

Ambit Biosciences

(AMBI-NASDAQ)

Stock Rating: Outperform
Stock Price: \$12.80
Target Price: \$24.00

Tuesday, December 3, 2013
Biotechnology

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Initial Thoughts on Quizartinib FDA Update

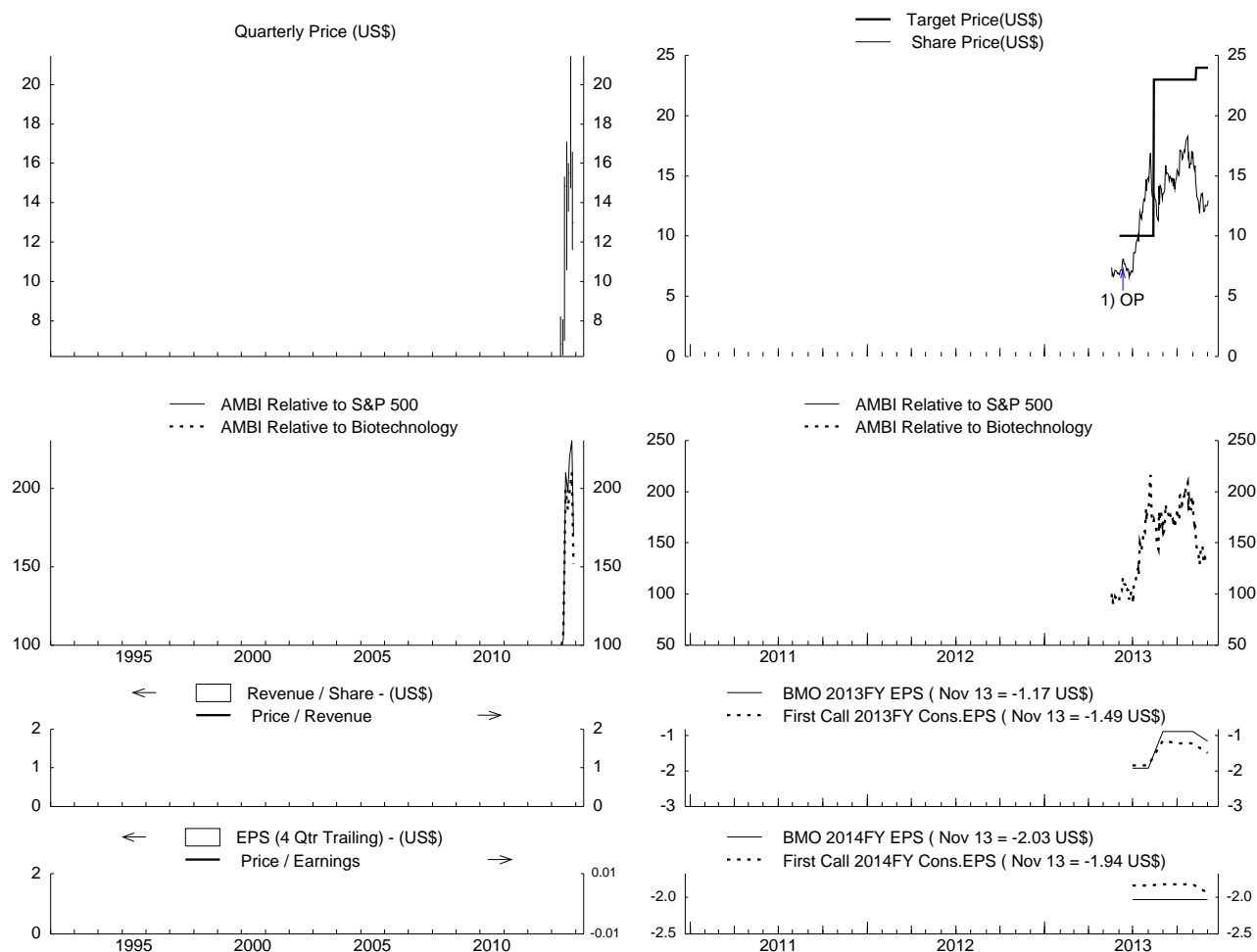
Ambit Biosciences (AMBI) provided a regulatory update on its FLT3 inhibitor quizartinib after market close today and following recent feedback from FDA. With focus on development of quizartinib for patients with relapsed/refractory FLT3-ITD+ acute myeloid leukemia (AML), FDA rejected the use of complete response with incomplete hematologic recovery (CRi) as a surrogate endpoint for accelerated approval filing. Based on FDA feedback, AMBI will move forward with a previously planned randomized phase 3 study in relapsed/refractory FLT3-ITD+ AML with an overall survival (OS) endpoint, pending refinement of an appropriate starting dose in the trial. Data for lower doses of quizartinib in relapsed/refractory FLT3-ITD+ AML will be presented at this weekend's ASH meeting, along with updated frontline chemotherapy combination data and data in pediatric AML.

Our View:

- FDA rejection of CRi as a basis of accelerated approval filing is a disappointment, particularly given multiple databases supporting the value of the surrogate.
- Expectations for accelerated approval have been relatively tempered, however, and our own estimates consider timelines for full phase 3 completion.
- We look forward to more specifics on phase 3 timelines, trial design, and dose selection on tomorrow morning's investor call (877-280-4954, #75822572) and will provide further update following the call.

Please refer to pages 2 to 5 for Disclosure Statements, including the Analyst's Certification.

Ambit Biosciences (AMBI)



FYE (Dec.)	EPS US\$	P/E Hi - Lo	DPS US\$	Yield% Hi - Lo	Payout %	BV US\$	P/B Hi - Lo	ROE %	AMBI - Rating as of 15-May-13 = NR		
Range*:		na na		NC			>15 >15		Date	Rating Change	Share Price
Current*	ND	na	0.00	0.0	na	3.6	4.7	na	1 10-Jun-13	NR to OP	\$8.10

* Current EPS is the 4 Quarter Trailing to Q3/2013.

* Valuation metrics are based on high and low for the fiscal year.

* Range indicates the valuation range for the period presented above.

Last Price (December 2, 2013): \$12.98
Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

Important Disclosures

Analyst's Certification

I, Jim Birchenough, M.D., hereby certify that the views expressed in this report accurately reflect my personal views about the subject securities or issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

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Methodology and Risks to Our Price Target

Methodology: Our price target is based on 25x 2020 EPS of \$3.72 discounted 30%.

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Distribution of Ratings (September 30, 2013)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	35.8%	20.3%	47.8%	36.7%	48.3%	52.6%
Hold	Market Perform	59.4%	13.1%	51.1%	56.9%	50.2%	41.7%
Sell	Underperform	4.9%	3.4%	1.1%	6.4%	1.5%	5.6%

* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.

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(S) = Speculative investment;

NR = No rating at this time; and

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http://researchglobal.bmocapitalmarkets.com/documents/2013/prior_rating_system.pdf

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