

Ambit Biosciences

(AMBI-NASDAQ)

Stock Rating: Outperform
Industry Rating: Outperform

Upgrading to Outperform on Resolution of Dosing Issues

Event

Ambit Biosciences announced late yesterday that FDA had agreed to a dosing regimen for its phase 3 study of quizartinib in patients with FLT3-ITD+ acute myeloid leukemia (AML), along with other design elements for the phase 3. Dosing in the study will start at quizartinib 30mg dose and escalate to quizartinib 60mg dose at day 16 if no increase in QTc interval and as day 30 if no response. The QUANTUM-R study will begin in early 1Q14 and is designed to enroll 326 patients with FLT3-ITD+ AML, and randomize 2:1 to either quizartinib vs. physicians' choice of chemotherapy. In the study patients in the quizartinib group will be offered quizartinib maintenance therapy following stem cell transplant. The study has 90% power to detect a reduced hazard of death (hazard ratio of 0.65) and median improvement in overall survival (OS) from 4 months to 6 months, after 280 deaths. Top-line data from QUANTUM-R is expected by YE2015 with an earlier interim analysis planned after 140 deaths.

Impact & Analysis

We are upgrading our rating on AMBI to Outperform from Market Perform and increasing our price target to \$14 following earlier-than-expected resolution of dosing issues with FDA and on review of the QUANTUM-R study in aggregate. Data for quizartinib at the recent ASH meeting confirms a high level of efficacy at lower doses with CRc rate of 47% and CRi rate of 42% at 30mg dose and with 32% of patients progressing to transplant. While FDA has not accepted CRi as a surrogate endpoint for accelerated approval, we continue to believe that CRi does correlate strongly with overall survival (OS) and see a high likelihood of success with agreement with FDA on dosing.

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.

December 12, 2013

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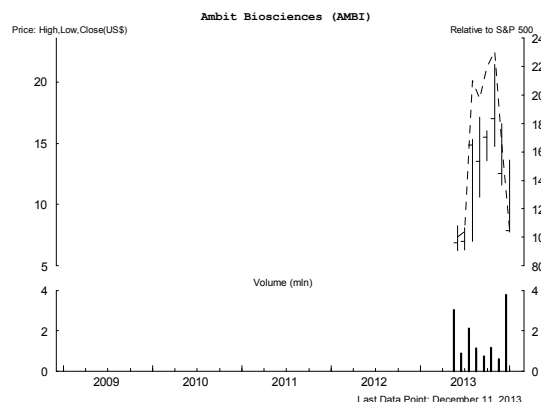
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Securities Info

| | | | |
|-----------------------|---------------|----------------------|------------------|
| Price (11-Dec) | \$7.85 | Target Price | \$14.00 ↑ |
| 52-Wk High/Low | \$4/\$6 | Dividend | -- |
| Mkt Cap (mm) | \$140 | Yield | -- |
| Shs O/S (mm, BASIC) | 17.9 | Float O/S (mm) | 11.0 |
| Options O/S (mm) | na | ADVol (30-day, 000s) | 141 |

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. | | -\$1.42 | -\$1.94 | -\$2.03 |
| 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 | | 2.4x | na | na |
| 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 | TotalDebt/EBITDA | | nm |
| Total Debt (\$mm) | \$0 | EBITDA/IntExp | | na |
| Net Debt/Cap. | nm | Price/Book | | 2.2x |

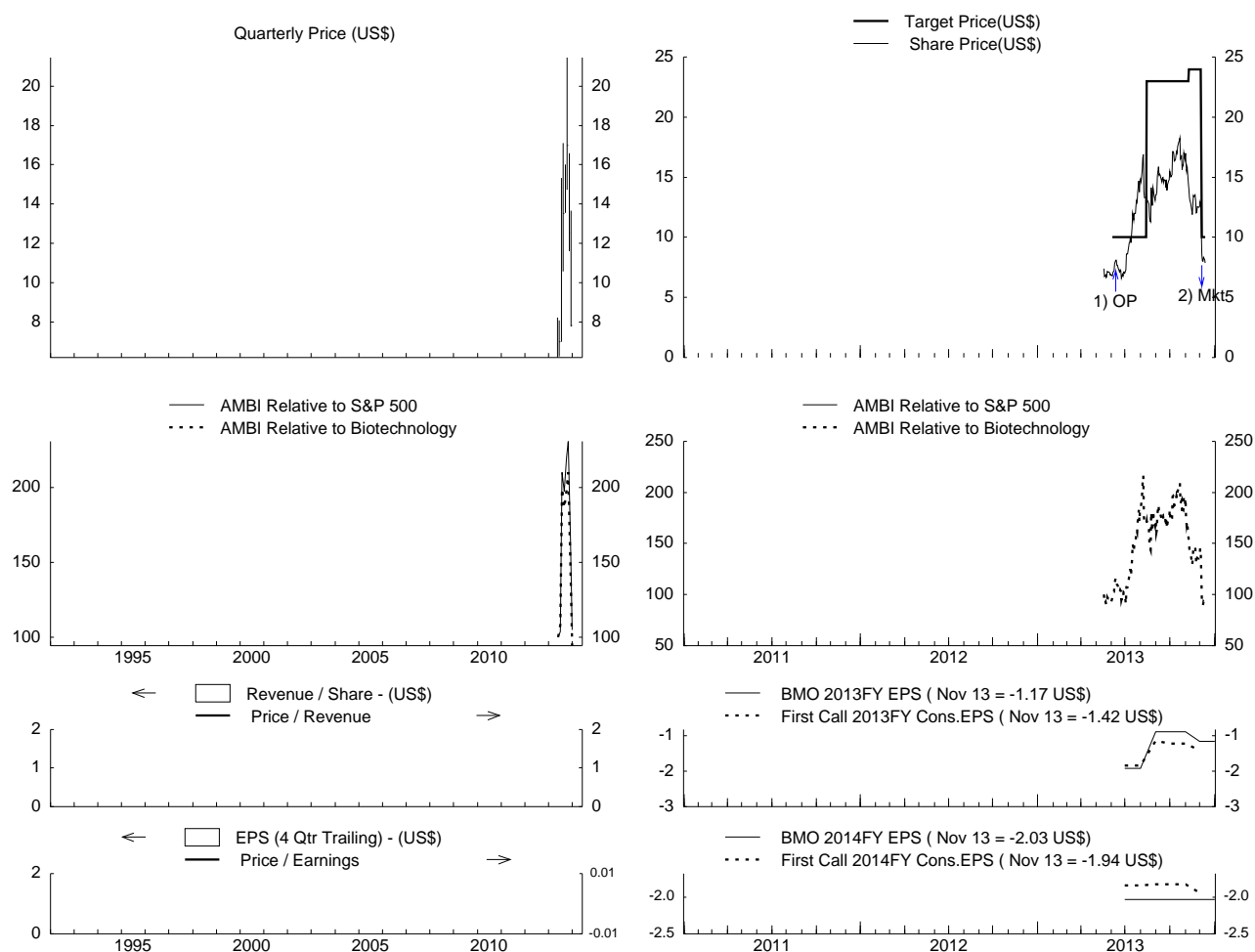
Notes: Quarterly EPS may not sum due to share count. All values in US\$.

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

Changes

| | |
|---------------|--------------------|
| Rating | Target |
| Mkt to OP | \$10.00 to \$14.00 |

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 | 3.5 | na | 1 10-Jun-13 | NR to OP | \$8.10 |
| | | | | | | | | | 2 4-Dec-13 | OP to Mkt | \$8.56 |

* 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 11, 2013): \$7.85
Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

Important Disclosures

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Methodology and Risks to Our Price Target/Valuation

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.

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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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

R = Restricted – Dissemination of research is currently restricted.

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