



Epizyme Reports Third Quarter 2018 Financial Results and Tazemetostat Progress

November 2, 2018

Enrollment in Phase 2 Cohort of Follicular Lymphoma Patients with EZH2 Activating Mutations on Track to be Completed by Year End

Updated Efficacy and Safety Data for Tazemetostat in Epithelioid Sarcoma Support Company's Planned Submission of a New Drug Application in the First Half of 2019

Recent Financing Extends Operating Runway into the First Quarter of 2020

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 2, 2018-- [Epizyme, Inc.](#) (Nasdaq: EPZM), a clinical-stage company developing novel epigenetic therapies, today reported financial results for the third quarter of 2018 and provided updates on its tazemetostat clinical development program. Tazemetostat is a first-in-class, selective, orally available EZH2 inhibitor, in development for hematologic malignancies and solid tumor cancers, as a monotherapy and combination agent.

"2018 has been a year of important milestones. We have seen clinically meaningful activity with tazemetostat in patients with follicular lymphoma, both with and without EZH2 activating mutations, and are pleased that enrollment of patients with EZH2 activating mutations has re-opened in the U.S. With this, we remain on track with our previous guidance of completing enrollment in our Phase 2 study by the end of the year," said Robert Bazemore, president and chief executive officer of Epizyme. "Tazemetostat has also demonstrated clinically meaningful activity, with both durable objective responses and encouraging overall survival, in patients with epithelioid sarcoma, a difficult-to-treat rare cancer. Based on these positive data, we are confident in our planned NDA submission for epithelioid sarcoma in the first half of 2019. With our highly experienced management team, we are positioned to lead the company through several near-term inflection points and the commercial launch of tazemetostat, if approved. I am enthusiastic about our future and ability to execute our mission of rewriting treatment for people with cancer."

Tazemetostat Clinical Program Updates

- **Enrollment of Follicular Lymphoma Patients with EZH2 Activating Mutations to be Completed by End of 2018:** Clinical sites in the U.S. have resumed screening patients with follicular lymphoma with EZH2 mutations in the company's ongoing Phase 2 study. The company is on track to complete enrollment of this cohort by the end of 2018, in line with previous guidance. Enrollment of patients with wild-type EZH2 was completed in 2017. Epizyme plans to continue engaging with FDA to refine its registration strategy in follicular lymphoma, and provide an update on its plans in early 2019.
- **Positive Data in Epithelioid Sarcoma Support Planned NDA Submission:** Epizyme [presented positive interim data](#) from the fully enrolled epithelioid sarcoma cohort of its ongoing Phase 2 study of tazemetostat during the European Society for Medical Oncology (ESMO) 2018 Congress in October. Data as of August 21, 2018 from the 62 patients enrolled showed that oral, twice daily administration of tazemetostat resulted in durable objective responses and encouraging clinically meaningful overall survival in both treatment-naive patients and patients who had been previously treated with an anticancer therapy. In addition, tazemetostat was generally well-tolerated with low rates of discontinuations due to treatment-related adverse events. The company is on-track to submit its New Drug Application for tazemetostat in epithelioid sarcoma in the first half of 2019, with a path to submission for accelerated approval.

Business Updates

- In October 2018, Epizyme announced the closing of its underwritten public offering of 9,583,334 shares of its common stock at a public offering price of \$9.00 per share, which includes 1,250,000 shares issued upon the exercise in full by the underwriter of its option to purchase additional shares at the public offering price, less the underwriting discount. The aggregate gross proceeds to Epizyme from the offering, before deducting underwriting discounts and offering expenses, are \$86.25 million.

Third Quarter 2018 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$180.8 million as of September 30, 2018, which

compares to \$307.2 million as of September 30, 2017.

- **R&D Expenses:** Research and development (R&D) expenses were \$27.0 million for the third quarter of 2018, which compares to \$28.7 million for the third quarter of 2017. The decrease was primarily due to decreased clinical trial expenses and discovery stage research expenses offset by an increase in tazemetostat manufacturing costs.
- **G&A Expenses:** General and administrative (G&A) expenses were \$11.5 million for the third quarter of 2018, which compares to \$9.3 million for the third quarter of 2017. The increase was primarily due to increases in pre-commercialization activities and in personnel related expenses.
- **Net Loss:** Net loss was \$37.5 million, or \$0.54 per share, for the third quarter of 2018, which compares to a net loss of \$37.6 million, or \$0.63 per share, for the third quarter of 2017.

Financial Guidance

Following its October financing, Epizyme expects that its existing cash, cash equivalents and marketable securities will be sufficient to fund its planned operations into the first quarter of 2020.

Due to Epizyme's recent update during ESMO, the company will not host a conference call on these results.

About the Tazemetostat Clinical Trial Program

Tazemetostat, a potent, selective, orally available, 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; and combination studies in diffuse large B-cell lymphoma and non-small cell lung cancer.

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 also is 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 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; whether Fast Track Designation and Orphan Drug Designations will provide the benefits for which tazemetostat is eligible; 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)

	September 30, 2018	December 31, 2017
Cash, cash equivalents, and marketable securities	\$180,783	\$276,439
Total assets	203,146	289,359
Deferred revenue, net of current portion	3,806	28,809
Total stockholders' equity	171,831	235,371

EPIZYME, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

(Amounts in thousands except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	\$-	\$-	\$ 12,000	\$ 10,000
Operating expenses:				
Research and development	27,027	28,741	83,994	80,728
General and administrative	11,528	9,311	31,801	28,750
Total operating expenses	38,555	38,052	115,795	109,478
Loss from operations	(38,555)	(38,052)	(103,795)	(99,478)
Other income, net	1,063	455	3,110	1,335
Net loss	\$(37,492)	\$(37,597)	\$(100,685)	\$(98,143)
Loss per share allocable to common stockholders:				
Basic	\$(0.54)	\$(0.63)	\$(1.45)	\$(1.67)
Diluted	\$(0.54)	\$(0.63)	\$(1.45)	\$(1.67)
Weighted average shares outstanding:				
Basic	69,539	59,899	69,472	58,837
Diluted	69,539	59,899	69,472	58,837

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Source: Epizyme, Inc.

Media:

Erin Graves, 617-500-0615

Epizyme, Inc.

media@epizyme.com

or

Investors:

Monique Allaire, 617-896-9511

THRUST Strategic Communications

monique@thrustsc.com