Epizyme, Inc.
Form 10-Q
August 07, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-35945

EPIZYME, INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-1349956**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Technology Square, Cambridge, Massachusetts	**02139**
(Address of principal executive offices)	**(Zip code)**

617-229-5872

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
	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).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares outstanding of the registrant s common stock as of August 1, 2017: 58,466,534 shares.

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PART I FINANCIAL INFORMATION

PART II OTHER INFORMATION

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Forward-looking Information

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. These statements may be identified by such forward-looking terminology as anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, could, s statements or variations of such terms. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- our plans to develop and commercialize novel epigenetic therapies for patients with cancer and other diseases;
- our ongoing and planned clinical trials, including the timing of initiation and enrollment in the trials, the timing of availability of data from the trials and the anticipated results of the trials;
- our ability to achieve anticipated milestones under our collaborations;
- the timing of and our ability to apply for, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

All of our forward-looking statements are as of the date of this Quarterly Report on Form 10-Q only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report on Form 10-Q or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions,

estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report on Form 10-Q, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report on Form 10-Q which modify or impact any of the forward-looking statements contained in this Quarterly Report on Form 10-Q will be deemed to modify or supersede such statements in this Quarterly Report on Form 10-Q.

Our management s discussion and analysis of our financial condition and results of operations are based upon our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q, which have been prepared by us in accordance with accounting principles generally accepted in the United States of America, or GAAP, for interim periods and with Regulation S-X promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act. This discussion and analysis should be read in conjunction with these unaudited consolidated financial statements and the notes thereto as well as in conjunction with our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, or our Annual Report. The three months ended June 30, 2017 and 2016 are referred to as the second quarter of 2017 and 2016, respectively. Unless the context indicates otherwise, all references herein to our company include our wholly-owned subsidiary.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

EPIZYME, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(Amounts in thousands except per share data)

	June 30, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 88,529	$ 77,895
Marketable securities	104,475	164,297
Accounts receivable	25	23
Prepaid expenses and other current assets	8,631	6,457
Total current assets	201,660	248,672
Property and equipment, net	2,985	3,124
Restricted cash and other assets	665	645
Total Assets	$ 205,310	$ 252,441
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 9,594	$ 4,994
Accrued expenses	16,143	16,007
Current portion of capital lease obligation	427	620
Other current liabilities	15	
Total current liabilities	26,179	21,621
Capital lease obligation, net of current portion		110
Deferred revenue, net of current portion	28,809	28,809
Other long-term liabilities	282	201
Commitments and contingencies		
Stockholders Equity:		
Common stock $0.0001 par value; 125,000 shares authorized; 58,433 shares and 58,050 shares issued and outstanding, respectively	6	6
Additional paid-in capital	564,428	555,473
Accumulated other comprehensive loss	(60)	(106)
Accumulated deficit	(414,334)	(353,673)
Total stockholders equity	150,040	201,700

Total Liabilities and Stockholders	Equity	$ 205,310	$ 252,441

See notes to consolidated financial statements.

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EPIZYME, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(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:				
Interest income, net	428	404	866	624
Other income	10	16	14	31
Other income, net	438	420	880	655
Net loss	$ (28,024)	$ (27,981)	$ (60,546)	$ (50,860)
Other comprehensive income (loss):				
Unrealized gain on available for sale securities	34	25	46	25
Comprehensive loss	$ (27,990)	$ (27,956)	$ (60,500)	$ (50,835)
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

See notes to consolidated financial statements.

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EPIZYME, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(Amounts in thousands)

	Six Months Ended, June 30,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (60,546)	$ (50,860)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	824	791
Stock-based compensation	5,778	5,126
Amortization of discount on investments	(69)	(27)
Changes in operating assets and liabilities:		
Accounts receivable	(2)	202
Prepaid expenses and other current assets	(1,947)	(3,095)
Accounts payable	4,600	(980)
Accrued expenses	138	(393)
Deferred revenue		(944)
Restricted cash and other assets	(20)	116
Other liabilities	96	(86)
Net cash used in operating activities	(51,148)	(50,150)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of available for sale securities	(80,846)	(199,441)
Maturities of available for sale securities	140,552	
Purchases of property and equipment	(683)	(319)
Net cash provided by (used in) investing activities	59,023	(199,760)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment under capital lease obligation	(303)	(274)
Proceeds from public offering, net of commissions	1,587	130,067
Proceeds from stock options exercised	1,128	1,498
Issuance of shares under employee stock purchase plan	347	150
Payment of public offering costs		(374)
Net cash provided by financing activities	2,759	131,067
Net increase (decrease) in cash and cash equivalents	10,634	(118,843)
Cash and cash equivalents, beginning of period	77,895	208,323
Cash and cash equivalents, end of period	$ 88,529	$ 89,480

SUPPLEMENTAL CASH FLOW INFORMATION:				
Purchases of property and equipment unpaid at period end	$		$	
Unrealized gain on investments	$	46	$	
Cumulative catch up related to the adoption of ASU 2016-09 (Note 2)	$	115	$	

See notes to consolidated financial statements.

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EPIZYME, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. Overview

Epizyme, Inc. (collectively referred to with its wholly owned, controlled subsidiary, Epizyme Securities Corporation, as Epizyme or the Company) is a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize novel epigenetic therapies for patients with cancer and other diseases. The Company s lead product candidate, tazemetostat, is a potent and selective inhibitor of EZH2, an enzyme that plays an important role in various cancers. The Company owns the global development and commercialization rights to tazemetostat outside of Japan. Eisai Co. Ltd (Eisai) holds the rights to develop and commercialize tazemetostat in Japan, and holds a limited right of first negotiation for the rest of Asia.

The Company has additional programs in development, including pinometostat, a clinical program that is subject to a collaboration with Celgene Corporation and Celgene RIVOT Ltd., an affiliate of Celgene Corporation (Celgene) (refer to Note 8, *Collaborations*), three preclinical programs for small molecule histone methyltransferase, or HMT, inhibitors that are subject to a collaboration with Celgene, one clinical and two preclinical programs for small molecule HMT inhibitors that are subject to a collaboration with Glaxo Group Limited, an affiliate of GlaxoSmithKline (GSK) (refer to Note 8, *Collaborations*), and multiple novel targets for which the Company retains worldwide global development and commercialization rights.

Through June 30, 2017, the Company has raised an aggregate of $740.3 million to fund its operations, of which $217.8 million was non-equity funding through its collaboration agreements, $446.5 million was from the sale of common stock in the Company s public offerings, which includes $1.6 million during the six months ended June 30, 2017 and $76.0 million from the sale of redeemable convertible preferred stock in private financings prior to the Company s initial public offering in May 2013. As of June 30, 2017, the Company had $193.0 million in cash, cash equivalents, and marketable securities.

The Company commenced active operations in early 2008. Since its inception, the Company has generated an accumulated deficit of $414.3 million through June 30, 2017, and will require substantial additional capital to fund its research and development. The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, risks of failure of clinical trials and preclinical studies, the need to obtain additional financing to fund the future development of tazemetostat and the rest of its pipeline, the need to obtain marketing approval for its product candidates, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations and ability to transition from clinical-stage manufacturing to commercial-stage production of products.

2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in

conjunction with the financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2016 (the Annual Report).

The unaudited condensed consolidated financial statements include the accounts of Epizyme, Inc. and its wholly owned, controlled subsidiary, Epizyme Securities Corporation. All intercompany transactions and balances of subsidiaries have been eliminated in consolidation. In the opinion of management, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the results for the reported interim periods. The Company considers events or transactions that occur after the balance sheet date but before the consolidated financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The three months ended June 30, 2017 and 2016 are referred to as the second quarter of 2017 and 2016, respectively. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

Significant Accounting Policies

There have been no material changes to the Company s significant accounting policies during the six months ended June 30, 2017, as compared to the significant accounting policies disclosed in Note 2, *Summary of Significant Accounting Policies*, of the Company s financial statements included in the Annual Report.

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Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, *Revenue From Contracts With Customers*. ASU 2014-09 amends Accounting Standards Codification (ASC) 605, *Revenue Recognition*, by outlining a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. In addition, the FASB recently issued ASUs 2016-10 and 2016-12, which provide clarifying amendments to ASU 2014-09. ASU 2014-09 and its related amendments will be effective for the Company for interim and annual periods beginning after December 15, 2017. The Company expects to adopt ASU 2014-09, as amended, effective January 1, 2018. The Company plans on utilizing the modified retrospective approach to implement this standard and is in the process of evaluating its collaboration agreements with Celgene, GSK and Eisai (as the Eisai agreement relates to the receipt of royalties on the sale of any EZH2 product in Japan) to determine the impact the adoption of this standard may have on its consolidated financial statements and internal control over financial reporting.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize a right-of-use asset and lease liability for most lease arrangements. The new standard is effective for annual reporting periods beginning after December 15, 2018 with early adoption permitted. The Company is currently evaluating the potential changes to the Company s future financial reporting and disclosures that may result from adopting this ASU.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. The new standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. The new standard also clarifies that an entity should determine each separately identifiable source or use within the cash receipts and cash payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. The new standard will be effective for the Company on January 1, 2018. The adoption of this standard is not expected to have a material impact on the Company s consolidated statements of cash flows.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash*, or ASU 2016-18, which requires an entity to reconcile and explain the period-over-period change in total cash, cash equivalents and restricted cash within its statements of cash flows. ASU 2018-18 is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted. A reporting entity must apply the amendments in ASU 2016-18 using a full retrospective approach. The Company is currently evaluating the impact the adoption of the ASU will have on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. The new standard does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if the fair value, vesting conditions, or classification of the award changes as a result of the change in terms or conditions. The new standard is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted. A reporting entity must apply the amendments in the ASU prospectively to an award modified on or after the adoption date. The Company is currently evaluating the impact the adoption of the ASU will have on its consolidated financial statements.

Going Concern

At each reporting period, the Company evaluates whether there are conditions or events that raise substantial doubt about the Company s ability to continue as a going concern within one year after the date that the financial statements are issued. The Company is required to make certain additional disclosures if it concludes substantial doubt exists and it is not alleviated by the Company s plans or when its plans alleviate substantial doubt about the Company s ability to continue as a going concern.

The Company s evaluation entails analyzing prospective operating budgets and forecasts for expectations of the Company s cash needs, and comparing those needs to the current cash, cash equivalent and marketable security balances. After considering the Company s current research and development plans and the timing expectations related to the progress of its programs, and after considering its existing cash, cash equivalents and marketable securities as of June 30, 2017, the Company did not identify conditions or events that raise substantial doubt about the Company s ability to continue as a going concern within one year from the date these financial statements were issued.

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Share-Based Payment

As of January 1, 2017, the Company adopted ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*. The standard revised the accounting for share-based compensation arrangements, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. Under this guidance, a company recognizes all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement when the awards vest or are settled. The amendments also removed the requirement to delay the recognition of an excess tax benefit until it reduces current taxes payable. In addition, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. The standard also allows the Company to repurchase more of an employee s shares for tax withholding purposes without triggering liability accounting, clarifies that all cash payments made on an employee s behalf for withheld shares should be presented as a financing activity on the cash flows statement, and provides an accounting policy election to account for forfeitures as they occur. Upon adoption, the Company recognized previously unrecognized excess tax benefits using the modified retrospective transition method, which increased deferred tax assets and the valuation allowance by $25.7 million and charged $0.1 million to retained earnings, with a corresponding credit to additional paid-in-capital related to the Company s election to account for forfeitures as they occur. The adoption of the standard did not materially impact the Company s stock-based compensation expense.

3. Marketable Securities

The following table summarizes the available for sale securities held at June 30, 2017 (in thousands):

Description	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 43,570	$	$ (17)	$ 43,553
Corporate notes	57,973		(43)	57,930