

Epizyme, Inc.
Form 8-K
September 05, 2018

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 5, 2018

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))
Indicate by check mark whether the registrant is an emerging growth company as defined in 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.

The Company continues to engage with the U.S. Food and Drug Administration (the FDA) regarding the FDA's partial clinical hold on new patient enrollment in clinical trials of tazemetostat, the Company's lead product candidate. Epizyme has submitted complete responses to both the Division of Hematology Products (DHP) and to the Division of Oncology Products 2 (DOP2) to address the partial clinical hold.

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 5, 2018

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