

Ambit Biosciences

(AMBI-NASDAQ)

Stock Rating: Market Perform
Industry Rating: Outperform

Uncertainty on Dose Could Impact Phase 3 Timelines; Downgrading to Market Perform

Event

Ambit Biosciences (AMBI) provided further detail this morning on a regulatory update for its FLT3 inhibitor quizartinib following recent feedback from FDA. With focus on development of quizartinib for patients with relapsed/refractory FLT3-ITD+ acute myeloid leukemia (AML), FDA has 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. FDA has requested additional exposure-efficacy data from the phase 2b analysis of quizartinib 30mg and 60mg dose, which AMBI has provided. AMBI believes that efficacy is unchanged at a lower 30mg dose while QTc risk is lower. Data for lower doses of quizartinib in relapsed/refractory FLT3-ITD+ AML will be presented at this weekends ASH meeting.

Impact & Analysis

We are downgrading our rating on AMBI to Market Perform from Outperform and reducing our price target to \$10 following the quizartinib regulatory update. Uncertainty on adequacy of lower-dose data for purposes of phase 3 initiation will weigh on the stock in the near term and overall timelines for phase 3 completion are at risk, in our opinion. With no prescribed timeline for FDA to respond to AMBI's data analysis and only 40 patients of 30mg data, there is some risk that FDA could ask for further analysis, efficacy/safety data below 30mg and additional clinical study. We would take a wait-and-see approach pending better visibility on phase 3 protocol and timelines.

Valuation & Recommendation

Our \$10 price target reflects a probability adjusted NPV for US opportunity for quizartinib in the relapsed/refractory FLT3-ITD+ AML, with peak sales of \$150M and 50% likelihood of success.

December 4, 2013

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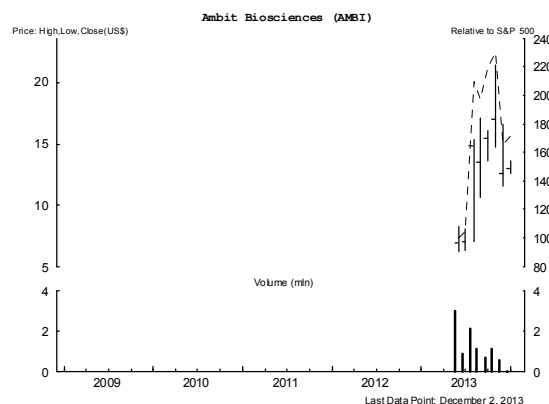
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Securities Info

Price (3-Dec)	\$12.80	Target Price	\$10.00 ↓
52-Wk High/Low	\$21/\$6	Dividend	--
Mkt Cap (mm)	\$229	Yield	--
Shs O/S (mm, BASIC)	17.9	Float O/S (mm)	11.0
Options O/S (mm)	na	ADVol (30-day, 000s)	32

Price Performance



Valuation/Financial Data

(FY-Dec.)	2012A	2013E	2014E	2015E
EPS GAAP	NA	-\$1.17	-\$2.03	-\$2.18
P/E		nm	nm	nm
First Call Cons.		-\$1.49	-\$1.94	-\$1.99
FCF	NA	NA	-\$2.32	na
P/FCF		na	nm	na
EBITDA (\$mm)	-\$23	-\$7	-\$38	-\$43
EV/EBITDA		nm	nm	nm
Rev. (\$mm)	\$18	\$26	\$0	\$0
EV/Rev		5.8x	na	#DIV/0!
Quarterly EPS	1Q	2Q	3Q	4Q
2012A	NA	NA	NA	NA
2013E	NAA	NAA	-\$0.34A	-\$0.46

Balance Sheet Data (30-Jun)

Net Debt (\$mm)	-\$79	Total Debt/EBITDA	nm
Total Debt (\$mm)	\$0	EBITDA/IntExp	na
Net Debt/Cap.	nm	Price/Book	3.6x

Notes: Quarterly EPS may not sum due to share count. All values in US\$.

Source: BMO Capital Markets estimates, Bloomberg, Thomson Reuters, and IHS Global Insight.

Changes

Rating
 OP to Mkt

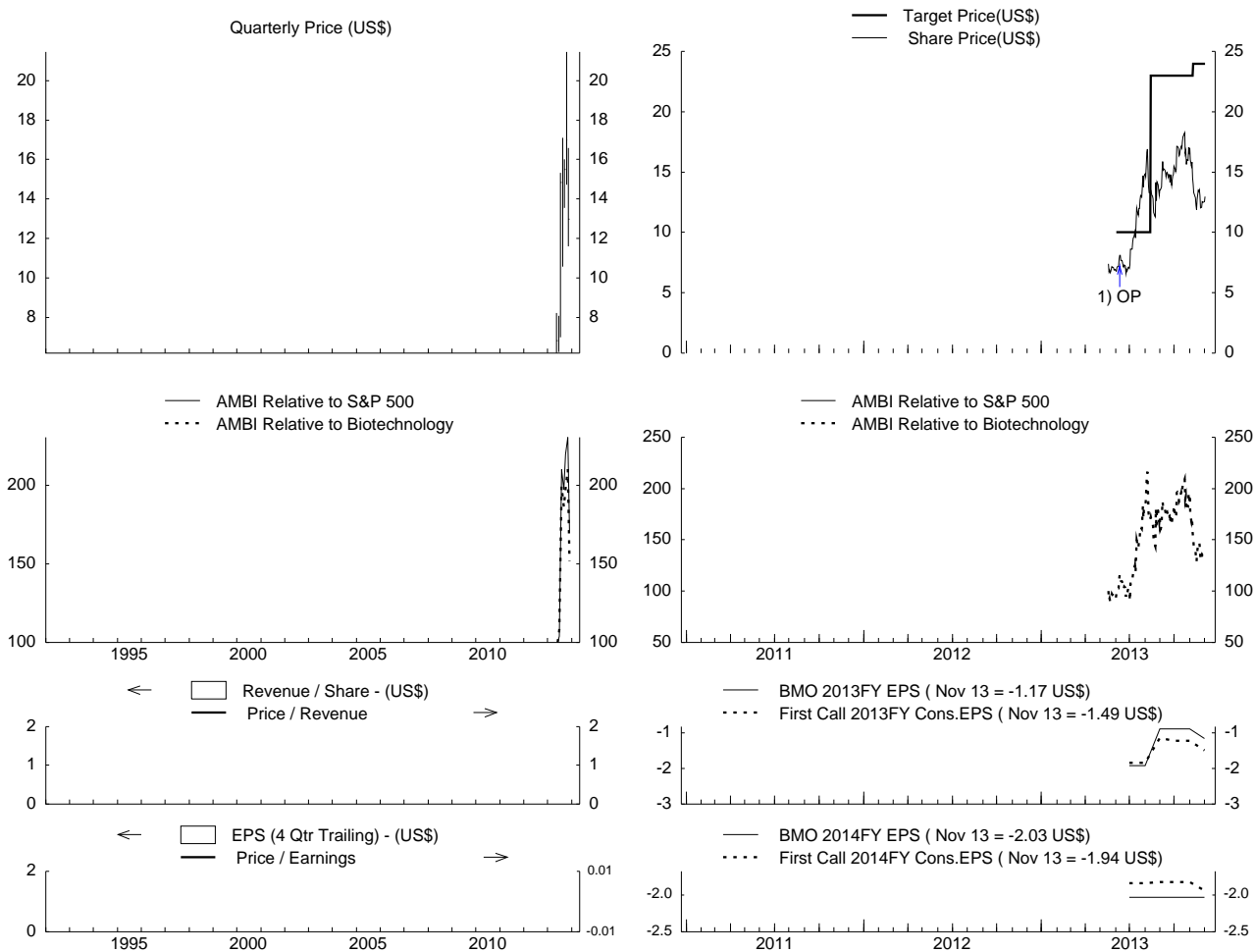
Target
 \$24.00 to \$10.00

AMBI Income Statement 2012A-2020E

INCOME STATEMENT (\$M)	2012A	1Q13A	2Q13A	3Q13A	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
REVENUES													
Product Revenues	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 79.3	\$ 122.0	\$ 163.2
Collaboration agreements	17.6	6.6	11.5	7.7	-	25.8	-	-	-	-	-	-	-
Grant revenue and other	-	-	-	-	-	-	-	-	-	-	-	-	-
TOTAL REVENUES	\$ 17.6	\$ 6.6	\$ 11.5	\$ 7.7	\$ -	\$ 25.8	\$ -	\$ -	\$ -	\$ -	\$ 79.3	\$ 122.0	\$ 163.2
EXPENSES (GAAP)													
Cost of Goods Sold (COGS)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 4.0	\$ 6.1	\$ 8.2
R&D Expense	36.7	9.0	6.7	4.5	6.5	26.7	29.0	32.0	33.0	36.0	34.0	34.0	36.0
SG&A Expense	6.6	1.8	2.2	3.1	2.0	9.0	8.5	11.0	21.5	30.0	30.0	30.0	30.0
In-process R&D	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	(2.5)	-	-	(2.5)	-	(2.5)	-	-	-	-	-	-	-
TOTAL EXPENSES	\$ 40.8	\$ 10.8	\$ 8.9	\$ 5.1	\$ 8.5	\$ 33.2	\$ 37.5	\$ 43.0	\$ 54.5	\$ 66.3	\$ 68.0	\$ 70.1	\$ 74.2
Operating Income	\$ (23.2)	\$ (4.2)	\$ 2.7	\$ 2.6	\$ (8.5)	\$ (7.4)	\$ (37.5)	\$ (43.0)	\$ (54.5)	\$ (22.2)	\$ 11.3	\$ 51.9	\$ 89.0
Depreciation and amortization	-	-	-	-	-	-	-	-	-	-	-	-	-
EBIT	(23.2)	(4.2)	2.7	2.6	(8.5)	(7.4)	(37.5)	(43.0)	(54.5)	(22.2)	11.3	51.9	89.0
Interest and other income	0.0	-	0.0	0.0	-	0.0	-	-	-	-	-	-	-
Interest and other expense	(1.7)	(0.2)	(0.1)	(0.1)	-	(0.3)	-	-	-	-	-	-	-
Other Income (Expense)	(2.3)	(4.0)	2.6	(6.7)	-	(10.0)	-	-	-	-	-	-	-
Interest and Other Income (Expense)	(4.0)	(4.1)	2.5	(6.7)	-	(10.4)	-	-	-	-	-	-	-
Pre-Tax Income	(27.2)	(8.3)	5.2	(6.1)	(8.5)	(17.7)	(37.5)	(43.0)	(54.5)	(22.2)	11.3	51.9	89.0
Income Taxes	(0.1)	0.0	-	(0.0)	-	(0.0)	-	-	-	-	-	-	-
Consolidated Net Income (GAAP)	\$ (27.0)	\$ (8.3)	\$ 5.2	\$ (6.1)	\$ (8.5)	\$ (17.7)	\$ (37.5)	\$ (43.0)	\$ (54.5)	\$ (22.2)	\$ 11.3	\$ 51.9	\$ 89.0
Net loss attributable to redeemable non-controlling interest	0.4	0.1	(0.0)	-	-	-	-	-	-	-	-	-	-
Net loss attributable to Ambit Biosciences	(26.6)	(8.2)	5.1	(6.1)	(8.5)	(17.6)	(37.5)	(43.0)	(54.5)	(22.2)	11.3	51.9	89.0
Accretion to redemption value of redeemable convertible preferred stock	(3.2)	(2.3)	-	-	-	(2.3)	-	-	-	-	-	-	-
Change in fair value of redeemable non-controlling interest	(0.9)	(1.5)	-	-	-	(1.5)	-	-	-	-	-	-	-
Net Income (GAAP)	\$ (30.7)	\$ (12.0)	\$ 5.1	\$ (6.1)	\$ (8.5)	\$ (21.5)	\$ (37.5)	\$ (43.0)	\$ (54.5)	\$ (22.2)	\$ 11.3	\$ 51.9	\$ 89.0
EPS (GAAP) (basic)	\$ (16.591.99)	\$ (3,019.30)	\$ 0.45	\$ (0.34)	\$ (0.46)	\$ (1.17)	\$ (2.03)	\$ (2.18)	\$ (2.31)	\$ (0.94)	\$ 0.48	\$ 2.18	\$ 3.72
EPS (GAAP) (diluted)	\$ (16.591.99)	\$ (3,019.30)	NM	\$ (0.34)	\$ (0.46)	\$ (1.17)	\$ (2.03)	\$ (2.18)	\$ (2.31)	\$ (0.94)	\$ 0.48	\$ 2.18	\$ 3.72
Total of Reconciliation Items	0.7	0.4	0.4	-	-	0.8	-	-	-	-	-	-	-
Net Income (Non-GAAP)	\$ (26.3)	\$ (7.9)	\$ 5.6	\$ (6.1)	\$ (8.5)	\$ (16.9)	\$ (37.5)	\$ (43.0)	\$ (54.5)	\$ (22.2)	\$ 11.3	\$ 51.9	\$ 89.0
Impact of Adjustments to EPS	400.97	99.75	0.04	-	-	99.79	-	-	-	-	-	-	-
EPS (Non-GAAP) (basic)	\$ (14.225.11)	\$ (1,980.95)	\$ 0.69	\$ (0.34)	\$ (0.46)	\$ (1,981.06)	\$ (2.03)	\$ (2.20)	\$ (2.31)	\$ (0.94)	\$ 0.48	\$ 2.18	\$ 3.72
EPS (Non-GAAP) (diluted)	\$ (14.225.11)	\$ (1,980.95)	\$ 0.57	\$ (0.34)	\$ (0.46)	\$ (1,981.18)	\$ (2.03)	\$ (2.20)	\$ (2.31)	\$ (0.94)	\$ 0.48	\$ 2.18	\$ 3.72
Weighted average shares outstanding (basic)	0.0	0.0	8.1	17.9	18.4	18.3	18.4	19.7	23.6	23.7	23.8	23.9	23.9
Weighted average shares outstanding (diluted)	0.0	0.0	9.8	17.9	18.4	18.3	18.4	19.7	23.6	23.7	23.8	23.9	23.9

Source: Company reports and BMO Capital Markets

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.

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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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