Olema Oncology Reports Second Quarter 2025 Financial and Operating Results

August 11, 2025

- *Selected 90 mg once-daily palazestrant for Part 2 of the OPERA-01 Phase 3 monotherapy trial and for the OPERA-02 Phase 3 trial in combination with ribociclib*
- *OPERA-01 enrollment ongoing with top-line data expected in the second half of 2026; OPERA-02 on track to initiate in Q3 2025*
- *Mature data from the Phase 1b/2 study of palazestrant in combination with ribociclib to be presented at ESMO 2025*
- *Ended the second quarter with $361.9 million in cash, cash equivalents, and marketable securities*

SAN FRANCISCO, Aug. 11, 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 second quarter ended June 30, 2025.

"Having achieved regulatory alignment on the selected dose for our pivotal palazestrant program during the second quarter, we are focused on accelerating enrollment in OPERA-01, which is on track for top-line data in the second half of 2026, and initiating the OPERA-02 combination trial in the frontline setting,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “Palazestrant’s demonstrated activity and combinability with multiple compounds offers the potential for it to become a best-in-class, backbone endocrine therapy for metastatic breast cancer. Our Phase 1 study of OP-3136, our potent and selective KAT6 inhibitor, is also generating strong investigator interest and patient enrollment, reinforcing our leadership in developing novel therapies for breast cancer and beyond.”

Recent Progress

- Selected 90 mg of once-daily palazestrant for Part 2 of the ongoing registrational OPERA-01 Phase 3 trial in second- and third-line (2/3L) estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) metastatic breast cancer, and for the OPERA-02 Phase 3 trial in combination with ribociclib in frontline ER+/HER2- metastatic breast cancer.
- Continued enrollment in the Phase 1 study evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of OP-3136, as a monotherapy and in combination with fulvestrant and palazestrant, in participants with advanced solid tumors.

Anticipated Upcoming Events

- Present mature data from the Phase 1b/2 study of palazestrant in combination with ribociclib in ER+/HER2- metastatic breast cancer at the European Society of Medical Oncology (ESMO) Congress 2025 in a presentation entitled “Palazestrant (OP-1250) plus ribociclib in patients with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+, HER2-) advanced breast cancer (ABC)”
- Initiate the OPERA-02 trial of palazestrant in combination with ribociclib in frontline metastatic breast cancer in Q3 2025.
- Report initial clinical results for OP-3136 in 2026.
- Report top-line data from OPERA-01 in the second half of 2026.

Second Quarter 2025 Financial Results
Cash, cash equivalents, and marketable securities of $361.9 million as of June 30, 2025.

Net loss for the quarter ended June 30, 2025 was $43.8 million, as compared to $30.4 million for the quarter ended June 30, 2024. The increase in net loss for the second quarter was related to a one-time milestone payment of $10 million made to Aurigene in conjunction with our KAT6 clinical development program as well as increased spending on research and development activities as a result of the ongoing late-stage clinical trials for palazestrant and the advancement of OP-3136, partially offset by higher interest income earned from marketable securities.

GAAP research and development (R&D) expenses were $43.9 million for the quarter ended June 30, 2025, as compared to $29.1 million for the quarter ended June 30, 2024. The increase in R&D expenses was primarily related to a one-time milestone payment of $10 million made to Aurigene as well as increased spending on clinical development-related activities as Olema continues to advance palazestrant through late-stage clinical trials, and the advancement of OP-3136.

Non-GAAP R&D expenses were $40.2 million for the quarter ended June 30, 2025, excluding $3.7 million non-cash stock-based compensation expense. Non-GAAP R&D expenses were $24.9 million for the quarter ended June 30, 2024, which excluded $4.2 million non-cash stock-based compensation expense. 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 $4.0 million for the quarter ended June 30, 2025, as compared to $4.4 million for the quarter ended June 30, 2024. The decrease in G&A expenses was primarily due to a decrease in non-cash stock-based compensation expense of $0.5 million.

Non-GAAP G&A expenses were $3.0 million for the quarter ended June 30, 2025, excluding $1.0 million non-cash stock-based compensation expense. Non-GAAP G&A expenses were $2.9 million for the quarter ended June 30, 2024, excluding $1.5 million non-cash stock-based compensation expense. 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 study. 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 and is anticipated to be evaluated in combination with ribociclib in the planned pivotal Phase 3 clinical trial, OPERA-02. Learn more at www.opera01study.com. Palazestrant has also been evaluated in multiple Phase 1/2 studies in combination with ribociclib, palbociclib, alpelisib, and everolimus.

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 study.

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,” “on track,” “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 the receipt and presentation of results of clinical trials of palazestrant and OP-3136 each as a monotherapy and in combination trials, the potential for palazestrant to become a best-in-class, backbone endocrine therapy for metastatic breast cancer, Olema’s leadership and ability to develop novel therapies for breast cancer and beyond, 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 or OP-3136, and the combinability of palazestrant or OP-3136

with other drugs. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, 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
(Unaudited)
(In thousands)

	June 30, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 361,913.00	$ 434,086.00
Total assets	**382,002**	**450,979**
Total current liabilities	$ 33,164.00	$ 41,758.00
Total liabilities	$ 36,766.00	$ 42,015.00
Total stockholders' equity	$ 345,236.00	$ 408,964.00
Total liabilities and stockholders' equity	**382,002**	**450,979**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development (1)	$ 43,902	$ 29,109	$ 74,526	$ 58,992
General and administrative (2)	3,962	4,421	8,211	8,877
Total operating expenses	47,864	33,530	82,737	67,869
Loss from operations	(47,864)	(33,530)	(82,737)	(67,869)
Other income:				
Interest income	4,042	3,108	8,566	6,460
Other income (loss)	38	40	(2)	57
Total other income	4,080	3,148	8,564	6,517
Net loss	$ (43,784)	$ (30,382)	$ (74,173)	$ (61,352)
Net loss per share, basic and diluted	$ (0.51)	$ (0.54)	$ (0.87)	$ (1.10)
Weighted average shares used to compute net loss per share, basic and diluted (3)	85,497,426	56,282,402	85,462,021	55,928,363

(1) Research and development expenses for the three- and six-months ended June 30, 2025 include a $10.0 million milestone payment in connection with the Aurigene Agreement. Research and development expenses for the six-months ended June 30, 2024 include a $5.0 million milestone payment in connection with the Aurigene Agreement.

(1) and (2) used to reference to the table below.

(3) The weighted average shares used to compute net loss per share, basic and diluted include the effect from the pre-funded warrants.

Reconciliation of GAAP to Non-GAAP Information

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
(1) Research and development reconciliation				
GAAP research and development	$ 43,902	$ 29,109	$ 74,526	$ 58,992
Less: stock-based compensation expense	3,709	4,233	7,010	7,645
Non-GAAP research and development	**$ 40,193**	**$ 24,876**	**$ 67,516**	**$ 51,347**
(2) General and administrative reconciliation				
GAAP general and administrative	$ 3,962	$ 4,421	$ 8,211	$ 8,877
Less: stock-based compensation expense	983	1,491	2,060	2,988
Non-GAAP general and administrative	**$ 2,979**	**$ 2,930**	**$ 6,151**	**$ 5,889**