

Epizyme (EPZM)

Q3:13 Update - Top-Line EPZ-5676 Data in Q4:13 - Upside in DOT1L and EZH2 Programs Beyond Initial Indications- Reiterate OUTPERFORM

- **EPZM reported Q3:13 loss of (\$0.34), ending the quarter with \$139.6M in cash, and reaffirmed YE:13 cash guidance of \$115M.** Collaboration revenues were \$8.5 million and expenses were slightly higher than in Q2, driven by expansion of the platform and clinical costs and were in line with our estimates. Next financial milestones include a \$25M payment for '5676 proof of concept (Celgene) and \$10M '6438 Phase 2 initiation (Eisai) likely to occur in 2014.
- **EPZM announced that top-line dose-escalation data from the Phase I study for EPZ-5676 is anticipated in Q4:13.** EPZM will not present this data at ASH 2013 (Dec 7-10, New Orleans, LA), however, several other abstracts have been submitted for the conference. Importantly EPZM also announced that based on data to date, a pediatric MLL-r study is set to begin in 2014, suggesting to us that '5676 has an exceptionally strong safety profile. We expect signs of efficacy in the MLL-r patient dose cohort study set to begin enrolling in Q4:13 could lead to a rapid route to registration for EPZ-5676, potentially ahead of our current H2:16 est.
- **EPZM plans to initiate a trial for EPZ-5676 in expanded indications beyond the pediatric setting, including MLL-PTD in 2014.** Data presented at AACR ([here](#)) shows that MLL-PTD cell lines responded similarly to MLL-r cell lines with respect to DOT1L inhibition. MLL-PTD can be identified by cytogenetic markers and has an estimated annual incidence of 2300 patients in U.S., EU and Japan. The MLL-PTD opportunity represents upside to our model and price target.
- **EZP-6438 dose escalation studies continue, with no DLT observed to date, Phase II studies are set to begin in EZH2 mutated DLBCL and Grade 3 FL in 2014.** Epizyme will also expand development of '6438 beyond EZH2 mutated NHL into other INI1-deficient tumors based upon pre-clinical work published in April ([here](#)) and at AACR ([here](#)). A companion diagnostic is also being developed with partner Roche. EZH2 has an oncogenic roll in MRT and synovial sarcomas, which have an incidence of 1,700 patients which represent upside to our estimates.
- **Reiterate OUTPERFORM rating and \$37 price target.** Our price target of \$37/share is derived from applying 8x and 15x multiples to our 2019 estimated sales and royalty revenues, respectively, discounted by 35% annually (fully-diluted share count, assumes an increase of 2 million additional shares for future financings). We note that with positive data, a decline in our discount rate from 35% per year to 20% per year yields a potential value in 12 months of \$66/share.

FYE Dec	2012A	2013E			2014E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	\$8.9A		N/A	\$0.0E		\$12.1E
Q2 Jun	--	14.8A		14.8A	0.0E		12.1E
Q3 Sep	--	8.4A	6.0A	9.5A	25.0E		18.8E
Q4 Dec	--	10.0E		6.8E	15.0E		23.4E
Year*	\$45.2A	\$42.2E	\$39.7E	\$44.0E	\$40.0E		\$64.8E
Change	--	-7%			-5%		
EPS	2012A	2013E			2014E		
	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	(\$0.33)A		N/A	(\$0.68)E	(\$0.66)E	(\$0.27)E
Q2 Jun	--	(0.25)A		(0.25)A	(0.71)E	(0.69)E	(0.25)E
Q3 Sep	--	(0.34)A	(0.43)A	(0.30)A	0.13E	0.15E	0.01E
Q4 Dec	--	(0.33)E	(0.31)E	(0.38)E	(0.25)E	(0.23)E	0.09E
Year*	(\$0.03)A	(\$1.26)E	(\$1.32)E	(\$1.62)E	(\$1.52)E	(\$1.43)E	(\$0.65)E
P/E	--	--			--		
Change	--	-3743%			-20%		

Consensus estimates are from Thomson First Call.

* Numbers may not add up due to rounding.

October 23, 2013

Price
\$39.62

Rating
OUTPERFORM

12-Month Price Target
\$37

Gregory R. Wade, Ph.D.
(415) 274-6863
greg.wade@wedbush.com

David M. Nierengarten, Ph.D.
(415) 274-6862
david.nierengarten@wedbush.com

Christopher N. Marai, Ph.D.
(415) 274-6861
christopher.marai@wedbush.com

Company Information

Shares Outst (M)	28.4
Market Cap (M)	\$1125.8
52-Wk Range	\$18.60 - \$45.72
Book Value/sh	\$3.38
Cash/sh	\$4.91
Enterprise Value (M)	\$986.2
LT Debt/Cap %	0.0
Cash Burn (M)	\$65.9

Company Description

Epizyme, Inc., is based in Cambridge, MA and is focused on the development of histone methyl transferase inhibitors in genetically defined cancers. The company has two candidates in Phase I testing: EPZ-5676 for MLL-r AML and ALL and EPZ-6438 for a subtype of NHL.



Source: Thomson Reuters

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Risks to the achievement of our price target include clinical, regulatory or market failure for EPZ-5676 and/or EPZ-6438.

Investment Thesis

Epizyme is focused on developing drugs that are highly specific for individual HMTs and the company seeks to prove that the treatment of a genetically definable patient with a potent and highly selective HMT inhibitor can lead to deep and durable levels of disease control. EPZM's most advanced product candidate, EPZ-5676, is in Phase I in AML/ALL patients, including mixed lineage rearranged leukemia (MLL-r). The company's second most advanced product candidate, EPZ-6438, is in an ongoing Phase I/II trial in a genetically defined subtype of non-Hodgkin's lymphoma (NHL). The company has entered into therapeutic collaborations with Celgene, Eisai, and GlaxoSmithKline (GSK), but maintains 100% of the US rights to EPZ-5676 and rights to opt into 50% of the US economics for EPZ-6438. As a result of the cause and effect link between the oncogenic HMT driver and malignancy, we would expect early evidence of deep and durable efficacy, potentially in even just a few genetically pre-defined patients, to lead to significant appreciation of EPZM's shares as investors price in clinical, regulatory and market success.

Milestones

Q4:13	Begin second stage of the Phase I/II study of EPZ-5676 in AML/ALL patients with MLL-r
Q4:13	Interim data for the Phase I study of EPZ-5676 in the AML/ALL setting
H1:14	Partner Eisai to initiate Phase II study of EPZ-6438 in the NHL (DLBCL and grade 3 FL) setting
H2:14	Begin pivotal Phase II trial for EPZ-5676 in adults with MLL-r
2014	Final data for the Phase I study of EPZ-6438 in the NHL setting
2014	Initiation of Phase II trials for EPZ-6436 in patients with INI1-deficient tumors (synovial sarcoma)
2014	Final data for the Phase I/II study of EPZ-5676 in the MLL-r setting
2014	Initiation of Phase I study of EPZ-5676 in the pediatric MLL-r setting
2014	Initiation of Phase I/II study of EPZ-5676 in the MLL-PTD setting
Q1:15	Begin pivotal Phase II/III trial for EPZ-6438 in EZH2-driven NHL
Q2:15	Begin pivotal Phase II trial for EPZ-5676 in children with MLL-r
H2:15	Data from pivotal Phase II trial for EPZ-5676 in adults with MLL-r
H2:15	Data from pivotal Phase II/III trial for EPZ-6438 in EZH2-driven NHL
H2:16	File NDA for EPZ-5676
H1:17	File NDA for EPZ-6438

Financial Model

10/22/2013
Ticker: (EPZM:Nasdaq)
Epizyme, Inc

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Gregory R. Wade, Ph.D.
415-274-6863

Epizyme, Inc (EPZM)
in thousands except per share data

	2012A	Q1A	Q2A	Q3A	Q4E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues:													
Net Product Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$78,726	\$324,500	\$519,702	\$644,826
Other Revenues	\$0	0	0	0	0	0	0	0	0	10,453	45,565	72,180	89,834
Royalties	\$45,222	8,882	14,839	8,444	10,000	42,165	40,000	25,000	40,000	60,000	0	0	0
Total Revenues	45,222	8,882	14,839	8,444	0	42,165	40,000	25,000	40,000	149,180	370,065	591,882	734,660
Cost and Expenses:													
Cost of Sales	0	0	0	0	0	0	0	0	0	3,936	16,225	25,985	32,241
R&D	38,482	13,361	13,937	14,584	15,313	57,195	67,628	75,312	81,521	88,240	95,514	103,388	111,910
SG&A	7,508	2,998	3,079	3,587	3,648	13,312	16,111	18,390	21,917	44,342	96,092	137,084	163,360
Total Operating Expenses	45,990	16,359	17,016	18,171	18,961	70,507	83,739	93,702	103,438	136,519	207,831	266,457	307,512
Operating Income (Loss)	(768)	(7,477)	(2,177)	(9,727)	(18,961)	(28,342)	(43,739)	(68,702)	(63,438)	12,661	162,234	325,425	427,149
Net Interest Income (Expense)/Other Income	67	(20)	(142)	23	(412)	(551)	579	(16)	30	(1,565)	(516)	3,777	6,126
Income Before Income Taxes	(701)	(7,497)	(2,319)	(9,704)	(19,373)	(28,893)	(43,160)	(68,718)	(63,408)	11,096	161,718	329,201	433,274
Provision for Income Taxes	1	0	0	0	0	0	195	87	0	2,103	8,571	128,389	168,977
Net Income (Loss)	(702)	(7,497)	(2,319)	(9,704)	(19,373)	(28,893)	(43,355)	(68,805)	(63,408)	8,993	153,147	200,813	264,297
GAAP EPS	(0.03)	(0.33)	(0.25)	(0.34)	(0.33)	(1.26)	(1.52)	(2.30)	(2.07)	0.29	4.96	6.48	8.50
Total Shares Outstanding	21,448	22,502	9,146	28,415	28,440	22,126	28,503	29,590	30,678	30,778	30,878	30,978	31,078
Cash Burn	44,154	0	0	0	0	(27,784)	(42,348)	(67,951)	(62,691)	9,768	154,257	202,271	266,076
Cash Balance	97,981	85,047	148,689	139,575	120,759	120,759	77,616	102,998	39,757	39,585	141,940	302,423	363,571

Source: Wedbush PacGrow Life Sciences

Analyst Biography

Gregory Wade, Ph.D.

Greg is a Managing Director and joined Wedbush in March 2009 from Pacific Growth Equities where he was a Senior Research Analyst covering emerging Pharmaceutical and Biotechnology companies. He started at Pacific Growth in February 2000 as a Research Associate and became an Analyst in 2004. Prior to Pacific Growth Equities, Greg was a Director in the business development group at ISIS Pharmaceuticals and prior to that was with Procyon BioPharma in London, Canada. While completing his Ph.D. in Physiology at the University of Western Ontario Greg worked as an Associate at the venture capital company Helix Investments Canada where he focused on early stage investments in life science companies.

Greg's team includes Dr. David Nierengarten (Analyst) and Dr. Christopher Marai (Analyst) and together they cover 30+ companies focused on antibiotics, rare diseases, prostate cancer, hematology/oncology, gastrointestinal disorders, vaccines, biodefense and drug/device combinations.

Greg's Edge: Greg's edge comes from the breadth and duration of his tenure on the sell-side. Coverage of nearly 60 different companies over 13 years provides him with a measured perspective and industry and key opinion leader contacts help to inform his view.

Analyst Certification

I, Gregory R. Wade, Ph.D., David M. Nierengarten, Ph.D., Christopher N. Marai, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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Neutral: 41%	Neutral: 2%
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Company	Disclosure
Epizyme	1,3,5,7

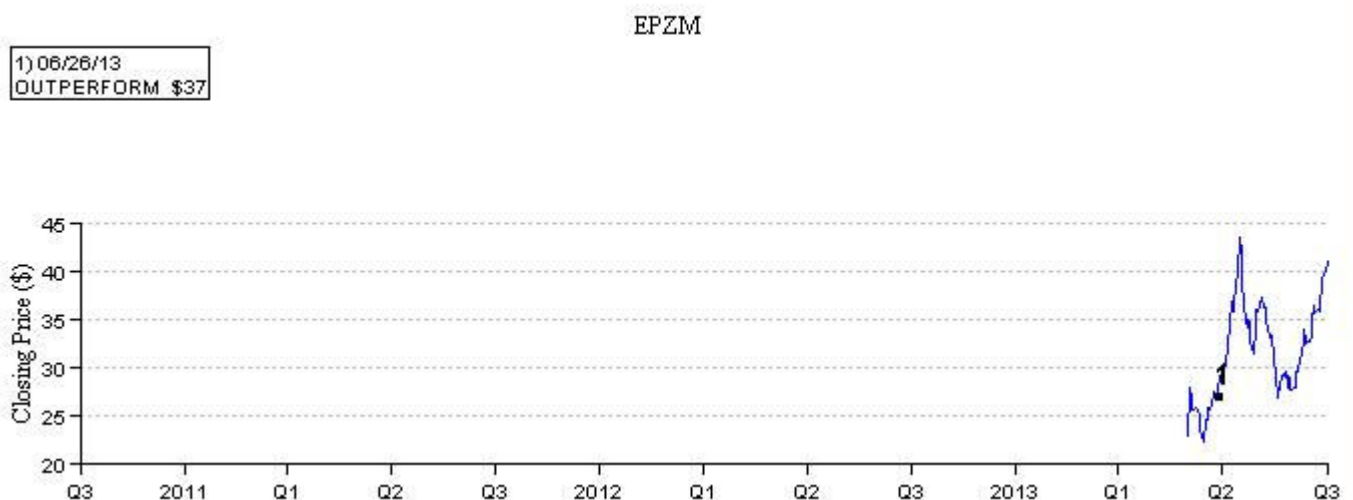
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OTHER DISCLOSURES

RESEARCH DEPT. * (213) 688-4505 * www.wedbush.com
EQUITY TRADING Los Angeles (213) 688-4470 / (800) 421-0178 * EQUITY SALES Los Angeles (800) 444-8076
CORPORATE HEADQUARTERS (213) 688-8000

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WEDBUSH

EQUITY RESEARCH DEPARTMENT

(213) 688-4529

DIRECTOR OF RESEARCH

Mark D. Benson (213) 688-4435

MANAGER, RESEARCH OPERATIONS

Ellen Kang (213) 688-4529

RETAIL AND CONSUMER

Consumer Products

Rommel T. Dionisio (212) 938-9934
Kurt M. Frederick, CFA CPA (415) 274-6822

Footwear, Apparel and Accessories

Corinna Freedman (212) 668-9876
Alicia Reese (212) 938-9927

Healthy Lifestyles

Kurt M. Frederick, CFA CPA (415) 274-6822

Restaurants

Nick Setyan (213) 688-4519
Colin Radke (213) 688-6624

Specialty Retail: Hardlines

Joan L. Storms, CFA (213) 688-4537
John Garrett, CFA (213) 688-4523

Seth Basham, CFA (212) 938-9954

RETAIL/CONSUMER MARKET RESEARCH

Gabriella Santaniello (213) 688-4557

INDUSTRIAL GROWTH TECHNOLOGY

Clean Technology

Craig Irwin (212) 938-9926
Min Xu (212) 938-9925

Environmental Services / Building Products

Al Kaschak (213) 688-4539
Taryn Kuida (213) 688-4505

Industrial Biotechnology

Liana Moussatos, Ph.D. (415) 263-6626
Christopher N. Marai, Ph.D. (415) 274-6861

Water and Renewable Energy Solutions

David Rose, CFA (213) 688-4319

TECHNOLOGY, INTERNET, MEDIA & SOCIAL MEDIA

Communications and Application Software / Internet

Shyam Patil, CFA (213) 688-8062

Communications Equipment

Rohit Chopra (212) 668-9871
Sanjit Singh (212) 938-9922
Ryan Flanagan (212) 938-9942

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Gil B. Luria (213) 688-4501
Aaron Turner (213) 688-4429

Enterprise Software

Steve Koenig (415) 274-6801
Kevin Ikeda (213) 688-4423

Entertainment: Retail

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Entertainment: Software

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Social Internet and E-Commerce

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Media

James Dix, CFA (213) 688-4315

Movies and Entertainment

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Semiconductors

Betsy Van Hees (415) 274-6869
Ryan Jue, CFA (415) 263-6669

LIFE SCIENCES

Biotechnology/Biopharmaceuticals/BioDefense

Gregory R. Wade, Ph.D. (415) 274-6863
David M. Nierengarten, Ph.D. (415) 274-6862
Christopher N. Marai, Ph.D. (415) 274-6861

Emerging Pharmaceuticals

Liana Moussatos, Ph.D. (415) 263-6626
Richard Lau (415) 274-6851
Christopher N. Marai, Ph.D. (415) 274-6861

Healthcare Services - Managed Care

Sarah James (213) 688-4503

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Tao Levy (212) 938-9948

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EQUITY SALES

Los Angeles (213) 688-4470 / (800) 444-8076
San Francisco (415) 274-6800
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Los Angeles (213) 688-4470 / (800) 421-0178
San Francisco (415) 274-6811
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Boston (617) 832-3700

CORPORATE HEADQUARTERS

1000 Wilshire Blvd., Los Angeles, CA 90017-2465
Tel: (213) 688-8000 www.wedbush.com