August 4, 2017

Epizyme Reports Second Quarter 2017 Financial Results and Clinical and Business Progress

Key Clinical Milestones Achieved in Studies of Mesothelioma, Epithelioid Sarcoma and Pediatric Solid Tumors

Expansion of Collaborations to Accelerate Investigation of Tazemetostat Across Multiple Tumor Types

Conference Call to be Held Today at 8:00 a.m. ET

CAMBRIDGE, Mass., Aug. 04, 2017 (GLOBE NEWSWIRE) -- Epizyme, Inc. (NASDAQ:EPZM), a clinical-stage biopharmaceutical company creating novel epigenetic therapies, today reported operating results for the second quarter 2017 and highlighted recent business and clinical progress.

"Our focus throughout 2017 has been on executing important clinical and regulatory milestones across our tazemetostat program to enable us to bring this first-in-class agent to patients as quickly as we can," said Robert Bazemore, president and chief executive officer of Epizyme. "In addition, we have continued to pursue avenues to accelerate patient enrollment in our studies, including the recently established collaboration with US Oncology Research to support recruitment for our NHL study. We are also pleased to have reached key milestones in our solid tumor program, including completing enrollment in both our Phase 2 mesothelioma study and the epithelioid sarcoma cohort in our Phase 2 INI1-negative solid tumor study, and establishing the recommended dose in our Phase 1 study in children. We believe we have a significant opportunity with tazemetostat in hematological malignancies and solid tumors, and look forward to further evaluating its monotherapy and combination potential and engaging with FDA for our NHL program in the second half of the year."

Tazemetostat Clinical Program Updates

- In July 2017, Epizyme completed enrollment in the epithelioid sarcoma (ES) cohort of its ongoing, multi-arm Phase 2 study in adult patients with INI1-negative solid tumors. Following the announcement of positive interim data at the American Society of Clinical Oncology (ASCO) Annual Meeting and discussion with the U.S. Food and Drug Administration, the company has identified a path to submission for accelerated approval for the treatment of patients with ES, and is targeting the first New Drug Application for tazemetostat in this indication in 2018.
- In July 2017, Epizyme announced that the National Cancer Institute (NCI) initiated its Pediatric MATCH study, which will evaluate tazemetostat in one of the study arms as a monotherapy for pediatric patients with certain genetically defined solid tumors or non-Hodgkin lymphoma. This study is part of the company's Cooperative Research and Development Agreement (CRADA) executed between Epizyme and the NCI.
- In July 2017, the company established the recommended dose for tazemetostat in its study of pediatric patients with solid tumors, and initiated the dose-expansion portion of the study.
- In June 2017, the company completed enrollment in its ongoing Phase 2 study designed to evaluate tazemetostat as a treatment for adults with mesothelioma characterized by BAP1 loss-of-function. The company expects to report data from this study in 2018.
- In June 2017, Epizyme announced that tazemetostat will be evaluated in combination with atezolizumab (TECENTRIQ®) in a Phase 1b/2 clinical study of metastatic non-small cell lung cancer as part of MORPHEUS, Genentech's open-label, multi-center, randomized umbrella study evaluating the efficacy and safety of multiple immunotherapy-based treatment combinations in solid tumors. This study is an expansion of the company's clinical collaboration with Genentech, a member of the Roche Group, and is expected to begin enrolling patients by the end of the year.
- In June 2017, positive interim efficacy data, grouped by EZH2 mutational status, were presented during a plenary session at the International Conference on Malignant Lymphoma (ICML) from the ongoing Phase 2 clinical trial of tazemetostat as a single-agent treatment for relapsed or refractory patients with follicular lymphoma (FL) or diffuse large B-cell lymphoma (DLBCL). Promising clinical activity and durability were observed across all study cohorts, with enhanced efficacy in the EZH2 mutation cohorts. Importantly, tazemetostat continues to demonstrate a favorable safety profile across the clinical development program.

Recent Business Highlights

- In August 2017, Epizyme announced a collaboration with US Oncology Research to implement a separate screening protocol in 68 locations in the U.S. (including satellite locations affiliated with primary sites) to identify relapsed or refractory FL and DLBCL patients with tumors bearing EZH2 mutations who may be candidates for enrollment in Epizyme's ongoing Phase 2 clinical trial. US Oncology Research will direct identified patients to the tazemetostat Phase 2 clinical trial for protocol screening and potential enrollment into the trial. Sites began screening patients in July 2017.
- In June 2017, the U.S. FDA granted Orphan Drug designation to tazemetostat for the treatment of patients with soft tissue sarcoma (STS). Orphan Drug designation conveys eligibility for certain development incentives and market exclusivity for STS independent from Epizyme's intellectual property protection.

Upcoming 2017 Milestones

- Epizyme anticipates engaging with the U.S. FDA in the second half of 2017 to review data from its ongoing Phase 2 study in relapsed or refractory patients with NHL and discussing potential registration paths for tazemetostat.
- The company plans to begin a clinical study evaluating tazemetostat as a combination agent for the treatment of patients with FL by the end of 2017.
- Epizyme plans to announce the next development candidate from its novel, internally discovered pipeline of epigenetic programs by the end of 2017.

Second Quarter 2017 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities were $193.0 million as of June 30, 2017, as compared to $211.2 million as of March 31, 2017.
- **Revenue:** $10.0 million was recognized in the second quarter of 2017, compared to $0.5 million for the second quarter of 2016. Revenue in the second quarter of 2017 represents a $10.0 million milestone payment from GlaxoSmithKline (GSK) following their initiation of GLP toxicology studies for a first-in-class methyltransferase inhibitor discovered by Epizyme and licensed to GSK.
- **R&D Expenses:** Research and development (R&D) expenses were $27.3 million for the second quarter of 2017, compared to $21.5 million for the second quarter of 2016. The increase is primarily due to the expansion of the tazemetostat clinical development program, as well as increased research activities related to Epizyme's next potential development candidate and new target families.
- **G&A Expenses**: General and administrative (G&A) expenses were $11.2 million for the second quarter of 2017, compared to $7.4 million for the second quarter of 2016. The increase is primarily due to an increase in commercial-related activities and legal spending to support the company's growing intellectual property portfolio.
- **Net Loss:** Net loss was $28.0 million for each of the quarters ended June 30, 2017 and June 30, 2016.

2017 Financial Guidance
Epizyme believes, based on its current operating plan, that its cash, cash equivalents and marketable securities of $193.0 million as of June 30, 2017 will be sufficient to fund the Company's planned operations into at least the third quarter of 2018.

About the Tazemetostat Clinical Trial Program
Tazemetostat, a first-in-class EZH2 inhibitor, is currently being studied as a monotherapy in ongoing Phase 2 programs in both follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) forms of non-Hodgkin lymphoma (NHL); certain molecularly defined solid tumors, including epithelioid sarcoma and other INI1-negative tumors; and mesothelioma and combination studies in DLBCL. Tazemetostat has been granted Fast Track designation by the U.S. Food and Drug Administration for FL regardless of EZH2 mutation status and for DLBCL with EZH2-activating mutations, as well as Orphan Drug designation for soft tissue sarcoma and malignant rhabdoid tumors.

About Epizyme, Inc.
Epizyme, Inc. is a clinical-stage biopharmaceutical company committed to rewriting cancer treatment through novel epigenetic medicines. Epizyme is broadly developing its lead product candidate, tazemetostat, a first-in-class EZH2 inhibitor, with studies underway in both solid tumors and hematological malignancies, as a monotherapy and combination therapy and in relapsed and front-line disease. Using the Company's proprietary platform, Epizyme has pioneered the identification and development of small molecule inhibitors of chromatin modifying proteins (CMPs), such as tazemetostat. 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, which can allow cancer cells to grow and proliferate. By focusing on the genetic drivers of cancers, Epizyme's science seeks to match targeted medicines with the specific patients that need it. For more information, visit www.epizyme.com and connect with us on Twitter at @EpizymeRx.

TECENTRIQ® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

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 and in the 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; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials; whether results from clinical studies will warrant meetings with regulatory authorities, submissions for regulatory approval or review by governmental authorities under the accelerated approval process; whether fast track and orphan drug designations will provide the benefits for which tazemetostat is eligible; expectations for regulatory approvals to conduct trials or to market products; whether the Company's cash resources will be sufficient to fund 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; and other factors discussed in the "Risk Factors" section of the Company's most recent Form 10-Q filed with the SEC 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 and should not be relied upon as representing the Company's views as of any date subsequent to 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.

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

	June 30, 2017	December 31, 2016
	(In thousands)	
Consolidated Balance Sheets Data :		
Cash, cash equivalents and marketable securities	$ 193,004	$ 242,192
Total assets	205,310	252,441
Deferred revenue	28,809	28,809
Total stockholders' equity	150,040	201,700

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Collaboration revenue	$ 10,000	$ 473	$ 10,000	$ 945
Operating expenses:				
Research and development	27,292	21,450	51,987	39,190
General and administrative	11,170	7,424	19,439	13,270
Total operating expenses	38,462	28,874	71,426	52,460
Loss from operations	(28,462)	(28,401)	(61,426)	(51,515)
Other income, net	438	420	880	655
Net loss	$ (28,024)	$ (27,981)	$ (60,546)	$ (50,860)
Loss per share allocable to common stockholders:				
Basic	$ (0.48)	$ (0.49)	$ (1.04)	$ (0.90)
Diluted	$ (0.48)	$ (0.49)	$ (1.04)	$ (0.90)
Weighted average shares outstanding:				
Basic	58,377	57,352	58,298	56,250
Diluted	58,377	57,352	58,298	56,250

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