UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported):
August 4, 2020

EPIZYME, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35945**	**26-1349956**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

400 Technology Square, Cambridge, Massachusetts	**02139**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 229-5872

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common stock, $0.0001 par value	**EPZM**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On August 4, 2020, Epizyme, Inc., a Delaware corporation (the "Company") announced its financial results for the quarter ended June 30, 2020. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided under Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1	Press release issued by the Company on August 4, 2020*
104	Cover Page Interactive Date File (embedded within Inline XBRL document)

* The exhibit shall be deemed to be furnished, and not filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EPIZYME, INC.

Date: August 4, 2020

By: /s/ Robert B. Bazemore
Robert B. Bazemore
President and Chief Executive Officer

Epizyme Reports Business Progress and Second Quarter 2020 Financial Results

TAZVERIK® Approved for Multiple Cancer Indications; Executing Well on Commercial Launches for TAZVERIK in Epithelioid Sarcoma and Follicular Lymphoma

Conference Call to be Held Today, August 4 at 8:30 a.m. ET

CAMBRIDGE, Mass., Aug. 4, 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 second quarter 2020 financial results.

“With back-to-back FDA approvals for TAZVERIK over the course of the last six months, we have a significant opportunity to provide a safe and effective new therapeutic option to patients in need,” said Robert Bazemore, president and chief executive officer of Epizyme. “As we move into the second half of the year, we are focused on the successful execution of our launches and all other aspects of our business. Despite the evolving COVID-19 situation, our commercial launches are proceeding very well, and our in-house and clinical collaboration efforts to evaluate tazemetostat in additional combinations and indications remain on track. We have delivered on the major corporate objectives we set for the first half of 2020, and we look forward to the continued advancement of our programs in order to help as many patients as possible.”

Recent Progress

- **TAZVERIK Approval and Commercial Launch Underway in Relapsed or Refractory Follicular Lymphoma (FL):** TAZVERIK was granted accelerated approval and became commercially available to eligible patients on June 18, 2020. Epizyme’s field team began engaging immediately with the FL prescribing community, with the first prescription filled on June 25, 2020, and initial feedback from physicians and payors on this approval and the TAZVERIK label has been highly positive.
- **TAZVERIK Added to NCCN Clinical Practice Guidelines for FL:** Shortly after the FDA approval of TAZVERIK in FL, the National Comprehensive Cancer Network updated its Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for FL to include TAZVERIK as a recommended category 2A treatment for patients with relapsed or refractory FL. The NCCN Guidelines are the recognized clinical standard for cancer care by U.S. healthcare providers and payers and are maintained by a committee of expert physicians from leading U.S. cancer centers.

- **Continued Commercial Execution for TAZVERIK in Epithelioid Sarcoma (ES):** TAZVERIK became commercially available to patients on February 1, 2020, following its accelerated approval on January 23, 2020, for the treatment of metastatic or locally advanced ES. Amidst the COVID-19 situation, the field-based teams are executing well and leveraging virtual and other non-personal methods to continue to engage with customers. At the end of the second quarter, TAZVERIK had generated total net product sales of $3.5 million since its launch, primarily comprised of sales in ES.

- **Expansion Development of Tazemetostat Remains on-Track:** Epizyme's expansion program to further investigate tazemetostat's therapeutic potential in earlier lines of therapy for FL, including several combination regimens with anti-cancer therapies, as well as in other cancer indications and combinations, is advancing as planned and remains on track.

Financial Guidance

Based on its current operating plans, Epizyme continues to believe that its existing cash, cash equivalents and marketable securities will fund the company's operations into at least 2022. The company expects its non-GAAP adjusted cash-based operating expenses for 2020 will be between $235 and $255 million, which excludes any milestone payments paid by the company and non-cash items, such as stock-based compensation and amortization or depreciation of intangibles.

Second Quarter 2020 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $322.1 million as of June 30, 2020, as compared to $376.5 million as of March 31, 2020.
- **Revenue:** Total revenue for the second quarter of 2020 was $2.5 million, comprised of $2.2 million in net sales of TAZVERIK in the U.S. and $0.2 million in collaboration revenue, compared to $1.4 million in Q1 2020, comprised of $1.3 million in net sales of TAZVERIK in the U.S. following its launch in January 2020 and $0.1 million in collaboration revenue.
- **Operating Expenses:** Total GAAP operating expenses were $60.0 million for the second quarter of 2020, compared to $52.7 million for the first quarter of 2020. Total non-GAAP adjusted operating expenses were $50.9 million for the second quarter of 2020, compared to $45.7 million for the first quarter of 2020.
    - **R&D expenses:** GAAP R&D expenses were $26.4 million for the second quarter of 2020, compared to $25.2 million for the first quarter of 2020, while non-GAAP adjusted R&D expenses were $23.4 million for the second quarter of 2020, compared to $22.9 million for the first quarter of 2020. The increase was primarily due to expenses related to the support of our clinical trials and development candidates.
    - **SG&A expenses:** GAAP SG&A expenses were $32.7 million for the second quarter of 2020, compared to $ 26.9 million for the first quarter of 2020, while non-GAAP adjusted SG&A expenses were $27.1 million for the second quarter of 2020, compared to $22.5 million for the first quarter of 2020. The increase was primarily due to expenses related to the company's expansion of its infrastructure to support the launch in FL.

- **Eisai Milestone Payments:** Following the approval of TAZVERIK in the FL indication, the final milestone owed to Eisai of $25 million under the collaboration agreement was paid and funded by the third and final tranche of the $70 million loan facility with Pharmakon Advisors.

- **Net Loss (GAAP):** Net loss attributable to common stockholders was $58.5 million, or $0.58 per share, for the second quarter of 2020, compared to $50.9 million, or $0.51 per share, for the first quarter of 2020.

A reconciliation of cash-based financial measures directly comparable to GAAP financial measures is presented in the table attached to this press release.

Conference Call Information

Epizyme will host a conference call today, August 4, at 8:30 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 5081295. 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 (³20%) adverse reactions in patients with epithelioid sarcoma are pain, fatigue, nausea, decreased appetite, vomiting and constipation. The most common (³20%) 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 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.

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: the successful launch of commercial sales of TAZVERIK for epithelioid sarcoma and follicular lymphoma in the approved indications; 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 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.

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

Consolidated Balance Sheet Data:	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 117,152	$ 139,482
Marketable securities	204,910	241,605
Intangible assets, net	49,079	—
Total assets	427,383	424,589
Total current liabilities	30,655	34,386
Deferred revenue	3,933	3,806
Long-term debt, net of debt discount	68,464	23,309
Liability related to sale of future royalties	13,388	12,793
Total stockholders' equity	293,363	331,137

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

	Three Months Ended June 30		Six Months Ended June 30		Three Months Ended March 31
	2020	2019	2020	2019	2020
Revenues					
Product revenue, net	$ 2,234	$ —	$ 3,519	$ —	$ 1,284
Collaboration revenue	233	5,900	303	13,791	70
Total revenue	2,467	5,900	3,822	13,791	1,354
Operating expenses					
Cost of product revenue	1,022	—	1,637	—	614
Research and development	26,352	40,907	51,516	67,803	25,163
Selling, general and administrative	32,659	15,698	59,584	27,684	26,927

Total operating expenses	60,033	56,605	112,737	95,487	52,704
Operating loss	(57,566)	(50,705)	(108,915)	(81,696)	(51,350)
Other income, net:					
Interest (expense) income, net	(569)	2,253	187	3,911	756
Other expense, net	(15)	(13)	(64)	(19)	(48)
Non-cash interest expense related to sale of future royalties	(301)	—	(596)	—	(295)
Other (expense) income, net:	(885)	2,240	(473)	3,892	413
Loss before income taxes	(58,451)	(48,465)	(109,388)	(77,804)	(50,937)
Income provision	—	—	—	—	—
Net loss	$ (58,451)	$ (48,465)	$ (109,388)	$ (77,804)	$ (50,937)
Reconciliation of net loss to net loss attributable to common stockholders					
Net loss	$ (58,451)	$ 48,465)	$ (109,388)	$ (77,804)	$ (50,937)
Accretion of convertible preferred stock	—	—	—	(2,940)	—
Net loss attributable to common stockholders	$ (58,451)	$ (48,465)	$ (109,388)	$ (80,744)	$ (50,937)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.58)	$ (0.53)	$ (1.09)	$ (1.04)	$ (0.51)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	101,104	90,876	100,360	77,315	99,616

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

	Three Months Ended June 30		Six Months Ended June 30		Three Months Ended March 31
Reconciliation of GAAP to Non-GAAP Cost of Product Revenue	**2020**	**2019**	**2020**	**2019**	**2020**
GAAP Cost of Product Revenue	$ 1,022	$ —	$ 1,637	$ —	$ 614
Less: Depreciation and Amortization	(623)	—	(921)	—	(298)
Non-GAAP Cost of Product Revenue	$ 399	$ —	$ 716	$ —	$ 316
Reconciliation of GAAP to Non-GAAP Research and Development					
GAAP Research and Development	$ 26,352	$ 40,907	$ 51,516	$ 67,803	$ 25,163
Less: Stock-Based Compensation Expenses	(2,803)	(1,732)	(4,966)	(2,897)	(2,162)
Less: Depreciation and Amortization	(130)	(157)	(268)	(315)	(138)
Less: Eisai R&D Milestone Expense	—	(10,000)	—	(10,000)	—
Non-GAAP Research and Development	$ 23,419	$ 29,018	$ 46,282	$ 54,591	$ 22,863
Reconciliation of GAAP to Non-GAAP Selling, General and Administrative:					
GAAP Selling, General and Administrative	$ 32,659	$ 15,698	$ 59,584	$ 27,684	$ 26,927
Less: Stock-Based Compensation Expenses	(5,488)	(2,996)	(9,836)	(5,042)	(4,348)
Less: Depreciation and Amortization	(100)	(52)	(193)	(101)	(93)
Non-GAAP Selling, General and Administrative	$ 27,071	$ 12,650	$ 49,555	$ 22,541	$ 22,486
Reconciliation of GAAP to Non-GAAP Operating Expenses					
GAAP Operating Expenses	$ 60,033	$ 56,605	$ 112,737	$ 95,487	$ 52,704
Less: Stock-Based Compensation Expenses	(8,291)	(4,728)	(14,802)	(7,939)	(6,510)
Less: Depreciation and Amortization	(853)	(209)	(1,382)	(416)	(529)
Less: Eisai R&D Milestone Expense	—	(10,000)	—	(10,000)	—
Non-GAAP Operating Expenses	$ 50,889	$ 41,668	$ 96,553	$ 77,132	$ 45,665