Epizyme Reports Second Quarter 2018 Financial Results and Provides Business Updates

August 2, 2018

Conference Call to be Held Today at 8:30 a.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 2, 2018-- Epizyme, Inc. (NASDAQ: EPZM), a clinical-stage company developing novel epigenetic therapies, today reported financial results for the second quarter of 2018 and provided key business updates.

"In the second quarter, we presented encouraging new clinical data regarding tazemetostat's anti-tumor activity and tolerability in follicular lymphoma and mesothelioma," said Robert Bazemore, president and chief executive officer of Epizyme. "As we enter the second half of 2018, we have focused the organization on several strategic priorities. First and foremost, we are working diligently to resolve the partial clinical hold and resume enrollment in tazemetostat clinical studies. In addition, we are progressing tazemetostat toward a first NDA for the treatment of epithelioid sarcoma, continuing to advance its development in follicular lymphoma based on the strength of our clinical data, and advancing our novel inhibitor of G9a, EZM8266, toward the clinic. We believe the actions we have taken will allow us to capitalize on our near-term tazemetostat opportunities while also extending our cash runway."

Partial Clinical Hold Update

A partial clinical hold pausing the enrollment of new patients into tazemetostat clinical trials was implemented in the second quarter of 2018 in the United States, France and Germany following a safety report of a single pediatric patient who developed a secondary T-cell lymphoblastic lymphoma (T-LBL). Epizyme has reconsented all patients in its clinical trials and updated its informed consent form based on this safety report. The company also reviewed the single T-LBL case in detail, recently completed a comprehensive assessment of tazemetostat safety data and clinical activity observed to date across clinical trials, and convened a panel of external experts to review and validate the assessment. This information will be included in a formal response to regulatory authorities.

Epizyme plans to continue its engagement with the U.S. Food and Drug Administration (FDA) in the weeks ahead and then finalize its response to regulatory authorities, including changes that may be proposed to study protocols. Once the company has gained alignment with regulators in the U.S., France and Germany, it is anticipated that the partial clinical hold would be lifted and that enrollment activities would be allowed to proceed in those countries.

ES Program Update

At the European Society for Medical Oncology (ESMO) Congress in October 2018, Epizyme plans to present updated Phase 2 data from patients with epithelioid sarcoma (ES) who are receiving tazemetostat as a monotherapy. Enrollment in this trial was completed in July 2017. A recent assessment of interim data from the full 62-patient ES cohort in this study has shown that the objective response rate has remained consistent with what was observed in the initial 31 enrolled patients. In addition, durability data from the cohort continue to mature.

Epizyme is continuing to prepare its first New Drug Application (NDA) submission for tazemetostat for the treatment of patients with ES. In order to include more mature durability data in its submission and based on the potential impact of the partial clinical hold on the timing of the company's pre-NDA meeting with the FDA, Epizyme now plans to submit its NDA in the first half of 2019.

DLBCL Program Update

Epizyme has been conducting a Phase 2 trial that is assessing tazemetostat activity in cohorts of patients with relapsed and/or refractory diffuse large B-cell lymphoma (DLBCL). These cohorts include DLBCL patients with EZH2 activating mutations and with wild-type EZH2 who are receiving tazemetostat as monotherapy. The trial also includes a cohort of DLBCL patients who are receiving tazemetostat in combination with prednisolone. Epizyme has conducted an interim assessment of data from this trial and concluded that the clinical activity seen in these cohorts is not sufficient to warrant further development of tazemetostat in DLBCL as a monotherapy or in combination with prednisolone. Epizyme plans to present clinical data from each of these study cohorts at a medical meeting in the second half of 2018. The company has two additional combination studies in DLBCL ongoing and plans to evaluate other potential combinations in this aggressive and difficult-to-treat cancer longer term.

Recent Progress

- **New Chief Medical Officer:** Epizyme recently appointed Dr. Shefali Agarwal as chief medical officer. In this role, Dr. Agarwal will oversee all of the company's activities related to the global strategic development of tazemetostat and additional pipeline candidates. A trained medical oncologist, Dr. Agarwal brings to Epizyme nearly two decades of clinical research and regulatory expertise as well as leadership experience in clinical development, clinical operations and medical

affairs.

- **Positive Data in Follicular Lymhoma (FL):** At the 23rd Congress of the European Hematology Association (EHA) in Stockholm, positive interim data were reported from the follicular lymphoma cohorts in Epizyme's ongoing Phase 2 study of tazemetostat in non-Hodgkin lymphoma. The data as of May 1, 2018 showed that tazemetostat continued to demonstrate meaningful clinical activity as a monotherapy and was generally well tolerated in adult patients with relapsed and/or refractory FL. An objective response rate (ORR) of 71 percent was observed in the cohort of FL patients with EZH2 activating mutations (n=28), with an interim median duration of response (DOR) of approximately 32 weeks. An ORR of 33 percent was observed in the fully-enrolled cohort of FL patients with wild-type EZH2 (n=54), with an interim median DOR of approximately 76 weeks. The median DOR figures in these cohorts continue to mature, with more than half of the responders still on therapy. After resolving the partial clinical hold, Epizyme plans to re-engage with the FDA to refine the company's registration plans for tazemetostat in relapsed and/or refractory FL.
- **Clinical Activity in Mesothelioma:** At the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, clinical data were reported from Epizyme's Phase 2 study of tazemetostat as a monotherapy in relapsed and/or refractory malignant mesothelioma patients with BRCA1-associated protein 1 (BAP1) loss-of-function. The primary endpoint in this trial was met with 51 percent of patients (31/61) having achieved disease control at 12 weeks, exceeding the pre-specified disease control rate threshold of ≥35 percent. Tazemetostat was generally well tolerated in this study.

Second Quarter 2018 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities were $215.6 million as of June 30, 2018, which compares to $247.9 million as of March 31, 2018.
- **Revenue:** Revenue for the second quarter of 2018 was $12.0 million, which compares with $10.0 million in revenue for the second quarter of 2017. The increase is due to greater milestone-related revenue from the company's collaboration and license agreement with GlaxoSmithKline.
- **R&D Expenses:** Research and development (R&D) expenses were $31.3 million for the second quarter of 2018, which compares to $27.3 million for the second quarter of 2017. The increase is primarily due to greater tazemetostat manufacturing expense, increased clinical and regulatory activities associated with tazemetostat's development and preclinical studies related to the company's G9a inhibitor candidate.
- **G&A Expenses**: General and administrative (G&A) expenses were $10.9 million for the second quarter of 2018, which compares to $11.2 million for the second quarter of 2017. The decline is primarily due to reduced consulting costs.
- **Net Loss:** The company's net loss was $29.1 million, or $0.42 per share, for the second quarter of 2018, which compares to a net loss of $28.0 million, or $0.48 per share, for the second quarter of 2017.

Financial Guidance

Epizyme has extended its cash runway guidance based on changes that are being made to its planned operating expenditures. The company now expects that its existing cash, cash equivalents and marketable securities will be sufficient to fund its planned operations into the fourth quarter of 2019.

Conference Call Reminder

As previously announced, management plans to host a conference call and webcast at 8:30 a.m. ET today to discuss the company's second quarter 2018 results and other business updates. To participate, please dial (877) 844-6886 (domestic) or (970) 315-0315 (international) and refer to conference ID 5734199. A live webcast will be available in the investor section of the company's website at www.epizyme.com. The webcast also will be archived on the website for 60 days.

About the Tazemetostat Clinical Trial Program

Tazemetostat, a first-in-class EZH2 inhibitor, is currently being studied as a monotherapy in ongoing Phase 2 programs in certain molecularly defined solid tumors, including epithelioid sarcoma and other INI1-negative tumors; follicular lymphoma (FL); and combination studies in diffuse large B-cell lymphoma (DLBCL) and non–small cell lung cancer (NSCLC).

About Epizyme, Inc.

Epizyme, Inc. is a clinical-stage biopharmaceutical company committed to rewriting treatment for cancer and other serious diseases through novel epigenetic medicines. Epizyme is broadly developing its lead product candidate, tazemetostat, a first-in-class EZH2 inhibitor, with studies underway in both solid tumors and hematological malignancies, as a monotherapy and combination therapy in relapsed and front-line disease. The company is also developing a novel G9a program with its next development candidate, EZM8266, which is targeting sickle cell disease. By focusing on the genetic drivers of disease, Epizyme's science seeks to match targeted medicines with the patients who need them. For more information, visit 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," "plan," "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 relating to the company's ability to have the partial clinical hold lifted and resume enrollment in its tazemetostat trials and the timing of such

resumption, and the impact of the safety finding in the company's pediatric trial on enrollment of patients in ongoing and future trials of tazemetostat following the lifting of the partial clinical hold and the resumption of enrollment; uncertainties inherent in the initiation of future clinical studies and in the 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; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials; whether results from clinical studies will warrant meetings with regulatory authorities, submissions for regulatory approval or review by governmental authorities under the accelerated approval process; expectations for regulatory approvals to conduct trials or to market products; whether the company's cash resources will be sufficient to fund 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 most recent Form 10-Q filed with the SEC and in the company's 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 and should not be relied upon as representing the company's views as of any date subsequent to 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.

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

	June 30, 2018	December 31, 2017
Cash, cash equivalents, and marketable securities	$ 215,624	$ 276,439
Total assets	239,325	289,359
Deferred revenue, net of current portion	3,806	28,809
Total stockholders' equity	205,578	235,371

EPIZYME, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(Amounts in thousands except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaboration revenue	$ 12,000	$ 10,000	$ 12,000	$ 10,000
Operating expenses:				
Research and development	31,346	27,292	56,968	51,987
General and administrative	10,914	11,170	20,274	19,439
Total operating expenses	42,260	38,462	77,242	71,426
Loss from operations	(30,260)	(28,462)	(65,242)	(61,426)
Other income, net	1,132	438	2,049	880
Net loss	$ (29,128)	$ (28,024)	$ (63,193)	$ (60,546)
Loss per share allocable to common stockholders:				
Basic	$ (0.42)	$ (0.48)	$ (0.91)	$ (1.04)
Diluted	$ (0.42)	$ (0.48)	$ (0.91)	$ (1.04)
Weighted average shares outstanding:				
Basic	69,490	58,377	69,438	58,298
Diluted	69,490	58,377	69,438	58,298

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