

## ARIAD Pharmaceuticals, Inc.

### Iclusig Comes Back With a New Label and REMS; Upgrade to Outperform and Increase Price Target to \$12

On Friday, December 20, Ariad announced that it has reached agreement with the FDA for immediate reauthorization of Iclusig marketing in the United States, with a narrower label and accompanying Risk Mitigation Strategy (REMS) and post-marketing requirements (PMRs). Ariad plans to resume shipping of Iclusig by mid-January 2014. The new label stipulates that Iclusig is indicated in adult patients with T315I-positive chronic myeloid leukemia (CML) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), or in adult patients with CML and Ph+ ALL where no other tyrosine kinase inhibitor (TKI) therapy is indicated. We note that on October 31, the Food and Drug Administration (FDA) suspended marketing of Iclusig based on the risk of life-threatening blood clots and severe narrowing of blood vessels associated with Iclusig treatment. We had been expecting the re-commercialization of Iclusig with a narrower label, and we consider the REMS accompanied by four PMRs without an Elements to Assure Safe Use (ETASU) to be a favorable. We discuss the new label, REMS, and PMRs in detail herein.

We are upgrading Ariad shares to Outperform and increasing our price target from \$3 to \$12 (exhibit 1, on page 5), based on the following: 1) limited downside with REMS and PMRs in place, in our opinion; 2) positive physician feedback during ASH and high number of single-agent INDs filed during marketing suspension; 3) potential for safer administration of Iclusig with lower doses in the future; 4) potential attempt at the frontline setting at lower doses as long-term upside; 5) other potential indications of Iclusig that are not included in our model: GIST, and NSCLC with FGFR and RET mutations; and 6) valuation: although the addressable patient population in 2014 is cut in half because of the narrower label (from 2,500 to 1,300), the incidence is still substantial and the Iclusig patient population will build over time. We have increased our peak worldwide Iclusig revenue forecast to \$747 million in 2026 from our previous estimate of \$275 million. Our revised probability-adjusted NPV now assumes \$10 per share for Iclusig and \$2 for AP26113, compared with our previous estimate of \$1 and \$2 per share, respectively.

- Iclusig is now accompanied by a REMS and PMRs without a dedicated restricted distribution plan, thus enabling relatively easy growth with limited downside risk, in our opinion.** We had expected an ETASU in the REMS that could impose greater restrictions in the distribution of Iclusig. We believe with the new label, REMS, PMRs, and no ETASU, associated risks can be identified and managed without severely impeding Iclusig uptake and sales growth. From a regulatory perspective, we believe that Iclusig has been de-risked in the near term until perhaps 2016-2018 when we expect the readout of the required randomized control study (part of the PMRs) assessing the long-term safety of Iclusig treatment.

*Ariad Pharmaceuticals is a biopharmaceutical company based in Cambridge, Massachusetts. The company focuses its research, development, and commercial efforts on the oncology space, in particular leukemia and lung cancer.*

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December 23, 2013

Stock Rating: **Outperform**  
Company Profile: **Aggressive Growth**  
Price Target: \$12.00

Symbol: ARIA (NASDAQ)  
Price: \$6.43 (52-Wk.: \$2-\$23)  
Market Value (mil.): \$1,025  
Fiscal Year End: December  
Long-Term EPS Growth Rate:  
Dividend/Yield: None

	2012A	2013E	2014E
<b>Estimates</b>			
EPS FY	\$-1.34	\$-1.54	\$-0.78
CY		\$-1.54	\$-0.78
Sales (mil.)	1	44	109
<b>Valuation</b>			
FY P/E	NM	NM	NM
CY P/E		NM	NM

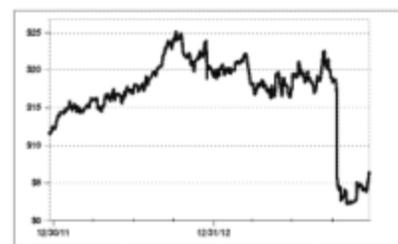
#### Trading Data (FactSet)

Shares Outstanding (mil.)	185
Float (mil.)	179
Average Daily Volume	15,567,546

#### Financial Data (FactSet)

Long-Term Debt/Total Capital (MRQ)	0.2
Book Value Per Share (MRQ)	1.4
Enterprise Value (mil.)	973.0
EBITDA (TTM)	-256.8
Enterprise Value/EBITDA (TTM)	-3.8x
Return on Equity (TTM)	-132.7

#### Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates