



## Olema Oncology Reports First Quarter 2025 Financial and Operating Results

May 13, 2025

- Pivotal Phase 3 OPERA-02 trial of palazestrant in combination with ribociclib in frontline metastatic breast cancer on track for initiation in 2025, supported by promising updated efficacy data from ongoing Phase 1b/2 study
- Pivotal Phase 3 OPERA-01 trial of palazestrant monotherapy in 2/3L metastatic breast cancer continues to advance with top-line data anticipated in 2026; trial-in-progress poster to be highlighted at ASCO Annual Meeting
- Preclinical data for OP-3136 presented at AACR demonstrating anti-tumor activity in ovarian, non-small cell lung, and prostate cancer models; Phase 1 trial recruitment ongoing
- Ended the first quarter with \$392.7 million in cash, cash equivalents, and marketable securities

SAN FRANCISCO, May 13, 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 first quarter ended March 31, 2025.

"During the first quarter, we continued to make important operational progress advancing our pipeline and we enter the second quarter well-positioned across the business," said Sean P. Bohlen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "Our focus remains on our pivotal palazestrant program, laying the foundation to successfully initiate OPERA-02 in frontline metastatic breast cancer, while advancing OPERA-01 towards an anticipated top-line readout next year. We were also pleased to present promising new preclinical data at AACR supporting the use of OP-3136, our potent KAT6 inhibitor, in a number of solid tumor applications beyond breast cancer. Investigator interest in our OP-3136 program remains strong and we are continuing to enroll patients in the Phase 1 study. With a clear strategy and strong balance sheet to support execution against our key priorities, we are working diligently to advance the promise of Olema's science and striving to change the treatment paradigm for endocrine-driven cancers."

### Recent Progress

- Disclosed updated median progression-free survival (mPFS) from the ongoing Phase 1b/2 study of palazestrant in combination with cyclin-dependent kinase 4/6 inhibitor (CDK4/6i) ribociclib in patients with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer at the TD Cowen 45th Annual Health Care Conference in March, including a mPFS of 13.8 months among all patients treated with 120 mg of palazestrant and 600 mg of ribociclib daily (n=56) and 13.1 months in patients previously treated with a CDK4/6i plus an endocrine therapy (n=40) as of a February 18, 2025 cutoff date.
- Advanced the pivotal Phase 3 OPERA-01 trial of palazestrant as a monotherapy in second- and third-line (2/3L) ER+/HER2- metastatic breast cancer.
- Continued enrollment in the Phase 1 study evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of OP-3136 in participants with advanced solid tumors.
- Presented new preclinical data for OP-3136 at the American Association for Cancer Research (AACR) Annual Meeting in April, demonstrating anti-tumor activity in pre-clinical *in vitro* and *in vivo* ovarian, non-small cell lung, and prostate cancer models, regardless of KAT6A expression status, as well as synergy with standard of care drugs.

### Anticipated Upcoming Events

- Present trial-in-progress poster, "OPERA-01: A randomized, open-label, phase 3 study of palazestrant (OP-1250) monotherapy vs standard-of-care endocrine therapy for patients with ER+, HER2- advanced breast cancer after endocrine and CDK4/6 inhibitor therapy," at the American Society of Clinical Oncology (ASCO) Annual Meeting in June; report top-line data from OPERA-01 in 2026.
- Initiate the pivotal Phase 3 OPERA-02 trial of palazestrant in combination with ribociclib in frontline metastatic breast cancer in 2025.
- Present mature data from the Phase 1b/2 trial of palazestrant in combination with ribociclib at an upcoming medical meeting.

### First Quarter 2025 Financial Results

Cash, cash equivalents, and marketable securities as of March 31, 2025, were \$392.7 million.

Net loss for the quarter ended March 31, 2025 was \$30.4 million, as compared to \$31.0 million for the quarter ended March 31, 2024. The decrease in net loss for the first quarter was related to higher interest income earned from marketable securities, primarily offset by increased spending on clinical development and research activities as a result of late-stage clinical trials for palazestrant and the advancement of OP-3136.

GAAP research and development (R&D) expenses were \$30.6 million for the quarter ended March 31, 2025, as compared to

\$29.9 million for the quarter ended March 31, 2024. 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, and clinical operations and development-related activities associated with the advancement of OP-3136, and personnel-related costs, partially offset by a one-time \$5 million milestone payment incurred to Aurigene and a decrease in non-cash stock-based compensation expense of \$0.1 million.

Non-GAAP R&D expenses were \$27.3 million for the quarter ended March 31, 2025, excluding \$3.3 million non-cash stock-based compensation expense. Non-GAAP R&D expenses were \$26.5 million for the quarter ended March 31, 2024, which included a \$5.0 million milestone payment in connection with the Aurigene Agreement and excluded \$3.4 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 \$4.2 million for the quarter ended March 31, 2025, as compared to \$4.5 million for the quarter ended March 31, 2024. The decrease in G&A expenses was primarily due to a decrease in non-cash stock-based compensation expense of \$0.4 million, offset by increased spending on corporate-related costs.

Non-GAAP G&A expenses were \$3.2 million for the quarter ended March 31, 2025, excluding \$1.1 million non-cash stock-based compensation expense. Non-GAAP G&A expenses were \$3.0 million for the quarter ended March 31, 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 trial. Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts. For more information, please visit [www.olema.com](http://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](http://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 each 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 or OP-3136, the combinability of palazestrant or OP-3136 with other drugs, the applicability of OP-3136 in solid tumor applications beyond breast cancer, patient enrollment in our clinical trials, and Olema’s potential to change the treatment paradigm of endocrine-driven cancers. 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 March 31, 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.

#### Media and Investor Relations Contact

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**Olema Pharmaceuticals, Inc.**  
**Condensed Consolidated Balance Sheets Data**  
**(Unaudited)**  
(In thousands)

	<b>March 31,</b>	<b>December 31,</b>
	<b>2025</b>	<b>2024</b>
Cash, cash equivalents and marketable securities	\$ 392,707	\$ 434,086
<b>Total assets</b>	<b>409,639</b>	<b>450,979</b>
Total current liabilities	26,064	41,758
Total liabilities	26,187	42,015
Total stockholders’ equity	383,452	408,964
<b>Total liabilities and stockholders’ equity</b>	<b>\$ 409,639</b>	<b>\$ 450,979</b>

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

	<b>Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
Operating expenses:		
Research and development (1)	\$ 30,624	\$ 29,883
General and administrative (2)	4,249	4,456
Total operating expenses	34,873	34,339
Loss from operations	(34,873)	(34,339)
Other income:		
Interest income	4,524	3,352
Other (loss) income	(40)	17
Total other income	4,484	3,369
Net loss	\$ (30,389)	\$ (30,970)
Net loss per share, basic and diluted	\$ (0.36)	\$ (0.56)

Weighted average shares used to compute net loss per share, basic and diluted	85,426,223	55,574,324
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**Reconciliation of GAAP to Non-GAAP Information**  
(In thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
<b>(1) Research and development reconciliation</b>		
GAAP research and development (3)	\$ 30,624	\$ 29,883
Less: share-based compensation expense	3,301	3,412
<b>Non-GAAP research and development</b>	<b>\$ 27,323</b>	<b>\$ 26,471</b>
<b>(2) General and administrative reconciliation</b>		
GAAP general and administrative	\$ 4,249	\$ 4,456
Less: share-based compensation expense	1,077	1,497
<b>Non-GAAP general and administrative</b>	<b>\$ 3,172</b>	<b>\$ 2,959</b>

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