Epizyme Reports Business Progress and Third Quarter 2020 Financial Results

November 6, 2020

Company Reports 55% Growth in Net Revenue of TAZVERIK® Compared with 2Q 2020

Expansion of Loan Facility with Pharmakon Advisors; $150 Million Drawn Down to Fund Important Growth Initiatives and Extend Operating Runway into At Least 2023

On-Track to Initiate Efficacy Portions of Confirmatory Trials in ES and FL and Phase 2 Castration-Resistant Prostate Cancer Trial in Early 2021

Conference Call to be Held Today, November 6 at 8:00 a.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 6, 2020-- Epizyme, (Nasdaq: EPZM), a fully integrated, commercial-stage biopharmaceutical company developing and delivering novel epigenetic therapies, today provided business and portfolio updates and reported third quarter 2020 financial results.

"2020 has been a year of big milestones for Epizyme, and we are executing our TAZVERIK® launches well, given the unprecedented challenges presented by the COVID-19 pandemic on FL patients' access to their physicians and on access to our customers," said Robert Bazemore, president and chief executive officer of Epizyme. "While we acknowledge the impact the COVID-19 dynamics have had on the initial uptake in FL, we are reaching both the ES and FL patient populations expected based on our label, and our view of the value proposition of TAZVERIK is unchanged. We believe that the combination of our commercial and clinical performance, and strong balance sheet, sets us up for a positive future."

TAZVERIK® (tazemetostat) Program Updates

- **Execution of TAZVERIK U.S. Commercialization in Relapsed or Refractory Follicular Lymphoma (FL) and Epithelioid Sarcoma (ES):** TAZVERIK generated net product revenue in both ES and FL of $3.4 million in the third quarter, with growth over the second quarter of 2020 of 55% largely driven by the U.S. Food and Drug Administration (FDA) approval of TAZVERIK in FL on June 18, 2020. During the third quarter, the COVID-19 pandemic continued to negatively impact FL patient visits to physicians, new patient starts across all lines of treatment, as well as the ability of Epizyme's field-based teams to fully access FL prescribers. Epizyme reports that new prescriptions for TAZVERIK in FL have increased month over month and are being written for both EZH2 mutation and wild-type patients; in the academic and community settings; and across multiple treatment lines in relapsed or refractory patients. In addition, payor coverage for ES and FL has been in-line with the TAZVERIK label. Epizyme continues to adapt its commercial strategy to the COVID-19 pandemic to support increased adoption of TAZVERIK in appropriate patients.
- **Two Lancet Oncology Publications on TAZVERIK Phase 2 Data in ES and FL:** In October 2020, *The Lancet Oncology* published results of the company's Phase 2 trial cohorts evaluating TAZVERIK for the treatment of ES and relapsed or refractory FL, which supported the accelerated approvals by the FDA for both indications in 2020.
- **Confirmatory Trials for ES and FL On-Track:** Enrollment in the safety run-in portions of Epizyme's two confirmatory trials of TAZVERIK is on track to be completed in 2020, followed by initiation of the efficacy portions in early 2021. The ES confirmatory trial is evaluating TAZVERIK in combination with doxorubicin compared with doxorubicin plus placebo as a front-line treatment for ES, and the FL confirmatory trial is evaluating TAZVERIK in combination with "R2" (Revlimid ® plus Rituxan®) compared with R2 plus placebo in the second-line treatment setting in patients with FL.

Tazemetostat Expansion Program Updates

- **Advancing to Efficacy Portion of Combination Trial in Metastatic Castration-Resistant Prostate Cancer (mCRPC):** Epizyme completed enrollment in the safety run-in portion of its combination study in mCRPC, and initiation of the efficacy expansion stage is planned for early 2021. Epizyme anticipates reporting safety and efficacy data from the safety run-in portion of the study at a medical meeting in 2021.

Upcoming Presentations at ASH

- **Data in FL to be Presented at 62nd American Society of Hematology (ASH) Annual Meeting and Exposition:** Epizyme will present data from its FL development program during multiple poster sessions at ASH, which will be held virtually December 5-8, 2020:
  - **Title:** Tazemetostat is Associated with Lower Risk for Safety Outcomes Versus the PI3-Kinases Idelalisib, Duvelisib and Copanlisib, in Patients with Relapsed/Refractory Follicular Lymphoma Who Have Received at Least 2 Prior Systemic Treatments: a Matching-Adjusted Indirect Comparison of Single-Arm Trials

        - **Session Name:** 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Poster II
        - **Date:** Sunday, December 6, 2020
    - **Title:** A Phase 1b/3 Randomized, Double-Blind, 3-Stage Study of Tazemetostat or Placebo Plus Lenalidomide and Rituximab in Patients with Relapsed/Refractory Follicular Lymphoma
        - **Session Name:** 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Poster II
        - **Date:** Sunday, December 6, 2020
    - **Title:** Analyzing Efficacy Outcomes from the Phase 2 Study of Single-Agent Tazemetostat as Third-Line Therapy in Patients with Relapsed or Refractory Follicular Lymphoma to Identify Predictors of Response
        - **Session Name:** 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma-Clinical Studies: Poster II
        - **Date:** Sunday, December 6, 2020
    - **Title:** A Phase 2, Open-Label, Multicenter Study of Tazemetostat in Combination with Rituximab for the Treatment of Relapsed or Refractory Follicular Lymphoma
        - **Session Name:** 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma-Clinical Studies: Poster III
        - **Date:** Monday, December 7, 2020

Leadership Update

- **Organization Strengthened with Strategic Promotions:** In October 2020, Matthew Ros was promoted to executive vice president and chief strategy and business officer of Epizyme and Vicki Vakiener was promoted to chief commercial officer. As part of these promotions, Mr. Ros is overseeing execution of Epizyme's long-term corporate strategy. Ms. Vakiener is overseeing commercial execution of TAZVERIK in ES and FL.

Third Quarter 2020 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $279.9 million as of September 30, 2020, as compared to $322.1 million as of June 30, 2020.
- **Revenue:** Total revenue for the third quarter of 2020 was $3.6 million, comprised of $3.4 million in net sales of TAZVERIK in the U.S. and $0.1 million in collaboration revenue, compared to $2.5 million in the second quarter of 2020, comprised of $2.2 million in net sales of TAZVERIK in the U.S. and $0.2 million in collaboration revenue.
- **Cost of sales:** Cost of sales were $1.6 million for the third quarter of 2020, which reflects the costs of TAZVERIK units sold, amortization of intangible assets and third-party royalties on net product revenue.
- **Operating Expenses:** Total GAAP operating expenses were $57.9 million for the third quarter of 2020, compared to $60.0 million for the second quarter of 2020. Total non-GAAP adjusted operating expenses were $50.2 million for the third quarter of 2020, compared to $50.9 million for the second quarter of 2020.
    - **R&D expenses:** GAAP R&D expenses were $25.7 million for the third quarter of 2020, compared to $26.4 million for the second quarter of 2020. Non-GAAP adjusted R&D expenses were $23.5 million for the third quarter of 2020, compared to $23.4 million for the second quarter of 2020.
    - **SG&A expenses:** GAAP SG&A expenses were $30.6 million for the third quarter of 2020, compared to $32.7 million for the second quarter of 2020. Non-GAAP adjusted SG&A expenses were $26.2 million for the third quarter of 2020, compared to $27.1 million for the second quarter of 2020.
- **Net Loss (GAAP):** Net loss attributable to common stockholders was $56.1 million, or $0.55 per share, for the third quarter of 2020, compared to $58.5 million, or $0.58 per share, for the second quarter of 2020.

Updated Financial Guidance

- **Agreement with Pharmakon Advisors to Expand Loan Facility Extends Operating Runway:** Epizyme and Pharmakon Advisors, an affiliate of Royalty Pharma, have expanded their original loan agreement established in November 2019, enabling Epizyme to draw down an additional $150 million from the loan facility, subject to customary closing conditions. Based on its current plans and projections, Epizyme believes that its existing cash, cash equivalents and marketable securities combined with the proceeds from the loan facility will fund the company's operations into at least 2023.
- **Updated 2020 Operating Expenses:** Epizyme updated its guidance for full year non-GAAP adjusted cash operating expenses to between $215 million to $235 million, from the previous $235 million to $255 million. The change is due primarily to a reduction in travel and other expenses and a change in how the company's manufacturing expenses are recorded with a commercial product, partially offset by an increase in commercial-related expenses to address COVID-19 related challenges. A reconciliation of the non-GAAP financial measures to the most directly comparable GAAP financial measures is presented in the table attached to this press release.

Conference Call Information

Epizyme will host a conference call today, November 6, at 8:00 a.m. ET. To participate in the conference call, please dial (877) 844-6886 (domestic) or (970) 315-0315 (international) and refer to conference ID 9556565. A webcast will be available in the investor section of the company's website at

www.epizyme.com, and will be archived for 60 days following the call.

About Non-GAAP Financial Measures

In addition to financial information prepared in accordance with the U.S. generally accepted accounting principles (GAAP), this press release includes the following non-GAAP financial measures: total non-GAAP adjusted operating expenses on a historical and projected basis, non-GAAP R&D expenses on a historical basis and non-GAAP SG&A expenses on a historical basis. Epizyme derives these non-GAAP financial measures by excluding certain expenses and other items from the respective GAAP financial measure, that is most directly comparable to each non-GAAP financial measure. Specifically, the non-GAAP financial measures exclude stock-based compensation expense, amortization or depreciation of intangibles and milestone payments related to TAZVERIK that are payable under the company's collaboration agreement with Eisai Pharmaceuticals. The company's management believes that these non-GAAP financial measures are useful to both management and investors in analyzing its ongoing business and operating performance. Management does not intend the presentation of these non-GAAP financial measures to be considered in isolation or as a substitute for results prepared in accordance with GAAP, but as a complement to provide greater transparency. In addition, these non-GAAP financial measures may differ from similarly named measures used by other companies. A quantitative reconciliation of projected non-GAAP adjusted operating expenses to total operating expenses is not available without unreasonable effort primarily due to the company's inability to predict with reasonable certainty the amount of future stock-based compensation expense.

About TAZVERIK

TAZVERIK is a methyltransferase inhibitor indicated for the treatment of:

- Adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.
- Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies.
- Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.

These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

The most common (≥20%) adverse reactions in patients with epithelioid sarcoma are pain, fatigue, nausea, decreased appetite, vomiting and constipation. The most common (≥20%) adverse reactions in patients with follicular lymphoma are fatigue, upper respiratory tract infection, musculoskeletal pain, nausea and abdominal pain.

View the U.S. Full Prescribing Information here: Epizyme.com

About Epizyme, Inc.

Epizyme, Inc. is a fully integrated, commercial-stage biopharmaceutical company committed to its mission of rewriting treatment for cancer and other serious diseases through novel epigenetic medicines. In addition to an active research and discovery pipeline, Epizyme has one U.S. FDA approved product, TAZVERIK® (tazemetostat), for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma (ES) who are not eligible for complete resection; adult patients with relapsed or refractory follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies; and adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options. These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The company is also exploring the treatment potential of tazemetostat in investigational clinical trials in other solid tumors and hematological malignancies, as a monotherapy and combination therapy in both relapsed and front-line disease settings. By focusing on the genetic drivers of disease, Epizyme seeks to match medicines with the patients who need them. For more information, visit www.epizyme.com.

About Pharmakon Advisors

Pharmakon Advisors, LP is the investment manager of the BioPharma Credit funds and of BioPharma Credit PLC (LON:BPCR), the only listed specialist investor in debt from the life sciences industry. Established in 2009, Pharmakon has invested $5 billion across 40 different financing transactions for companies in the life sciences.

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: whether the commercial launch of TAZVERIK for epithelioid sarcoma and follicular lymphoma in the approved indications will be successfully executed; whether tazemetostat will receive marketing approval for epithelioid sarcoma or follicular lymphoma in other jurisdictions, full approval in the United States or approval in any other indication; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials, such as the ongoing confirmatory 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; expectations for regulatory approvals, including accelerated approval, to conduct trials or to market products; the impact of the COVID-19 pandemic on the company's business, results of operations and financial condition; whether the conditions to the additional draw-down under the company's loan facility are satisfied and the draw-down is consummated; 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 success of tazemetostat or 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.

TAZVERIK® is a registered trademark of Epizyme, Inc.

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

	September 30, 2020	December 31, 2019
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 93,422	$ 139,482
Marketable securities	186,485	241,605
Intangible, net	48,041	—
Total assets	381,756	424,589
Total current liabilities	34,780	34,386
Deferred revenue	3,812	3,806
Long-term debt, net of debt discount	68,554	23,309
Liability related to sale of future royalties	13,701	12,793
Total stockholders' equity	244,409	331,137

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2020	2019	2020	2019
Revenues				
Product revenue, net	$ 3,445	$ -	$ 6,963	$ -
Collaboration revenue	121	5,715	424	19,506
Total revenue	3,566	5,715	7,387	19,506
Operating expenses				
Cost of product revenue	1,608	-	3,244	-
Research and development	25,738	26,579	77,253	94,382
Selling, general and administrative	30,575	17,089	90,161	44,773
Total operating expenses	57,921	43,668	170,658	139,155
Operating loss	(54,355)	(37,953)	(163,271)	(119,649)
Other income, net:				
Interest (expense) income, net	(1,364)	1,879	(1,177)	5,790
Other expense, net	(42)	(15)	(105)	(34)
Non-cash interest expense related to sale of future royalties	(312)	-	(908)	-
Other (expense) income, net:	(1,718)	1,864	(2,190)	5,756
Loss before income taxes	(56,073)	(36,089)	(165,461)	(113,893)
Income provision	-	-	-	-
Net loss	$ (56,073)	$ (36,089)	$ (165,461)	$ (113,893)
Reconciliation of net loss to net loss attributable to common stockholders				
Net loss	$ (56,073)	$ (36,089)	$ (165,461)	$ (113,893)
Accretion of convertible preferred stock	-	-	-	(2,940)
Net loss attributable to common stockholders	$ (56,073)	$ (36,089)	$ (165,461)	$ (116,833)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.55)	$ (0.40)	$ (1.64)	$ (1.33)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	101,512	91,044	100,747	88,145

EPIZYME, INC.
Reconciliation of Selected GAAP Measures to Non-GAAP Measures (UNAUDITED)
(Amounts in thousands)

	Three Months Ended September 30		Nine Months Ended September 30	
Reconciliation of GAAP to Non-GAAP Cost of Product Revenue	**2020**	**2019**	**2020**	**2019**
GAAP Cost of Product Revenue	$ 1,608	$ -	$ 3,244	$ -
Less: Depreciation and Amortization	(1,038)	-	(1,959)	-
Non-GAAP Cost of Product Revenue	$ 570	$ -	$ 1,285	$ -
Reconciliation of GAAP to Non-GAAP Research and Development				
GAAP Research and Development	$ 25,738	$ 26,579	$ 77,253	$ 94,382
Less: Stock-Based Compensation Expenses	(2,079)	(1,104)	(7,045)	(4,001)
Less: Depreciation and Amortization	(142)	(148)	(410)	(463)
Less: Eisai R&D Milestone Expense	-	-	-	(10,000)
Non-GAAP Research and Development	$ 23,517	$ 25,327	$ 69,798	$ 79,918
Reconciliation of GAAP to Non-GAAP Selling, General and Administrative:				
GAAP Selling, General and Administrative	$ 30,575	$ 17,089	$ 90,161	$ 44,773
Less: Stock-Based Compensation Expenses	(4,307)	(2,573)	(14,143)	(7,615)
Less: Depreciation and Amortization	(112)	(62)	(305)	(163)
Non-GAAP Selling, General and Administrative	$ 26,156	$ 14,454	$ 75,713	$ 36,995
Reconciliation of GAAP to Non-GAAP Operating Expenses				
GAAP Operating Expenses	$ 57,921	$ 43,668	$ 170,658	$ 139,155
Less: Stock-Based Compensation Expenses	(6,386)	(3,677)	(21,188)	(11,616)
Less: Depreciation and Amortization	(1,292)	(210)	(2,674)	(626)
Less: Eisai R&D Milestone Expense	-	-	-	(10,000)
Non-GAAP Operating Expenses	$ 50,243	$ 39,781	$ 146,796	$ 116,913
	-	-	-	-

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