UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 12, 2024

Olema Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39712**	**30-0409740**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
780 Brannan Street **San Francisco, California**		**94103**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 415 651-3316

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	OLMA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 12, 2024, Olema Pharmaceuticals, Inc. (the "Company") reported its financial results for the quarter ended September 30, 2024. A copy of the press release is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in Item 2.02, including the press release attached as Exhibit 99.1 hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended, nor shall it be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 12, 2024, of Olema Pharmaceuticals, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OLEMA PHARMACEUICALS, INC.

Date: November 12, 2024

By: /s/ Shane Kovacs
Shane Kovacs
Chief Operating and Financial Officer

Olema Oncology Reports Third Quarter 2024 Financial Results and Provides Corporate Update

- *Presented compelling new preclinical data demonstrating anti-tumor activity for OP-3136, a novel KAT6 inhibitor, with enhanced activity of palazestrant combinations at EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics (ENA 2024)*
- *New clinical data for palazestrant (OP-1250) in combination with ribociclib to be presented at the San Antonio Breast Cancer Symposium (SABCS) in December*
- *IND submission for OP-3136 expected before year end; clinical study to initiate early 2025*
- *Cash, cash equivalents, and marketable securities of $214.8 million as of September 30, 2024*

SAN FRANCISCO - November 12, 2024 - Olema Pharmaceuticals, Inc. (“Olema”, “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 results for the third quarter ended September 30, 2024, and provided a corporate update.

“We look forward to presenting updated data from our ongoing Phase 2 clinical study of palazestrant in combination with ribociclib in frontline metastatic breast cancer patients at SABCS in December. The OPERA-01 Phase 3 clinical trial of palazestrant as a monotherapy in second/third-line patients continues to advance and we remain on track for top-line readout in 2026,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “At ENA 2024, we presented three new, robust preclinical data sets. Palazestrant demonstrated combinability and enhanced tumor suppression with both everolimus and capivasertib. OP-3136, our potent and selective KAT6 inhibitor, demonstrated robust anti-tumor activity as a single agent, as well as synergy and enhanced anti-tumor activity in combination with palazestrant. These data reinforce our belief in the potential of OP-3136 as an exciting new therapy for breast and other cancers, and we remain on track to submit the IND application before year end.”

Recent Progress

- Continued enrollment of patients in OPERA-01, the pivotal Phase 3 clinical trial of palazestrant as a monotherapy in second/third-line ER+/HER2- metastatic breast cancer.
- Presented preclinical data for OP-3136 and palazestrant at the 36th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics (ENA 2024) in Barcelona, Spain.
- Initiated Phase 1b/2 clinical study of palazestrant in combination with everolimus.
- Successfully completed Investigational New Drug (IND)-enabling studies for OP-3136.

Anticipated Upcoming Milestones

- Present updated Phase 2 data showing palazestrant in combination with ribociclib at the San Antonio Breast Cancer Symposium (SABCS) in December 2024.
- Submit the IND application for OP-3136 to the U.S. Food and Drug Administration (FDA) before year-end; initiate the Phase 1 clinical study for OP-3136 in early 2025.

Third Quarter 2024 Financial Results

Cash, cash equivalents, and marketable securities as of September 30, 2024, were $214.8 million.

Net loss for the quarter ended September 30, 2024, was $34.6 million, as compared to $21.5 million for the quarter ended September 30, 2023. The increase in net loss for the third quarter was primarily related to increased spending on clinical development and research activities as a result of late-stage clinical trials for palazestrant and the advancement of our KAT6 inhibitor program, as well as general and administrative (G&A) activities. The increase was partially offset by higher interest income earned from marketable securities.

GAAP research and development (R&D) expenses were $33.2 million for the quarter ended September 30, 2024, as compared to $19.5 million for the quarter ended September 30, 2023. The increase in R&D expenses was primarily related to increased spending on clinical operations and development-related activities as we continue to advance palazestrant through late-stage clinical trials, research-related activities associated with the advancement of our KAT6 inhibitor program, and personnel related costs, including an increase in non-cash stock-based compensation expense of $1.5 million.

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. Non-GAAP R&D expenses were $16.7 million for the quarter ended September 30, 2023, excluding $2.8 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 $4.4 million for the quarter ended September 30, 2024, as compared to $3.9 million for the quarter ended September 30, 2023. The increase in G&A expenses was primarily due to increased spending on corporate-related costs and an increase in non-cash stock-based compensation expense of less than $0.1 million.

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. Non-GAAP G&A expenses were $2.6 million for the quarter ended September 30, 2023, 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 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, CNS penetration, and combinability with 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 both as a single agent in an ongoing Phase 3 clinical trial, OPERA-01, and in Phase 1/2 combination studies with CDK4/6 inhibitors (palbociclib and ribociclib), a PI3Ka inhibitor (alpelisib), and an mTOR inhibitor (everolimus). For more information on OPERA-01, please visit www.opera01study.com.

About OP-3136
OP-3136 is a novel, orally available small molecule that potently and selectively inhibits 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 CDK4/6 inhibitors. Olema has successfully completed IND-enabling studies in support of a potential Investigational New Drug (IND) application with the FDA and expects to initiate Phase 1 clinical trials for OP-3136 in early 2025.

About Olema Oncology
Olema Oncology is a clinical-stage biopharmaceutical company committed to transforming the standard of care and improving outcomes for women living with cancer. 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 a potent KAT6 inhibitor (OP-3136). Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts. For more information, please visit us at www.olema.com.

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,” “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 (OP-1250) and OP-3136, each as a monotherapy and in combination trials, Olema’s financial condition and resources, results of operations, cash position, potential beneficial characteristics including but not limited to safety, tolerability, activity, efficacy and therapeutic effects of palazestrant, the potential of palazestrant to advance the standard of care for women living with cancer, combinability with other drugs, palazestrant, or OP-3136, and the sufficiency and timing of Olema’s preclinical program, including the potential beneficial characteristics of its KAT6 inhibitor compounds and the timing of a potential IND application and advancement into clinical development for OP-3136. 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, 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.

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 214,763	$ 261,807
Total assets	**230,173**	**276,945**
Total current liabilities	30,700	21,621
Total liabilities	31,262	23,050
Total stockholders' equity	198,911	253,895
Total liabilities and stockholders' equity	**$ 230,173**	**$ 276,945**

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

	Three Months Ended September 30,		Nine Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development (1)	$ 33,226	$ 19,453	$ 92,218	$ 60,268
General and administrative (2)	4,395	3,889	13,272	14,277
Total operating expenses	**37,621**	**23,342**	**105,490**	**74,545**
Loss from operations	(37,621)	(23,342)	(105,490)	(74,545)
Other income:				
Interest income	2,928	1,919	9,388	4,774
Other income (expense)	138	(79)	195	(112)
Total other income	3,066	1,840	9,583	4,662
Net loss	**$ (34,555)**	**$ (21,502)**	**$ (95,907)**	**$ (69,883)**
Net loss per share, basic and diluted	$ (0.60)	$ (0.48)	$ (1.80)	$ (1.66)
Weighted average shares used to compute net loss per share, basic and diluted	57,262,803	44,977,161	53,194,081	41,999,978

Reconciliation of GAAP to Non-GAAP Information
(In thousands)

	Three Months Ended September 30,		Nine Months Ended June 30,	
	2024	2023	2024	2023
(1) Research and development reconciliation				
GAAP research and development (3)	$ 33,226	$ 19,453	$ 92,218	$ 60,268
Less: share-based compensation expense	4,280	2,801	11,925	8,858
Non-GAAP research and development	**$ 28,946**	**$ 16,652**	**$ 80,293**	**$ 51,410**
(2) General and administrative reconciliation				
GAAP general and administrative	$ 4,395	$ 3,889	$ 13,272	$ 14,277
Less: share-based compensation expense	1,346	1,304	4,334	4,047
Non-GAAP general and administrative	**$ 3,049**	**$ 2,585**	**$ 8,938**	**$ 10,230**

(3) Research and development expenses for the nine-months ended September 30, 2024 include a $5.0 million milestone payment in connection to the Aurigene Agreement.

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IR and Media Contact
Courtney O’Konek, Vice President, Corporate Communications

media@olema.com