

# Ambit Biosciences

(AMBI-NASDAQ)

**Stock Rating:** Outperform

**Industry Rating:** Outperform

## Progress Continues Towards Validating an Accelerated Path for Quizartinib

### Event

Ambit Biosciences (AMBI) reported 2Q13 operating results today and provided an update to key initiatives. AMBI ended 2Q13 with \$85.3M, sufficient to fund operations through YE15 and the completion of the first quizartinib phase 3 trial. In 2Q13, AMBI held a "Type C" meeting with FDA to discuss in part, requirements for a successful end-of-phase 2 meeting. AMBI characterized the interaction with FDA as highly encouraging, noting that FDA requested documentation supporting the validity of a complete response with incomplete hematologic recovery (CRi) as a surrogate for clinical benefit. AMBI is analyzing internal and external data to support the use of CRi and will present these data along with the complete phase 2b data (FDA saw partial data in 2Q13) and phase 3 study design to FDA in November. AMBI remains on track to initiate a phase 3 trial of quizartinib in relapsed/refractory AML in early 2014 with a second phase 3 study in newly diagnosed patients being designed with input from ongoing clinical trials.

### Impact

Reiterating Outperform rating as we remain encouraged that AMBI will gain agreement from FDA on the potential validity of CRi as a surrogate for clinical efficacy in relapsed/refractory AML, providing a path accelerated approval filing for quizartinib as a first-in-class FLT-3 inhibitor for relapsed/refractory FLT-3+ve AML. Further, we expect positive data at ASH in December from external CRi validation collaborators and more importantly chemotherapy combination data in both elderly and younger newly diagnosed patients, which, with emerging maintenance use data, potentially positions quizartinib as the mainstay therapy for FLT-3+ve AML.

### Forecasts

We estimate a per share loss of (\$0.90) in 2013.

### Valuation

\$23/share price target is based on 25x 2020 EPS of \$3.72 discounted 30%.

### Recommendation

We rate AMBI shares Outperform.

August 14, 2013

## Biotechnology

**Jim Birchenough, M.D.**

BMO Capital Markets Corp.

415-591-2129

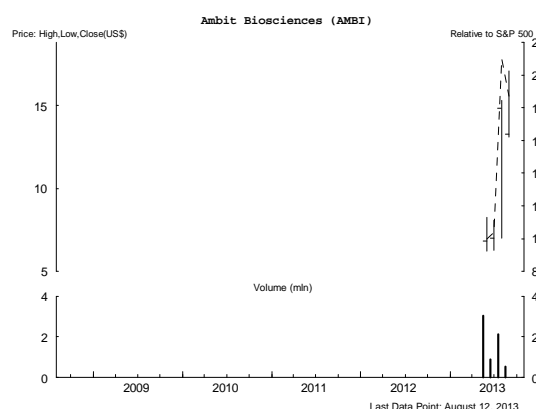
jim.birchenough@bmo.com

**Chuck Whitesell / Nick Abbott, PhD**

### Securities Info

<b>Price (13-Aug)</b>	<b>\$13.50</b>	<b>Target Price</b>	<b>\$23 ↑</b>
52-Wk High/Low	\$17/\$6	Dividend	--
Mkt Cap (mm)	\$242	Yield	--
Shs O/S (mm, BASIC)	17.9	Float O/S (mm)	2.5
Options O/S (mm)	na	ADVol (30-day, 000s)	88

### Price Performance



### Valuation/Financial Data

(FY-Dec.)	2011A	2012A	2013E	2014E
EPS GAAP	NA	NA	-\$0.90↑	-\$2.03
P/E			nm	nm
First Call Cons.			-\$1.84	-\$1.84
FCF	NA	NA	NA	-\$2.32
P/FCF			na	nm
EBITDA (\$mm)	-\$34	-\$23	-\$11	-\$38
EV/EBITDA			nm	nm
Rev. (\$mm)	\$24	\$18	\$25	\$0
EV/Rev			9.5x	#DIV/0!
<b>Quarterly EPS</b>	<b>1Q</b>	<b>2Q</b>	<b>3Q</b>	<b>4Q</b>
2012A	NA	NA	NA	NA
2013E	NAA	NAA	-\$0.06↑	-\$0.46

### Balance Sheet Data (31-Mar)

Net Debt (\$mm)	-\$5	Total Debt/EBITDA	nm
Total Debt (\$mm)	\$3	EBITDA/IntExp	na
Net Debt/Cap.	15.7%	Price/Book	#VALUE!

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

**Annual EPS**  
2013E -\$1.92 to -\$0.90

**Quarterly EPS**  
Q3/13E -\$0.44 to -\$0.06

**Target**  
\$10.00 to \$23.00

Please refer to pages 3 to 6 for Important Disclosures, including the Analyst's Certification.

## Adjustments to Model

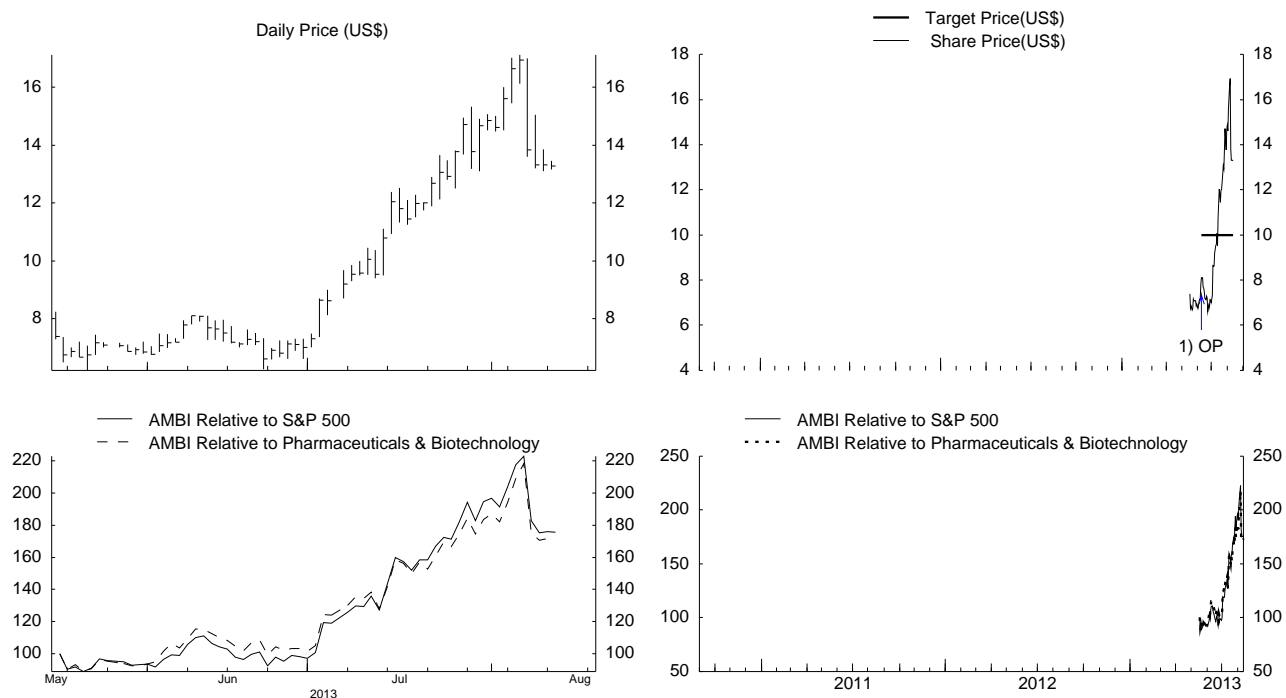
Based on success with identifying an effective lower dose of quizartinib and with a maintenance trial design envisioned in phase 3 we have adjusted our financial model to reflect potential longer-term maintenance dosing over time. Revenue estimates from 2017 to 2020 increase accordingly to \$46.1M, \$79.3M, \$122.0M, and \$163.2M with corresponding EPS increases to (\$0.94), \$0.48, \$2.18 and \$3.72 from (\$1.25), (\$0.43), \$0.35 and \$0.84.

## Exhibit 1: AMBI Income Statement 2012A-2020E

INCOME STATEMENT (\$M)	2012A	1Q13A	2Q13A	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
<b>REVENUES</b>														
Product Revenues	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 46.1	\$ 79.3	\$ 122.0	\$ 163.2	\$ 184.9
Collaboration agreements	17.6	6.6	11.5	7.0	-	25.1	-	-	-	-	-	-	-	-
Grant revenue and other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>TOTAL REVENUES</b>	<b>\$ 17.6</b>	<b>\$ 6.6</b>	<b>\$ 11.5</b>	<b>\$ 7.0</b>	<b>\$ -</b>	<b>\$ 25.1</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 46.1</b>	<b>\$ 79.3</b>	<b>\$ 122.0</b>	<b>\$ 163.2</b>	<b>\$ 184.9</b>
<b>EXPENSES (GAAP)</b>														
Cost of Goods Sold (COGS)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 2.3	\$ 4.0	\$ 6.1	\$ 8.2	\$ 9.2
R&D Expense	36.7	9.0	6.7	6.0	6.5	28.2	29.0	32.0	33.0	36.0	34.0	34.0	36.0	36.0
SG&A Expense	6.6	1.8	2.2	2.0	2.0	8.0	8.5	11.0	21.5	30.0	30.0	30.0	30.0	30.0
Inprocess R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	(2.9)	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>TOTAL EXPENSES</b>	<b>40.8</b>	<b>10.8</b>	<b>8.9</b>	<b>8.0</b>	<b>8.5</b>	<b>36.1</b>	<b>37.5</b>	<b>43.0</b>	<b>54.5</b>	<b>68.3</b>	<b>68.0</b>	<b>70.1</b>	<b>74.2</b>	<b>75.2</b>
<b>Operating Income</b>	<b>(23.2)</b>	<b>(4.2)</b>	<b>2.7</b>	<b>(1.0)</b>	<b>(8.5)</b>	<b>(11.0)</b>	<b>(37.5)</b>	<b>(43.0)</b>	<b>(54.5)</b>	<b>(22.2)</b>	<b>11.3</b>	<b>51.9</b>	<b>89.0</b>	<b>109.7</b>
Depreciation and amortization	-	-	-	-	-	-	-	-	-	-	-	-	-	-
EBIT	(23.2)	(4.2)	2.7	(1.0)	(8.5)	(11.0)	(37.5)	(43.0)	(54.5)	(22.2)	11.3	51.9	89.0	109.7
Interest and other income	0.0	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest and other expense	(1.7)	(0.2)	-	-	-	(0.2)	-	-	-	-	-	-	-	-
Other Income (Expense)	(2.3)	(4.0)	2.5	-	-	(1.5)	-	-	-	-	-	-	-	-
Interest and Other Income (Expense)	(4.0)	(4.1)	2.5	-	-	(1.6)	-	-	-	-	-	-	-	-
Pre-Tax Income	(27.2)	(8.3)	5.2	(1.0)	(8.5)	(12.6)	(37.5)	(43.0)	(54.5)	(22.2)	11.3	51.9	89.0	109.7
Income Taxes	(0.1)	0.0	-	-	-	0.0	-	-	-	-	-	-	-	-
Consolidated Net Income (GAAP)	\$ (27.0)	\$ (8.3)	\$ 5.2	\$ (1.0)	\$ (8.5)	\$ (12.6)	\$ (37.5)	\$ (43.0)	\$ (54.5)	\$ (22.2)	\$ 11.3	\$ 51.9	\$ 89.0	\$ 109.7
Net loss attributable to redeemable non-controlling interest	0.4	0.1	(0)	-	-	-	-	-	-	-	-	-	-	-
Net loss attributable to Ambit Biosciences	(26.6)	(8.2)	5.1	(1.0)	(8.5)	(12.6)	(37.5)	(43.0)	(54.5)	(22.2)	11.3	51.9	89.0	109.7
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)	-	-	-	-	-	-	-	-
<b>Net Income (GAAP)</b>	<b>(30.7)</b>	<b>(12.0)</b>	<b>5.1</b>	<b>(1.0)</b>	<b>(8.5)</b>	<b>(16.4)</b>	<b>(37.5)</b>	<b>(43.0)</b>	<b>(54.5)</b>	<b>(22.2)</b>	<b>11.3</b>	<b>51.9</b>	<b>89.0</b>	<b>109.7</b>
EPS (GAAP) (basic)	\$ (16,591.93)	\$ (3,019.30)	\$ 0.46	\$ (0.06)	\$ (0.46)	\$ (0.90)	\$ (2.03)	\$ (2.18)	\$ (2.31)	\$ (0.94)	\$ 0.48	\$ 2.18	\$ 3.72	\$ 4.56
<b>EPS (GAAP) (diluted)</b>	<b>\$ (16,591.93)</b>	<b>\$ (3,019.30)</b>	<b>NM</b>	<b>\$ (0.06)</b>	<b>\$ (0.46)</b>	<b>\$ (0.90)</b>	<b>\$ (2.03)</b>	<b>\$ (2.18)</b>	<b>\$ (2.31)</b>	<b>\$ (0.94)</b>	<b>\$ 0.48</b>	<b>\$ 2.18</b>	<b>\$ 3.72</b>	<b>\$ 4.56</b>
Total of Reconciliation Items	0.7	0.4	0.4	-	-	0.8	-	-	-	-	-	-	-	-
Net Income (Non-GAAP)	\$ (26.3)	\$ (7.9)	\$ 5.6	\$ (1.0)	\$ (8.5)	\$ (11.8)	\$ (37.5)	\$ (43.0)	\$ (54.5)	\$ (22.2)	\$ 11.3	\$ 51.9	\$ 89.0	\$ 109.7
Impact of Adjustments to EPS	400.97	99.75	0.04	-	-	99.79	-	-	-	-	-	-	-	-
EPS (Non-GAAP) (basic)	\$ (14,225.11)	\$ (1,990.95)	\$ 0.69	\$ (0.06)	\$ (0.46)	\$ (1,990.78)	\$ (2.03)	\$ (2.29)	\$ (2.31)	\$ (0.94)	\$ 0.48	\$ 2.18	\$ 3.72	\$ 4.56
EPS (Non-GAAP) (diluted)	\$ (14,225.11)	\$ (1,990.95)	\$ 0.57	\$ (0.06)	\$ (0.46)	\$ (1,990.90)	\$ (2.03)	\$ (2.29)	\$ (2.31)	\$ (0.94)	\$ 0.48	\$ 2.18	\$ 3.72	\$ 4.56
Weighted average shares outstanding (basic)	0.0	0.0	8.1	18.0	18.4	18.3	18.4	19.7	23.6	23.7	23.8	23.9	23.9	24.0
Weighted average shares outstanding (diluted)	0.0	0.0	9.8	18.0	18.4	18.3	18.4	19.7	23.6	23.7	23.8	23.9	23.9	24.0

Source: Company reports and BMO Capital Markets

Ambit Biosciences (AMBI)



AMBI - Rating as of 15-May-13 = NR

Date	Rating Change	Share Price
1 10-Jun-13	NR to OP	\$7.79

Last Daily Data Point: August 12, 2013

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Hold	Market Perform	56.8%	10.2%	45.9%	53.9%	45.5%	41.1%
Sell	Underperform	5.3%	3.2%	1.4%	6.5%	3.5%	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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