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): January 08, 2024

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 January 8, 2024, Olema Pharmaceuticals, Inc. (the "Company") announced the selection of a development candidate for the Company's program targeting KAT6, an epigenetic target that is dysregulated in breast cancer and other cancers. 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 January 8, 2024, the Company announced the selection of a development candidate for the Company's program targeting KAT6, an epigenetic target that is dysregulated in breast cancer and other cancers. The compound, named OP-3136, is an orally bioavailable, potent KAT6A/B-selective inhibitor developed by Olema in collaboration with Aurigene Oncology ("Aurigene").

The Company presented data regarding the discovery and pre-clinical development of its KAT6 program in a poster session at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston, Massachusetts. OP-3136 is orally bioavailable in multiple non-clinical species with desirable pharmacokinetics and has demonstrated highly selective and potent activity against KAT6A and KAT6B versus other KAT family members. In KAT6-amplified and overexpressing estrogen receptor-positive ("ER+") breast cancer cell lines, OP-3136 strongly inhibited cell proliferation whereas KAT6-low cell lines were insensitive to the compounds. In a non-clinical xenograft model, OP-3136 caused dose-dependent tumor growth inhibition and tumor regression comparable to or better than a positive-control patented KAT6 inhibitor and demonstrated synergy in combination with CDK4/6 inhibitors or palazestrant (OP-1250).

Olema is initiating non-clinical Investigational New Drug ("IND") enabling studies in order to support a potential IND submission to the U.S. Food and Drug Administration for OP-3136 by the end of 2024.

Pursuant to the Drug Discovery Collaboration and License Agreement by and between the Company and Aurigene, dated as of June 7, 2022, the Company will make a $5,000,000 milestone payment to Aurigene upon the initiation of IND-enabling studies.

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 Olema's preclinical program, including the potential beneficial characteristics and potency of its KAT6 inhibitor compound and its applicability to breast and other cancers, the potential synergistic activity of Olema's KAT6 inhibitor compounds with CDK4/6 inhibitors or palazestrant (OP-1250), anticipated timing of an IND submission and development of OP-3136. 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 January 8, 2024, 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: January 8, 2024

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

Olema Oncology Nominates OP-3136, an Orally Bioavailable KAT6 Inhibitor, as a Development Candidate

OP-3136 demonstrated potent anti-tumor activity alone and in combination with both palazestrant and CDK4/6 inhibitors in preclinical ER+ breast cancer models

Initiating IND-enabling studies with goal to advance into clinical development by end of 2024

SAN FRANCISCO, Jan. 08, 2024 – Olema Pharmaceuticals, Inc. (“Olema”, “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 the selection of a development candidate for the Company’s program targeting KAT6, an epigenetic target that is dysregulated in breast cancer and other cancers. The compound, named OP-3136, is an orally bioavailable, potent KAT6A/B-selective inhibitor developed by Olema in collaboration with Aurigene Oncology.

“We are excited to advance our KAT6 program with the nomination of OP-3136 as a development candidate. OP-3136 has the potential to become a new targeted therapy for breast cancer and other cancers,” said Dr. David C. Myles, Ph.D., Chief Discovery and Non-Clinical Development Officer of Olema Oncology. “Our KAT6 program supports our commitment to discovering and developing new treatment options for women living with cancer and is a natural complement to Olema’s ongoing development of palazestrant in ER+/HER2- breast cancer. We look forward to providing future updates on our progress with OP-3136 development.”

Olema presented data regarding the discovery and pre-clinical development of its KAT6 program in a poster session at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics (ANE 2023) in Boston, Massachusetts. OP-3136 is orally bioavailable in multiple non-clinical species with desirable pharmacokinetics and has demonstrated highly selective and potent activity against KAT6A and KAT6B versus other KAT family members. In KAT6-amplified and overexpressing estrogen receptor-positive (ER+) breast cancer cell lines, OP-3136 strongly inhibited cell proliferation whereas KAT6-low cell lines were insensitive to the compounds. In a non-clinical xenograft model, OP-3136 caused dose-dependent tumor growth inhibition and tumor regression comparable to or better than a positive-control patented KAT6 inhibitor and demonstrated synergy in combination with CDK4/6 inhibitors or palazestrant (OP-1250).

Olema is initiating non-clinical Investigational New Drug (IND) enabling studies in order to support a potential IND submission to the U.S. Food and Drug Administration (FDA) for OP-3136 by the end of 2024.

About Olema Oncology

Olema Oncology is a biopharmaceutical company committed to transforming the standard of care and improving outcomes for women living with cancer. Olema is advancing a pipeline of novel therapies by leveraging our deep understanding of endocrine-driven cancers, nuclear receptors, and mechanisms of acquired resistance. In addition to our lead product candidate, palazestrant (OP-1250), a proprietary, orally-available complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD), Olema is developing a potent KAT6 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 Olema’s preclinical program, including the potential beneficial characteristics and potency of its KAT6 inhibitor compound and its applicability to breast and other cancers, the potential synergistic activity of Olema’s KAT6 inhibitor compounds with CDK4/6 inhibitors or palazestrant (OP-1250), anticipated timing of an IND submission and development of OP-3136. 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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