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 7, 2023

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)**	**(I.R.S. Employer Identification No.)**
780 Brannan Street **San Francisco, California**		**94103**
(Address of principal executive offices)		**(Zip Code)**

(415) 651-3316

(Registrant's Telephone Number, Including Area Code)

N/A

(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 (see General Instructions A.2. below):

☐ 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, $0.0001 par value 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 7, 2023, Olema Pharmaceuticals, Inc. (the "Company") reported its financial results for the quarter ended September 30, 2023. 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 Olema Pharmaceuticals, Inc., 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 7, 2023, 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, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OLEMA PHARMACEUTICALS, INC.

Dated: November 7, 2023

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

Olema Oncology Reports Third Quarter 2023 Financial Results and Provides Corporate Update

- *OPERA-01 pivotal Phase 3 monotherapy clinical trial on track, with clinical site activation ongoing and first patient expected to be enrolled in fourth quarter*
- *New clinical data for palazestrant (OP-1250) in combination with CDK4/6 inhibitors to be presented at the 2023 San Antonio Breast Cancer Symposium (SABCS) in December*
- *Strong cash, cash equivalents and marketable securities position of $276.9 million as of September 30, 2023*

SAN FRANCISCO, November 7, 2023 – Olema Pharmaceuticals, Inc. ("Olema", "Olema Oncology", Nasdaq: OLMA), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted therapies for women's cancers, today reported financial results for the third quarter ended September 30, 2023, and provided a corporate update.

"With the recent oral presentation of our Phase 2 monotherapy clinical results at ESMO in Madrid, we are already experiencing increased awareness of and interest in our OPERA-01 Phase 3 monotherapy clinical trial," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "Our Phase 2 study of palazestrant in combination with ribociclib is now rapidly enrolling and we look forward to presenting new palazestrant combination data at SABCS in December, including a Poster Spotlight Discussion for our interim Phase 2 palbociclib combination clinical results. We are proud of the advancements we are making across our business, and as we progress our CERAN and KAT6 programs we remain focused on defining the next generation of targeted therapies for women's cancers."

Recent Corporate Highlights

- OPERA-01, Olema's first pivotal Phase 3 clinical trial testing palazestrant as a monotherapy in second- and third-line metastatic breast cancer is ongoing, including clinical site activation and first patient expected to be enrolled in the fourth quarter.
- Presented palazestrant Phase 2 monotherapy clinical study results as an oral presentation at the European Society for Medical Oncology (ESMO) Congress 2023 in Madrid, Spain, on October 22, 2023. Results demonstrated that, across all 86 heavily pretreated patients, the median progression-free survival (PFS) was 4.6 months with a clinical benefit rate (CBR) of 40%; in patients with ESR1 mutations at baseline, the median PFS was 5.6 months with a CBR of 52%. In a subset analysis of 49 second- or third-line patients with or without prior chemotherapy, the median PFS was 7.2 months and CBR was 48% across all patients, and the median PFS was 7.3 months and CBR

was 59% in ESR1-mutant patients. Study results support continued development of palazestrant in the OPERA-01 monotherapy Phase 3 pivotal trial.
- Announced the appointment of Mr. Scott Garland, who brings more than 30 years of biopharmaceutical industry experience with deep commercial and executive leadership expertise, to Olema's Board of Directors.
- Announced the expansion of Olema's clinical collaboration with Novartis Institutes for BioMedical Research, Inc. (Novartis), increasing the size of the ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib to approximately 60 patients.
- Presented new preclinical data regarding the discovery of novel compounds targeting KAT6, an epigenetic target that is dysregulated in breast and other cancers, at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, demonstrating anti-tumor activity in preclinical models of ER+ breast cancer.
- Completed a combined financing for up to $180 million including an equity private placement of approximately $130 million of common stock as well as a new senior secured credit facility with an aggregate principal amount of up to $50 million with Silicon Valley Bank, $25 million of which is currently available.

Upcoming Milestones
- Present palazestrant interim Phase 1b/2 clinical study results in combination with CDK4/6 inhibitor, palbociclib, as a Poster Spotlight Discussion at the 2023 San Antonio Breast Cancer Symposium (SABCS) in December 2023.
- Present palazestrant interim Phase 1b clinical study results in combination with CDK4/6 inhibitor, ribociclib, at SABCS.
- Present trial-in-progress poster for OPERA-01, a randomized, open-label, Phase 3, study of palazestrant vs. standard-of-care treatment for ER+/HER2- advanced or metastatic breast cancer after endocrine and CDK4/6 inhibitor therapy, at SABCS, which will provide details on the trial design, inclusion/exclusion criteria, and trial endpoints.

Third Quarter 2023 Financial Results
Cash, cash equivalents and marketable securities as of September 30, 2023, were $276.9 million.

Net loss for the quarter ended September 30, 2023, was $21.5 million, as compared to $22.7 million for the same period of the prior year. The decrease in net loss was primarily related to decreased spending on general and administrative activities, and higher interest income earned from the marketable securities, which were offset by increased spending on clinical operations and development-related activities as Olema continues to advance palazestrant into late-stage clinical trials.

GAAP research and development (R&D) expenses were $19.5 million for the quarter ended September 30, 2023, as compared to $17.6 million for the quarter ended September 30, 2022. The increase was primarily a result of increased spending on clinical operations and development-related activities as Olema continues to advance palazestrant into late-stage clinical development.

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. Non-GAAP R&D expenses were $14.8 million for the quarter ended September 30, 2022, 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 in the tables below.

GAAP general and administrative (G&A) expenses were $3.9 million for the quarter ended September 30, 2023, as compared to $5.6 million for the quarter ended September 30, 2022. The decrease in G&A expenses was primarily due to decreased spending on (i) corporate- and legal-related costs, and (ii) personnel-related expenses, primarily due to lower headcount as a result of the restructuring and portfolio prioritization.

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. Non-GAAP G&A expenses were $4.1 million for the quarter ended September 30, 2022, 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 in the tables below.

About Olema Oncology

Olema Oncology is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted therapies for women’s cancers. Olema’s lead product candidate, palazestrant (OP-1250), is a proprietary, orally-available small molecule with dual activity as both a complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD). It is currently being evaluated both as a single agent in an ongoing Phase 3 clinical trial, and in combination with CDK4/6 inhibitors (palbociclib and ribociclib) and a PI3Ka inhibitor (alpelisib), in patients with recurrent, locally advanced or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. Palazestrant has been granted 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. Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts. For more information, please visit us at www.olema.com, or follow us on Twitter and LinkedIn.

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 non-cash 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," "expect," "will," "may," "goal," "potential" 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 Olema's financial condition and resources, results of operations, cash position, the sufficiency of the initiation and timeline of Olema's pivotal Phase 3 monotherapy clinical trial (OPERA-01), the timelines for initiation and enrollment for potential clinical studies and for results of clinical trials of palazestrant (OP-1250) as a monotherapy and in combination trials, potential beneficial characteristics, safety, tolerability, efficacy and therapeutic effects of palazestrant, the potential of palazestrant to help define the next generation of targeted therapies for women's cancers, palazestrant's combinability with other drugs, the capabilities of Olema's board of directors, and Olema's preclinical program, including the potential beneficial characteristics of its KAT6 inhibitor compounds and its applicability to breast and other 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 September 30, 2023, 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, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 276,901	$ 204,421
Total assets	**292,799**	**215,645**
Total current liabilities	15,966	16,549
Total liabilities	17,665	18,099
Total stockholders' equity	275,134	197,546
Total liabilities and stockholders' equity	**$ 292,799**	**$ 215,645**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development (1)	$ 19,453	$ 17,627	$ 60,268	$ 60,690
General and administrative (2)	3,889	5,595	14,277	19,079
Total operating expenses	23,342	23,222	74,545	79,769
Loss from operations	(23,342)	(23,222)	(74,545)	(79,769)
Other income (expense):				
Interest income	1,919	622	4,774	1,255
Other expense	(79)	(120)	(112)	(94)
Total other income	1,840	502	4,662	1,161
Net loss	($ 21,502)	($ 22,720)	($ 69,883)	($ 78,608)
Net loss per share, basic and diluted	($ 0.48)	($ 0.57)	($ 1.66)	($ 1.97)
Weighted average shares used to compute net loss per share, basic and diluted	44,977,161	40,036,201	41,999,978	39,930,418

Reconciliation of GAAP to Non-GAAP Information

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
(1) Research and development reconciliation				
GAAP research and development	$ 19,453	$ 17,627	$ 60,268	$ 60,690
Less: share-based compensation expense	2,801	2,812	8,858	9,088
Non-GAAP research and development	**$ 16,652**	**$ 14,815**	**$ 51,410**	**$ 51,602**
(2) General and administrative reconciliation				
GAAP general and administrative	$ 3,889	$ 5,595	$ 14,277	$ 19,079
Less: share-based compensation expense	1,304	1,463	4,047	4,880
Non-GAAP general and administrative	**$ 2,585**	**$ 4,132**	**$ 10,230**	**$ 14,199**

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