Epizyme, Inc.
Form 8-K
June 20, 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): June 19, 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 June 19, 2016, Epizyme, Inc. (the Company) reported preliminary data from its ongoing, global phase 2 clinical trial of orally administered tazemetostat, a first-in-class EZH2 inhibitor, in relapsed or refractory patients with non-Hodgkin lymphoma (NHL). In these data from the phase 2 trial, tazemetostat demonstrated a favorable safety profile and clinical activity consisting of objective responses in a heavily pre-treated patient population. These data were reported at the American Society of Hematology Meeting on Lymphoma Biology.

The Company s Independent Data Monitoring Committee has confirmed that futility has been surpassed in four of the five cohorts in the phase 2 trial: diffuse large B-cell lymphoma (DLBCL) with Germinal Center B-cell (GCB) subtype and EZH2 mutations; DLBCL with GCB subtype and wild-type EZH2; DLBCL with non-GCB subtype; and, follicular lymphoma (FL) with EZH2 mutations. The fifth cohort, which is enrolling patients with FL with wild-type EZH2, is ongoing, but has not yet reached futility assessment. The primary endpoint of the phase 2 study is overall response rate, and secondary endpoints include progression-free survival and duration of response.

The Company believes that trial enrollment is on track and consistent with incidence rates for NHL subtypes, with approximately 30% of the target study population having been enrolled and 20% of the enrolled patients having EZH2 mutations. As of the data cutoff of May 27, 2016, 82 patients across all five study arms were evaluable for safety. Efficacy has been assessed on 47 evaluable patients from the four cohorts confirmed to have surpassed their pre-specified futility hurdles. The non-evaluable patients include 16 patients in the arms that have surpassed futility who were too early for efficacy evaluation or for whom data had not yet been entered as of the data cutoff and 19 patients from the fifth cohort who have FL with wild-type EZH2.

Tazemetostat has demonstrated a favorable safety profile in all patients treated in the trial, consistent with the experience observed in the Company s ongoing phase 1 trial of tazemetostat. The majority of adverse events were grade 1 or grade 2 within the 82 safety-evaluable patients. The most common treatment-related adverse events (>5%), were nausea, asthenia, thrombocytopenia, neutropenia and fatigue, of which seven were grade 3 or higher. All adverse events resulted in low rates of both dose reductions (4%) and dose discontinuations (6%).

Among the 47 efficacy-evaluable patients, both objective responses (complete responses (CR) and partial responses (PR)) and stable disease (SD) have been observed. At data cutoff, best responses across the four cohorts were as follows:

DLBCL with GCB subtype and EZH2 mutations (n=5): one PR and two SD;

DLBCL with GCB subtype and wild-type EZH2 (n=19): two CRs, one PR and six SD;

DLBCL with non-GCB subtype (n=20): two CRs, four PRs and five SD; and,

FL with EZH2 mutations (n=3): three PRs.

All of the patients who have achieved a CR and the majority of patients who have achieved a PR or SD as best response are still on tazemetostat treatment as of the data cutoff.

Cautionary Note on Forward-Looking Statements

Any statements in this report about future expectations, plans and prospects for the Company and other statements containing the words anticipate, believe, estimate, expect, intend, may, plans, predict, project, targe would, could, should, continue, and similar expressions, constitute forward-looking statements within the meaning 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, availability and timing of data from

ongoing clinical studies, whether interim results from a clinical trial such as the results referenced in this report will be predictive of the final results of the trial or the results of future trials, expectations for regulatory approvals, availability of funding sufficient for 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 or companion diagnostics and other factors discussed in the Risk Factors section of the Company s Form 10-Q filed with the SEC on May 9, 2016, 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. 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. These forward-looking statements should not be relied upon as representing the Company s views as of any date subsequent to the date hereof.

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: June 20, 2016

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