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): May 08, 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

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:

☐ 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 May 8, 2024, Olema Pharmaceuticals, Inc. (the "Company") reported its financial results for the quarter ended March 31, 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 May 8, 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 PHARMACEUTICALS, INC.

Date: May 8, 2024

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

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

- *Completed enrollment in 60-patient Phase 1b/2 clinical studies of palazestrant in combination with each of ribociclib and palbociclib*
- *New clinical data from palazestrant-ribociclib combination study to be presented at the ESMO Breast Cancer Annual Congress 2024 in Berlin, Germany. Olema will host an investor conference call on May 15, 2024, at 8:00 a.m. ET to review the data*
- *Investigational New Drug (IND) application for OP-3136, a novel KAT6 inhibitor, expected to be filed with FDA in late 2024*
- *Cash, cash equivalents and marketable securities of $249.0 million as of March 31, 2024*

SAN FRANCISCO, May 8, 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 women’s cancers, today reported financial results for the first quarter ended March 31, 2024, and provided a corporate update.

“Our mission at Olema is uniquely focused on advancing the standard of care for women living with cancer,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “We are excited for the achievements we are making both with palazestrant, our oral complete ER antagonist program, and now with our KAT6 inhibitor program, OP-3136. We believe palazestrant has the potential to become the backbone endocrine therapy-of-choice for advanced or metastatic breast cancer, and we look forward to presenting new clinical data in combination with ribociclib at the 2024 ESMO Breast Cancer Annual Congress later this month.”

First Quarter 2024 Highlights

- Completed enrollment of 60-patient Phase 1b/2 studies of palazestrant (OP-1250) in combination with each of ribociclib and palbociclib.
- Nominated OP-3136, an orally bioavailable KAT6 inhibitor, as a development candidate. OP-3136 demonstrated potent anti-tumor activity alone and in combination with both palazestrant and CDK4/6 inhibitors in preclinical ER+ breast cancer models.
- Announced publication of data in *Molecular Cancer Therapeutics* describing the design, discovery and optimization of palazestrant.

Upcoming Milestones

- Present interim Phase 1b/2 clinical results of palazestrant in combination with ribociclib at ESMO Breast Cancer Annual Congress 2024, May 15-17, 2024, in Berlin, Germany.
- Present trial-in-progress poster on OPERA-01, a pivotal Phase 3 monotherapy clinical trial in the second- and third-line setting of ER+/HER2- advanced or metastatic breast cancer, at the 2024 ASCO Annual Meeting, May 31-June 4, 2024, in Chicago, IL.
- Initiate Phase 1b/2 clinical study of palazestrant in combination with mTOR inhibitor, everolimus, in Q3 2024.

- File an Investigational New Drug (IND), application with the U.S. Food and Drug Administration (FDA) for OP-3136 in late 2024 and advance clinical development.

First Quarter 2024 Financial Results
Cash, cash equivalents and marketable securities as of March 31, 2024, were $249.0 million.

Net loss for the quarter ended March 31, 2024, was $31.0 million, as compared to $28.3 million for the quarter March 31, 2023. The increase in net loss for the first quarter was primarily related to increased spending on research and clinical development-related activities as a result of late-stage clinical trials for palazestrant and the advancement of our KAT6 inhibitor program. This increase was offset by decreased spending on general and administrative activities and higher interest income earned from marketable securities.

GAAP research and development (R&D) expenses were $29.9 million for the quarter ended March 31, 2024, as compared to $22.8 million for the quarter ended March 31, 2023. The increase in R&D expenses was primarily related to a $5.0 million milestone payment incurred in connection with the exclusive global licensing agreement entered into in June 2022 between Olema and Aurigene (Aurigene Agreement) associated with the advancement of our KAT6 inhibitor program, and increased spending on clinical development-related activities, as we continue to advance palazestrant into late-stage clinical trials. The increase was offset by decreased spending on clinical pharmacology studies and nonclinical research programs and a one-time restructuring charge recorded in the first quarter of 2023.

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 to the Aurigene Agreement and excluded $3.4 million non-cash stock-based compensation expense. Non-GAAP R&D expenses were $19.7 million for the quarter ended March 31, 2023, excluding $3.1 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 $4.5 million for the quarter ended March 31, 2024, as compared to $6.8 million for the quarter ended March 31, 2023. The decrease in G&A expenses was primarily due to decreased spending on corporate- and legal-related costs, and personnel-related expenses, including a one-time restructuring charge recorded in the first quarter of 2023.

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. Non-GAAP G&A expenses were $5.2 million for the quarter ended March 31, 2023, 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.

ESMO Breast Cancer Investor Conference Call

Olema will host a webcast and conference call for analysts and investors to review the data being presented at ESMO Breast Cancer Annual Congress 2024 on Wednesday, May 15, 2024, at 8:00 a.m. ET (2:00 p.m. CEST). Please register for the webcast by visiting the Investors & Media section of Olema's website at 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, 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, please visit www.opera01study.com.

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. In addition to our lead product candidate, palazestrant (OP-1250), a proprietary, orally-available complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD), 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) as a monotherapy and in combination trials, timings of presentations at conferences and conference calls, 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 or become the backbone endocrine therapy-of-choice for advanced or metastatic breast cancer, palazestrant’s combinability with other drugs, the initiation of a phase 1b/2 clinical study of palazestrant in combination with everolimus and timing thereof, 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 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 March 31, 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)

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 248,977	$ 261,807
Total assets	**263,694**	**276,945**
Total current liabilities	26,224	21,621
Total liabilities	27,376	23,050
Total stockholders' equity	236,318	253,895
Total liabilities and stockholders' equity	**$ 263,694**	**$ 276,945**

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

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development (1)	$ 29,883	$ 22,826
General and administrative (2)	4,456	6,776
Total operating expenses	34,339	29,602
Loss from operations	(34,339)	(29,602)
Other income:		
Interest income	3,352	1,305
Other income:	17	11
Total other income	3,369	1,316
Net loss	$ (30,970)	$ (28,286)
Net loss per share, basic and diluted	$ (0.56)	$ (0.70)
Weighted average shares used to compute net loss per share, basic and diluted	55,574,324	40,354,493

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

	Three Months Ended March 31,	
	2024	**2023**
(1) Research and development reconciliation		
GAAP research and development (3)	$ 29,883	$ 22,826
Less: share-based compensation expense	3,412	3,088
Non-GAAP research and development	**$ 26,471**	**$ 19,738**
(2) General and administrative reconciliation		
GAAP general and administrative	$ 4,456	$ 6,776
Less: share-based compensation expense	1,497	1,542
Non-GAAP general and administrative	**$ 2,959**	**$ 5,234**

(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.

###

IR and Media Contact:
Geoffrey Mogilner, Vice President, Investor Relations and Communications

ir@olema.com