



November 9, 2015

Epizyme Announces Third Quarter 2015 Financial Results and Provides Corporate Update

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Epizyme, Inc. (NASDAQ:EPZM), a clinical stage biopharmaceutical company creating novel epigenetic therapies for cancer patients, today reported business highlights and operating and financial results for the third quarter of 2015.

"Epizyme is well-positioned, with tazemetostat achieving proof of concept in both hematological malignancies and genetically defined solid tumors, while demonstrating an acceptable safety profile," said Robert Bazemore, President and Chief Executive Officer, Epizyme. "Epizyme is executing on our strategic goal of bringing tazemetostat to patients as quickly as possible, and we are operating from a sound financial position. Our vision is to build Epizyme into a multi-product oncology company bringing targeted epigenetic therapies to patients."

Program Summaries

Tazemetostat:

In 2015, proof of concept was achieved in patients with relapsed or refractory B-cell Non-Hodgkin Lymphoma (NHL) and in patients with advanced solid tumors. Interim data from NHL patients enrolled in an ongoing phase 1 study were presented at the International Conference on Malignant Lymphoma meeting in June 2015 showing a 60 percent response rate in the 15 evaluable NHL patients. Data from the solid tumor patients from the same study were presented at the European Cancer Congress meeting in September 2015 reporting a 55 percent disease control rate in the nine patients with INI1-negative or SMARCA4-negative tumors who were treated at or above the recommended phase 2 dose of 800 mg orally administered twice daily. In these presentations of interim data from the ongoing phase 1 study, Epizyme reported that tazemetostat had an acceptable safety profile.

Epizyme is currently conducting a registration-supporting 5-arm phase 2 clinical study of tazemetostat as a monotherapy in patients with relapsed or refractory B-cell NHL, prospectively stratified by cell of origin and EZH2 mutational status. Epizyme expects to enroll approximately 150 patients in this study and to present interim data from the study at a medical conference by mid-2016.

Epizyme also plans to initiate two registration-supporting clinical trials in patients with INI1-negative tumors or synovial sarcoma, including a registration-supporting phase 2 study of tazemetostat in adult patients, and a proof-of-concept phase 1 trial in pediatric patients, both of which are on track to begin in the fourth quarter of 2015.

In the first half of 2016, Epizyme plans to initiate additional clinical evaluations of tazemetostat as a combination therapy, including a phase 1/2 study with R-CHOP in front-line high-risk patients with diffuse large B-cell lymphoma and a combination study with a B-cell signaling agent or immuno-oncology agent in B-cell lymphoma.

Pinometostat:

A dose-escalation study of pinometostat in pediatric patients with MLL-r acute leukemia is ongoing and enrollment in the dose escalation cohorts is expected to complete in the fourth quarter of 2015. Epizyme anticipates presenting final study results after all patients conclude treatment and related data analyses are complete.

Epizyme and Celgene are exploring the potential clinical development of pinometostat in combination with other agents based on encouraging preclinical data.

Third Quarter 2015 Financial Results

Collaboration Revenue: Collaboration revenue was \$0.4 million in the third quarter of 2015 and \$2.0 million for the nine months ended September 30, 2015 compared with \$8.2 million and \$31.1 million in the comparable periods of 2014. The decrease in collaboration revenue primarily reflects the completion of a significant portion of our performance obligations under our collaborations during 2014 and achievement of a \$3.0 million milestone under our agreement with GlaxoSmithKline during

2014. We expect to recognize an additional \$2.4 million of deferred revenue related to the Celgene agreement through December 31, 2016 as we complete our pinometostat phase 1 clinical trials.

R&D Expenses: Research and development expenses were \$16.8 million for the third quarter 2015 and \$94.4 million for the nine months ended September 30, 2015 compared to \$22.2 million and \$55.1 million for the comparable periods of 2014. Costs related to the expansion of tazemetostat clinical trials and related EZH2 activities and the \$40.0 million upfront payment to Eisai in the first quarter of 2015 were partially offset by reductions in external spending on pinometostat and discovery and preclinical programs during the nine months ended September 30, 2015 compared to the same period of the prior year. Epizyme expects development expenses will continue to increase in 2015 as compared to 2014 since the Company is now solely responsible for funding tazemetostat clinical trials and related development costs outside of Japan. These increased expenses are likely to be partially offset by decreases in spending for pinometostat.

G&A Expenses: General and administrative expenses were \$6.7 million for the third quarter of 2015 and \$17.9 million for the nine months ended September 30, 2015 compared with \$5.7 million and \$15.9 million in the comparable periods in 2014. The increase in G&A expense was primarily related to higher personnel-related expenses and an increase in patent filings and related professional fees.

Net Loss: Net loss was \$23.1 million in the third quarter 2015 and \$110.2 million for the nine months ended September 30, 2015 compared with \$19.7 million and \$40.0 million in the comparable periods in 2014.

Cash and Cash Equivalents: Cash and cash equivalents as of September 30, 2015 were \$229.9 million, compared with \$190.1 million as of December 31, 2014. Epizyme's follow-on public offering in March 2015 raised \$117.0 million in proceeds before expenses and the exercise of the underwriters' over-allotment option provided an additional \$13.7 million in proceeds before expenses. The company received an upfront payment of \$10.0 million under the amended and restated collaboration and license agreement with Celgene in July 2015. The company expects that, based on its current operating plan, cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements through at least the end of the second quarter of 2017.

Shares Outstanding: Shares outstanding as of September 30, 2015 were 41.7 million. Weighted average shares outstanding were 41.5 million and 39.2 million for the three and nine months ended September 30, 2015 respectively and 33.7 million and 32.6 million for the comparable periods in 2014.

Conference Call Information

Epizyme will host a conference call and live audio webcast today at 8:00 a.m. ET to discuss third quarter 2015 financial results and provide a corporate update. To participate in the conference call, please dial (877) 844-6886 (domestic) or (970) 315-0315 (international) and refer to conference ID 67279629. The live webcast can be accessed under "Events and Presentations" in the Investor Relations section of the Company's website at www.epizyme.com

The archived webcast will be available on the Company's website beginning approximately two hours after the event.

About Epizyme, Inc.

Epizyme, Inc. is a clinical-stage biopharmaceutical company creating novel epigenetic therapeutics for cancer patients. Epizyme has built a proprietary product platform that the Company uses to create small molecule inhibitors of chromatin modifying proteins (CMPs), such as histone methyltransferases or 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 and connect with us on Twitter at @EpizymeRx.

About EZH2 in Cancer

EZH2 is a histone methyltransferase that is increasingly understood to play a potentially oncogenic role in a number of cancers. These include Non-Hodgkin Lymphoma, rhabdoid tumors and other INI1-deficient cancers such as epithelioid sarcomas and synovial sarcoma as well as a range of other solid tumors.

About Tazemetostat

Epizyme is developing tazemetostat for the treatment of patients with Non-Hodgkin Lymphoma and patients with INI1-deficient solid tumors. Tazemetostat is a first-in-class small molecule inhibitor of EZH2 created by Epizyme using its proprietary product platform. In many human cancers, aberrant EZH2 enzyme activity results in misregulation of genes that control cell proliferation

resulting in the rapid and unconstrained growth of tumor cells. Tazemetostat is the WHO International Non-Proprietary Name (INN) for EPZ-6438.

Additional information about this program, including clinical trial information, may be found here:

<https://clinicaltrials.gov/ct2/show/NCT01897571>

About Pinometostat

Epizyme is developing pinometostat, a small molecule inhibitor of DOT1L created with Epizyme's proprietary product platform, for the treatment of patients with acute leukemia in which the MLL gene is rearranged due to a chromosomal translocation (MLL-r). Due to these rearrangements, DOT1L is misregulated, resulting in the increased expression of genes causing leukemia. Pinometostat is the WHO International Non-Proprietary Name (INN) for compound EPZ-5676.

Epizyme believes that pinometostat was the first HMT inhibitor to enter human clinical development. Epizyme is currently conducting a phase 1 study of pinometostat in pediatric patients with rearrangements of the MLL gene. Additional information about this ongoing phase 1 study can be found here:

<https://clinicaltrials.gov/ct2/show/NCT02141828>.

Pinometostat has been granted orphan drug designation for the treatment of acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML) by the Food and Drug Administration in the U.S. and by the European Commission in Europe.

Epizyme retains all U.S. rights to pinometostat and has granted Celgene an exclusive license to pinometostat outside of the U.S.

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 inherent in the initiation of future clinical studies or expansion of ongoing clinical studies, availability and timing of data from ongoing clinical studies, whether interim results from a clinical trial such as the results described in this release will be predictive of the final results of the trial or the results of future trials, expectations for regulatory approvals to conduct trials or to market products, development progress of the Company's companion diagnostics, 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 our Form 10-Q most recently filed with the SEC, and in our 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.
CONDENSED CONSOLIDATED
BALANCE SHEETS
(UNAUDITED)
(Amounts in thousands)

	September 30,	December 31,
	2015	2014
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ASSETS		
Cash and cash equivalents	\$ 229,938	\$ 190,095
Accounts receivable	177	2,075
Property and equipment, net	4,477	3,620
Other assets	3,106	3,413
Total Assets	<u>\$ 237,698</u>	<u>\$ 199,203</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Accounts payable, accrued expenses, and other liabilities	\$	15,457	\$	15,770
Capital lease obligations		1,423		-
Deferred revenue		31,264		23,151
Total stockholder's equity		189,554		160,282
Total Liabilities and Stockholders' Equity	\$	237,698	\$	199,203

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Collaboration revenue	\$ 358	\$ 8,177	\$ 2,005	\$ 31,062
Operating expenses:				
Research and development	16,788	22,244	94,390	55,090
General and administrative	6,676	5,669	17,883	15,931
Total operating expenses	23,464	27,913	112,273	71,021
Loss from operations	(23,106)	(19,736)	(110,268)	(39,959)
Other income, net	41	41	118	107
Loss before income taxes	(23,065)	(19,695)	(110,150)	(39,852)
Income tax expense	-	5	-	118
Net loss	<u>\$ (23,065)</u>	<u>\$ (19,700)</u>	<u>\$ (110,150)</u>	<u>\$ (39,970)</u>
Loss per share allocable to common stockholders:				
Basic and Diluted	\$ (0.56)	\$ (0.58)	\$ (2.81)	\$ (1.23)
Weighted average shares outstanding:				
Basic and Diluted	41,461	33,676	39,204	32,607

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