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 9, 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.)**
512 2nd Street, 4th Floor San Francisco, California		**94107**
(Address of principal executive offices)		**(Zip Code)**

(415) 651-3316

(Registrant's Telephone Number, Including Area Code)

Not Applicable

(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 May 9, 2023, Olema Pharmaceuticals, Inc. (the "Company") reported its financial results for the quarter ended March 31, 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 May 9, 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: May 9, 2023

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

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

- *Initiation of first pivotal Phase 3 monotherapy clinical trial of OP-1250 in second- and third-line metastatic breast cancer planned for the second half of 2023*
- *Interim Phase 2 clinical results of OP-1250 in combination with palbociclib to be presented at the 2023 ESMO Breast Cancer Annual Congress on May 12, 2023*
- *Company expects to present Phase 2 monotherapy and initial ribociclib combination clinical results in the second half of 2023*
- *Cash, cash equivalents and marketable securities of $186.0 million as of March 31, 2023, expected to fund operations into 2025*

SAN FRANCISCO, May 9, 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 first quarter ended March 31, 2023, and provided a corporate update.

“We are on track for the initiation of our first pivotal Phase 3 clinical trial in the second half of this year,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “Our ongoing Phase 2 studies continue to generate data in support of our underlying thesis that OP-1250 has the potential to become a best-in-class complete estrogen receptor antagonist and improve upon the current standard of care in the treatment of ER+/HER2- metastatic breast cancer. We look forward to presenting our next clinical update at the 2023 ESMO Breast Cancer Annual Congress in mid-May, and we believe we are well-positioned to achieve our goal to significantly improve endocrine therapy for women living with breast cancer.”

Anticipated Upcoming Milestones

- Present interim Phase 2 clinical study results of OP-1250 in combination with CDK4/6 inhibitor (palbociclib) at the 2023 ESMO Breast Cancer Annual Congress in Berlin, Germany, in a poster presentation on May 12, 2023.
- Present trials-in-progress clinical study overview of OP-1250 in combination with ribociclib or alpelisib in a poster presentation at the 2023 ASCO Annual Meeting, June 2-6, 2023, in Chicago, IL.
- Initiate a pivotal Phase 3 monotherapy clinical trial in the second- and third-line setting of ER+/HER2- advanced or metastatic breast cancer in the second half of 2023.
- Present Phase 2 monotherapy clinical study results in the second half of 2023.
- Present Phase 1b clinical study results of OP-1250 in combination with CDK4/6 inhibitor (ribociclib) in the second half of 2023.

First Quarter 2023 Financial Results

Cash, cash equivalents and marketable securities as of March 31, 2023, were $186.0 million. Olema anticipates that this balance will be sufficient to fund operations into 2025.

Net loss for the quarter ended March 31, 2023, was $28.3 million, as compared to $23.0 million for same period of the prior year. The increase in net loss related primarily to Olema's continued investment in OP-1250, increased spending on research and development (R&D) activities, and personnel-related costs, including a one-time restructuring charge of $2.8 million. The increase in R&D spending was partially offset by a decrease in general and administrative (G&A) costs.

GAAP R&D expenses were $22.8 million for the quarter ended March 31, 2023, as compared to $16.0 million for the quarter ended March 31, 2022. The increase in R&D expenses was primarily related to increases in advancing ongoing clinical studies of OP-1250 and associated manufacturing costs, nonclinical research and discovery program activities, and personnel-related expenses, including a one-time restructuring charge of $1.8 million.

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. Non-GAAP R&D expenses were $12.9 million for the quarter ended March 31, 2022, respectively, excluding $3.1 million non-cash stock-based compensation expense, respectively. 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 $6.8 million for the quarter ended March 31, 2023, as compared to $7.2 million for the quarter ended March 31, 2022. The decrease in G&A expenses was primarily due to lower corporate costs, and personnel-related expenses, including non-cash stock-based compensation expense. The decrease in spending was partially offset by a one-time restructuring charge of $1.0 million.

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. Non-GAAP G&A expenses were $5.3 million for the quarter ended March 31, 2022, excluding $1.9 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 focused on the discovery, development and commercialization of targeted therapies for women's cancers. Olema's lead product candidate, 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 2 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. OP-1250 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.

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 the company’s financial condition, results of operations, cash position, the sufficiency of the company’s financial resources, potential beneficial characteristics, safety, tolerability, efficacy and therapeutic effects of OP-1250, the potential of OP-1250 to become a best-in-class treatment option for ER+/HER2- metastatic breast cancer or significantly improve endocrine therapy for women living with ER+/HER2- metastatic breast cancer, OP-1250’s combinability with other drugs, and the timelines for potential clinical study results and clinical trials of OP-1250 as a monotherapy and in combination trials. 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 Annual Report on Form 10-Q for the quarter ended March 31, 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 or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

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

	March 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 185,954	$ 204,421
Total assets	**195,768**	**215,645**
Total current liabilities	19,410	16,549
Total liabilities	20,793	18,099
Total stockholders' equity	174,975	197,546
Total liabilities and stockholders' equity	**$ 195,768**	**$ 215,645**

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

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development (1)	$ 22,826	$ 16,009
General and administrative (2)	6,776	7,245
Total operating expenses	29,602	23,254
Loss from operations	(29,602)	(23,254)
Other income:		
Interest income	1,305	218
Other income	11	6
Total other income	1,316	224
Net loss attributable to common stockholders	$ (28,286)	$ (23,030)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (0.58)
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted	40,354,493	39,834,619

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

	Three Months Ended March 31,	
	2023	2022
(1) Research and development reconciliation		
GAAP research and development	$ 22,826	$ 16,009
Less: share-based compensation expense	3,088	3,067
Non-GAAP research and development	**$ 19,738**	**$ 12,942**
(2) General and administrative reconciliation		
GAAP general and administrative	$ 6,776	$ 7,245
Less: share-based compensation expense	1,542	1,898
Non-GAAP general and administrative	**$ 5,234**	**$ 5,347**

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IR Contact:
Shane Kovacs, Chief Operating and Financial Officer
ir@olema.com

Media Contact:
Ignacio Guerrero-Ros, Ph.D., Russo Partners
646-942-5604
ignacio.guerrero-ros@russopartnersllc.com