May 9, 2016

Epizyme Announces First Quarter 2016 Financial Results and Provides Update on Execution Against Multi-Year Company Vision

Presentation of early safety and efficacy data from the tazemetostat phase 2 non-Hodgkin lymphoma study planned for ASH Meeting on Lymphoma Biology

Conference call to be held today at 8:00 a.m. Eastern Time

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Epizyme, Inc. (NASDAQ:EPZM), a clinical stage biopharmaceutical company creating novel epigenetic therapies for people with cancer, today reported recent business and program highlights as part of its multi-year vision and financial results for the first quarter of 2016.

"We have made significant progress in our clinical development program for tazemetostat and all four areas of our multi-year vision," said Robert Bazemore, President and Chief Executive Officer of Epizyme. "We are well underway with plans to expand the tazemetostat clinical program into combination studies and its third cancer indication, continuing to advance our discovery pipeline and collaborative research efforts and have strengthened our team and business operations. With a number of milestones on the horizon, we are positioned to continue this momentum."

Accelerate Tazemetostat Program in Non-Hodgkin Lymphoma and Solid Tumors

- Epizyme has submitted an abstract to present a study update from its phase 2 program in patients with relapsed or refractory non-Hodgkin lymphoma (NHL) at the 2016 American Society of Hematology (ASH) Meeting on Lymphoma Biology in June. This presentation will include a progress update on the study enrollment, safety experience for all patients enrolled and an early look at clinical activity in the patient populations that have surpassed their futility hurdle as confirmed by the Independent Data Monitoring Committee (IDMC). The three arms confirmed to have surpassed the futility hurdle are: germinal center diffuse large B-cell lymphoma (DLBCL) with an EZH2 mutation; germinal center DLBCL with wild-type EZH2; and non-germinal center DLBCL. Futility in each of the DLBCL arms is based on observing at least one objective response in the first ten patients enrolled. Responses have been observed in the two arms enrolling patients with follicular lymphoma; however, neither arm has yet reached its futility hurdle, which is at least two objective responses out of the first ten patients enrolled.
- The IDMC recently approved Epizyme's planned expansion of enrollment in all five arms of the phase 2 study in patients with NHL. The total population will increase to 270 patients from 150. The three arms enrolling patients with DLBCL will now enroll 60 patients each, and the two arms enrolling patients with follicular lymphoma will now enroll 45 patients each. This expansion will enable more precision around the level of activity in each patient population, which will provide guidance for determining next steps in each population and the statistical design of potential subsequent studies. Pending abstract submission and acceptance, the Company plans to present a second study update at the ASH Annual Meeting in late 2016.
- Epizyme recently expanded the number of arms in the phase 2 study in adult patients with certain genetically defined solid tumor (INI1-negative tumors, SMARCA4-negative tumors or synovial sarcomas) to five arms from three due to a higher accrual of patients with certain types of INI1-negative tumors than it anticipated. The two arms enrolling patients with rhabdoid tumors and synovial sarcomas remain unchanged. A third arm will continue to enroll patients with other INI1-negative tumors, and the Company has now separated out two specific INI1-negative cohorts from the third arm. One arm will enroll patients with renal medullary carcinoma and another will enroll patients with epithelioid sarcoma. Pending abstract submission and acceptance, the Company plans to present preliminary data from the phase 2 adult solid tumor study at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium in late 2016.
- The phase 1 dose-escalation and expansion study of tazemetostat in pediatric patients with certain INI1-negative tumors, including rhabdoid tumors and synovial sarcomas, is enrolling well, and the study has escalated to the second dose level.

Expand Tazemetostat Program

- In May, the U.S. Food and Drug Administration (FDA) accepted the Company's Investigational New Drug (IND) application for tazemetostat for the treatment of adult patients with mesothelioma characterized by BAP1 loss-of-function. The Company plans to initiate a phase 2 trial in patients with mesothelioma in the third quarter of 2016.
- Earlier today, Epizyme announced that it has entered into a collaboration agreement with the Lymphoma Academic Research Organisation (LYSARC) for the first planned combination trial of tazemetostat. LYSARC is the operational arm of the Lymphoma Study Association, a premier cooperative French lymphoma group. This phase 1b/2 study will evaluate tazemetostat administered together with R-CHOP as a front-line therapy for elderly, high-risk patients with DLBCL, and is expected to begin in mid-2016.
- Data presented at the American Association for Cancer Research (AACR) conference in April further characterized the dosing and administration of tazemetostat. The findings show that tazemetostat is only a weak inducer of CYP3A-mediated metabolism, suggesting a low potential interaction with other treatments metabolized through this pathway. Pharmacokinetic data presented at that meeting also show that tazemetostat can be dosed with or without food. These findings further guide tazemetostat development as a monotherapy and in combination regimens.

Growth Discovery Pipeline

- Epizyme scientists continue to advance the development of small molecule inhibitors against five targets that have been selected and prioritized for research.

Maintain Established Leadership Position

- Epizyme added strength to its leadership team with new hires: Matthew Ros as Chief Operating Officer, Susan Graf as Chief Business Officer, Jeannie Chu as Vice President of Program and Portfolio Management and Michael Boretti, Ph.D. as Vice President of Business Development.

Q1 2016 Financials Results and Guidance

- Collaboration revenue was $0.5 million for the quarter ended March 31, 2016, compared to $0.9 million for the same period last year. The period-over-period decrease reflects increased recognition of deferred revenue from upfront payments from the Celgene collaboration in the first quarter of 2016 offset by decreased recognition of deferred revenue from upfront payments and research and development revenue related to the GlaxoSmithKline collaboration compared to the first quarter of 2015 as no revenue was recognized with respect to the GSK collaboration in the first quarter of 2016.
- Research and development (R&D) expenses were $17.7 million for the quarter ended March 31, 2016, compared to $57.1 million for the first quarter of 2015. The period-over-period decrease was driven by the first quarter 2015 payment to Eisai of $40.0 million related to the reacquisition of the worldwide rights, excluding Japan, to tazemetostat, and was partially offset by increased spending on the tazemetostat clinical development program.

  Epizyme expects that R&D expenses will increase in 2016, when compared to 2015. The planned increase is primarily related to the development costs of tazemetostat, including Epizyme's trials in patients with non-Hodgkin lymphoma and adult and pediatric patients with certain genetically defined solid tumors, as well as planned combination studies in patients with DLBCL and the planned study in patients with mesothelioma. In addition, discovery and preclinical research costs are expected to increase as the Company advances its wholly owned small molecule programs against five novel targets and continues the research efforts under its Celgene collaboration.

- General and administrative (G&A) expenses were $5.8 million for the quarter ended March 31, 2016, compared to $5.2 million for the same period last year. The increase in G&A expense was largely due to higher professional services costs and personnel-related expenses associated with the expansion of Epizyme's operations. Epizyme expects that G&A spend will increase in 2016 as compared to 2015 due to increases in staffing and infrastructure to support expanded clinical trial activities, increased research investment and other expanded operational activities, including increased intellectual property costs.
- Net loss was $22.9 million for the quarter ended March 31, 2016, compared to a net loss of $61.3 million for the quarter ended March 31, 2015.
- Cash and cash equivalents were $312.7 million as of March 31, 2016, compared with $208.3 million as of December 31, 2015. This increase in cash was driven by the Company's January 2016 financing.
- Financial guidance from Epizyme states that the Company believes its cash and cash equivalents as of March 31, 2016 will be sufficient to fund the Company's planned operations through at least the end of 2017.

Conference Call Information

Epizyme will host a conference call and live audio webcast today at 8:00 a.m. Eastern Time to discuss its Q1 2016 financial results and provide business updates. To participate in the conference call, please dial (877) 497-1428 (domestic) or (929) 387-3949 (international) and refer to "Epizyme Call" or conference ID 90135413. The live and archived versions of the webcast can be accessed under Events in the Investor Center section of the Company's website at http://www.epizyme.com.

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.

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 preclinical data and 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, whether the Company's collaborations will be successful, 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, ability to enter into third party collaborations on favorable terms or at all, 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 Form 10-K filed with the SEC on March 9, 2016 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. 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)

	March 31, 2016	December 31, 2015
Consolidated Balance Sheets Data:		
Cash and cash equivalents	$ 312,656	$ 208,323
Total assets	322,704	217,903
Deferred revenue	30,237	30,709
Total stockholders' equity	279,010	169,532

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

	Three Months Ended March 31,	
	2016	2015
Collaboration revenue	$ 472	$ 911

Operating expenses:		
Research and development	17,740	57,051
General and administrative	5,846	5,237
Total operating expenses	23,586	62,288
Loss from operations	(23,114)	(61,377)
Other income, net	235	51
Net loss	$(22,879)	$(61,326)
Loss per share allocable to common stockholders:		
Basic	$ (0.41)	$ (1.75)
Diluted	$ (0.41)	$ (1.75)
Weighted average shares outstanding:		
Basic	55,149	34,992
Diluted	55,149	34,992

View source version on businesswire.com: http://www.businesswire.com/news/home/20160509005384/en/

Investors:
Rebecca Cohen, 617-401-0722
Epizyme, Inc.
Investor Relations and Corporate Communications
rcohen@epizyme.com
Media:
Michael Lampe, 484-575-5040
Scient Public Relations
michael@scientpr.com

Source: Epizyme, Inc.