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, 2022

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, 2022, Olema Pharmaceuticals, Inc. reported its financial results for the quarter ended March 31, 2022. 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 this 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, 2022, 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, 2022

By: /s/ John B. Moriarty, Jr.
John B. Moriarty, Jr.
Executive Vice President, Chief Legal Officer and Corporate Secretary

Olema Oncology Reports First Quarter 2022 Financial Results and Provides Corporate Update

- *Phase 1/2 trial of OP-1250 continues to enroll patients in the dose expansion stage, with selection of Recommended Phase 2 Dose expected in Q2 2022*
- *Phase 1b combination study with palbociclib ongoing; Additional combination trials with CDK4/6 and PI3Kα inhibitors planned to initiate in 2H 2022*
- *Company expects to present updated monotherapy and initial combination data in 2022*
- *Strong cash, cash equivalents, and marketable securities of $267.9 million as of March 31, 2022, sufficient to fund operations into 2024*

SAN FRANCISCO, May 9, 2022 – 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 women's cancers, today reported first quarter financial results for the period ended March 31, 2022 and provided a business update.

"Following the successful completion of the Phase 1a dose escalation portion of our trial for OP-1250 late last year, we are pleased with the continued robust enrollment we are achieving across our development program. Both our Phase 1/2 monotherapy expansion study and the Phase 1b combination trial with palbociclib are advancing, and we expect to initiate additional combination trials later this year. In parallel, we plan to evaluate OP-1250's potential in the treatment of patients with ER+/HER2+ breast cancer and CNS metastases, an important and underserved patient population with limited treatment options," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "Our knowledge and clinical experience with OP-1250 is rapidly expanding. We are fortunate to be supported by both a strong team and balance sheet as we approach potential near-term value drivers for our business. We look forward to presenting updated clinical data later this year."

Recent Corporate Highlights

- Achieved target enrollment of 30 patients in Phase 1b monotherapy dose expansion at 60 mg and 120 mg dose levels (N=15 per cohort).
- Enrolled initial dose cohorts in the dose escalation portion of the Phase 1b combination study with palbociclib and dose escalation of OP-1250 continues.
- Presented two posters at the American Association for Cancer Research (AACR) Annual Meeting, held April 8-13, 2022. Data presented showed that 10 mg/kg OP-1250, a complete estrogen receptor (ER) antagonist (CERAN), alone or in combination with

palbociclib, substantially inhibits primary tumor growth in an endocrine-resistant breast cancer model with ERα Y537S mutation. A second poster showed that OP-1250 is able to effectively reverse estradiol-induced transcriptional changes associated with the activated estrogen receptor in two ER+ cell lines, MCF7 and CAMA-1.

Anticipated Milestones

- Select the Recommended Phase 2 Dose (RP2D) for OP-1250 in the second quarter of 2022, followed by initiation of the Phase 2 portion of the trial. Phase 2 will include enrollment across three cohorts: patients with measurable disease (N=50), patients with non-measurable disease (N=15) and patients with CNS metastasis (N=15).
- Initiate additional Phase 1b combination studies with CDK4/6 and PI3Kα inhibitors in 2022.
- Initiate Phase 1b study of OP-1250 in patients with ER+/HER2+ breast cancer and CNS metastases in the second half of 2022.
- Present updated monotherapy and initial combination data for OP-1250.

Financial Results

- Cash, cash equivalents and marketable securities as of March 31, 2022, were $267.9 million. Olema anticipates that this balance will be sufficient to fund operations into 2024.
- Net loss for the quarter ended March 31, 2022, was $23.0 million, compared to $15.3 million for the same period of the prior year. The increase in net loss related primarily to Olema's continued investment in OP-1250, and an increase in general and administrative (G&A) costs.
- GAAP research and development (R&D) expenses were $16.0 million for the quarter ended March 31, 2022, compared to $10.7 million for the same period of the prior year. The increase in R&D expenses was primarily related to the advancement of the development program for OP-1250, increase in nonclinical development activities, and higher personnel-related expenses, including non-cash stock-based compensation expenses. Non-GAAP R&D expenses were $12.9 million for the quarter ended March 31, 2022, excluding $3.1 million non-cash stock-based compensation expense. Non-GAAP R&D expenses were $9.0 million for the quarter ended March 31, 2021, excluding $1.7 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 news release.
- GAAP G&A expenses were $7.2 million for the quarter ended March 31, 2022, as compared to $4.8 million for the same period of the prior year. The increase in G&A expenses was primarily related to higher personnel-related expenses, including non-cash stock-based compensation expenses, and other corporate costs. 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. Non-GAAP G&A expenses were $3.3 million for the quarter ended March 31, 2021, excluding $1.5 million non-cash stock-based compensation expense.

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 an orally-available small molecule with combined activity as both a complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD). It is currently being evaluated as a single agent in an ongoing Phase 1/2 clinical trial, and in Phase 1b combination with palbociclib, in patients with recurrent, locally advanced, or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. 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 research and development expense is defined by Olema as GAAP research and development expense excluding stock-based compensation expense, and non-GAAP general and administrative expense is defined by Olema as GAAP general and administrative 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," "expect,"

“intend,” “will,” “may,” “goal,” “estimate,” “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 development of OP-1250, both as a monotherapy and in combination trials, including timelines related to data presentation, trial initiation and advancement, and enrollment, the beneficial characteristics, safety, efficacy and therapeutic effects of OP-1250, as well as the sufficiency of our financial resources. 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, the risk that Olema’s ongoing or future clinical studies in humans may show that OP-1250 is not a tolerable and effective treatment for breast cancer and other risks and uncertainties affecting Olema, as well as those discussed in the section titled “Risk Factors” in Olema’s Annual Report on Form 10-Q for the quarter ended March 31, 2022 to be filed on May 9, 2022 and future filings and reports that Olema makes from time to time with the United States 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, 2022	December 31, 2021
	(Unaudited)	*(*)*
Cash, cash equivalents and marketable securities	$ 267,867	$ 287,250
Total assets	**$ 277,418**	**$ 295,945**
Total current liabilities	$ 10,168	$ 9,019
Total liabilities	$ 12,328	$ 11,377
Total stockholders’ equity	$ 265,090	$ 284,568
Total liabilities and stockholders’ equity	**$ 277,418**	**$ 295,945**

(*) Derived from audited financial statements

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

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	
Operating expenses:		
Research and development (1)	$ 16,009	$ 10,692
General and administrative (2)	7,245	4,758
Total operating expenses	23,254	15,450
Loss from operations	(23,254)	(15,450)
Other income:		
Interest income	218	111
Other income	6	-
Total other income	224	111
Net loss	$ (23,030)	$ (15,339)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.58)	$ (0.39)
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted	39,834,619	39,325,793

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

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	
(1) Research and development reconciliation		
GAAP research and development	$ 16,009	$ 10,692
Less: share-based compensation expense	3,067	1,734
Non-GAAP research and development	**$ 12,942**	**$ 8,958**
(2) General and administrative reconciliation		
GAAP general and administrative	$ 7,245	$ 4,758
Less: share-based compensation expense	1,898	1,474
Non-GAAP general and administrative	**$ 5,347**	**$ 3,284**

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