Epizyme, Inc.
Form 8-K
March 16, 2015

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): March 11, 2015

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 1.01 Entry into a Material Definitive Agreement

On March 11, 2015, the Company entered into an amended and restated collaboration and license agreement with Eisai Co. Ltd., or Eisai, under which the Company reacquired worldwide rights, excluding Japan, to its EZH2 program, including EPZ-6438. Under the amended and restated collaboration agreement, the Company will be responsible for global development, manufacturing and commercialization outside of Japan of EPZ-6438 and any other EZH2 product candidates, with Eisai retaining development and commercialization rights in Japan, as well as a right to elect to manufacture EPZ-6438 and any other EZH2 product candidates in Japan. Under the original collaboration and license agreement, the Company had granted Eisai an exclusive worldwide license to its small molecule HMT inhibitors directed to EZH2, including EPZ-6438, while retaining an opt-in right to co-develop, co-commercialize and share profits with Eisai as to licensed products in the United States.

Upon the execution of the amended and restated collaboration and license agreement, the Company agreed to pay Eisai a $40.0 million upfront payment. The Company also agreed to pay Eisai up to $20.0 million in clinical development milestone payments, up to $50.0 million in regulatory milestone payments and royalties at a percentage in the mid-teens on worldwide net sales of any EZH2 product, excluding net sales in Japan. The Company is eligible to receive from Eisai royalties at a percentage in the mid-teens on net sales of any EZH2 product in Japan.

Under the original agreement, Eisai was solely responsible for funding all research, development and commercialization costs for licensed compounds. Under the amended agreement, the Company will be solely responsible for funding global development and commercialization costs for EZH2 compounds outside of Japan, and Eisai will be solely responsible for funding Japan-specific development and commercialization costs for EZH2 compounds. In connection with the amendment and restatement of the collaboration and license agreement with Eisai, the Company and Eisai have agreed upon a transition to the Company of ongoing development and manufacturing activities being conducted by or on behalf of Eisai.

In the event that the Company seeks to license rights to a third party to develop or commercialize an EZH2 product in any country in Asia other than Japan, Eisai has a limited right of first negotiation for such rights. In the event that the Company is awarded a priority review voucher from the FDA with respect to an EZH2 product, Eisai is entitled to specified compensation if the Company uses the voucher on a non-EZH2 program or sells the voucher to a third party.

Subject to exceptions specified in the agreement, for an exclusivity period extending until eight years after the first commercial sale of a product covered by the agreement, neither the Company nor Eisai may research, develop or commercialize HMT inhibitors directed to EZH2, other than pursuant to the agreement.

The Company s amended and restated collaboration and license agreement with Eisai will remain in effect until the expiration of all payment obligations under the agreement with respect to all licensed products. The royalty term for each licensed product in each country commences on the first commercial sale of the applicable licensed product in the applicable country and ends on the latest of expiration of specified patent coverage, expiration of specified regulatory exclusivity or ten years following the first commercial sale. The Company or Eisai may terminate the agreement for convenience as to their respective territories, upon 90 days prior written notice. The agreement will also terminate as to the Company s territory if the Company ceases all development and commercialization activities for the United States and specified major countries in Europe and as to Eisai s territory if Eisai ceases all development and commercialization activities for Japan. The agreement may also be terminated by either party in the event of an uncured material breach by the other party or by the Company in the event Eisai,

or an affiliate or sublicensee, participates or actively assists in an action or proceeding challenging or denying the validity of one of the Company s patents. If the Company terminates the agreement for its convenience, the agreement terminates as a result of the Company s cessation of development and commercialization activities or Eisai terminates the agreement for the Company s uncured material breach, Eisai may elect to have worldwide development and commercialization rights revert to Eisai, and if Eisai so elects, Eisai will be required to pay the Company specified royalties on net sales of the licensed products and reimburse certain development expenses incurred by the Company. If Eisai terminates the agreement for its convenience, the agreement terminates as a result of Eisai s cessation of development and commercialization activities or the Company terminates the agreement for Eisai s uncured material breach or Eisai s, or its affiliate s or sublicensee s, participation in, or assistance with, an action or proceeding challenging or denying the validity of one of the Company s patents, Japanese development and commercialization rights to the licensed products revert to the Company, and the Company will be required to pay Eisai specified royalties on net sales of licensed products in Japan.

In connection with the amended and restated collaboration and license agreement, we entered into an amended and restated letter agreement with Eisai relating to the December 2012 companion diagnostics agreement, which we and Eisai are a party to with Roche Molecular Systems, Inc., or Roche, under which we and Eisai were funding Roche s development of a companion diagnostic to identify patients who possess certain point mutations of EZH2. Under the original letter agreement, the $21.5 million of development costs under the amended agreement with Roche were the responsibility of Eisai. Upon the execution of the amended and restated letter agreement with Eisai, we assumed responsibility for $8.5 million of the remaining development costs under the agreement with Roche.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

10.1	Amended and Restated Collaboration and License Agreement dated as of March 12, 2015 by and between the Registrant and Eisai Co., Ltd.
10.2	Amended and Restated Letter Agreement dated as of March 12, 2015 by and between the Registrant and Eisai Co., Ltd. relating to Companion Diagnostics Agreement

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: March 16, 2015

By: /s/ Robert J. Gould
Robert J. Gould, Ph.D.

President and Chief Executive Officer

EXHIBIT INDEX

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Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.