

Ambit Biosciences

(AMBI-NASDAQ)

Stock Rating: Outperform Industry Rating: Outperform

Focus on Quizartinib Phase 3 Initiation

Event

Ambit reported 4Q13 operating results yesterday and provided an update to key initiatives. The net loss per share of \$0.10 was narrower than the consensus estimate of a loss of \$0.44. AMBI ended 4Q13 with \$71.2M. With primary focus on the phase 3 development of FLT3 inhibitor quizartinib, AMBI plans to initiate the registrational study in 2Q14, with an interim analysis anticipated in 2H15 and top-line data in 1Q16. The phase 3 study plans to enroll 326 patients who have relapsed (within six months) or are refractory to frontline chemotherapy, including those relapsing following a hematopoietic stem cell transplant (HSCT). Patients will be randomized 2:1 to quizartinib monotherapy vs. one of three chemotherapy regimens, with overall survival as the primary endpoint. Patients in both arms have an option to proceed to a potentially curative HSCT, and those in guizartinib arm will be offered quizartinib maintenance post transplant. AMBI estimated that 35-40% of patients in quizartinib arm and 15-20% in chemotherapy arm could proceed to HSCT. Other highlights included a company-sponsored phase 1 trial evaluating quizartinib maintenance in AML patients, irrespective of FLT3-ITD status, who have received a HSCT and are in remission, with data scheduled for presentation in a future medical conference, and three ongoing or planned investigator-sponsored studies evaluating quizartinib in combination with chemotherapies in newly diagnosed AML patients over 60 years of age.

Impact & Analysis

We maintain our Outperform rating following review of 4Q13 results. We continue to believe that quizartinib is a best-in-class FLT3 inhibitor and that clear benefit in establishing CRi will translate increased rate of stem cell transplant (SCT) and extended overall survival (OS) in phase 3. We remain optimistic that a high value partnership can be achieved in 2014 and bring in non-dilutive capital to advance the pipeline beyond quizartinib.

Valuation & Recommendation

Our \$14 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 65% likelihood of success.

March 21, 2014

Jim Birchenough, M.D.BMO Capital Markets Corp

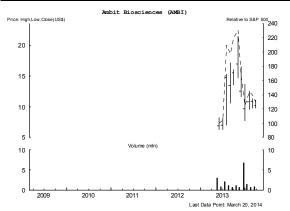
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Securities Info

\$10.21	Target Price	\$14.00
\$21/\$6	Dividend	
\$183	Yield	
17.9	Float O/S (mm)	12.3
na	ADVol (30-day, 000s)	45
	\$21/\$6 \$183 17.9	\$21/\$6 Dividend \$183 Yield 17.9 Float O/S (mm)

Price Performance



Valuation/Financial Data

(FY-Dec.)	2012A	2013A	2014E	2015E
EPS GAAP	NA	-\$1.19	-\$1.77↑	-\$1.91↑
P/E			nm	nm
First Call Cons.			-\$1.94	-\$2.03
FCF	NA	NA	-\$2.32	na
P/FCF			nm	na
EBITDA (\$mm)	-\$23	-\$7	-\$38	-\$43
EV/EBITDA			nm	nm
Rev. (\$mm)	\$18	\$27	\$0	\$0
Quarterly EPS	1Q	2Q	3Q	4Q
2013A	NA	NA	-\$0.34	-\$0.10
2014E	-\$0.40↑	-\$0.42↑	-\$0.45↑	-\$0.49↑
Balance Sheet Dat	ta (30-Sep)			
Net Debt (\$mm)	-\$71	TotalDeb	t/EBITDA	nm
Total Debt (\$mm)	\$0	EBITDA/	IntExp	na
Net Debt/Cap.	nm	Price/Boo	ok .	3.1x

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

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

Changes Annual EPS Quarterly EPS

2014E -\$2.03 to -\$1.77 Q1/14E -\$0.46 to -\$0.40 Q3/14E -\$0.51 to -\$0.45 2015E -\$2.18 to -\$1.91 Q2/14E -\$0.49 to -\$0.42 Q4/14E -\$0.57 to -\$0.49

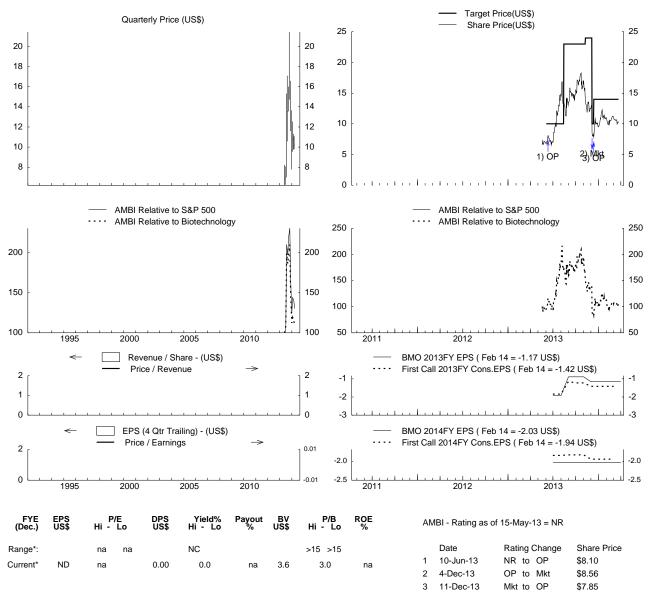
Exhibit 1: AMBI Income Statement 2013A-2020E

INCOME STATEMENT (\$M)	2013A	15	1Q14E	2Q14E	Ш	3Q14E	46	4Q14E	2014E	2015E	2016E	2017E	2018E		2019E	202	2020E
REVENUES																	
Product Revenues	9	છ	•	s	,	9	છ	,	, &	ا چ	ا ج	\$ 46.1	69	8 8	122.0	8	163.2
Collaboration agreements	27.1		ì		ì				1	1	1	-			•		ì
Grant revenue and other	1		ì		ì	1		,	1	1	1				•		ì
TOTAL REVENUES	\$ 27.1	\$		s	 .	•	\$		•	•	· •	\$ 46.1	ss.	\$ 8.62	122.0	\$	163.2
EX PENSES (GAAP)																	
	•	•		•	•	,	•			•	•		(•	0
Cost of Goods Sold (COGS)		Ð		Ð		, i	Ð		9	9	·	Ð	Ð	4.0		Ð	8.2
R&D Expense	26.3		6.5		7.0	7.5		8.0	29.0	32.0	33.0	36.0		34.0	34.0		36.0
SG&A Expense	10.3		2.0		2.0	2.0	_	2.5	8.5	11.0	21.5			0.0	30.0		30.0
In-process R&D																	
Other	(2.5)					•		ì	•	•	1			-	1		•
TOTAL EXPENSES	34.1		8.5		0.6	9.6		10.5	37.5	43.0	54.5	68.3		0.89	70.1		74.2
Operating Income	(7.0)		(8.5)		(0.6)	(9.5)		(10.5)	(37.5)	(43.0)	(54.5	(22.2)		11.3	51.9		89.0
Depreciation and amortization	٠		ì			1			•	1	•	1	1		•		
ЕВП	(7.0)		(8.5)		(0 6)	(9.5)	_	(10.5)	(37.5)	(43.0)	(54.5)	(2.22)		.3	51.9		0 68
								ì									
Interest and other income	0.0		í		ì	1			•	1	1	•		_	•		í
Interest and other expense	(0.3)		í		í	1			1	•	1	1		_	•		i.
Other Income (Expense)	(3.9)				ا .	•			1	1	1	1			1		•
Interest and Other Income (Expense)	(4.3)		í			•			1	ı	1				•		1
Pre-Tax Income	(11.3)		(8.5)	_	(0.6)	(9.5)	(-	(10.5)	(37.5)	(43.0)	(54.5)	(22.2)		11.3	51.9		89.0
Income Taxes	(0.0)		ì		i i	1			•	1	1			1	1		1
Consolidated Net Income (GAAP)	\$ (11.3)	G	(8.5)	8	(0.6)	\$ (9.5)	\$	(10.5)	\$ (37.5)	\$ (43.0)	\$ (54.5)	(22.2)	69	11.3	51.9	ь	89.0
Net loss attibutable to redeemable non-controlling interest	0.1								1	1				1	1		- 1
Net loss attibitable to Ambit Biosciences	(11.2)		(8,5)		(0 6)	(9.5)		(10.5)	(37.5)	(43.0)	(54.5)	(2.22)		11.3	51.9		0 08
	7		(0.5)		6	5	-	(0:01)	(2:12)	Cont				?	2		
Accretion to redemption value of redeemable convertible preferred stock	- (* 0)					1			•	•	1	1			1		
Net Income (GAAP)	(11.6)		(8.5)	_	(0.6)	(9.5)	6	(10.5)	(37.5)	(43.0)	(54.5)		•	11.3	51.9		89.0
EPS (GAAP) (basic)	\$ (1.19)	G	(0.47)	0)	(0.50)	\$ (0.53)	\$	(0.58)	\$ (2.09)	\$ (2.24)	\$ (2.36)	(0.96)	မှ	0.49	2.23	မှ	3.80
EPS (GAAP) (diluted)	(1.19)	s	(0.40)	0) \$	(0.42)	\$ (0.45)	\$ ((0.49)	\$ (1.77)	(1.91)	\$ (2.07)) \$ (0.84	1) \$ 0.	.43 \$	1.95	\$	3.32
Total of Reconciliation Items	2.3								1	1	1			-			- 1
Net Income (Non-GAAP)	(0.6)	69	(8.5)	9	6 (0.6)	(6.5)	69	(10.5)	\$ (37.5)	\$ (43.0)	\$ (54.5)	(22.2)	· 49	11.3	51.9	(f	89.0
	7			•								•	•			,	
Impact of Adjustments to EPS	99.87		í						1	1	1				•		1
EPS (Non-GAAP) (basic)	\$ (0.81)	₩	(0.47)	9	(0:00)	\$ (0.53)	\$	(0.58)	\$ (2.09)	\$ (2.26)	\$ (2.36)	(0.96)	6 9	0.49	2.23	69	3.80
EPS (Non-GAAP) (diluted)	\$ (0.81)	49	(0.40)	9) \$	(0.42)	\$ (0.45)	\$	(0.49)	\$ (1.77)	\$ (1.92)	\$ (2.07)) \$ (0.84)	69	0.43	1.94	ss.	3.32
Weighted average shares outstanding (basic)	11.0		17.9	-	17.9	17.9	_	18.0	17.9	19.2	23.0	23.1		23.2	23.3		23.4
Weighted average shares outstanding (diluted)	11.0		21.2	N	1.2	21.2		21.3	21.2	22.5	26.4			9.9	26.7		26.8

Source: Company reports and BMO Capital Markets

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Last Price (March 20, 2014): \$10.21 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

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^{*} 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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Methodology: Our \$14 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 65% likelihood of success.

Risks: There are a number of risks associated with investment in biotechnology companies. These risks include, but are not limited to, risk of clinical trial delay or failure, adverse regulatory decisions including product non-approval, unanticipated adverse effects of drugs which may result in removal from market, risk of manufacturing difficulties, capital market risk which may impair the ability to fund product discovery, research, regulatory filing, manufacture and/or commercialization, risk in attaining and retaining appropriate development or commercial partners, lower-than-expected product adoption, difficulties in gaining appropriate reimbursement for products from payors, unforeseen generic and branded competition, risk to patents being invalidated, and failure to meet earnings and revenue expectations.

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Rating		BMOCM US	BMOCM US	BMOCM US	BMOCM	BMOCM	Starmine
Category	BMO Rating	Universe*	IB Clients**	IB Clients***	Universe****	IB Clients****	Universe
Buy	Outperform	38.0%	20.4%	49.0%	38.8%	50.4%	52.5%
Hold	Market Perform	56.1%	13.8%	49.0%	54.0%	46.5%	41.8%
Sell	Underperform	5.8%	5.6%	2.0%	7.2%	3.1%	5.7%

- * Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.
- ** Reflects rating distribution of all companies from which BMO Capital Markets Corp. has received compensation for Investment Banking services as percentage within ratings category.
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Mkt = Market Perform - Forecast to perform roughly in line with the analyst's coverage universe on a total return basis;

Und = Underperform - Forecast to underperform the analyst's coverage universe on a total return basis;

(S) = Speculative investment;

NR = No rating at this time; and

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