Epizyme, Inc.
Form 10-Q
November 09, 2015
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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, 2015

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 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 x
Non-accelerated filer ¨ (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 30, 2015 was 41,703,345 shares.

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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)

	September 30, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 229,938	$ 190,095
Accounts receivable	177	2,075
Prepaid expenses and other current assets	2,504	2,840
Total current assets	232,619	195,010
Property and equipment, net	4,477	3,620
Restricted cash and other assets	602	573
Total Assets	$ 237,698	$ 199,203
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,972	$ 8,300
Accrued expenses	12,081	7,043
Current portion of capital lease obligation	548	
Current portion of deferred revenue	1,900	1,702
Total current liabilities	17,501	17,045
Capital lease obligation, net of current portion	875	
Deferred revenue, net of current portion	29,364	21,449
Other long-term liabilities	404	427
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, $0.0001 par value; 5,000 shares authorized; 0 shares issued and outstanding		
Common stock, $0.0001 par value; 125,000 shares authorized; 41,698 shares and 34,426 shares issued and outstanding, respectively	4	3
Additional paid-in capital	410,785	271,364
Accumulated deficit	(221,235)	(111,085)
Total stockholders equity	189,554	160,282

Total Liabilities and Stockholders Equity	$ 237,698	$ 199,203

See notes to condensed 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Collaboration revenue	$ 358	$ 8,177	$ 2,005	$ 31,062
Operating expenses:				
Research and development	16,788	22,244	94,390	55,090
General and administrative	6,676	5,669	17,883	15,931
Total operating expenses	23,464	27,913	112,273	71,021
Loss from operations	(23,106)	(19,736)	(110,268)	(39,959)
Other income, net:				
Interest income, net	20	24	57	66
Other income	21	17	61	41
Other income, net	41	41	118	107
Loss before income taxes	(23,065)	(19,695)	(110,150)	(39,852)
Income tax expense		5		118
Net loss	$ (23,065)	$ (19,700)	$ (110,150)	$ (39,970)
Loss per share allocable to common stockholders:				
Basic and Diluted	$ (0.56)	$ (0.58)	$ (2.81)	$ (1.23)
Weighted average shares outstanding:				
Basic and Diluted	41,461	33,676	39,204	32,607
Comprehensive loss	$ (23,065)	$ (19,700)	$ (110,150)	$ (39,970)

See notes to condensed consolidated financial statements.

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EPIZYME, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(Amounts in thousands)

	Nine Months Ended September 30,	
	2015	**2014**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (110,150)	$ (39,970)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Acquired in-process research and development	40,000	
Depreciation and amortization	1,058	548
Stock-based compensation	7,766	4,678
Loss on disposal of property and equipment	5	
Changes in operating assets and liabilities:		
Accounts receivable	1,898	31,558
Prepaid expenses and other current assets	336	(852)
Accounts payable	(5,328)	1,107
Accrued expenses	5,038	2,020
Deferred revenue	8,113	(13,722)
Restricted cash and other assets	(29)	226
Other long-term liabilities	(23)	9
Net cash (used in) provided by operating activities	(51,316)	(14,398)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of in-process research and development	(40,000)	
Purchases of property and equipment	(188)	(1,230)
Net cash used in investing activities	(40,188)	(1,230)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment under capital lease obligation	(309)	
Proceeds from public offering, net of commissions	130,712	101,283
Proceeds from stock options exercised	875	2,348
Excess tax benefit from stock option plan		28
Issuance of shares under employee stock purchase plan	436	454
Payment of public offering costs	(367)	(649)
Proceeds from reimbursement of public offering costs		269
Net cash provided by financing activities	131,347	103,733

Net increase in cash and cash equivalents	39,843	88,105
Cash and cash equivalents, beginning of period	190,095	123,564
Cash and cash equivalents, end of period	$ 229,938	$ 211,669
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Equipment acquired under capital lease	1,732	

See notes to condensed consolidated financial statements.

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EPIZYME, INC.

NOTES TO CONDENSED 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 novel epigenetic therapies for cancer patients. 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 cancers.

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, 2014 (the Annual Report).

The unaudited condensed 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, 2015 and 2014 are referred to as the third quarter of 2015 and 2014, 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.

In March 2015, the Company conducted a public offering of its common stock, selling 6,000,000 shares at a price of $20.75 per share. The Company received net proceeds before expenses from the sale of these 6,000,000 shares of $117.0 million after deducting underwriting discounts and commissions paid by the Company. In April 2015, the Company issued and sold an additional 701,448 shares in connection with the March 2015 public offering at a price of $20.75 per share pursuant to the underwriters option to purchase additional shares that the Company granted in connection with such public offering. The Company received net proceeds before expenses from the sale of these 701,448 shares of $13.7 million after deducting underwriting discounts and commissions paid by the Company.

2. Summary of Significant Accounting Policies

In the nine months ended September 30, 2015, the Company updated its accounting policy regarding property and equipment as a result of property and equipment acquired pursuant to a capital lease.

Property and Equipment

The Company records property and equipment at cost. Property and equipment acquired under a capital lease is recorded at the lesser of the present value of the minimum lease payments under the capital lease or the fair value of the leased property at lease inception.

The Company calculates depreciation and amortization using the straight-line method over the following estimated useful lives:

Asset Category	Useful Lives
Laboratory equipment	5 - 20 years
Office furniture and equipment	3 - 10 years or term of respective lease, if shorter
Leasehold improvements	3 - 10 years or term of respective lease, if shorter

Amortization of capital lease assets is included in depreciation expense. The Company capitalizes expenditures for new property and equipment and improvements to existing facilities and charges the cost of maintenance to expense. The Company eliminates the cost of property retired or otherwise disposed of, along with the corresponding accumulated depreciation, from the related accounts, and the resulting gain or loss is reflected in the results of operations.

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Additionally, the Company updated its accounting policies as a result of the amended and restated collaboration and license agreement the Company executed with Eisai Co., Ltd. (Eisai), pursuant to which the Company recorded the reacquisition of worldwide rights, excluding Japan, to its EZH2 program, including tazemetostat (also known as EPZ-6438), as an acquisition of in-process research and development.

Acquired In-Process Research and Development

The Company records upfront payments that relate to the acquisition of a development-stage product candidate as research and development expense in the period in which they are incurred, provided that the acquired development-stage product candidate did not also include processes or activities that would constitute a business, the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 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. ASU 2014-09 was originally pronounced to become effective for the Company for interim and annual periods beginning after December 15, 2016. In July 2015, the FASB approved a one-year deferral of the effective date of ASU 2014-09. This ASU will now be effective for annual and interim periods beginning on or after December 15, 2017. Early adoption is permitted, however not before the original effective date of annual periods beginning after December 15, 2016. The Company is evaluating the impact that this ASU may have on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. ASU 2014-15 amends ASC 205-40, *Presentation of Financial Statements Going Concern*, by providing guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements, including requiring management to perform interim and annual assessments of an entity s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements and providing certain disclosures if there is substantial doubt about the entity s ability to continue as a going concern. ASU 2014-15 will be effective for the Company for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. The Company is still evaluating the impact of this ASU on its consolidated financial statements; however, it is disclosure-only in nature.

In April 2015, the FASB issued ASU No. 2015-05, *Customer s Accounting for Fees Paid in a Cloud Computing Arrangement*. ASU 2015-05 amends ASC 350-40, *Internal-Use Software*, by providing customers with guidance on determining whether a cloud computing arrangement contains a software license that should be accounted for as internal-use software. ASU 2015-05 will be effective for the Company for annual periods beginning after December 15, 2015 and interim periods within annual periods beginning after December 15, 2015. The Company is evaluating the impact that this ASU may have on its consolidated financial statements, if any.

In June 2015, the FASB issued ASU No. 2015-10, *Technical Corrections and Improvements*. ASU 2015-10 covers a wide range of Topics in the ASC. The amendments in this ASU represent changes to clarify the ASC, correct unintended application of guidance, or make minor improvements to the ASC that are not expected to have a

significant effect on current accounting practice or create a significant administrative cost to most entities. Additionally, some of the amendments will make the ASC easier to understand and easier to apply by eliminating inconsistencies, providing needed clarifications, and improving the presentation of guidance in the ASC. The amendments in ASU 2015-10 that require transition guidance are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. All other amendments will be effective upon the issuance of this ASU. The Company does not anticipate that the adoption of this standard will have a material impact on its consolidated financial statements and footnote disclosures.

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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 estimates and assumptions developed by the Company, reflective of those that a market participant would use, as inputs to certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

The Company s financial instruments as of September 30, 2015 and December 31, 2014 consisted primarily of cash and cash equivalents, accounts receivable and accounts payable. As of September 30, 2015 and December 31, 2014, the Company s financial assets recognized at fair value consisted of the following:

	Fair Value as of September 30, 2015			
	Total	Level 1	Level 2	Level 3
	(In thousands)			
Cash equivalents	$ 196,975	$ 196,975	$	$
Total	$ 196,975	$ 196,975	$	$

	Fair Value as of December 31, 2014			
	Total	Level 1	Level 2	Level 3
	(In thousands)			
Cash equivalents	$ 184,257	$ 184,257	$	$
Total	$ 184,257	$ 184,257	$	$

4. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2015	December 31, 2014
	(In thousands)	
Employee compensation and benefits	$ 2,780	$ 2,623
Research and development and professional expenses	9,301	4,420
Accrued expenses	$ 12,081	$ 7,043

5. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the three and nine months ended September 30, 2015 due to the expected loss before income taxes to be incurred for the year ending December 31, 2015, as well as the Company s continued maintenance of a full valuation allowance against its net deferred tax assets.

The Company recorded less than $0.1 million and $0.1 million of income tax expense in the three and nine months ended September 30, 2014, respectively, due to provision-to-return adjustments identified related to the year ended December 31, 2013.

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6. Commitments and Contingencies

Commitments

In the first quarter of 2015, the Company acquired computer equipment pursuant to a capital lease. Future minimum equipment lease payments under this capital lease, net of imputed interest, as of September 30, 2015 are as follows:

		(In thousands)
Future minimum lease payments in year ending December 31:		
2015	$	166
2016		665
2017		665
2018		112
Total future minimum lease payments		1,608
Less: Amount representing imputed interest on equipment lease		(185)
Capital lease obligation	$	1,423

The Company also entered into an agreement in June 2015 to lease approximately 4,000 square feet of office space in Durham, North Carolina through July 2017. Total future minimum lease payments under this office lease agreement are approximately $0.2 million.

In connection with the amended and restated collaboration and license agreement that the Company executed with Eisai in March 2015, the Company and Eisai entered into an amended and restated letter agreement related to their December 2012 companion diagnostic agreement with Roche Molecular Systems (Roche). Upon the execution of the amended and restated letter agreement with Eisai, the Company assumed responsibility for up to $15.5 million of the then remaining development costs under the agreement with Roche. Eisai continues to be responsible for up to $1.0 million of the remaining Japan-specific development costs under the agreement with Roche.

Contingencies

In connection with the execution of the amended and restated collaboration and license agreement with Eisai, the Company agreed to pay Eisai up to a total of $20.0 million upon the achievement of specified clinical development milestones and up to a total of $50.0 million upon the achievement of specified regulatory milestones. In addition, the Company agreed to pay Eisai royalties at a percentage in the mid-teens on worldwide net sales of any EZH2 product, excluding net sales in Japan.

7. Collaborations

Eisai

In April 2011, the Company entered into a collaboration and license agreement with Eisai under which the Company granted Eisai an exclusive worldwide license to its small molecule HMT inhibitors directed to the EZH2 HMT,

including the Company s product candidate tazemetostat, while retaining an opt-in right to co-develop, co-commercialize and share profits with Eisai as to licensed products in the United States (the original agreement). Additionally, as part of the research collaboration, the Company provided research and development services related to the licensed compounds through December 31, 2014.

The Company recognized $1.4 million and $5.0 million of collaboration revenue in the three and nine months ended September 30, 2014, respectively, under the original agreement. As of December 31, 2014, the Company had completed its performance obligations under the original agreement. Accordingly, the Company had no remaining deferred revenue as of December 31, 2014 related to the original agreement.

In March 2015, the Company entered into an amended and restated collaboration and license agreement with Eisai, under which the Company reacquired worldwide rights, excluding Japan, to its EZH2 program, including tazemetostat. Under the amended and restated collaboration and license agreement, the Company is responsible for global development, manufacturing and commercialization outside of Japan of tazemetostat and any other EZH2 product candidates, with Eisai retaining development and commercialization rights in Japan, as well as a right to elect to manufacture tazemetostat and any other EZH2 product candidates in Japan.

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Under the original agreement, Eisai was solely responsible for funding all research, development and commercialization costs for EZH2 compounds. Under the amended and restated collaboration and license agreement, the Company is solely responsible for funding global development, manufacturing and commercialization costs for EZH2 compounds outside of Japan, including up to $15.5 million of the then remaining development costs due under a Roche companion diagnostic agreement, and Eisai is solely responsible for funding Japan-specific development and commercialization costs for EZH2 compounds.

The Company recorded the reacquisition of worldwide rights, excluding Japan, to the EZH2 program, including tazemetostat, under the amended and restated collaboration and license agreement with Eisai as an acquisition of an in-process research and development asset. As this asset was acquired without corresponding processes or activities that would constitute a business, has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use, the Company recorded the $40.0 million upfront paym