



August 13, 2014

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

- Presented pre-clinical data showing EPZ-6438 synergy with NHL standards of care and targeted therapies at American Society of Hematology (ASH) Meeting on Lymphoma Biology on August 12, 2014
- Presented early clinical observations from first three cohorts (12 evaluable patients) of ongoing Phase 1 dose escalation study of single agent EPZ-6438 (E7438) at ASH Meeting on Lymphoma Biology on August 12, 2014: maximum tolerated dose (MTD) not reached, allowing for dose escalation in ongoing cohorts 4 and 5; pharmacokinetics (PK) was dose-proportional with pharmacodynamic (PD) evidence of target engagement; objective responses were seen in two non-Hodgkin lymphoma (NHL) patients of varying histologies
- More complete EPZ-6438 Phase 1 data presentation anticipated at a scientific conference later in 2014
- EPZ-6438 Phase 2 initiations in NHL patients and patients with INI1-deficient tumors planned for fourth quarter of 2014
- Initiated pediatric MLL-r Phase 1b dose escalation study of DOT1L inhibitor EPZ-5676 in May 2014; adult MLL-r and MLL-PTD Phase 1 expansion stage study ongoing
- Abstracts on EPZ-5676 adult dose escalation and expansion stage data and PK modeling from pediatric study submitted for the 2014 ASH Annual Meeting (December 6-9, San Francisco)
- Epizyme Chief Scientific Officer Robert Copeland, Ph.D. invited to give plenary talk at EORTC-AACR-NCI Symposium (November 18-21, Barcelona)
- Ended second quarter 2014 with \$232.1 million in cash, cash equivalents and accounts receivable; reiterated cash and cash equivalent guidance for EOY 2014 of more than \$170 million and cash runway until at least mid-2016

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 second quarter 2014 operating and financial results and reiterated 2014 guidance.

"We are pleased with our progress to date in 2014 and are excited by the potential to further expand our ongoing clinical programs," said Robert Gould, Ph.D., Chief Executive Officer, Epizyme. "For our EZH2 inhibitor, EPZ-6438, yesterday we announced pre-clinical data and early clinical observations from the ongoing Phase 1 study, including pre-clinical findings that support its potential use in NHL patients with mutant or wild type EZH2. Additionally, we saw two objective responses among NHL patients enrolled in the first three cohorts of the Phase 1 study, and one of these patients remains on study. Enrollment is ongoing in dose cohorts 4 and 5 at higher doses, and pending review of further EPZ-6438 Phase 1 results later this year, we plan to initiate two Phase 2 proof-of-concept (POC) studies in NHL and INI1-deficient solid tumors in the fourth quarter. For our DOT1L inhibitor EPZ-5676, enrollment in the adult Phase 1 expansion stage study and pediatric Phase 1b study is ongoing. We now have active POC studies in adult MLL-r, adult MLL-PTD, and pediatric MLL-r acute leukemia patients."

"Epizyme is well-positioned to continue creating innovative personalized therapeutics for patients in need and value for our shareholders," said Jason Rhodes, President and Chief Financial Officer, Epizyme. "We began 2014 with \$157.2 million in cash, cash equivalents and accounts receivable and ended the second quarter of 2014 with \$232.1 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 expect to end 2014 with more than \$170 million in cash and cash equivalents, which we expect will fund the Company until at least mid-2016, prior to including any potential future milestone payments."

### **2014 Data Disclosures and Clinical Studies**

- Ongoing Phase 1 dose escalation study of EPZ-6438 in patients with advanced solid tumors or B-cell lymphomas - early clinical observations disclosed in August 2014; further planned clinical data disclosure at a scientific conference later in 2014, including dose cohorts 4 and 5 that are now enrolling at higher doses
- Ongoing Phase 1 clinical study expansion stage of EPZ-5676 in MLL-r adult patients and MLL-PTD adult patients - abstract of dose escalation and expansion stage data submitted for 2014 ASH Annual Meeting
- Ongoing Phase 1b POC clinical study of EPZ-5676 in MLL-r pediatric patients initiated in May 2014 - abstract on PK

modeling from study submitted for 2014 ASH Annual Meeting

- Planned initiation of Phase 2 POC clinical study of EPZ-6438 in non-Hodgkin lymphoma patients in fourth quarter of 2014, pending results of Phase 1 dose escalation study
- Planned initiation of Phase 2 POC clinical study of EPZ-6438 in INI1-deficient tumors, such as malignant rhabdoid tumor or synovial sarcoma in fourth quarter of 2014, pending results of Phase 1 dose escalation study

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

**Collaboration Revenue:** Collaboration revenue was \$9.5 million for the second quarter 2014 and \$22.9 million for the six months ended June 30, 2014, compared to \$14.8 million and \$23.7 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 \$17.5 million, including non-cash expenses of \$1.0 million, for the second quarter 2014 and \$32.8 million, including non-cash expenses of \$1.8 million, for the six months ended June 30, 2014, compared to \$13.9 million, including non-cash expenses of \$0.4 million, and \$27.3 million, including non-cash expenses of \$0.6 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 \$5.3 million, including non-cash expenses of \$0.8 million, for the second quarter 2014 and \$10.3 million, including non-cash expenses of \$1.6 million, for the six months ended June 30, 2014, compared to \$3.1 million, including non-cash expenses of \$0.4 million, and \$6.1 million, including non-cash expenses of \$0.7 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 \$5.5 million.

**Net Loss:** Net loss was \$13.4 million for the second quarter 2014 and \$20.3 million for the six months ended June 30, 2014, compared to net losses of \$2.2 million and \$9.7 million in the comparable periods in 2013.

**Cash, Cash Equivalents and Accounts Receivable:** Cash, cash equivalents and accounts receivable as of June 30, 2014, were \$232.1 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 \$15 million in the six months ended June 30, 2014. Epizyme continues to expect full-year 2014 net cash used in operating activities to be approximately \$50 million, including \$34 million in accounts receivable recorded in 2013 but collected in 2014. Excluding these accounts receivable, adjusted net cash used in operating activities in 2014 is expected to be approximately \$80 million. Epizyme expects to end 2014 with more than \$170 million in cash and cash equivalents, which is expected to fund the Company until at least mid-2016, prior to including any potential future milestone payments.

**Shares Outstanding:** Shares outstanding as of June 30, 2014, were 33.4 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 33.2 million for the second quarter 2014 and 32.1 million for the six months ended June 30, 2014.

## **Conference Call Information**

Epizyme will host a conference call and live audio webcast today at 8:00 a.m. ET to discuss second 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 80954146. The live webcast and corresponding presentation 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 May 14, 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.

## Non-GAAP Financial Performance Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release reports projected adjusted net cash used in operating activities for 2014, a non-GAAP financial measure that we believe provides investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. Projected adjusted net cash used in operating activities excludes accounts receivable recorded in 2013 but collected in 2014. This measure is non-GAAP and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP.

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

	June 30, 2014	December 31, 2013
Cash and cash equivalents	\$ 229,872	\$ 123,564
Total assets	238,371	162,988
Deferred revenue	37,485	46,872
Stockholders' equity	189,604	104,313

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Collaboration revenue	\$ 9,494	\$ 14,839	\$ 22,885	\$ 23,721
Operating expenses:				
Research and development	17,499	13,937	32,846	27,298
General and administrative	5,306	3,079	10,262	6,077
Total operating expenses	22,805	17,016	43,108	33,375

Loss from operations	(13,311)	(2,177)	(20,223)	(9,654)
Other income (expense), net	38	(35)	66	(55)
Income tax expense	113	-	113	-
Net loss	<u>\$ (13,386)</u>	<u>\$ (2,212)</u>	<u>\$ (20,270)</u>	<u>\$ (9,709)</u>
Less: accretion of redeemable convertible preferred stock to redemption value	-	107	-	264
Loss allocable to common stockholders	<u>\$ (13,386)</u>	<u>\$ (2,319)</u>	<u>\$ (20,270)</u>	<u>\$ (9,973)</u>
Loss per share allocable to common stockholders:				
Basic	\$ (0.40)	\$ (0.25)	\$ (0.63)	\$ (1.82)
Diluted	\$ (0.40)	\$ (0.25)	\$ (0.63)	\$ (1.82)
Weighted average shares outstanding:				
Basic	33,156	9,146	32,064	5,489
Diluted	33,156	9,146	32,064	5,489

Investors/Media:  
Epizyme, Inc.  
Manisha Pai, 617-229-7560  
[mpai@epizyme.com](mailto:mpai@epizyme.com)

Source: Epizyme, Inc.

News Provided by Acquire Media