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 10, 2021

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 November 10, 2021, Olema Pharmaceuticals, Inc. reported its financial results for the quarter ended September 30, 2021. 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 November 10, 2021, of Olema Pharmaceuticals, Inc.

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 10, 2021

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

Olema Oncology Reports Third Quarter 2021 Financial Results and Provides Corporate Update

- *Completed dose-escalation stage of Phase 1/2 clinical trial of OP-1250 in patients with metastatic, ER+ / HER2- breast cancer*
- *Interim safety, tolerability, pharmacokinetic and initial efficacy data from Phase 1 dose escalation to be presented at 2021 San Antonio Breast Cancer Symposium*
- *Phase 1b dose expansion to initiate by year-end 2021; Phase 2 to initiate in Q1 2022*
- *First planned clinical study in combination with CDK4/6 inhibitor to initiate in Q1 2022*

SAN FRANCISCO, November 10, 2021 – 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 provided an update on recent company developments and reported third quarter financial results for the period ended September 30, 2021.

"Our team has made great progress advancing OP-1250 through the dose escalation portion of our ongoing Phase 1/2 clinical trial and we look forward to presenting interim pharmacokinetic, safety, tolerability and initial efficacy data at the San Antonio Breast Cancer Symposium in December," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "We are encouraged by the emerging clinical profile of OP-1250 and plan to initiate Phase 2 monotherapy expansion as well as the first planned Phase 1b combination trial with a CDK4/6 inhibitor in the first quarter of 2022."

"OP-1250 has the potential to be a differentiated, best-in-class complete estrogen receptor (ER) antagonist (CERAN) that we believe could become the backbone endocrine therapy of choice for ER+ breast cancer. As we enroll more patients, we look forward to generating additional clinical data in support of OP-1250's use both as monotherapy and in combination with other approved breast cancer treatments," continued Dr. Bohen.

Recent Corporate Highlights

- Completed dose escalation in the ongoing Phase 1/2 study of OP-1250 in patients with metastatic, ER+ / HER2- breast cancer.
- Selected the OP-1250 starting dose and initiated preparations for the first planned combination study with a CDK4/6 inhibitor.
- Presented new nonclinical data on OP-1250 at the 1st JCA-AACR Precision Cancer Medicine International Conference held virtually from September 10-12, 2021 (U.S.)

and September 11-12, 2021 (Japan). The poster presentation reviewed a series of nonclinical assessments Olema conducted on a panel of antiestrogens with known chemical structures to evaluate their ability to inhibit ER activity, block breast cancer proliferation and degrade ER receptors.

- Presented a Trials-in-Progress poster at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, held virtually from October 7-10, 2021. The poster reviewed the design of Olema's ongoing Phase 1/2 open-label, first-in-human, multicenter, dose-escalation and dose-expansion study evaluating OP-1250 monotherapy in adult subjects with recurrent, locally advanced or metastatic ER+ / HER2- breast cancer (NCT04505826).
- Expanded Olema's operational footprint with the opening of new office space in Cambridge, Massachusetts.

Anticipated Milestones

- Present interim Phase 1 monotherapy dose escalation data at the 2021 San Antonio Breast Cancer Symposium.
- Initiate dose expansion by year-end with up to two doses. Each cohort will enroll approximately 15 patients with measurable disease, and findings will help inform the selection of a recommended Phase 2 dose (RP2D).
- Initiate Phase 2 in the first quarter of 2022. Preliminary anti-tumor efficacy will be assessed across three cohorts: patients with measurable disease (N=50), patients with non-measurable disease (N=15) and patients with CNS metastasis (N=15).
- Initiate the first Phase 1b clinical trial of OP-1250 in combination with a CDK4/6 inhibitor in the first quarter of 2022.

Financial Highlights

- Cash, cash equivalents and marketable securities as of September 30, 2021 were $306.0 million. Olema anticipates that this balance of cash will be sufficient to fund operations through the end of 2023.

- Net loss for the quarter ended September 30, 2021 was $17.7 million, compared to $7.8 million for the same period of the prior year.

- Research and development (R&D) expenses were $12.5 million for the quarter ended September 30, 2021, compared to $4.7 million for the same period of the prior year. The increase in R&D expenses was primarily related to the advancement of the ongoing Phase 1/2 clinical trial of OP-1250, increase in nonclinical development activities, higher personnel-related expenses and higher non-cash stock-based compensation expenses.

- General and administrative (G&A) expenses were $5.2 million for the quarter ended September 30, 2021, compared to $3.2 million for the same period of the prior year. The increase in G&A expenses was primarily related to an increase in personnel, public company-related expenses, other corporate costs and higher non-cash stock-based compensation expenses.

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 in patients with recurrent, locally advanced or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. Olema is based in San Francisco and has operations in Cambridge, Massachusetts.

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, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 to be filed on November 10, 2021 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)

	September 30, 2021	December 31, 2020
	(Unaudited)	*(Audited)*
Cash, cash equivalents and marketable securities	$ 305,954	$ 338,549
Total assets	**$ 309,795**	**$ 342,722**
Total liabilities	$ 8,901	$ 4,585
Total stockholders' equity	$ 300,894	$ 338,137
Total liabilities and stockholders' equity	**$ 309,795**	**$ 342,722**

Olema Pharmaceuticals, Inc.
Condensed consolidated statements of operations and comprehensive loss
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 12,523	$ 4,673	$ 35,125	$ 7,415
General and administrative	5,239	3,195	14,609	3,982
Total operating expenses (1)	17,762	7,868	49,734	11,397
Loss from operations	(17,762)	(7,868)	(49,734)	(11,397)
Other income (expense):				
Interest income	105	23	333	59
Interest expense	—	—	—	(653)
Other income (expense)	(56)	1	(57)	1
Total other income (expense), net	49	24	276	(593)
Net loss	$ (17,713)	$ (7,844)	$ (49,458)	$ (11,990)
Repurchase and retirement of Series A and Series A-1 convertible preferred stock	—	(1,869)	—	(1,869)
Net loss attributable to common stockholders	$ (17,713)	$ (9,713)	$ (49,458)	$ (13,859)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.45)	$ (3.71)	$ (1.25)	$ (5.29)
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted	39,607,745	2,617,543	39,450,655	2,617,543

(1) Total operating expenses includes the following non-cash stock-based compensation expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 2,405	$ 392	$ 6,427	$ 495
General and administrative	1,752	190	4,859	241
Total	$ 4,157	$ 582	$ 11,286	$ 736

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