

Epizyme, Inc.
Form 8-K
January 19, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 13, 2017

EPIZYME, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

001-35945
(Commission

File Number)

26-1349956
(IRS Employer

Identification No.)

400 Technology Square, Cambridge, Massachusetts
(Address of Principal Executive Offices)

02139
(Zip Code)

Registrant's telephone number, including area code: (617) 229-5872

(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 Instruction 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))

Item 8.01 Other Events

On January 13, 2017, in response to the company's written request, Epizyme, Inc. (the "Company") received a positive written response from the U.S. Food and Drug Administration (the "FDA") allowing enrollment of patients with follicular lymphoma ("FL") in the United States as part of the Company's ongoing, global Phase 2 study of tazemetostat as a treatment for multiple types of relapsed/refractory non-Hodgkin lymphoma. Enrollment of patients outside of the United States with diffuse large B-cell lymphoma ("DLBCL") and FL and of patients in the United States with DLBCL began in November 2015.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Epizyme, Inc. and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties inherent in the initiation of future clinical studies and in the availability and timing of data from ongoing clinical studies; enrollment in clinical trials; whether interim results from a clinical trial such as the early data referenced in this release will be predictive of the final results of the trial; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials; whether results from clinical studies will warrant meetings with regulatory authorities or submissions for regulatory approval; whether a fast track designation will lead to a faster development or regulatory review or approval process; expectations for regulatory approvals to conduct trials or to market products; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates; and other factors discussed in the "Risk Factors" section of the Company's most recent Form 10-Q filed with the SEC and in the Company's other filings from time to time with the SEC. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof and should not be relied upon as representing the Company's views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

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.

EPIZYME, INC.

Date: January 19, 2017

By: /s/ Robert B. Bazemore

Name: Robert B. Bazemore

Title: President and Chief Executive Officer