# J.P.Morgan

# **Ironwood Pharmaceuticals**

J.P. Morgan Conference Update: - ALERT

Ironwood Pharmaceuticals CEO Peter Hecht presented earlier today at the J.P. Morgan Healthcare Conference with a focus on linaclotide. The company highlighted positive phase 3 linaclotide data from 4 trials, 2 in chronic constipation (CC) and 2 in irritable bowel syndrome with constipation (IBS-C). Looking to 2011, the company also mapped out key milestones, which included regulatory filings for linaclotide in the US (3Q11) and Europe (2H11). Overall we remain bullish on linaclotide and reiterate our Overweight rating.

- Regulatory filling on track for 2H11. With positive data in hand, the company is now in the process of preparing for an NDA filing of linaclotide in IBS-C and CC. Consistent with prior commentary, the company remains on track to file in the US in 3Q11 and in the EU in 2H11. We estimate approval in the US in mid 2012 and EU approval by year end 2012.
- Impact on pain a key differentiating factor. The company highlighted linaclotide's robust clinical profile demonstrated in 4 phase 3 clinical trials in CC and IBS-C. In these trials, linaclotide showed consistent efficacy with rapid and sustained improvements across multiple endpoints. Importantly, linaclotide also had a beneficial impact on abdominal pain, which we view as a key differentiating factor.
- Large underserved market. In the US, the company anticipates focusing on the 10 million patients that suffer multiple symptoms, are dissatisfied with existing treatment options and are actively seeking therapy. Indeed, market research indicates that >70% of patients are not satisfied with current treatment options.
- Next data point likely at DDW. The company anticipates presenting the phase 3 data from both IBS-C trials at a medical meeting later this year. We believe the data will likely be presented at the Digestive Disease Week (DDW) meeting (May 7-10, 2011; Chicago).
- **Highlights from breakout session.** The company noted that qualitatively linaclotide is a very different therapy compared to Takeda's Amitiza, which is currently approved in CC and IBS-C. Although highly focused on the NDA filing (CC and IBS-C) near term, the company sees potential opportunities for expansion into other indications such as opioid-induced constipation and dyspepsia. The company also noted that the diarrhea observed in clinical trials does not appear to be a great concern for patients.
- **Reiterate Overweight rating.** With four positive phase 3 trials, we believe there is a high probability of regulatory approval in both the US and the EU. Additionally, these trials have confirmed linaclotide's differentiated clinical profile. Hence, we reiterate our Overweight rating.

# **Overweight**

**IRWD, IRWD US**Price: \$10.87 **12 January 2011** 

# **Biotechnology**

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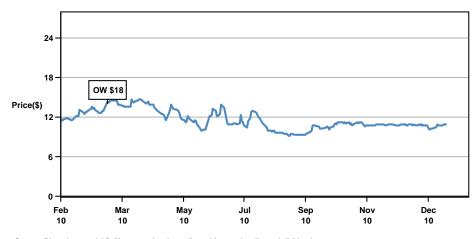
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#### Ironwood Pharmaceuticals (IRWD) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
15-Mar-10	OW	14.04	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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