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): December 05, 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)**	**(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 7.01 Regulation FD Disclosure.

On December 5, 2023, Olema Pharmaceuticals, Inc. (the "Company") announced interim results from an ongoing Phase 1b/2 clinical study of palazestrant (OP-1250) in combination with CDK4/6 inhibitor ribociclib, interim Phase 2 clinical data of palazestrant in combination with CDK4/6 inhibitor palbociclib, and a trials-in-progress poster for the OPERA-01 monotherapy Phase 3 pivotal trial. A copy of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

As described above, on December 5, 2023, the Company announced interim results from an ongoing Phase 1b/2 clinical study of palazestrant in combination with CDK4/6 inhibitor ribociclib, interim Phase 2 clinical data of palazestrant in combination with palbociclib, and a trials-in-progress poster for the OPERA-01 monotherapy Phase 3 pivotal trial. These results will be presented at the San Antonio Breast Cancer Symposium ("SABCS") at the Henry B. Gonzalez Convention Center in San Antonio, Texas on December 7, 2023.

Palazestrant Phase 1b/2 Study in Combination with Ribociclib

A poster titled "A Phase 1b/2 study of palazestrant (OP-1250) in combination with ribociclib in patients with estrogen receptor-positive, human epidermal growth factor receptor 2-negative, advanced and/or metastatic breast cancer" will be presented at SABCS. A more recent data cut, as of November 1, 2023, highlights the following:

- Across 19 patients who had completed at least one cycle of treatment as of the data cutoff date, the combination of up to 120 mg of palazestrant with 600 mg of ribociclib daily was well tolerated, with no safety signals or enhancement of toxicity and an overall safety profile remains consistent with the expected safety profile of ribociclib plus an endocrine therapy.
- Palazestrant did not affect ribociclib drug exposure in patients, and ribociclib had no clinically meaningful effect on palazestrant drug exposure.
- There were no dose-limiting toxicities, the maximum tolerated dose was not reached, and the majority of treatment-emergent adverse events were grade 1 or 2, with no grade 4 events observed. Neutropenia was reversible in all patients, and the timing was generally consistent with ribociclib-related neutropenia.
- Findings from this study support the continued use of palazestrant at the recommended Phase 2 dose of 120 mg in combination with 600mg of ribociclib, and enrollment in the dose-expansion portion of the study is ongoing.

The Company anticipates a potential initiation of a Phase 3 clinical trial of palazestrant in combination with ribociclib as early as the end of 2024.

Palazestrant Phase 1b/2 Study in Combination with Palbociclib

A poster titled "A Phase 1b/2 study of palazestrant (OP-1250), an oral complete estrogen receptor antagonist (CERAN) and selective ER degrader (SERD), with palbociclib in ER-positive, HER2-negative, advanced or metastatic breast cancer patients", will be presented in a Poster Spotlight Session by Prof. Arlene Chan, FRACP, MMed, Breast Cancer Research Centre-WA, Curtin University, Breast Clinical Trials Unit, Hollywood Private Hospital, Nedlands, Australia. The presentation will highlight that:

- Across 46 patients as of the cutoff date of September 15, 2023, the combination of palazestrant (120 mg) with palbociclib (125 mg) daily was well tolerated, with an overall safety profile consistent with the expected safety profile of palbociclib plus an endocrine therapy.
- There was no observed drug-drug interaction between palazestrant and palbociclib, and there was no induced metabolism or increase in exposure of either palbociclib or palazestrant when administered in combination. Most treatment-emergent adverse events were grade 1 or 2. Neutropenia incidence was similar to the PALOMA-3 study; it was reversible in all patients and the timing was generally consistent with the palbociclib-related neutropenia.
- Tumor responses and prolonged disease stabilization were observed in this patient group, including in those previously exposed to CDK4/6 inhibitors, in both ESR1 mutant and ESR1 wild-type tumors. Partial responses were observed in seven patients, with two confirmed partial responses and five unconfirmed partial responses. The clinical benefit rate was

46% in all patients and 60% in patients with an ESR1 mutation at baseline. In patients naïve to prior CDK4/6 inhibitor treatment, the CBR was 71%. 53% of patients had any reduction in target lesion size.

- Twenty-two (48%) patients remain on treatment, and efficacy data are still maturing. Findings from this study are consistent with previously reported data and support the ongoing clinical development of palazestrant in combination with CDK4/6 inhibitors for the treatment of ER+/HER2− metastatic breast cancer.

OPERA-01 Phase 3 Monotherapy Trial

Olema will present a poster titled "OPERA-01: A randomized, open-label, phase 3, study of palazestrant (OP-1250) vs standard-of-care treatment for ER+, HER2- advanced or metastatic breast cancer after endocrine and CDK4/6 inhibitor therapy", that details the ongoing clinical trial design, inclusion/exclusion criteria, and trial endpoints.

Forward Looking Statements

Statements contained in this Current Report on Form 8-K 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 potential beneficial characteristics, safety, tolerability, efficacy, and therapeutic effects of palazestrant, the development of palazestrant, the initiation and timing of clinical trials, and palazestrant's combinability with other drugs. 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 September 30, 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, including in the event that actual results differ materially from those anticipated in the forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated December 5, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Olema Pharmaceuticals, Inc.

Date: December 5, 2023

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

Olema Oncology Announces Palazestrant Demonstrates Attractive Combinability with CDK4/6 Inhibitors Ribociclib and Palbociclib in Phase 1b/2 Studies

- *Palazestrant (OP-1250) in combination with the CDK 4/6 inhibitors, ribociclib and palbociclib, demonstrated no significant drug-drug interaction, no dose-limiting toxicities and a tolerability profile consistent with the FDA-approved labels of ribociclib or palbociclib plus an endocrine therapy*
- *OPERA-01 trials-in-progress poster outlines Phase 3 trial design; clinical sites activated and enrolling with first patient dosed in November 2023*
- *Olema will host an investor conference call at 8:00 a.m. ET on December 6, 2023*

SAN FRANCISCO, December 5, 2023 – 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 announced interim results from an ongoing Phase 1b/2 clinical study of palazestrant (OP-1250) in combination with CDK4/6 inhibitor ribociclib, a Poster Spotlight Session on interim Phase 2 clinical data of palazestrant in combination with palbociclib, and a trials-in-progress poster for the OPERA-01 monotherapy Phase 3 pivotal trial at the San Antonio Breast Cancer Symposium (SABCS) at the Henry B. Gonzalez Convention Center in San Antonio, Texas. This disclosure was originally planned for December 7, 2023. However, on December 5, 2023, the 2023 San Antonio Breast Cancer Symposium (SABCS) published the posters ahead of schedule. These full data are scheduled to be presented on December 7, 2023, and copy of the posters are available now on Olema’s website under the Science section.

“We believe the results we are presenting at SABCS demonstrate that palazestrant has key characteristics that make it a potential best-in-class endocrine therapy for ER+/HER2- breast cancer: complete antagonism of the estrogen receptor, favorable tolerability and tumor response, and attractive combinability with CDK4/6 inhibitors,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “OPERA-01, our Phase 3 monotherapy pivotal trial of palazestrant, has initiated, with multiple trial sites now activated and patient dosing started. The data we are gathering in our Phase 2 combination studies with CDK4/6 inhibitors, ribociclib and palbociclib, support the potential initiation of a pivotal first-line combination trial as early as the end of 2024, bringing us closer to achieving our goal of transforming the standard of care for women’s cancers.”

Palazestrant Phase 1b/2 Study in Combination with Ribociclib: A poster titled “A Phase 1b/2 study of palazestrant (OP-1250) in combination with ribociclib in patients with estrogen receptor-positive, human epidermal growth factor receptor 2-negative, advanced and/or metastatic breast cancer” will be presented at SABCS. A more recent data cut, as of November 1, 2023, highlights the following:

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- There were no dose-limiting toxicities, the maximum tolerated dose was not reached, and the majority of treatment-emergent adverse events were grade 1 or 2, with no grade 4 events observed. Neutropenia was reversible in all patients, and the timing was generally consistent with ribociclib-related neutropenia.
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OPERA-01 Phase 3 Monotherapy Trial: Olema will present a poster titled “OPERA-01: A randomized, open-label, phase 3, study of palazestrant (OP-1250) vs standard-of-care treatment for ER+, HER2- advanced or metastatic breast cancer after endocrine and CDK4/6 inhibitor therapy”, that detailed the ongoing clinical trial design, inclusion/exclusion criteria, and trial endpoints. Please find more details at www.opera-01.com or at clinicaltrials.gov (NCT06016738).

Company Investor Webcast and Conference Call

Olema will host a webcast and conference call for analysts and investors to review data presented at SABCS 2023 as well as other ongoing studies tomorrow, Wednesday, December 6, 2023, at 8:00 a.m. ET (7:00 a.m. CT). Please register for the webcast by visiting the Investors & Media section of Olema’s website at olema.com.

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, palazestrant (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 3 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. Palazestrant 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. For more information, please visit us at www.olema.com.

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 potential beneficial characteristics, safety, tolerability, efficacy, and therapeutic effects of palazestrant, the development of palazestrant, the initiation and timing of clinical trials, palazestrant’s combinability with other drugs, the potential of palazestrant to become a best-in-class endocrine therapy in the treatment of ER+/HER2- metastatic breast cancer or transform the standard of care treatments for women living with ER+/HER2- metastatic breast cancer. 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 September 30, 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, including in the event that actual results differ materially from those anticipated in the forward-looking statements.

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Contact:
Geoffrey Mogilner, Vice President, Investor Relations and Communications
ir@olema.com