Olema Oncology Reports Fourth Quarter and Full Year 2024 Financial and Operating Results

March 18, 2025

- *Pivotal Phase 3 OPERA-01 trial of palazestrant as a monotherapy in patients with 2/3L metastatic breast cancer on track for top-line data in 2026*
- *Pivotal Phase 3 OPERA-02 trial of palazestrant in combination with ribociclib in patients with frontline metastatic breast cancer enabled by new Novartis collaboration and $250 million equity private placement; trial on track for initiation this year*
- *Promising updated results from the ongoing Phase 1b/2 study of palazestrant in combination with ribociclib in patients with ER+/HER2- advanced or metastatic breast cancer presented at SABCS in December 2024; updated mPFS presented at the TD Cowen Health Care Conference in March 2025; mature data expected to be presented this year at a major medical meeting*
- *OP-3136 Phase 1 trial initiated before the end of 2024; patients now enrolling*
- *Ended 2024 with $434.1 million in cash, cash equivalents, and marketable securities*

SAN FRANCISCO, March 18, 2025 (GLOBE NEWSWIRE) -- Olema Pharmaceuticals, Inc. ("Olema" or "Olema Oncology", Nasdaq: OLMA), a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of targeted therapies for breast cancer and beyond, today reported financial and operating results for the fourth quarter and full year ended December 31, 2024.

"2024 was a productive year for Olema and we closed the year with significant positive momentum. We announced a new clinical trial collaboration and supply agreement with Novartis, raised approximately $250 million through an equity private placement with high-quality, long-term investors, presented compelling data supporting palazestrant in combination with ribociclib at SABCS, received clearance from the FDA for our IND application for OP-3136, and moved quickly to begin enrolling patients in the OP-3136 Phase 1 study before the end of the year," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "Bolstered by a strong balance sheet, we are focused on exemplary execution throughout 2025. We plan to advance patient enrollment in the pivotal Phase 3 OPERA-01 trial in second- and third-line ER+/HER2- metastatic breast cancer, initiate our second pivotal Phase 3 trial, called OPERA-02, in frontline metastatic breast cancer, continue enrolling patients in the Phase 1 trial of OP-3136, present mature data from the Phase 1b/2 trial of palazestrant in combination with ribociclib, and further expand our capabilities through drug discovery and partnerships – all to help patients living with cancer feel better, longer."

Recent Progress

- Presented new preclinical data demonstrating anti-tumor activity for palazestrant in combination with capivasertib and everolimus as well as new preclinical data for OP-3136 as a single agent and in combination with palazestrant and other targeted agents at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in October.
- Announced a new clinical trial collaboration and supply agreement with Novartis in frontline metastatic breast cancer.
- Successfully completed a $250 million equity private placement with new and existing institutional and accredited investors.
- Announced intention to proceed with OPERA-02, the Company's second pivotal Phase 3 trial, of palazestrant in combination with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor ribociclib in frontline metastatic breast cancer.
- Presented updated clinical results from the ongoing Phase 1b/2 study of palazestrant in combination with ribociclib in patients with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer at the San Antonio Breast Cancer Symposium (SABCS) in December. Presented updated median progression-free survival (mPFS) from this trial at the TD Cowen 45th Annual Health Care Conference in March 2025.
- Received clearance from the U.S. Food and Drug Administration (FDA) for the Investigational New Drug (IND) application for OP-3136.
- Initiated the Phase 1 clinical trial for OP-3136 and began enrolling patients before year-end.

Anticipated Upcoming Events

- Advance patient accrual in the pivotal Phase 3 OPERA-01 clinical trial of palazestrant as a monotherapy in second- and third-line (2/3L) metastatic breast cancer; top-line data are anticipated in 2026.
- Initiate the pivotal Phase 3 OPERA-02 clinical trial of palazestrant in combination with ribociclib in frontline metastatic breast cancer.
- Present new preclinical data for OP-3136.
- Present mature data from the Phase 1b/2 clinical trial of palazestrant in combination with ribociclib at a medical meeting.

Fourth Quarter and Full Year 2024 Financial Results
Cash, cash equivalents, and marketable securities as of December 31, 2024, were $434.1 million.

Net loss for the quarter and year ended December 31, 2024 was $33.6 million and $129.5 million, respectively, as compared to $26.8 million and $96.7 million for the quarter and year ended December 31, 2023, respectively. The increase in net loss for the fourth quarter was primarily related to increased spending on clinical development and research activities as a result of late-stage clinical trials for palazestrant, the advancement of OP-3136, and lower interest income earned from marketable securities.

GAAP research and development (R&D) expenses were $32.3 million and $124.5 million for the quarter and year ended December 31, 2024, respectively, as compared to $25.9 million and $86.1 million for the quarterand year ended December 31, 2023. The increase in R&D expenses was primarily related to increased spending on clinical operations and development-related activities as the Company continues to advance palazestrant through late-stage clinical trials, research-related activities associated with the advancement of OP-3136, and personnel related costs, including an increase in non-cash stock-based compensation expense.

Non-GAAP R&D expenses were $27.7 million and $108.0 million for the quarter and year ended December 31, 2024, respectively, excluding $4.6 million and $16.5 million non-cash stock-based compensation expense. Non-GAAP R&D expenses were $23.0 million and $74.4 million for the quarter and year ended December 31, 2023, respectively, excluding $2.9 million and $11.8 million non-cash stock-based compensation expense, respectively. A reconciliation of GAAP to non-GAAP financial measures used in this press release can be found at the end of this press release.

GAAP G&A expenses were $4.5 million and $17.7 million for the quarter and year ended December 31, 2024, respectively, as compared to $4.5 million and $18.8 million for the quarter and year ended December 31, 2023. The decrease in G&A expenses was primarily due to decreased spending on corporate-related costs, offset by an increase in non-cash stock-based compensation expense.

Non-GAAP G&A expenses were $2.8 million and $11.7 million for the quarter and year ended December 31, 2024, respectively, excluding $1.7 million and $6.0 million non-cash stock-based compensation expense, respectively. Non-GAAP G&A expenses were $3.1 million and $13.3 million for the quarter and year ended December 31, 2023, excluding $1.4 million and $5.5 million non-cash stock-based compensation expense, respectively. A reconciliation of GAAP to non-GAAP financial measures used in this press release can be found at the end of this press release.

About Olema Oncology
Olema Oncology is a clinical-stage biopharmaceutical company committed to transforming the standard of care and improving outcomes for patients living with breast cancer and beyond. Olema is advancing a pipeline of novel therapies by leveraging our deep understanding of endocrine-driven cancers, nuclear receptors, and mechanisms of acquired resistance. Our lead product candidate, palazestrant (OP-1250), is a proprietary, orally available complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD), currently in a Phase 3 clinical trial called OPERA-01. In addition, Olema is developing OP-3136, a potent lysine acetyltransferase 6 (KAT6) inhibitor, now in a Phase 1 clinical trial. Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts. For more information, please visit www.olema.com.

About Palazestrant (OP-1250)
Palazestrant (OP-1250) is a novel, orally available small molecule with dual activity as both a complete estrogen receptor (ER) antagonist (CERAN) and selective ER degrader (SERD). It is currently being investigated in patients with recurrent, locally advanced or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. In clinical studies, palazestrant completely blocks ER-driven transcriptional activity in both wild-type and mutant forms of metastatic ER+ breast cancer and has demonstrated anti-tumor efficacy along with attractive pharmacokinetics and exposure, favorable tolerability, central nervous system penetration, and combinability with cyclin-dependent kinase 4/6 (CDK4/6) inhibitors. Palazestrant has been granted U.S. Food and Drug Administration (FDA) Fast Track designation for the treatment of ER+/HER2- metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given in combination with a CDK4/6 inhibitor. It is being evaluated as a single agent in the ongoing pivotal Phase 3 clinical trial, OPERA-01. Learn more at www.opera01study.com. Palazestrant is also being evaluated in multiple Phase 1/2 trials in combination with ribociclib, palbociclib, alpelisib, and everolimus. It will also be evaluated in combination with ribociclib in the planned pivotal Phase 3 trial, OPERA-02.

About OP-3136
OP-3136 is a novel, orally available small molecule that potently and selectively inhibits lysine acetyltransferase 6 (KAT6), an epigenetic target that is dysregulated in breast and other cancers. In preclinical studies, OP-3136 has demonstrated significant anti-proliferative activity in ER+ breast cancer models and is combinable and synergistic with endocrine therapies including palazestrant and cyclin-dependent kinase 4/6 (CDK4/6) inhibitors. The Investigational New Drug (IND) application for OP-3136 was cleared by the U.S. Food and Drug Administration (FDA) in December 2024 and patients are currently enrolling in the Phase 1 clinical trial.

Non-GAAP Financial Information
The results presented in this press release include both GAAP information and non-GAAP information. As used in this release, non-GAAP R&D expense is defined by Olema as GAAP R&D expense excluding stock-based compensation expense, and non-GAAP G&A expense is defined by Olema as GAAP G&A expense excluding stock-based compensation expense. We use these non-GAAP financial measures to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool, and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. Other companies, including companies in our industry, may calculate

similarly titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures and not rely on any single financial measure to evaluate our business.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Words such as "anticipate," "believe," "could," "expect," "goal," "intend," "may," "potential," "upcoming," "will" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These statements include those related to the timelines for initiation and enrollment for potential clinical studies and for results of clinical trials of palazestrant and OP-3136 as a monotherapy and in combination trials, Olema's financial condition and resources, results of operations, cash position and balance sheet strength, potential beneficial characteristics including but not limited to safety, tolerability, activity, efficacy and therapeutic effects of palazestrant, the combinability of palazestrant or OP-3136 with other drugs, and patient enrollment in our clinical trials. Because such statements deal with future events and are based on Olema's current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of Olema could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including, without limitation, those discussed in the section titled "Risk Factors" in Olema's Annual Report on Form 10-K for the year ended December 31, 2024, and future filings and reports that Olema makes from time to time with the U.S. Securities and Exchange Commission. Except as required by law, Olema assumes no obligation to update these forward-looking statements, including in the event that actual results differ materially from those anticipated in the forward-looking statements.

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Olema Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets Data
(in thousands)

	December 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 434,086	$ 261,807
Total assets	**450,979**	**276,945**
Total current liabilities	41,758	21,621
Total liabilities	42,015	23,050
Total stockholders' equity	408,964	253,895
Total liabilities and stockholders' equity	**$ 450,979**	**$ 276,945**

Olema Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development (1)	$ 32,299	$ 25,872	$ 124,517	$ 86,140
General and administrative (2)	4,469	4,544	17,741	18,821

Total operating expenses	**36,768**	**30,416**	**142,258**	**104,961**
Loss from operations	(36,768)	(30,416)	(142,258)	(104,961)
Other income:				
Interest income	3,294	3,551	12,682	8,325
Other income (expense)	(93)	93	102	(19)
Total other income	3,201	3,644	12,784	8,306
Net loss	**$ (33,567)**	**$ (26,772)**	**$ (129,474)**	**$ (96,655)**
Net loss per share, basic and diluted	$ (0.51)	$ (0.49)	$ (2.20)	$ (2.14)
Weighted average shares used to compute net loss per share, basic and diluted	65,793,359	54,783,945	58,743,522	45,247,098

Reconciliation of GAAP to Non-GAAP Information

(In thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	**2023**	**2024**	**2023**
(1) Research and development reconciliation				
GAAP research and development (3)	$ 32,299	$ 25,872	$ 124,517	$ 86,140
Less: share-based compensation expense	4,618	2,911	16,543	11,769
Non-GAAP research and development	**$ 27,681**	**$ 22,961**	**$ 107,974**	**$ 74,371**
(2) General and administrative reconciliation				
GAAP general and administrative	$ 4,469	$ 4,544	$ 17,741	$ 18,821
Less: share-based compensation expense	1,705	1,440	6,039	5,487
Non-GAAP general and administrative	**$ 2,764**	**$ 3,104**	**$ 11,702**	**$ 13,334**

(3) Research and development expenses for the twelve-months ended December 31, 2024 include a $5.0 million milestone payment in connection to the Aurigene Agreement.