



Olema Oncology Reports Third Quarter 2025 Financial and Operating Results

November 10, 2025

- Announced new clinical trial agreement with Pfizer to evaluate palazestrant in combination with atirmociclib in ER+/HER2- metastatic breast cancer
- Initiated OPERA-02 Phase 3 trial of palazestrant in combination with ribociclib in frontline ER+/HER2- metastatic breast cancer
- Presented compelling new data from Phase 1b/2 study of palazestrant plus ribociclib at ESMO 2025
- Ended the quarter with \$329.0 million in cash, cash equivalents, and marketable securities

SAN FRANCISCO, Nov. 10, 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 third quarter ended September 30, 2025.

"We have made significant progress advancing our programs this quarter, highlighted by the initiation of the Phase 3 OPERA-02 trial evaluating palazestrant in combination with ribociclib in the frontline setting and the presentation of compelling data at ESMO that further positions palazestrant to become a potential best-in-class backbone endocrine therapy for ER+/HER2- metastatic breast cancer," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "Our clinical trial agreement with Pfizer to combine palazestrant with atirmociclib further underscores our confidence in palazestrant's activity in combination with other agents in the metastatic setting."

Bohen continued, "Enrollment in the OPERA-01 trial evaluating palazestrant as a monotherapy in second- and third-line ER+/HER2- metastatic breast cancer continues to progress well and we remain on track for top-line data in the second half of next year. The Phase 1/2 study of our KAT6 inhibitor, OP-3136, recently expanded into combinations with fulvestrant and palazestrant and continues to benefit from strong investigator interest. As we look ahead to 2026, we remain focused on sustaining positive momentum across the business, transforming the breast cancer treatment paradigm, and bringing palazestrant to market."

Recent Progress

- Announced a clinical trial collaboration and supply agreement with Pfizer to evaluate the safety and combinability of palazestrant plus atirmociclib, Pfizer's investigational, highly selective-CDK4 inhibitor, in a Phase 1b/2 study in patients with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) metastatic breast cancer.
- Initiated the OPERA-02 Phase 3 trial of palazestrant in combination with ribociclib in frontline ER+/HER2- metastatic breast cancer.
- Presented updated data from the Phase 1b/2 study of palazestrant plus ribociclib at the European Society for Medical Oncology (ESMO) Congress 2025, demonstrating encouraging activity in both *ESR1* mutant and wild-type patients.
- Continued enrollment in the OPERA-01 Phase 3 trial of palazestrant as a monotherapy in second- and third-line ER+/HER2- metastatic breast cancer.
- Advanced 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

- Initiate the Phase 1b/2 study evaluating palazestrant with atirmociclib in ER+/HER2- metastatic breast cancer in Q4 2025.
- Present trial-in-progress poster entitled "OPERA-02: a phase 3 randomized, double-blind, active-controlled study of palazestrant with ribociclib versus letrozole with ribociclib for the first-line treatment of ER+, HER2- advanced breast cancer" at the San Antonio Breast Cancer Symposium (SABCS) in December 2025.
- Report initial clinical results for OP-3136 in mid-2026.
- Report top-line data from OPERA-01 in the second half of 2026.

Third Quarter 2025 Financial Results

Cash, cash equivalents, and marketable securities of \$329.0 million as of September 30, 2025.

Net loss for the quarter ended September 30, 2025 was \$42.2 million, as compared to \$34.6 million for the quarter ended September 30, 2024. The increase in net loss for the third quarter was primarily related to 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 \$40.0 million for the quarter ended September 30, 2025, as compared to \$33.2 million for the quarter ended September 30, 2024. The increase in R&D expenses was primarily related to increased spending on clinical development-related activities as Olema continues to advance palazestrant through late-stage clinical trials, and the advancement of OP-3136, partially offset by decreases in stock-based compensation expense of \$1.7 million.

Non-GAAP R&D expenses were \$37.4 million for the quarter ended September 30, 2025, excluding \$2.6 million non-cash stock-based compensation expense. Non-GAAP R&D expenses were \$28.9 million for the quarter ended September 30, 2024, which excluded \$4.3 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 general and administrative (G&A) expenses were \$5.9 million for the quarter ended September 30, 2025, as compared to \$4.4 million for the quarter ended September 30, 2024. The increase in G&A expenses was primarily due to corporate-related costs, including increases in stock-based compensation expense of \$0.3 million.

Non-GAAP G&A expenses were \$4.3 million for the quarter ended September 30, 2025, excluding \$1.7 million non-cash stock-based compensation expense. Non-GAAP G&A expenses were \$3.0 million for the quarter ended September 30, 2024, excluding \$1.3 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 antagonist (CERAN) and a selective estrogen receptor degrader (SERD), currently in two Phase 3 clinical trials. 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 antagonist (CERAN) and selective estrogen receptor 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 in combination with ribociclib in the ongoing pivotal Phase 3 clinical trial, OPERA-02. Palazestrant is also being evaluated in multiple Phase 1/2 studies in combination with ribociclib, palbociclib, alpelisib, everolimus, and atimociclib.

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 potential for palazestrant to become a best-in-class, backbone endocrine therapy for metastatic breast cancer, potential beneficial characteristics including but not limited to safety, tolerability, activity, efficacy and therapeutic effects of palazestrant or OP-3136, the combinability of palazestrant or OP-3136 with other drugs, including in the metastatic setting, timelines for initiation and enrollment for potential and current 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, Olema’s ability to transform the breast cancer paradigm, Olema’s potential commercial capabilities, Olema’s leadership and ability to develop novel therapies for breast cancer and beyond, and Olema’s financial condition and resources, results of operations, cash position and balance sheet strength. 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 September 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)

	<u>September 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Cash, cash equivalents and marketable securities	\$ 328,960	\$ 434,086
Total assets	352,453	450,979
Total current liabilities	41,655	41,758
Total liabilities	44,965	42,015
Total stockholders’ equity	307,488	408,964
Total liabilities and stockholders’ equity	\$ 352,453	\$ 450,979

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

	<u>Three Months Ended September 30,</u> <u>2025</u>	<u>2024</u>	<u>Nine Months Ended</u> <u>September 30,</u> <u>2025</u>	<u>2024</u>
Operating expenses:				
Research and development (1)	\$ 39,951	\$ 33,226	\$ 114,477	\$ 92,218
General and administrative (2)	5,926	4,395	14,137	13,272
Total operating expenses	45,877	37,621	128,614	105,490
Loss from operations	(45,877)	(37,621)	(128,614)	(105,490)
Other income:				
Interest income	3,648	2,928	12,214	9,388

Other income	12	138	10	195
Total other income	3,660	3,066	12,224	9,583
Net loss	\$ (42,217)	\$ (34,555)	\$ (116,390)	\$ (95,907)
Net loss per share, basic and diluted	\$ (0.49)	\$ (0.60)	\$ (1.36)	\$ (1.80)
Weighted average shares used to compute net loss per share, basic and diluted (3)	85,732,221	57,262,803	85,553,078	53,194,081

(1) Research and development expenses for the nine-months ended September 30, 2025 include a \$10.0 million milestone payment in connection with the Aurigene Agreement.

Research and development expenses for the nine-months ended September 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
(1) Research and development reconciliation				
GAAP research and development	\$ 39,951	\$ 33,226	\$ 114,477	\$ 92,218
Less: stock-based compensation expense	2,582	4,280	9,592	11,925
Non-GAAP research and development	\$ 37,369	\$ 28,946	\$ 104,885	\$ 80,293
(2) General and administrative reconciliation				
GAAP general and administrative	\$ 5,926	\$ 4,395	\$ 14,137	\$ 13,272
Less: stock-based compensation expense	1,668	1,346	3,728	4,334
Non-GAAP general and administrative	\$ 4,258	\$ 3,049	\$ 10,409	\$ 8,938