

Epizyme, Inc.
Form 8-K
September 07, 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): September 6, 2016

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

Epizyme, Inc. (the Company) reported that the Independent Data Monitoring Committee (the IDMC) convened on September 6, 2016 to assess the futility of tazemetostat in the follicular lymphoma with wild-type EZH2 cohort of the Company's ongoing phase 2 study in patients with relapsed or refractory non-Hodgkin lymphoma (NHL). Based on review of the clinical experience to date, the IDMC has confirmed that the study cohort has surpassed its pre-specified futility hurdle, and the Company will continue to accrue patients to fully enroll this cohort. Multiple objective responses have been observed in this cohort of patients, including complete and partial responses, as well as stable disease in patients still on study beyond the first ten evaluated for futility. In addition, there were no safety concerns raised by the IDMC in their review of the study.

All five study cohorts have now surpassed their pre-specified futility hurdles, and enrollment continues in all study arms. The Company plans to present mature data from all five study cohorts in the first half of 2017, consistent with prior guidance.

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, target, 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, availability and timing of data from ongoing clinical studies, whether interim results from a clinical trial such as the results presented 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 and other factors discussed in the Risk Factors section of the Company's Form 10-Q most recently filed with the SEC, and in its other filings from time to time with the SEC. In addition, the forward-looking statements included in this Form 8-K represent the Company's views as of the date hereof. Subsequent events and developments may 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: September 7, 2016

By: /s/ Robert B. Bazemore

Name: Robert B. Bazemore

Title: President and Chief Executive Officer