



November 6, 2014

## Epizyme Announces Third Quarter 2014 Financial Results and Provides Corporate Update

- *Initial data from ongoing Phase 1 study of EPZ-6438 support expanded Phase 2 study in EZH2 mutant and wild type non-Hodgkin lymphoma (NHL), to initiate in 1Q15: More complete, updated dose escalation data to be featured in late-breaking oral presentation at EORTC-NCI-AACR Symposium on November 20<sup>th</sup>*
- *EPZ-6438 Phase 1 trial for pediatric patients with INI1-deficient tumors expected to initiate in 1H15 and Phase 2 trial for adult patients with INI1-deficient tumors expected to initiate in 2015*
- *Preliminary results from Phase 1 study of EPZ-5676 to be published online today in ASH Annual Meeting abstract, and updated results to be presented at ASH Annual Meeting on December 8<sup>th</sup>*
  - *Drug was generally safe and well tolerated*
  - *Two patients achieved complete responses, additional biological activity was observed in several patients*
- *Received Notice of Allowance of U.S. Patent Application 14/070,675 with claims covering methods of treatment of lymphoma with a variety of EZH2 inhibitors, and Notice of Allowance of U.S. Patent Application 13/230,703 with claims covering the use of EZH2 inhibitors for treatment of patients carrying the most common EZH2 oncogenic mutations*

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Epizyme, Inc.](#) (NASDAQ:EPZM), a clinical stage biopharmaceutical company creating innovative personalized therapeutics for patients with genetically defined cancers, today announced third quarter 2014 operating and financial results and confirmed 2014 guidance.

"We have made excellent clinical progress over the past quarter, with readouts from both of our Phase 1 studies coming during the next five weeks. For our EZH2 inhibitor EPZ-6438, in August we announced early clinical observations from the ongoing Phase 1 study showing two objective responses among NHL patients enrolled in the first three cohorts of the Phase 1 study. We will present more complete, updated results from the dose escalation study in a late-breaking oral presentation at the EORTC-NCI-AACR Symposium on November 20<sup>th</sup>. We intend to initiate a Phase 2 study in NHL, as well as a Phase 1 study in pediatric INI1-deficient tumors and a Phase 2 in adult INI1-deficient tumors, all in 2015," said Robert Gould, Ph.D., President and Chief Executive Officer, Epizyme. "For our DOT1L inhibitor EPZ-5676, preliminary data from the Phase 1 study will be published online in an ASH Annual Meeting abstract this morning, with updated data to be presented at the meeting on December 8<sup>th</sup>. EPZ-5676 appeared to be safe and well tolerated, with two patients in the fourth dosing cohort achieving complete responses. We are reopening this dosing cohort to gain a better understanding of the activity of EPZ-5676. "

"Epizyme is well-positioned to continue moving its clinical programs and pipeline forward to create value for our shareholders by bringing innovative new therapeutics to patients in need," said Dr. Gould. "We began 2014 with \$157.2 million in cash, cash equivalents and accounts receivable and ended the third quarter of 2014 with \$213.8 million in cash, cash equivalents and accounts receivable. This cash position reflects our successful follow-on offering in February 2014 and collaborator non-equity funding. We anticipate ending 2014 with more than \$170 million in cash and cash equivalents. We expect that these funds, together with the research funding we expect to receive under our collaborations, will fund the Company until at least mid-2016, prior to including any potential future milestone payments."

### Upcoming Clinical Milestones

#### **EPZ-6438:**

- Updated data from the Phase 1 dose escalation study in patients with advanced solid tumors or B-cell lymphomas to be disclosed in late-breaking oral presentation at EORTC-NCI-AACR Symposium on November 20<sup>th</sup>
- Expected initiation of Phase 2 clinical study in NHL patients, both EZH2 mutant and wild type, in first quarter of 2015
- Expected initiation of Phase 1 POC clinical study in pediatric INI1-deficient tumors in first half of 2015
- Expected initiation of Phase 2 clinical study in adult INI1-deficient tumors in 2015

#### **EPZ-5676:**

- Preliminary data from ongoing Phase 1 clinical study in MLL-r and MLL-PTD adult patients, as of July 15<sup>th</sup> abstract data cut-off, to be published on ASH website today; updated data to be presented at ASH Annual Meeting on December 8<sup>th</sup>
- Poster on PK modeling from Phase 1 POC clinical study in MLL-r pediatric patients to be presented at ASH Annual Meeting on December 8<sup>th</sup>

#### **Pipeline:**

- Pre-clinical data on first-in-class PRMT5 inhibitor in mantle cell lymphoma models to be presented at ASH Annual Meeting on December 8<sup>th</sup>

#### **Third Quarter 2014 Financial Results and 2014 Guidance**

**Collaboration Revenue:** Collaboration revenue was \$8.2 million for the third quarter 2014 and \$31.1 million for the nine months ended September 30, 2014, compared to \$8.4 million and \$32.2 million in the comparable periods in 2013. Collaboration revenue includes amounts recognized from deferred revenue from payments received in previous periods as well as payments earned during the period.

**R&D Expenses:** Research and development expenses were \$22.2 million, including non-cash expenses of \$0.9 million, for the third quarter 2014 and \$55.1 million, including non-cash expenses of \$2.7 million, for the nine months ended September 30, 2014, compared to \$14.6 million, including non-cash expenses of \$0.4 million, and \$41.9 million, including non-cash expenses of \$1.0 million, in the comparable periods in 2013. The increase was largely driven by the expansion of Epizyme's product platform and the advancement of the Company's EPZ-5676 clinical trials and related DOT1L programs. Epizyme continues to expect research and development expenses in 2014 to be approximately \$75 million, including non-cash expenses of approximately \$3 million.

**G&A Expenses:** General and administrative expenses were \$5.7 million, including non-cash expenses of \$0.9 million, for the third quarter 2014 and \$15.9 million, including non-cash expenses of \$2.5 million, for the nine months ended September 30, 2014, compared to \$3.6 million, including non-cash expenses of \$0.6 million, and \$9.7 million, including non-cash expenses of \$1.3 million, in the comparable periods in 2013. The increase was largely driven by incremental expenses to support public company operations and the Company's growing organization. Epizyme continues to expect general and administrative expenses in 2014 to be approximately \$20 million, including non-cash expenses of approximately \$3.5 million.

**Net Loss:** Net loss was \$19.7 million for the third quarter 2014 and \$40.0 million for the nine months ended September 30, 2014, compared to net losses of \$9.7 million and \$19.4 million in the comparable periods in 2013.

**Cash, Cash Equivalents and Accounts Receivable:** Cash, cash equivalents and accounts receivable as of September 30, 2014, were \$213.8 million, compared to \$157.2 million as of December 31, 2013. The increase was driven by Epizyme's successful follow-on public offering in February 2014, with \$101 million in net proceeds, and collaborator non-equity funding of \$20 million in the nine months ended September 30, 2014. Epizyme expects to end 2014 with more than \$170 million in cash and cash equivalents. The Company expects that these funds, together with expected research funding under the Company's collaborations, will fund the Company until at least mid-2016 prior to including any potential future milestone payments.

**Shares Outstanding:** Shares outstanding as of September 30, 2014, were 34.1 million, following the sale of 3.7 million shares of common stock in the Company's February 2014 follow-on public offering. Weighted average shares outstanding were 33.7 million for the third quarter 2014 and 32.6 million for the nine months ended September 30, 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 2014 financial results and provide a corporate update. To participate in the conference call, please dial 1-877-844-6886 (domestic) or 1-970-315-0315 (international) and refer to conference ID 27197386. The live webcast can be accessed under "Events and Presentations" in the Investor Relations section of the Company's website at [www.epizyme.com](http://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 personalized therapeutics for patients with genetically defined cancers. Epizyme has built a proprietary product platform that the Company uses to create small molecule inhibitors of a 96-member class of enzymes known as histone methyltransferases, or HMTs. HMTs 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 HMTs, 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 a personalized approach to cancer treatment.

For more information, visit [www.epizyme.com](http://www.epizyme.com) and connect with us on Twitter at [@EpizymeRx](https://twitter.com/EpizymeRx).

### Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Epizyme, Inc., including statements about the Company's strategy, future operations, clinical development of the Company's therapeutic candidates, expectations regarding ongoing or future clinical studies, expectations regarding the sufficiency of the Company's cash balance to fund operating expenses, expectations regarding future financial performance and future expectations and plans and prospects for the Company 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, expectations of expanding ongoing 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 results of early clinical studies will be indicative of the results of future studies, expectations for regulatory approvals, 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 financial performance of the Company, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2014. 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)

	September 30, 2014	December 31, 2013
Cash and cash equivalents	\$ 211,669	\$ 123,564
Total assets	220,753	162,988
Deferred revenue	33,150	46,872
Stockholders' equity	172,754	104,313

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Collaboration revenue	\$ 8,177	\$ 8,444	\$ 31,062	\$ 32,165
Operating expenses:				
Research and development	22,244	14,584	55,090	41,882
General and administrative	5,669	3,587	15,931	9,664
Total operating expenses	27,913	18,171	71,021	51,546
Loss from operations	(19,736)	(9,727)	(39,959)	(19,381)
Other income (expense), net	41	23	107	(32)
Income tax expense	5	-	118	-

Net loss	<u>\$ (19,700)</u>	<u>\$ (9,704)</u>	<u>\$ (39,970)</u>	<u>\$ (19,413)</u>
Less: accretion of redeemable convertible preferred stock				
to redemption value	-	-	-	264
Loss allocable to common stockholders	<u>\$ (19,700)</u>	<u>\$ (9,704)</u>	<u>\$ (39,970)</u>	<u>\$ (19,677)</u>
Loss per share allocable to common stockholders:				
Basic	\$ (0.58)	\$ (0.34)	\$ (1.23)	\$ (1.49)
Diluted	\$ (0.58)	\$ (0.34)	\$ (1.23)	\$ (1.49)
Weighted average shares outstanding:				
Basic	33,676	28,406	32,607	13,212
Diluted	33,676	28,406	32,607	13,212

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