**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): October 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.)** |
| **780 Brannan Street**<br>**San Francisco, California** | | **94103** |
| **(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 1.01 Entry into a Material Definitive Agreement.**

On October 9, 2023, Olema Pharmaceuticals, Inc. (the "Company") entered into an Amendment No. 1 to Amended and Restated Clinical Collaboration and Supply Agreement (the "Amendment") with Novartis Institutes for BioMedical Research, Inc. ("Novartis"). The Amendment, among other things, increases the size of the dose expansion phase of the Company's ongoing Phase 1/2 clinical study testing palazestrant (OP-1250) in combination with ribociclib from 30 patients to approximately 60 patients.

A copy of the Amendment is filed as Exhibit 10.1 to this Current Report on Form 8-K.

**Item 7.01 Regulation FD Disclosure.**

On October 10, 2023, the Company issued a press release announcing its entry into the Amendment. A copy of the press release is furnished hereto as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 10.1 | Amendment No. 1 to Amended and Restated Clinical Collaboration and Supply Agreement, by and between the Company and Novartis Institutes for BioMedical Research, Inc., dated October 9, 2023. |
| 99.1 | Press release, dated October 10, 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: October 10, 2023

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

**Amendment No. 1 to Amended and Restated Clinical Collaboration and Supply Agreement**

Reference is hereby made to the Clinical Collaboration and Supply Agreement, dated July 22, 2020, as amended via the Amended and Restated Clinical Collaboration and Supply Agreement, dated January 13, 2022 (collectively the "**Agreement**"), by and between Olema Pharmaceuticals, Inc., a Delaware corporation, having a place of business at 780 Brannan Street, San Francisco, CA 94103 ("**Olema**"), and Novartis Institutes for BioMedical Research, Inc., a Delaware corporation, having a place of business at 181 Massachusetts Avenue, Cambridge, MA 02139 ("**Novartis**").

WHEREAS, Olema and Novartis (each, a "**Party**" and collectively, the "**Parties**") entered into the Agreement for the purpose of setting forth the Parties' respective rights and obligations in connection with the performance of a Combined Therapy Clinical Trial;

WHEREAS, the Parties hereby wish to amend the Development Plan and Protocol Synopsis to add an additional 30 patients to be enrolled in the dose expansion phase of the palazestrant (OP-1250) in combination with ribociclib study arm in the Combined Therapy Clinical Trial, and make such other changes to the Agreement as set forth via this Amendment No. 1 to Amended and Restated Clinical Collaboration and Supply Agreement (the "**Amendment No. 1**");

NOW THEREFORE, in consideration of the premises and the mutual covenants herein contained, the Parties mutually agree as follows:

1. The Development Plan in Appendix A of the Agreement is hereby deleted in its entirety and replaced with Exhibit A to this Amendment No. 1. All references to the Development Plan in the Agreement shall be deemed to reference the Development Plan set forth in Exhibit A hereto.

2. The Protocol Synopsis in Appendix D of the Agreement is hereby deleted in its entirety and replaced with Exhibit B to this Amendment No. 1. All references to the Protocol Synopsis in the Agreement shall be deemed to reference the Protocol Synopsis set forth in Exhibit B hereto.

This Amendment No. 1 is effective as of October 9, 2023 (the "**Amendment No. 1 Effective Date**"), such that the Agreement will be deemed to be in continuous force and effect, and will be deemed to be an integral part of the Agreement. Any initially capitalized terms not otherwise defined herein shall have the meanings given in the Agreement. Except as expressly amended hereby, all terms of the Agreement shall remain unchanged and in full force and effect. This Amendment No. 1 may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Amendment No. 1 may be executed by facsimile or electronic (e.g., pdf) signatures and such signatures shall be deemed to bind each Party hereto as if they were original signature. This

Amendment No. 1 shall be governed and construed in accordance with the internal laws of the State of New York, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

*[Signature Page Follows]*

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement to become effective as of the Amendment Effective Date.

**NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.**

By: /s/ Alice Shaw
Name: Alice Shaw
Title: Global Head, TCO

**OLEMA PHARMACEUTICALS, INC.**

By: /s/ Sean Bohen
Name: Sean Bohen
Title: CEO and President

**DEVELOPMENT PLAN**

**[***]**

**PROTOCOL SYNOPSIS**

**[***]**

# Olema Oncology Announces Expansion of Collaboration Agreement with Novartis

*Amended clinical collaboration and supply agreement increases the palazestrant/ribociclib combination Phase 1/2 clinical study size to approximately 60 patients*

*Expanded study supports the potential late-stage development of palazestrant in first-line advanced or metastatic breast cancer in combination with ribociclib*

**SAN FRANCISCO,** October 10, 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 an amendment to our existing clinical collaboration and supply agreement with Novartis Institutes for BioMedical Research, Inc. ("Novartis") to increase the size of the ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib to approximately 60 patients.

"The amendment announced today significantly increases the size of our ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib, in collaboration with Novartis," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "With the Phase 1b dose escalation portion now successfully completed, we are currently in Phase 2 dose expansion at the 120 mg dose of palazestrant in combination with 600 mg of ribociclib. We believe that this expanded study now has the potential to generate a clinical dataset sufficient to support the regulatory pathway for a first-line pivotal trial."

Olema first signed a clinical collaboration and supply agreement with Novartis in July 2020, the agreement was amended and restated in January 2022, and focuses on the evaluation of the safety, tolerability and efficacy of palazestrant in combination with Novartis' proprietary cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitor ribociclib and/or Novartis' proprietary phosphatidylinositol 3-kinase (PI3Ka) inhibitor alpelisib in patients with metastatic ER+ breast cancer. The amendment adds approximately 30 patients to be enrolled in the cohort expansion phase of the palazestrant clinical study in combination with ribociclib.

**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 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. 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, or follow us on Twitter and LinkedIn.

**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 timelines for potential clinical trials of palazestrant (OP-1250) in combination trials, the potential impact and sufficiency of clinical trial results for clinical trial timelines for palazestrant in combination trials, palazestrant’s combinability with other drugs, patient enrollment, and statements regarding Olema’s partnerships and collaborations. 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 June 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:
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