



August 8, 2016

## **Epizyme Announces Second Quarter 2016 Financial Results and Progress Against Corporate Objectives**

*Company Updates Financial Guidance Extending Runway into At Least Second Quarter of 2018*

*Conference Call to Be Held Today at 8:30 a.m. Eastern Time*

CAMBRIDGE, Mass., Aug. 08, 2016 (GLOBE NEWSWIRE) -- [Epizyme, Inc.](#) (NASDAQ:EPZM), a clinical-stage biopharmaceutical company creating novel epigenetic therapies, today reported financial results for the second quarter of 2016, recapped recent progress against the Company's multi-year vision and provided an update on clinical data timelines.

"We are pleased with our continued momentum in the clinical development of tazemetostat in non-Hodgkin lymphoma, or NHL, and genetically defined solid tumors, as well as the expansion of the tazemetostat clinical development program into mesothelioma," said Robert Bazemore, President and Chief Executive Officer of Epizyme. "For the remainder of the year, our focus is on the continued enrollment in and execution of our Phase 2 NHL and solid tumor studies to generate mature objective response and durability data, and to assess the differences in activity between study arms. With a robust clinical program underway for tazemetostat, and advancements in our preclinical and discovery efforts, we believe we are further solidifying Epizyme's position as the leader in epigenetic drug discovery and development."

### **Advancing the Clinical Development of Tazemetostat for the Treatment of Non-Hodgkin Lymphoma (NHL) and Genetically Defined Solid Tumors**

- | In June, Epizyme presented positive, early findings from its ongoing Phase 2 study of tazemetostat in patients with relapsed or refractory NHL at the American Society of Hematology Meeting on Lymphoma Biology. As of the data cutoff date in late May, approximately 30 percent of the planned 270 patients were enrolled into the study. Tazemetostat demonstrated clinical activity, including objective responses, in all five arms of the study and a favorable safety profile in a heavily pre-treated, multiply relapsed and highly refractory patient population. Overall patient enrollment is proceeding according to internal projections, and the study is now open for enrollment in the U.S.
- | Overall patient enrollment is also on-track in the Company's ongoing Phase 2 clinical study in adult patients and Phase 1 study in pediatric patients with INI-1 negative tumors or synovial sarcoma.
- | Epizyme plans to provide data on the efficacy and safety of tazemetostat from both the NHL and solid tumor Phase 2 studies in the first half of 2017. The Company plans to meet with regulatory authorities, beginning with the U.S. Food and Drug Administration (FDA) in mid-2017, to review data from all cohorts of its Phase 2 solid tumor study and discuss registration strategies based on these data. Epizyme also expects to meet with FDA to review Phase 2 NHL data and discuss registration strategies in 2017.
- | In June, Epizyme participated in FDA's Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC) meeting, which reviewed select novel, targeted agents for the treatment of pediatric cancer. Epizyme was one of five invited innovators, and presented on its ongoing pediatric clinical program. The Company received valuable feedback and support from Committee members on the development of tazemetostat as a treatment for rare and extremely aggressive cancers in pediatric patients.

### **Broadening Scope of Tazemetostat Clinical Program**

- | In August, Epizyme initiated a global study of tazemetostat in patients with mesothelioma. This is a multi-center Phase 2 study evaluating tazemetostat as a monotherapy treatment for patients with mesothelioma characterized by BAP1 loss-of-function. The study is open for enrollment in the U.S., with an accepted Investigational New Drug application, and is expected to open in international sites shortly. This study marks the first of five new indications into which the Company plans to expand tazemetostat in the clinic by the end of 2020.

- | In June, Epizyme entered into a collaboration agreement with Genentech, a member of the Roche Group, to conduct a clinical trial to investigate tazemetostat and Genentech's recently approved anti-PD-L1 cancer immunotherapy, Tecentriq™ (atezolizumab), when used in combination for the treatment of patients with relapsed or refractory diffuse large B-cell lymphoma. The study will be conducted by Genentech and is expected to begin in the second half of 2016.
- | In May, Epizyme entered into a collaboration agreement with the Lymphoma Study Association (LYSA), a premier cooperative group in France dedicated to clinical and translational research for lymphoma, to investigate the combination of tazemetostat with R-CHOP as a front-line treatment in elderly, high-risk patients with DLBCL. The study will be conducted by LYSA and is expected to be initiated in the second half of 2016.

## Second Quarter 2016 Financials Results and Guidance

- | Collaboration revenue was \$0.5 million and \$0.9 million for the three and six months ended June 30, 2016, respectively, compared to \$0.7 million and \$1.6 million for the three and six months ended June 30, 2015, respectively. The period-over-period decreases reflect decreased recognition of deferred revenue from upfront payments and research and development revenue related to the Company's collaboration with GlaxoSmithKline, partially offset by increased recognition of deferred revenue from upfront payments from its Celgene collaboration.
- | Research and development (R&D) expenses were \$21.5 million and \$39.2 million for the three and six months ended June 30, 2016, respectively, compared to \$20.6 million and \$77.6 million for the three and six months ended June 30, 2015, respectively. During the three months ended June 30, 2016, R&D expenses increased due to external and internal costs associated with the expansion of the tazemetostat program, which more than offset the period-over-period reduction of pinometostat-related costs. The period-over-period decrease from the six months ended June 30, 2015 was driven by the first quarter 2015 payment to Eisai of \$40.0 million for the reacquisition of the worldwide rights, excluding Japan, to tazemetostat. Epizyme expects that R&D expenses will increase significantly in the remainder of 2016. This will be driven by the planned expansion of clinical trial activity for tazemetostat, including initiation of the mesothelioma study, initiation of the two combination trials in DLBCL, and expansion of the Company's ongoing studies in NHL and solid tumors. In addition, discovery and preclinical research costs are expected to increase as Epizyme advances its wholly owned small molecule programs against multiple novel epigenetic targets and continues its research efforts under its Celgene collaboration.
- | General and administrative (G&A) expenses were \$7.4 million and \$13.3 million for the three and six months ended June 30, 2016, respectively, as compared to \$6.0 million and \$11.2 million for the three and six months ended June 30, 2015, respectively. The period-over-period increases in G&A expenses were largely due to staffing key leadership roles in the second quarter. Epizyme expects that G&A spend will increase modestly over the remainder of 2016.
- | Net loss was \$28.0 million and \$50.9 million for the three and six months ended June 30, 2016, respectively, compared to a net loss of \$25.8 million and \$87.1 million for the three and six months ended June 30, 2015, respectively.
- | Cash, cash equivalents and marketable securities were \$288.6 million as of June 30, 2016, as compared to \$208.3 million as of December 31, 2015.

Epizyme has established an operating plan and investment strategy designed to support its objectives through 2020 and extend its runway. Based on the updated operating plan, the Company now believes that its cash, cash equivalents and marketable securities as of June 30, 2016 will be sufficient to fund the Company's planned operations into at least the second quarter of 2018.

## Conference Call Information

Epizyme will host a conference call and audio webcast today at 8:30 a.m. Eastern Time to discuss its second quarter 2016 financial results and business updates. To participate in the conference call, please dial (877) 844-6886 (domestic) or (970) 315-0315 (international) and refer to conference ID 53968160. The live and archived versions of the webcast can be accessed under Events in the Investor Center section of the Company's website at <http://www.epizyme.com>.

## About Epizyme, Inc.

Epizyme, Inc. is a clinical-stage biopharmaceutical company creating novel epigenetic therapeutics for people with cancer. Epizyme has built a proprietary product platform to create small molecule inhibitors of chromatin modifying proteins (CMPs), such as histone methyltransferases (HMTs). CMPs are part of the system of gene regulation, referred to as epigenetics, that controls gene expression. Genetic alterations can result in changes to the activity of CMPs, making them oncogenic (cancer-causing). By focusing on the genetic drivers of cancers, Epizyme's targeted science seeks to match the right

medicines with the right patients. For more information, visit [www.epizyme.com](http://www.epizyme.com).

### Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Epizyme, Inc. and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plans," "predict," "project," "target," "potential," "will," "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 will be predictive of the final results of the trial or the results of future trials, expectations for regulatory approvals, whether the Company's collaborations will be successful, 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 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 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.

**EPIZYME, INC.**  
**CONSOLIDATED BALANCE SHEET DATA (UNAUDITED)**  
**(Amounts in thousands)**

	<u>June 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Cash and cash equivalents	\$ 89,480	\$ 208,323
Marketable securities	199,136	—
Total assets	300,858	217,903
Deferred revenue	29,765	30,709
Total stockholders' equity	255,164	169,532

**EPIZYME, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**  
**(Amounts in thousands except per share data)**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Collaboration revenue	\$ 473	\$ 736	\$ 945	\$ 1,647
Operating expenses:				
Research and development	21,450	20,551	39,190	77,602
General and administrative	7,424	5,970	13,270	11,207
Total operating expenses	28,874	26,521	52,460	88,809
Loss from operations	(28,401)	(25,785)	(51,515)	(87,162)
Other income, net	420	26	655	77
Net loss	<u>\$ (27,981)</u>	<u>\$ (25,759)</u>	<u>\$ (50,860)</u>	<u>\$ (87,085)</u>
Loss per share allocable to common stockholders:				
Basic	\$ (0.49)	\$ (0.63)	\$ (0.90)	\$ (2.29)
Diluted	\$ (0.49)	\$ (0.63)	\$ (0.90)	\$ (2.29)
Weighted average shares outstanding:				
Basic	57,352	41,087	56,250	38,056

Diluted

57,352

41,087

56,250

38,056

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