Epizyme, Inc. Form 10-Q October 23, 2013 Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2013

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 (State or other jurisdiction of

26-1349956 (I.R.S. Employer

incorporation or organization)

Identification No.)

400 Technology Square, Cambridge, Massachusetts (Address of principal executive offices) 617-229-5872

02139 (Zip code)

(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 x 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 x No "

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

Large accelerated filer "

Accelerated filer

Non-accelerated filer x (Do not check if a smaller reporting company) Smaller reporting company "Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

The number of shares outstanding of the registrant s common stock as of October 18, 2013: 28,419,288 shares.

PART I - FINANCIAL INFORMATION

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

EPIZYME, INC.

CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(Amounts in thousands except share and per share data)

	September 30, 2013		Dec	ember 31, 2012
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	139,575	\$	97,981
Accounts receivable		2,155		1,829
Prepaid expenses and other current assets		2,130		815
Total current assets		143,860		100,625
Property and equipment, net		2,028		2,140
Restricted cash and other assets		1,462		746
Total Assets	\$	147,350	\$	103,511
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)				
Current Liabilities:				
Accounts payable	\$	3,525	\$	2,967
Accrued expenses		5,384		4,328
Current portion of deferred revenue		21,556		28,208
•				
Total current liabilities		30,465		35,503
Deferred revenue, net of current portion		29,150		41,237
Other long-term liabilities		452		1,741
Commitments and contingencies				
Redeemable convertible preferred stock, \$0.0001 par value; 5,000,000 shares				
and 61,899,922 shares (Series A, B and C) authorized, respectively; 0 shares				
and 61,899,165 shares issued and outstanding, respectively; aggregate				
liquidation preference of \$0 and \$79,000, respectively				76,156
Stockholders Equity (Deficit):				
Common stock, \$0.0001 par value; 125,000,000 shares and 90,000,000 shares				
authorized, respectively; 28,418,420 shares and 1,694,862 shares issued,				
respectively; 28,408,698 shares and 1,672,639 shares outstanding, respectively		3		
Treasury stock, at cost; 0 shares and 11,544 shares, respectively				
Additional paid-in capital		159,290		1,471
Accumulated deficit		(72,010)		(52,597)
		(, ,)		(-))

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Total stockholders equity (deficit)	87,283	(51,126)
Total Liabilities and Stockholders Equity (Deficit)	\$ 147,350	\$ 103,511

See notes to consolidated financial statements.

EPIZYME, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME (UNAUDITED)

(Amounts in thousands except per share data)

	Three I	Months End 2013	ded S	Septembe N 2012	30 ¢ N	Months Endo 2013	ed Se	eptember 30 2012
Collaboration revenue	\$	8,444	\$	15,331	\$	32,165	\$	36,327
Operating expenses:								
Research and development		14,584		9,258		41,882		27,385
General and administrative		3,587		1,630		9,664		5,175
Total operating expenses		18,171		10,888		51,546		32,560
Operating (loss) income		(9,727)		4,443		(19,381)		3,767
Other income (expense):								
Interest income		20		44		54		108
Other income (expense), net		3		(39)		(86)		(39)
Other income (expense), net		23		5		(32)		69
Net (loss) income	\$	(9,704)	\$	4,448	\$	(19,413)	\$	3,836
Less: accretion of redeemable convertible preferre stock to redemption value	ed			159		264		326
Less: income allocable to participating securities				3,972				3,239
(Loss) income allocable to common stockholders basic		(9,704)		317		(19,677)		271
Undistributed income re-allocated to common stockholders				229				147
(Loss) income allocable to common stockholders diluted	\$	(9,704)	\$	546	\$	(19,677)	\$	418
(Loss) earnings per share allocable to common stockholders:								
Basic	\$	(0.34)	\$	0.19	\$	(1.49)	\$	0.17
Diluted	\$	(0.34)	\$	0.18	\$	(1.49)	\$	0.16
Weighted average shares outstanding:						, ,		
Basic		28,406		1,651		13,212		1,637
Diluted		28,406		3,017		13,212		2,641
Comprehensive (loss) income	\$	(9,704)	\$	4,448	\$	(19,413)	\$	3,836

See notes to consolidated financial statements.

EPIZYME, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(Amounts in thousands)

	Nine Months Ended September 2013 2012			-
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net (loss) income	\$	(19,413)	\$	3,836
Adjustments to reconcile net loss to net cash (used in) provided by operating				
activities:				
Depreciation and amortization		534		440
Stock-based compensation		1,819		210
Loss on disposal of property and equipment				20
Changes in operating assets and liabilities:				
Accounts receivable		(326)		(3,663)
Prepaid expenses and other current assets		(1,315)		(553)
Accounts payable		364		(517)
Accrued expenses		1,052		1,933
Deferred revenue		(18,739)		45,952
Restricted cash and other assets		(716)		(495)
Other long-term liabilities		(1,289)		1,190
Net cash (used in) provided by operating activities		(38,029)		48,353
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property and equipment		(230)		(239)
Net cash used in investing activities		(230)		(239)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from sale of redeemable convertible preferred stock				21,961
Proceeds from initial public offering, net of commissions		82,491		
Proceeds from stock options exercised		171		3
Payment of redeemable convertible preferred stock issuance costs				(38)
Payment of initial public offering costs		(2,809)		
Net cash provided by financing activities		79,853		21,926
Net increase in cash and cash equivalents		41,594		70,040
Cash and cash equivalents, beginning of period		97,981		33,341
Cash and cash equivalents, end of period	\$	139,575	\$	103,381
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:				

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Purchases of property and equipment unpaid at period end	192	
Conversion of redeemable convertible preferred stock to common stock	76,420	
Accretion of redeemable convertible preferred stock to redemption value	264	326
Vesting of restricted stock liability		9
Initial public offering costs incurred but unpaid at period end	6	
See notes to consolidated financial statements.		

EPIZYME, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. Overview and Basis of Presentation

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 innovative personalized therapeutics for patients with genetically defined cancers. The Company has built a proprietary product platform that it uses to create small molecule inhibitors of a 96-member class of enzymes known as histone methyltransferases (HMTs). Genetic alterations can result in changes to the activity of HMTs, making them oncogenic. The Company s therapeutic strategy is to inhibit oncogenic HMTs to treat the underlying causes of the associated genetically defined cancers.

The 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 consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company s Prospectus filed with the SEC pursuant to Rule 424(b)(4) on May 31, 2013 (the Prospectus).

The unaudited consolidated financial statements include the accounts of Epizyme and its subsidiary. 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 financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The three months ended September 30, 2013 and 2012 are referred to as the third quarter of 2013 and 2012, 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.

On June 5, 2013, the Company completed an initial public offering (IPO) of its common stock, which resulted in the sale of 5,913,300 shares, including all additional shares available to cover over-allotments, at a price of \$15.00 per share. The Company received net proceeds before expenses from the IPO of \$82.5 million after deducting underwriting discounts and commissions paid by the Company. In preparation for the IPO, the Company s Board of Directors and stockholders approved a one-for-three reverse stock split of the Company s common stock effective May 13, 2013. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted, where necessary, to give effect to this reverse stock split. In connection with the closing of the IPO, all of the Company s outstanding redeemable convertible preferred stock automatically converted to common stock at a one-for-three ratio as of June 5, 2013, resulting in an additional 20,633,046 shares of common stock of the Company becoming outstanding. Following these transactions, the Company s total issued common stock as of September 30, 2013 was 28,418,420 shares. The significant increase in shares outstanding in June 2013 is expected to impact the year-over-year comparability of the Company s (loss) earnings per share calculations through 2014.

2. Summary of Significant Accounting Policies

There have been no material changes to the significant accounting policies previously disclosed in the Company s Prospectus.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists.* ASU 2013-11 amends Accounting Standards Codification (ASC) 740, *Income Taxes*, by providing guidance on the financial statement presentation of an unrecognized benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The ASU does not affect the recognition or measurement of uncertain tax positions under ASC 740. ASU 2013-11 will be effective for the Company for interim and annual periods beginning after December 15, 2013, with early adoption permitted. The Company does not expect the adoption of this ASU to have any impact on its consolidated financial statements.

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3. Fair Value Measurements

The Company classifies fair value based measurements using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows: Level 1, quoted market prices in active markets for identical assets or liabilities; Level 2, observable inputs other than quoted market prices included in Level 1 such as quoted market prices for markets that are not active or other inputs that are observable or can be corroborated by observable market data; and Level 3, unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

The Company s financial instruments as of September 30, 2013 and December 31, 2012 consisted primarily of cash and cash equivalents, accounts receivable and accounts payable. The Company believes the carrying value of its cash, accounts receivable and accounts payable approximates the fair value due to the short-term nature of these instruments. As of September 30, 2013 and December 31, 2012, the Company s financial assets recognized at fair value consisted of the following:

	Fair Value as of September 30, 2013						
	Total	Level 1	Level 2	Level 3			
		(In thousa	nds)				
Cash equivalents	\$ 121,409	\$ 121,409	\$	\$			
Total	\$ 121,409	\$ 121,409	\$	\$			
	Fair Va	lue as of Dec	ember 31,	2012			
	Total	Level 1	Level 2	Level 3			
	(In thousands)						
Cash equivalents	\$ 97,375	\$ 97,375	\$	\$			
-							
Total	\$ 97,375	\$ 97,375	\$	\$			

4. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2013		ember 31, 2012
	(In th	ds)	
Employee compensation and benefits	\$1,882	\$	1,880
Current portion of contract termination obligations	538		1,274
Research and development and professional expenses	2,964		1,174
Accrued expenses	\$ 5,384	\$	4,328

Contract termination obligations include estimated repayments related to the termination of a research agreement in June 2012 and estimated lease exit charges related to the Company's former facility at 325 Vassar Street in Cambridge, Massachusetts. The Company's obligation related to its termination of a research agreement was accelerated as a result of the closing of the Company's IPO, and, as a result, this termination obligation was paid in full in June 2013. As of December 31, 2012, the Company had recorded contract termination obligations of \$3.0 million. During the nine months ended September 30, 2013, the Company recorded a net non-cash liability reduction of \$0.1 million and made cash payments of \$2.3 million, resulting in total remaining contract termination obligations of \$0.6 million as of September 30, 2013. The non-current portion of contract termination obligations is included in other long-term liabilities.

5. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the three or nine months ended September 30, 2013 and 2012 due to the expected loss before income taxes to be incurred and the actual loss before income taxes incurred for the years ended December 31, 2013 and 2012, respectively, as well as the Company s continued maintenance of a full valuation allowance against its net deferred tax assets.

6. Commitments

In September 2013, the Company entered into an amendment to the operating lease agreement for its current office and laboratory facility in Cambridge, Massachusetts, under which the Company leased additional office space for aggregate rent payments of \$2.5 million. These additional rent payments are expected to be paid from the commencement of the lease for this additional space, which is projected to be in the first quarter of 2014, through the end of the existing lease agreement, November 30, 2017.

7. Collaborations

Celgene

In April 2012, the Company entered into a collaboration and license agreement with Celgene Corporation and Celgene International Sàrl (collectively, Celgene) to discover, develop and commercialize, in all countries other than the United States, small molecule HMT inhibitors targeting the DOT1L HMT, including the Company s product candidate EPZ-5676, and any other HMT targets from the Company s product platform for patients with genetically defined cancers, excluding targets already selected by the Company s two other existing therapeutic collaborations (the available targets).

Agreement Structure

Under the terms of the agreement, the Company received a \$65.0 million upfront payment and \$25.0 million from the sale of its series C redeemable convertible preferred stock to an affiliate of Celgene, of which \$3.0 million was considered a premium and included as collaboration arrangement consideration for a total upfront payment of \$68.0 million. In addition, the Company is eligible to earn up to \$60.0 million in substantive clinical development milestone payments and up to \$100.0 million in substantive regulatory milestone payments related to DOT1L, where milestones are considered to be substantive if (a) the consideration is commensurate with either the Company s performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company s performance to achieve the milestone; (b) the consideration relates solely to past performance; and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company is also eligible to earn up to \$65.0 million in payments, including a combination of substantive clinical development milestone payments and an option exercise fee, and up to \$100.0 million in substantive regulatory milestone payments for each available target as to which Celgene exercises its option during an initial option period ending in July 2015. Celgene has the right to extend the option period until July 2016 by making a significant option extension payment. As to DOT1L and each available target as to which Celgene exercises its option, the Company retains all product rights in the United States and is eligible to receive royalties for each target at defined percentages ranging from the mid-single digits to the mid-teens on net product sales outside of the United States subject to reduction in specified circumstances. Due to the uncertainty of pharmaceutical development and the high historical failure rates generally associated with pharmaceutical development, the Company may not receive any milestone or royalty payments from Celgene. The first potential milestone payment that the Company might be

entitled to receive under this agreement is a \$25.0 million substantive milestone for achieving proof-of-concept, as defined in the agreement, for its DOT1L inhibitor.

The Company is obligated to conduct and solely fund research and development costs of the Phase I clinical trials for the DOT1L target and through the effectiveness of the first investigational new drug application (IND) for an HMT inhibitor directed to each available target selected by Celgene, after which Celgene and the Company will equally co-fund global development and each party will solely fund territory-specific development costs for its territory. In the third quarter of 2013, the Company recorded accounts receivable of \$0.7 million related to non-Phase I global development costs subject to the co-funding provisions of the agreement. Co-funded amounts receivable from Celgene are recorded net in research and development expense.

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Collaboration Revenue

Through September 30, 2013, in addition to amounts allocated to Celgene s purchase of shares of the Company s series C redeemable convertible preferred stock, the Company had received a total of \$68.0 million in upfront payments under the Celgene agreement, including a \$3.0 million implied premium on Celgene s purchase of shares of the Company s series C redeemable convertible preferred stock. Through September 30, 2013, the Company has recognized \$34.7 million of collaboration revenue in the consolidated statements o