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Epizyme Announces 2013 Operating and Financial Results and Provides 2014 Guidance

- Advanced EPZ-5676 DOT1L inhibitor program, achieved \$25 million proof of concept milestone with Celgene, and initiated Phase 1 study expansion stage for MLL-r and MLL-PTD patients**
- Initiated ongoing EPZ-6438 Phase 1 dose escalation study, achieving \$6 million milestone with Eisai**
- Achieved two pre-clinical milestones with GlaxoSmithKline, including \$4 million development candidate milestone for a collaboration target in 2013 and \$2 million lead candidate milestone for another collaboration target in February 2014**
- Advanced intellectual property position with three U.S. patents issued, including composition of matter claims for EPZ-5676 and EPZ-6438 that expire in 2032**
- Ended 2013 with \$157.2 million in cash, cash equivalents and accounts receivables, extended cash runway through mid-2016, with end-of-2014 cash guidance of approximately \$170 million**

CAMBRIDGE, Mass., Feb. 27, 2014 /PRNewswire/ -- [Epizyme, Inc.](#) (NASDAQ: EPZM), a clinical stage biopharmaceutical company creating innovative personalized therapeutics for patients with genetically defined cancers, today announced 2013 operating and financial results and provided 2014 guidance.

"2013 was a transformative year for Epizyme, with accomplishments across the entire company as we continue to advance our strategy of creating personalized therapeutics for patients with genetically defined cancers. Notably, in December 2013 we achieved a \$25 million proof of concept milestone in our EPZ-5676 clinical program with Celgene," said Robert Gould, Ph.D., Chief Executive Officer, Epizyme. "In 2014, we plan to have clinical studies ongoing that are intended to assess the proof of concept of our EPZ-5676 and EPZ-6438 therapeutic candidates in five genetically defined cancers. We also plan to disclose data from both of these programs in the second half of 2014, including Phase 1 study dose escalation and expansion stage data for EPZ-5676 and Phase 1 dose escalation study data for EPZ-6438."

In 2013, Epizyme also initiated the expansion stage of the EPZ-5676 Phase 1 study, which is only enrolling MLL-r and MLL-PTD patients, and initiated the ongoing Phase 1 dose escalation study for EPZ-6438, Epizyme's EZH2 inhibitor, referred to as E7438 by partner Eisai, earning a \$6 million milestone. In December 2013, Epizyme announced that the European Medicines Agency's Committee for Orphan Medicinal Products recommended orphan drug designation, which has since been granted, for EPZ-5676 to the European Commission, and EPZ-5676 was granted orphan drug designation by the U.S. Food and Drug Administration in August 2013, in each case for the treatment of acute myeloid leukemia and acute lymphoblastic leukemia.

The Company also recently announced that it achieved two pre-clinical milestones with GlaxoSmithKline (GSK), including a \$4 million development candidate milestone for a collaboration target in 2013 and a \$2 million lead candidate milestone for another collaboration target in February 2014.

"Epizyme's product platform continues to generate innovative histone methyltransferase, or HMT, inhibitors as therapeutic candidates," Dr. Gould continued. "The lead candidate selection milestone announced today in the GSK collaboration marks the fourth year in a row that we have identified a novel therapeutic candidate from our platform."

"Epizyme is well funded to advance our therapeutic programs and product platform and to continue to create value for patients and shareholders," said Jason Rhodes, President and Chief Financial Officer, Epizyme. "The integration of our R&D, business, and financing strategies is reflected in our strong cash position. We began 2013 with \$99.8 million in cash and receivables and ended the year with \$157.2 million in cash and receivables following our successful 2013 IPO, with \$80 million in net proceeds, and 2013 partner non-equity funding of \$48 million, largely from the achievement of major milestones in our collaborations with Celgene, Eisai, and GSK. With the successful completion of our follow-on offering in February 2014, which raised \$101 million in net proceeds, we expect to end 2014 with approximately \$170 million in cash and cash equivalents, which we expect will fund the Company through at least mid-2016 prior to including any potential future milestone payments."

2014 Clinical Studies and Data Disclosures

- Ongoing Phase 1 clinical study expansion stage of EPZ-5676 in MLL-r adult patients and MLL-PTD adult patients

- Planned Phase 1b clinical study of EPZ-5676 in MLL-r pediatric patients, initiating in the first half of 2014
- Ongoing Phase 1 dose escalation study of EPZ-6438
- Planned Phase 2 clinical study of EPZ-6438 in non-Hodgkin lymphoma patients with EZH2 point mutations, pending Phase 1 completion
- Planned Phase 2 clinical study of EPZ-6438 in synovial sarcoma patients, pending Phase 1 completion
- Planned clinical data disclosure for EPZ-5676 Phase 1 dose escalation and MLL-r/MLL-PTD expansion stage at a medical conference in the second half of 2014
- Planned clinical data disclosure for EPZ-6438 Phase 1 dose escalation study in the second half of 2014

2013 Financial Results and 2014 Guidance

Collaboration Revenue: Collaboration revenue was \$68.5 million for the year ended December 31, 2013, compared to \$45.2 million in 2012. Collaboration revenue includes deferred revenue from payments received in previous periods as well as payments earned during the year.

R&D Expenses: Research and development expenses were \$57.6 million, including non-cash expenses of \$1.7 million, for the year ended December 31, 2013, compared to \$38.5 million, including non-cash expenses of \$1.2 million, in 2012. The increase was largely driven by clinical study costs for EPZ-5676, the advancement of programs in the GSK collaboration, and the expansion of Epizyme's product platform. Epizyme expects 2014 R&D expenses to be approximately \$75 million, including non-cash expenses of approximately \$3 million.

G&A Expenses: General and administrative expenses were \$14.0 million, including non-cash expenses of \$1.8 million, for the year ended December 31, 2013, compared to \$7.5 million, including non-cash expenses of \$0.3 million in 2012. The increase was largely driven by incremental expenses to support public company operations. Epizyme expects 2014 G&A expenses to be approximately \$20 million, including non-cash expenses of approximately \$5.5 million.

Net Loss: Net loss was \$3.5 million for the year ended December 31, 2013, compared to net loss of \$0.7 million in 2012.

Cash and Receivables: Cash, cash equivalents and accounts receivable as of December 31, 2013, were \$157.2 million, compared to \$99.8 million as of December 31, 2012. The increase was driven by net proceeds of \$80 million from Epizyme's initial public offering in June 2013, a \$25 million proof of concept milestone achieved in the Celgene collaboration for the EPZ-5676 clinical program, a \$6 million milestone achieved in the Eisai collaboration for the initiation of the EPZ-6438 Phase 1 study, and a \$4 million development candidate milestone achieved for one of the targets in the GSK collaboration. Epizyme expects 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. In February 2014, Epizyme announced the closing of a public offering of its stock that raised \$101 million in net proceeds. Epizyme expects to end the year with approximately \$170 million in cash and cash equivalents.

Shares Outstanding: Shares outstanding as of December 31, 2013, were 28.5 million, following the sale of 5.9 million shares of common stock in the Company's initial public offering. Weighted average shares outstanding for the year ended December 31, 2013 were 17.0 million. In February 2014, Epizyme completed a follow-on offering, issuing 3.7 million shares of common stock for net proceeds of \$101 million. Including this follow-on offering, the Company expects shares outstanding as of March 31, 2014, to be 32.8 million.

Conference Call Information

Epizyme will host a conference call and live audio webcast today at 4:30 p.m. EST to discuss 2013 operating and financial results and provide 2014 guidance. To participate in the conference call, please dial 1-877-303-9053 (domestic) or 1-970-315-0464 (international) and refer to conference ID 2813029. 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 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 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 Registration Statement on Form S-1 filed with the Securities and Exchange Commission on January 28, 2014, as amended. 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)

	<u>December 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
Cash and cash equivalents	\$ 123,564	\$ 97,981
Total assets	162,988	103,511
Deferred revenue	46,872	69,445
Redeemable convertible preferred stock (Series A, B and C)	-	76,156
Stockholders' equity (deficit)	104,313	(51,126)

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2012</u>	<u>2013</u>	<u>2012</u>
Collaboration revenue	\$ 36,317	\$ 8,895	\$ 68,482	\$ 45,222
Operating expenses:				
Research and development	15,685	11,098	57,567	38,482
General and administrative	4,378	2,332	14,042	7,508
Total operating expenses	20,063	13,430	71,609	45,990
Income (loss) from operations	16,254	(4,535)	(3,127)	(768)

Other income (expense), net	25	(2)	(7)	67
Income tax expense	349	1	349	1
Net income (loss)	<u>\$ 15,930</u>	<u>\$ (4,538)</u>	<u>\$ (3,483)</u>	<u>\$ (702)</u>
Less: accretion of redeemable convertible preferred stock to redemption value	-	160	264	486
Less: income allocable to participating securities	4	-	-	-
Income (loss) allocable to common stockholders	<u>\$ 15,926</u>	<u>\$ (4,698)</u>	<u>\$ (3,747)</u>	<u>\$ (1,188)</u>
Earnings (loss) per share allocable to common stockholders:				
Basic	\$ 0.56	\$ (2.81)	\$ (0.22)	\$ (0.72)
Diluted	\$ 0.52	\$ (2.81)	\$ (0.22)	\$ (0.72)
Weighted average shares outstanding:				
Basic	28,434	1,670	17,049	1,645
Diluted	30,901	1,670	17,049	1,645

SOURCE Epizyme, Inc.

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