Epizyme, Inc.
Form 8-K
July 09, 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): July 8, 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

***Overview*.** On July 8, 2015, Epizyme, Inc. (the Company) entered into an amendment and restatement of the Company s collaboration and license agreement dated April 2, 2012 with Celgene RIVOT Ltd. and Celgene Corporation (collectively, Celgene). Under the original agreement, the Company granted Celgene an exclusive license, for all countries other than the United States, to small molecule HMT inhibitors targeting DOT1L, including pinometostat (EPZ-5676), and an option, on a target-by-target basis, to exclusively license, for all countries other than the United States, rights to small molecule HMT inhibitors targeting any other HMT targets, excluding EZH2 and targets covered by the Company s collaboration and license agreement dated January 8, 2011 with Glaxo Group Limited. Under the original agreement, Celgene s option was exercisable during an option period that would have expired on July 9, 2015. Under the amended and restated collaboration and license agreement:

- Celgene retains its exclusive license to small molecule HMT inhibitors targeting DOT1L, including pinometostat (EPZ-5676),
- Celgene s option rights have been narrowed to HMT inhibitors targeting three predefined targets (the Option Targets),
- The exclusive licenses to HMT inhibitors targeting two of the Option Targets that Celgene may acquire have been expanded to include the United States, with the exclusive license to the third Option Target continuing to be for all countries other than the United States,
- Celgene s option period has been extended for each of the Option Targets and is exercisable at the time of the Company s IND filing for an HMT inhibitor targeting the applicable Option Target, upon the payment by Celgene at such time of a pre-specified development milestone-based license payment,
- Celgene s license may be maintained beyond the end of Phase 1 clinical development for each of the Option Targets, upon payment by Celgene at such time of a pre-specified development milestone-based license payment, and
- The Company s research and development obligations with respect to each Option Target under the amended agreement have been extended for at least an additional three years, subject to Celgene exercising its option with respect to such Option Target at IND filing. Subject to the Company s Opt-Out rights described below, the Company s research and development obligations have been expanded to include the completion of a Phase 1 clinical trial as to each Option Target following Celgene s exercise of its option at IND filing.

Under the terms of the amended agreement, the Company will receive a $10.0 million upfront payment in exchange for the Company s extension of Celgene s option rights to the Option Targets and the Company s research and development obligations. In addition, the Company is eligible to earn up to $75.0 million in development milestones and license payments, up to $365.0 million in regulatory milestone payments and up to $170.0 million in sales milestone payments related to the Option Targets. The Company remains eligible to earn $35.0 million in an additional clinical development milestone payment and up to $100.0 million in regulatory milestone payments related to DOT1L. The Company is also eligible to receive royalties as follows:

As to DOT1L, the Company retains all product rights in the United States and is eligible to receive royalties at defined percentages ranging from the mid-single digits to the mid-teens on annual net product sales outside of the United States, subject to reductions in specified circumstances;

As to the Option Target for which Celgene s option rights do not include the United States, if Celgene exercises its option as to such Option Target, the Company will retain all product rights in the United States and will be eligible to receive royalties, once an initial threshold of net product sales (for which the Company will not receive royalties) is exceeded, at defined percentages ranging from the mid-single digits to the low-double digits on net product sales outside of the United States, subject to reductions in specified circumstances; and

As to the other two Option Targets, if Celgene exercises its option as to those Option Targets, the Company will be eligible to receive royalties, once an initial threshold of net product sales (for which the Company will not receive royalties) is exceeded, for each such Option Target at defined percentages ranging from the mid-single digits to the low-double digits on net product sales on a worldwide basis, subject to reductions in specified circumstances.

For DOT1L and, after Celgene s payment of the specified IND filing license payment for each Option Target, for each such Option Target, the Company is responsible for the conduct and funding of Phase 1 clinical trials, subject to the Company s right to opt-out of such responsibilities as described below. Celgene may obtain a license to small molecule HMT inhibitors targeting each Option Target at the time of the Company s IND filing for an HMT inhibitor for such target by exercising its option and paying the Company a specified license payment. Celgene may maintain its license with respect to an Option Target after the Company s conduct of Phase 1 clinical trials of the Option Target by paying the Company a specified additional license payment. If Celgene does not elect to obtain a license during the option exercise period applicable to an Option Target, or to pay the specified IND license payment or end of Phase 1 license payment, the Company will retain worldwide rights to HMT inhibitors directed to the Option Target, other than HMT inhibitors that may be provided by Celgene if the Company were to agree to their introduction into the collaboration.

Research Obligations. The Company is primarily responsible for the research strategy under the collaboration. During each applicable option period the Company is required to use commercially reasonable efforts to carry out an agreed research plan for each Option Target. Subject to the Company s Opt-Out right described below. For the DOT1L target and each of the Option Targets, the Company is required to conduct and solely fund development costs of the Phase 1 clinical trials for HMT inhibitors directed to such targets, including for pinometostat (EPZ-5676). After completion of Phase 1 development, as to DOT1L and the Option Target for which the Company retains U.S. rights, Celgene and the Company will equally co-fund global development and each party will solely fund territory-specific development costs for its territory; and, as to the other two Option Targets, after completion of Phase 1 development, Celgene will solely fund all development costs on a worldwide basis.

Governance. The Company s collaboration with Celgene is guided by (a) a joint research committee, with authority over all activities performed under the research plan with respect to the two Option Targets as to which the Company grants worldwide rights; (b) a joint development committee, with authority over shared development activities with respect to DOT1L and the Option Target for which the Company retains U.S. rights; and (c) a joint commercialization committee, with authority over the commercialization of products developed under shared development programs with respect to DOT1L and the Option Target for which the Company retains U.S. rights. Subject to limitations specified in the amended agreement, if the applicable governance committee is not able to make a decision by consensus and the parties are not able to resolve the issue through escalation to specified senior executive officers of the parties, then (a) prior to Celgene s exercise of its option, the Company generally has final decision-making authority over research and development matters with respect to the Option Targets; (b) with respect to DOT1L and any Option Targets for which Celgene has exercised its option, Celgene generally has final decision-making authority over global development matters, including over global activities and related expenses that the Company is obligated to co-fund, unless the Company exercises its opt-out right as to such licensed program, and except that with respect to the Option Target for which the Company retains U.S. rights, the parties have mutual decision-making authority even after Celgene exercises its option as long as Celgene engages in a competitive development program with respect to such Option Target. Each party has final decision-making authority over commercialization matters in its respective

territory.

Opt-Out Right. On an Option Target-by-Option Target basis, the Company has the right, in its sole discretion, to opt-out of further participation in any research and/or development activities after completion of the initial research plan and prior to the filing of an IND for an HMT inhibitor directed to the applicable Option Target (the Pre-IND Opt-Out). Following exercise of a Pre-IND Opt-Out, if Celgene exercises its option as to the Option Target, Celgene will no longer be required, to the extent not already paid, to make the specified IND license payment or end of Phase 1 license payment to the Company, specified sales milestone payments will no longer be payable and all royalties on net product sales of applicable licensed products that become payable to the Company will be reduced by a specified percentage. Additionally, if Celgene exercises its option as to such Option Target, the Company is obligated to grant Celgene an exclusive worldwide license to HMT inhibitors directed to the applicable Option Target, even if the Company would otherwise retain U.S. rights to HMT inhibitors directed to the applicable Option Target. Additionally, on a licensed program-by-licensed program basis, the Company has the right, in its sole discretion, to opt-out of further participation in and co-funding of development, other than specified costs necessary to complete development activities in process at the time the Company exercises its opt-out right. The Company can exercise its licensed program opt-out right at specified times: (a) when the clinical trial stopping rules set forth in a clinical trial protocol for DOT1L or the Option Target for which the Company retains U.S. rights dictate that such clinical trial be stopped (the Post-EOP1 Clinical Opt-Out); or (b) for any or no reason, in a licensed program for DOT1L or the Option Target for which the Company retains U.S. rights, during specified periods before the scheduled initiation of the first pivotal clinical trial or before the estimated date of filing of the first new drug application for an HMT inhibitor directed to the licensed target or any time after regulatory approval of an HMT inhibitor directed to the licensed target (the Late Stage Opt-Out). In the event of a Post-EOP1 Clinical Opt-Out, the royalties that become payable to the Company on net product sales of licensed products directed to DOT1L or the Option Target for which the Company retains U.S. rights, as applicable, will be reduced by a specified percentage. Following a Post-EOP1 Clinical Opt-Out or a Late Stage Opt-Out, the Company is no longer required to co-fund global development for the applicable program other than specified costs necessary to complete development activities in process at the time the Company exercises its opt-out right, and the Company is obligated to grant Celgene an exclusive license to HMT inhibitors directed to the applicable target in the United States. Following the Company s exercise of a Post-EOP1 Clinical Opt-Out or a Late Stage Opt-Out, if any, the Company would be eligible to receive specified milestone payments and royalties based on net product sales in the United States of HMT inhibitors directed to the licensed target in the event that Celgene develops and commercializes a product in the United States.

Exclusivity Restrictions. Subject to exceptions specified in the amended agreement, during the option period, the Company may not research, develop or commercialize HMT inhibitors directed to DOT1L and the three Option Targets. Subject to exceptions specified in the amended agreement, following each applicable option period, the Company may not research, develop or commercialize HMT inhibitors directed to DOT1L or any target licensed by Celgene.

Right of First Negotiation. The amended agreement eliminated the right of first negotiation that the Company had previously granted to Celgene under the original agreement with respect to business combination transactions that the Company may desire to pursue with third parties.

Term and Termination. The amended agreement with Celgene will expire on a product-by-product and country-by-country basis on the date of the expiration of the applicable royalty term with respect to each licensed product in each country and in its entirety upon the expiration of all applicable royalty terms for all licensed products in all countries. The royalty term for each licensed product in each country is the

period commencing with first commercial sale of the applicable licensed product in the applicable country and ending on the latest of expiration of specified patent coverage, specified regulatory exclusivity or 15 years following the first commercial sale in the applicable country. Celgene has the right to terminate the amended agreement in its entirety, upon 60 or 120 days notice depending on the timing of such termination. The amended agreement may also be terminated in its entirety during the option period, and on a licensed target-by-licensed target basis after the option period, by either Celgene or the Company in the event of a material breach by the other party. The amended agreement may be terminated on a licensed target-by-licensed target basis by either Celgene or the Company in the event the other party, or an affiliate or sublicensee of the other party, participates or actively assists in a legal challenge to specified patents of the terminating party or in its entirety in the event the other party becomes subject to specified bankruptcy, insolvency or similar circumstances.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 1.01 shall be deemed to be furnished, and not filed:

99.1 Press release issued by the Company on July 9, 2015

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: July 9, 2015

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

President and Chief Executive Officer

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
99.1	Press release issued by the Company on July 9, 2015