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): August 9, 2022

Olema Pharmaceuticals, Inc.

s(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 August 9, 2022, Olema Pharmaceuticals, Inc. (the "Company") reported its financial results for the quarter ended June 30, 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.

Item 7.01 Regulation FD Disclosure.

On August 9, 2022, the Company issued a press release titled "Olema Oncology Advances OP-1250 into Phase 2 Monotherapy Expansion in Patients with ER+/HER2- Advanced Breast Cancer." A copy of the press release is furnished pursuant to item 7.01 as Exhibit 99.2 and is incorporated herein by reference.

The information in Item 2.02, including the press release attached as Exhibit 99.1 hereto, and in item 7.01, including the press release attached as Exhibit 99.2 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 August 9, 2022, of Olema Pharmaceuticals, Inc.
99.2	Press release, dated August 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: August 9, 2022

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

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

- *Received Fast Track designation from U.S. FDA for OP-1250 for the treatment of ER+/HER2- metastatic breast cancer*
- *Reported progress across OP-1250 clinical development program, including selection of the recommended Phase 2 dose, initiation of Phase 2 monotherapy enrollment, and continued dose escalation in Phase 1b combination with palbociclib*
- *Company expects to present updated monotherapy and initial combination data in Q4 2022*
- *Strong cash, cash equivalents and marketable securities position of $240.7 million as of June 30, 2022, sufficient to support execution of clinical, research and operational goals into the second half of 2024*

SAN FRANCISCO, August 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 second quarter financial results for the period ended June 30, 2022, and provided a business update.

"Our objective is for OP-1250 to become the endocrine therapy of choice for ER+ breast cancer and, based on the progress we are making across the program and receipt of Fast Track designation from FDA, we believe we are well on our way toward achieving that goal. Our enrollment continues to be robust and the emerging data show a favorable tolerability profile, encouraging early anti-tumor activity, and combinability with palbociclib," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "As we continue to generate more data, OP-1250 is revealing its potential, validating our confidence to move ahead our next set of trials and preparing for a pivotal monotherapy study next year. We are well capitalized into the second half of 2024, and we look forward to presenting more data as the year progresses."

Recent Corporate Highlights

- Received Fast Track designation from the U.S. Food and Drug Administration (FDA) for OP-1250 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. A drug candidate that receives Fast Track designation is eligible for more frequent communication with the FDA throughout the drug development process for the purpose of expediting the drug's development, review and potential approval.
- Announced interim data from Phase 1b monotherapy expansion of OP-1250 for ER+/HER2- breast cancer.

- Based on pharmacokinetics, safety and tolerability, and encouraging early anti-tumor activity in Phase 1b monotherapy expansion, 120 mg once-daily dosing of OP-1250 was selected as the recommended Phase 2 dose (RP2D).
- Following the selection of RP2D, Phase 2 enrollment continues and will include three cohorts: patients with measurable disease (N=50), patients with non-measurable disease (N=15) and patients with CNS metastasis (N=15).
- Dose escalation in the Phase 1b combination study with the CDK4/6 inhibitor palbociclib continues, with evaluation at 120 mg OP-1250 ongoing. Combinability has been demonstrated across the completed dose escalation cohorts (30 mg, 60 mg and 90 mg OP-1250), including no dose limiting toxicities, no induced metabolism of palbociclib, and overall tolerability consistent with expected profile of palbociclib plus an endocrine therapy.
- Announced an exclusive global license agreement with Aurigene Discovery Technologies Limited (Aurigene) to research, develop and commercialize novel small molecule inhibitors of an undisclosed oncology target.

Anticipated Milestones

- Initiate a Phase 1b combination study with each of ribociclib, a CDK4/6 inhibitor, and alpelisib, a PI3Kα inhibitor, in the third quarter of 2022.
- Present updated monotherapy and initial combination data with palbociclib at medical meetings in the fourth quarter of 2022, pending abstract acceptance.
- Initiate a pivotal monotherapy study in second-line or later settings in mid-2023.
- Present additional monotherapy and combination data in 2023.

Financial Results

- Cash, cash equivalents and marketable securities as of June 30, 2022, were $240.7 million. Olema anticipates that this balance will be sufficient to fund operations into the second half of 2024.
- Net loss for the quarter ended June 30, 2022, was $32.9 million, compared to $16.4 million for the 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 activities, including the $8.0 million upfront payment to Aurigene, and an increase in general and administrative (G&A) costs.
- GAAP research and development (R&D) expenses were $27.1 million for the quarter ended June 30, 2022, compared to $11.9 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 and an increase in nonclinical research and discovery program activities, including the $8.0 million upfront payment to Aurigene. Non-GAAP R&D expenses were $23.9 million for the quarter ended June 30, 2022, excluding $3.2 million of non-cash stock-based compensation expense. Non-GAAP

R&D expenses were $9.6 million for the quarter ended June 30, 2021, excluding $2.3 million of 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 $6.2 million for the quarter ended June 30, 2022, as compared to $4.6 million for the same period of the prior year. The increase in G&A expenses was primarily related to higher personnel-related expenses and other corporate costs. Non-GAAP G&A expenses were $4.7 million for the quarter ended June 30, 2022, excluding $1.5 million of non-cash stock-based compensation expense. Non-GAAP G&A expenses were $3.0 million for the quarter ended June 30, 2021, excluding $1.6 million of 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 a Phase 1b combination trial 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 June 30, 2022 to be filed on August 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)

	June 30, 2022	December 31, 2021
	(Unaudited)	*(*)*
Cash, cash equivalents and marketable securities	$ 240,711	$ 287,250
Total assets	**$ 250,600**	**$ 295,945**
Total current liabilities	$ 12,308	$ 9,019
Total liabilities	$ 14,317	$ 11,377
Total stockholders' equity	$ 236,283	$ 284,568
Total liabilities and stockholders' equity	**$ 250,600**	**$ 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Operating expenses:				
Research and development (1) (3)	$ 27,054	$ 11,910	$ 43,063	$ 22,602
General and administrative (2)	6,239	4,612	13,484	9,370
Total operating expenses	33,293	16,522	56,547	31,972
Loss from operations	(33,293)	(16,522)	(56,547)	(31,972)
Other income (expense):				
Interest income	415	117	633	228
Other income (expense)	20	(1)	26	(1)
Total other income	435	117	659	227
Net loss	$ (32,858)	$ (16,405)	$ (55,888)	$ (31,745)
Net loss per share, basic and diluted	$ (0.82)	$ (0.42)	$ (1.40)	$ (0.81)
Weighted average shares used to compute net loss per share, basic and diluted	39,918,219	39,415,330	39,876,650	39,370,809

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
(1) Research and development reconciliation				
GAAP research and development (3)	$ 27,054	$ 11,910	$ 43,063	$ 22,602
Less: share-based compensation expense	3,211	2,288	6,278	4,022
Non-GAAP research and development	**$ 23,843**	**$ 9,622**	**$ 36,785**	**$ 18,580**
(2) General and administrative reconciliation				
GAAP general and administrative	$ 6,239	$ 4,612	$ 13,484	$ 9,370
Less: share-based compensation expense	1,517	1,633	3,415	3,107
Non-GAAP general and administrative	**$ 4,722**	**$ 2,979**	**$ 10,069**	**$ 6,263**

(3) Research and development expenses include $8.0 million upfront payment in connection to the Aurigene Agreement during the three- and six-months periods ended June 30, 2022.

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Contact:
Eva Stroynowski
Vice President, Communications and Investor Relations
eva@olema.com

Olema Oncology Advances OP-1250 into Phase 2 Monotherapy Expansion in Patients with ER+/HER2- Advanced Breast Cancer

SAN FRANCISCO, August 9, 2022 – Olema Pharmaceuticals, Inc. ("Olema" or "Olema Oncology," Nasdaq: OLMA), today announced the advancement of OP-1250, a complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD), into Phase 2 clinical development for the treatment of ER+/HER2- metastatic breast cancer.

"We are excited about the potential of OP-1250 and are expeditiously advancing the development program as we work to further position OP-1250 as a differentiated CERAN and potential endocrine therapy of choice for ER+ breast cancer." said Naseem Zojwalla, M.D., Chief Medical Officer of Olema Oncology. "Enrollment is underway in Phase 2 monotherapy, and we look forward to further evaluating OP-1250's benefit in treating ER+/HER2- breast cancer patients."

Selection of the recommended Phase 2 dose (RP2D) of 120 mg OP-1250 once-daily was based on pharmacokinetics, safety and tolerability, and encouraging early anti-tumor activity from Phase 1b expansion, which evaluated both 60 mg and 120 mg dose cohorts. As of July 1, 2022, a total of 50 patients had been treated in Phase 1b expansion (N=25 for each cohort).

- Pharmacokinetic analyses demonstrated dose-proportional exposure of OP-1250, high oral bioavailability, and steady-state plasma levels with minimal peak-to-trough variability.
- The majority of reported adverse events were Grade 1 or 2 at both dose levels, and the most common treatment-emergent adverse events occurring in ≥10% of patients were nausea, vomiting, fatigue, and headache, which were similar across both doses.
- Two cases of Grade 4 and one case of Grade 3 neutropenia have been observed in patients in the 120 mg cohort of the Phase 1b expansion. One patient with Grade 4 neutropenia paused treatment for one week, restarted at a lower dose and subsequently had an unconfirmed partial response at the first scan. A second patient had Grade 4 febrile neutropenia with no evidence of infection. The patient discontinued treatment and remains off-study. Concurrent with disease progression at 8 weeks, a third patient had Grade 3 neutropenia, which has since resolved.
- Encouraging early anti-tumor activity continued to be observed, with a total of 4 partial responses in 31 efficacy-evaluable patients in the Phase 1b expansion as of July 1, 2022 (1 confirmed partial response at 60 mg and 3 unconfirmed partial responses, pending confirmation at a subsequent scan, at 120 mg).

Phase 2 enrollment continues and will include three cohorts: patients with measurable disease (N=50), patients with non-measurable disease (N=15), and patients with CNS metastasis (N=15). Olema plans to initiate a pivotal monotherapy trial in mid-2023.

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