of two INDs that incorporate our novel genetic and epigenetic reprogramming technologies, we are now a clinical stage-company advancing a pipeline of novel cell therapies for patients with solid tumors," said Liz Homans, CEO of Lyell Immunopharma. "During the past year, we've further strengthened our team with key executive and Board appointments and have grown the organization to focus on executing as a fully integrated clinical stage company. The coming year will be an exciting one for us as we initiate multiple clinical trials across our product pipeline. We are eager to clinically assess the impact of our innovative technologies designed to enable reprogrammed T cells to outlast and eradicate solid tumors in patients."

"We are embarking on what I believe to be among the most informative clinical trials in the field of oncology this year, as they will specifically evaluate the questions of exhaustion and durable stemness as key barriers to successful cell therapies for solid tumor cancers," stated Rick Klausner, MD, Chair of Lyell's Board of Directors.

Full Year 2021, Recent Highlights, and Upcoming Milestones

LYL797, a chimeric antigen receptor (CAR) T-cell therapy targeting ROR1+ solid tumors that incorporates Gen-R™ and Epi-R™ reprogramming technologies

- Announced FDA clearance of the IND for LYL797, a CAR T-cell therapy for patients with solid tumors expressing receptor tyrosine kinase-like orphan receptor 1 (ROR1).
- The two Lyell technologies incorporated are designed to address major barriers to successful Adoptive Cell Therapy (ACT): Gen-R, a genetic reprogramming technology that endows T cells with the ability to resist exhaustion, and Epi-R, an epigenetic reprogramming technology that creates populations of T cells with the properties of durable stemness. T cells with properties of durable stemness are able to proliferate, persist and self-renew, as well as generate differentiated effector cell progenies to provide durable anti-tumor functionality.
- Initiated screening for the Phase 1 open label dose escalation and expansion trial with relapsed/refractory triple-negative breast cancer or non-small cell lung cancer who have failed at least two lines of therapy, initial data expected in 2023.

LYL132, a TCR therapy targeting NY-ESO-1 solid tumors that incorporates Epi-R, being developed in collaboration with GSK for solid tumors

- Announced FDA clearance of the IND for LYL132, a T-cell receptor (TCR) therapy for patients with solid tumors expressing New York esophageal squamous cell carcinoma 1 (NY-ESO-1).
- LYL132 incorporates Epi-R and is under investigation as a potential next-generation enhancement to letetresgene autoleucel (lete-cel), a GSK TCR therapy targeting NY-ESO-1 currently in pivotal clinical development.

LYL845, a TIL therapy designed to target multiple solid tumor indications that incorporates Epi-R

- On track to submit an IND in the second half of 2022 for LYL845, a tumor infiltrating lymphocyte (TIL) therapy.
- Initially targeting melanoma, with plans to expand into other solid tumor indications, potentially including non-small cell lung cancer (NSCLC), colon, head and neck, cervical, breast and pancreatic.

LYL331, a TCR therapy targeting NY-ESO-1 solid tumors that incorporates Gen-R, being developed in collaboration with GSK for solid tumors

- GSK has communicated to Lyell that due to updated manufacturing timing, the IND for LYL331 is likely to be submitted in late 2022 / early 2023.
- LYL331 is a TCR therapy for patients with solid tumors expressing NY-ESO-1.
- LYL331 incorporates Gen-R and, along with LYL132, is under investigation as a potential next-generation enhancement to lete-cel.

Corporate and Operational

Lyell had the following corporate and operational highlights during 2021:

- Announced cGMP qualification of LyFE™, Lyell's manufacturing facility designed to produce cell products at scale for upcoming clinical trials across its CAR, TIL and TCR products.
- Completed an initial public offering with net proceeds of $391.8 million from the sale of 25 million shares of common stock.
- Expanded executive management team with appointments of scientific and business leaders: Gary Lee, PhD appointed as Chief Scientific Officer and Charlie Newton appointed as Chief Financial Officer.
- Expanded Board of Directors with appointments of industry and medical leaders: Otis Brawley, M.D., Elizabeth Nabel, M.D. and Lynn Seely, M.D.

Fourth Quarter and Full 2021 Financial Results

GAAP and Non-GAAP Operating Results

- Lyell reported a net loss of $83.7 million and $250.2 million for the fourth quarter and year ended December 31, 2021, respectively, compared to $38.9 million and $204.5 million for the same periods in 2020. Non-GAAP net loss, which excludes non-cash stock-based compensation, non-cash expenses related to the change in the estimated fair value of success payment liabilities and non-cash impairment adjustment of other investments, was $41.7 million and $147.9 million for the fourth quarter and year ended December 31, 2021, respectively, compared to $24.3 million and $165.9 million for the same periods in 2020.
- Research and development (R&D) expenses were $19.3 million and $138.7 million for the fourth quarter and year ended December 31, 2021, respectively, compared to $35.1 million and $182.2 million for the same periods in 2020. The quarterly decrease in R&D expense on a GAAP basis was primarily due to a decrease in success payment expense, which offset an increase in personnel and infrastructure costs to support the expansion of our R&D and manufacturing capabilities. The annual decrease in R&D expense on a GAAP basis was primarily due to a decrease in collaboration and business development 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, 2021 were $32.2 million and $119.7 million, respectively, compared to $27.6 million and $161.9 million for the same periods in 2020.
- General and administrative (G&A) expenses were $31.9 million and $89.1 million for the fourth quarter and year ended December 31, 2021, respectively, compared to $14.9 million and $46.9 million for the same periods in 2020. The increase in G&A expense on a GAAP basis was primarily due to an increase in personnel-related expenses, including stock-based compensation expense. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the fourth quarter and year ended December 31, 2021 were $13.4 million and $42.2 million, respectively, compared to $7.8 million and $28.6 million for the same periods in 2020.
- Total other (loss) income, net was $(36.2) million and $(35.4) million for the fourth quarter and year ended December 31, 2021, respectively, compared to $0.7 million and $7.5 million for the same periods in 2020. The decrease in total other (loss) income, net was due primarily to the full impairment of our investment in PACT Pharma, Inc. Series C-1 convertible preferred stock valued at $36.4 million for the year ended December 31, 2021.

A discussion of these 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, 2021 were $898.3 million, compared to $692.6 million as of December 31, 2020, an increase of $205.7 million that supports the advancing of our multi-modality cell therapy pipeline. Lyell successfully completed its initial public offering in June 2021 with net proceeds of $391.8 million. Based on the current operating plan, Lyell believes that its cash, cash equivalents and marketable securities balances will be sufficient to meet working capital and capital expenditure needs into 2025.

About Lyell Immunopharma, Inc.

Lyell is a T-cell reprogramming company dedicated to the mastery of T cells to cure patients with solid tumors. The Company focuses on addressing what it believes are the primary barriers that limit consistent, reliable and curative responses to adoptive T-cell therapy: T-cell exhaustion and lack of durable stemness, which includes the ability to proliferate, persist and self-renew, as well as generate differentiated effector cell progenies to provide durable anti-tumor functionality. Lyell is applying its proprietary *ex vivo* genetic and epigenetic reprogramming technology platforms, Gen-R and Epi-R, to address these barriers in order to develop new medicines with improved, durable and potentially curative clinical outcomes. Lyell is based in South San Francisco, 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: Lyell's anticipated progress, business plans, business strategy and planned clinical trials; Lyell's plans to submit INDs and the timing thereof; the potential clinical benefits and therapeutic potential of Lyell's product candidates; Lyell's estimated cash runway and the timing of use of its capital resources; the timing of initial data from Lyell's Phase 1 open label dose escalation and expansion trial in LYL797; statements regarding GSK's plans to submit an IND and the timing thereof; 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 effects of the evolving COVID-19 pandemic; Lyell's ability to submit planned INDs on the anticipated timing or at all; initiation of planned clinical trials and enrollment of patients in its future clinical trials; Lyell's ability to manufacture and supply its product candidates for its future clinical trials; the preclinical profiles of Lyell's product candidates not translating in clinical trials; the potential for results from clinical trials to differ from preclinical, 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 Annual Report on Form 10-K for the year ended December 30, 2021 and in Lyell's future reports to be filed with the SEC, including Lyell's Annual Report on Form 10-K for the year ended December 31, 2021. 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,	
	2021	**2020**	**2021**	**2020**
Revenue	$ 2,822	$ 2,312	$ 10,650	$ 7,756
Operating expenses (income):				
Research and development	19,285	35,090	138,693	182,243
General and administrative	31,873	14,869	89,057	46,881
Other operating income, net	(798)	(8,123)	(2,324)	(9,431)
Total operating expenses	50,360	41,836	225,426	219,693
Loss from operations	(47,538)	(39,524)	(214,776)	(211,937)
Interest income	323	621	1,165	5,939
Other (expense) income, net	(44)	46	(161)	1,526
Impairment of other investments	(36,447)	—	(36,447)	—
Total other (loss) income, net	(36,168)	667	(35,443)	7,465
Net loss	$ (83,706)	$ (38,857)	$ (250,219)	$ (204,472)

Balance Sheet Data:

	As of December 31,	
	2021	**2020**
Cash, cash equivalents and marketable securities	$ 898,325	$ 692,614

Property and equipment, net	$	120,098	$	77,045
Total assets	$	1,127,406	$	908,280
Convertible preferred stock	$	—	$	1,010,968
Total stockholders' equity (deficit)	$	929,787	$	(292,528)

Non-GAAP Financial Measures

To supplement our financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), we present non-GAAP net loss, non-GAAP R&D expenses and non-GAAP G&A expenses. Non-GAAP net loss and non-GAAP R&D expenses exclude non-cash stock-based compensation expense and non-cash expenses related to the change in the estimated fair value of success payment liabilities from GAAP net loss and GAAP R&D expenses, respectively. Non-GAAP net loss further adjusts for the income tax effect, if any, of the non-GAAP adjustments. 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 and non-cash expenses related to the change in the estimated fair value of success payment liabilities from our non-GAAP financial measures because they are non-cash expenses 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,	
	2021	2020	2021	2020
Net loss - GAAP	$ (83,706)	$ (38,857)	$ (250,219)	$ (204,472)
Adjustments:				
Stock-based compensation expense	21,178	12,971	62,201	33,261
Change in the estimated fair value of success payment liabilities	(15,630)	1,544	3,713	5,337
Impairment of other investments	36,447	—	36,447	—
Net loss - Non-GAAP[(1)]	$ (41,711)	$ (24,342)	$ (147,858)	$ (165,874)

(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 U.S. deferred tax assets for all periods presented.

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Unaudited Reconciliation of GAAP to Non-GAAP Research and Development Expense

(in thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Research and development - GAAP	$ 19,285	$ 35,090	$ 138,693	$ 182,243
Adjustments:				
Stock-based compensation expense	(2,713)	(5,944)	(15,328)	(14,977)
Change in the estimated fair value of success payment liabilities	15,630	(1,544)	(3,713)	(5,337)
Research and development - Non-GAAP	$ 32,202	$ 27,602	$ 119,652	$ 161,929

Lyell Immunopharma, Inc.

Unaudited Reconciliation of GAAP to Non-GAAP General and Administrative Expense

(in thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
General and administrative - GAAP	$ 31,873	$ 14,869	$ 89,057	$ 46,881
Adjustments:				
Stock-based compensation expense	(18,465)	(7,027)	(46,873)	(18,284)
General and administrative - Non-GAAP	$ 13,408	$ 7,842	$ 42,184	$ 28,597

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