Epizyme, Inc.
Form 8-K
November 28, 2016

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): November 28, 2016

EPIZYME, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35945**	**26-1349956**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
400 Technology Square, Cambridge, Massachusetts		**02139**

(Address of Principal Executive Offices) **(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 November 28, 2016, Epizyme, Inc. (the Company) announced advancements in its clinical programs evaluating tazemetostat, its first-in-class EZH2 inhibitor. In its announcement, the Company reported that the United States Food and Drug Administration has granted Fast Track designation for the investigation of tazemetostat for the treatment of patients with relapsed or refractory diffuse large B-cell lymphoma whose tumors carry an EZH2 activating mutation. In addition, the Company reported that, following review by the Independent Data Monitoring Committee, the Company expanded the epithelioid sarcoma cohort of its ongoing phase 2 trial of tazemetostat in adult patients with certain genetically defined solid tumors. This expansion is based on encouraging early activity seen to date, including confirmed objective responses, in the cohort. The arm has passed its prespecified interim futility analysis. The Company plans to enroll an additional 30 patients with epithelioid sarcoma, bringing the cohort to a total of 60 patients.

The Company also announced that the synovial sarcoma arm of the phase 2 trial in adult patients with certain genetically defined solid tumors has been fully enrolled. Although this arm has passed its prespecified interim futility analysis and some patients remain on treatment, the Company has concluded that the activity of tazemetostat in this cohort is insufficient to continue further investigation of tazemetostat as a monotherapy in adult patients with synovial sarcoma. Unlike the cancers in the other four arms of the study, synovial sarcoma is characterized by a functional dysregulation of INI1, rather than by a complete loss of INI1. The Company is now focusing its efforts on the four cohorts of INI1-negative tumors in the phase 2 trial, including the epithelioid sarcoma cohort. Enrollment continues in these cohorts, and the Company plans to present data from the phase 2 trial in the first half of 2017.

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, proje potential, will, would, could, should, continue, and similar expressions, constitute forward-looking statement 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; whether interim results from a clinical trial such as the early data referenced in this report 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: November 28, 2016

By: /s/ Robert B. Bazemore
Name: Robert B. Bazemore
Title: President and Chief Executive Officer