Ironwood Pharmaceuticals

4 for 4: Linaclotide Produces Robust 26-Week Results in Clinical Data Finale - ALERT

Overweight

IRWD, IRWD US
Price: $10.57

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US Biotechnology

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After market close, Ironwood and partners Forest/Almirall announced positive results from Study '302 of linaclotide in IBS-C, the final of the four phase 3 registration trials for the agent (2 in IBS-C and 2 in chronic constipation). The trial met all primary and secondary endpoints. That said, some on the Street were concerned that the key abdominal pain endpoint not reaching a robust level of statistical significance relative to other endpoints in the 12-week Study '31 trial (p=0.0262) was an overhang for the longer 26-week trial. We had viewed this as an overblown concern, and indeed over 12 and 26 weeks the abdominal pain endpoint was robustly significant (p<0.0001). NDA filing is expected in 3Q10, and EU filing is expected in 2H11. Given the totality of the phase 3 data for linaclotide (impressive efficacy and clean safety), we believe there is a high probability for regulatory approval and estimate the peak market potential could be $3B in the US alone. Reiterate Overweight rating on IRWD shares.

- **Linaclotide meets all primary/secondary endpoints; abdominal pain overhang removed.** Abdominal pain/CSBM (composite 1)- 12.7% vs. 3.0%; (p<0.0001), CSBM responder- 18.0% vs. 5.0% (p<0.0001), abdominal pain responder- 38.9% vs. 19.6% (p<0.0001) and abdominal pain/CSBM (composite 2)- 33.7% vs. 13.9% (p<0.0001), were similar at 12 weeks if not better to Study '31 results, as were EU regulatory endpoints of abdominal pain/discomfort responder- 54.1% vs. 38.5% (p<0.0001) and IBS relief- 39.4% vs. 16.6% (p<0.0001). Importantly, in our view, the mean change from baseline for abdominal pain and CSBMs were also robustly significant over 26 weeks.

- **Safety in line with prior phase 3 study.** No surprise diarrhea was the most common AE, 19.7% vs. placebo 2.5% (discontinued due to diarrhea: 4.5% vs. 0.2%). These data, along with rates of flatulence, abdominal pain, and headache were roughly similar between phase 3 IBS-C studies. Viral gastroenteritis was observed in Study 302, but this was roughly similar to placebo (3.7% vs. placebo 2.2%). Overall, we are comfortable with linaclotide's safety profile.

- **What to look for on the tomorrow's call?** Further information on long-term safety studies timelines (2 ongoing; n=2,500) and details on room stability product study requirements. Additionally, details on the regulatory process in US and EU. Finally, we would look for further confirmatory evidence of linaclotide's commercial differentiators – rapid onset of action and sustainable benefit (we do not foresee these as issues at all, given previous results).

- **Conference call details:** Tuesday, 11/2/2010 at 8:30am EST. U.S./Canada: (888) 213-3752; International: (913) 312-0840; Conference ID number: 2151484.

- **Reiterating Overweight rating on Ironwood.** We believe today's data further solidifies linaclotide's differentiated clinical profile. Given four positive phase 3 trials, we believe there is a high probability of regulatory approval in both the US and the EU. As such, with an estmated $3B peak market potential in the US alone, we recommend owning IRWD shares.

See page 2 for analyst certification and important disclosures.

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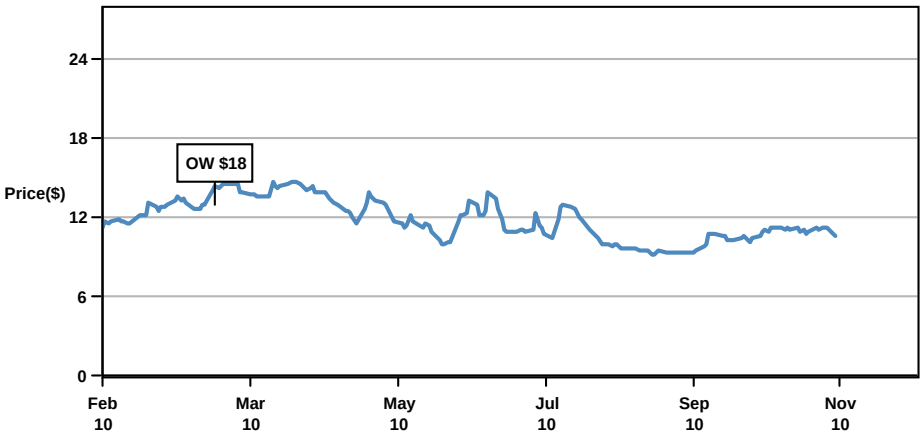
Ironwood Pharmaceuticals (IRWD) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
15-Mar-10	OW	12.91	18.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Mar 15, 2010. This chart shows J.P. Morgan's continuing coverage of this stock; the current analyst may or may not have covered it over the entire period.
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