

## Ironwood Pharmaceuticals

### Incremental Linaclotide Details on Conf. Call; Reiterate OW - ALERT

This morning, Ironwood held a conference call to discuss results of the 2nd phase 3 trial in IBS-C. Recall, this trial was the final of the four phase 3 registration trials in IBS-C and CC. Few new details were given on the call, but we would like to highlight that looking at the abdominal pain plot, the benefit does appear to improve over time (which some were previously concerned with). We would expect full data from the IBS-C studies to be presented at major medical meeting, perhaps Digestive Disease Week 2011 (Chicago, May 7-10, 2011). Near-term news flow consists of the safety data in 1H11 and DDW, both of which are meaningful to further assess the commercial potential (safety risks, physician feedback, etc). We think the data thus far in CC and IBS-C are quite compelling, which could ultimately create a clinical hurdle for future development in this indication. Our long term peak forecast remains \$3B in the US alone, following several years of market development. We're maintaining our OW rating on IRWD shares.

- **Linaclotide clinical profile continues to impress; not expecting duration of therapy label restrictions.** Improvements in abdominal pain and CSMB were observed with the first week and sustained over 26 weeks. Interestingly, abdominal pain did appear to increase slightly over time, which we view as a positive. Given 26 week data, coupled with long-term safety data, the product label may not specify a limit to duration of therapy, which would be a significant positive.
- **Next steps.** NDA and EMEA filing is expected 3Q11 and 2H11, respectively. Next steps include completion of the clinical package for linaclotide, getting appropriate long-term safety data for the filing, and completing room temperature stability studies. Given the clinical trial results to date, we believe the regulatory pathway is low risk. We estimate approval in the US in mid-2012, and EU approval by end-2012.
- **Quick market assessment.** In our model, we estimate the prevalence of CC and IBS-C to be ~35M and ~12M patients, respectively, in the US. On the call, Ironwood noted there are <10M dissatisfied, multi-symptom, therapy seeking patients in the US. Of note, IBS symptoms are under-diagnosed, while only approximately 25% of patient with CC seek medical care, leaving room for market growth. Related to IBS-C, population based surveys indicate that over 90% of patients are not satisfied with current treatments. We estimate linaclotide sales could exceed \$1B by 2016 (~3.5-4 years after launch) in the US alone.
- **Reiterate Overweight rating.** On back of four positive phase 3 trials, we believe regulatory risk is low for linaclotide and the commercial profile is coming in quite good in the IBS-C and CC data. News flow is weighted to 1H11 with safety data and the DDW meeting, which should keep investors tuned in. Beyond the filing in 3Q11, however, news flow looks somewhat limited.

See page 2 for analyst certification and important disclosures.

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## Overweight

IRWD, IRWD US

Price: \$10.57

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### Biotechnology

**Geoffrey Meacham, Ph.D.**<sup>AC</sup>  
(1-212) 622-6531  
geoffrey.c.meacham@jpmorgan.com

**Anupam Rama**  
(1-212) 622-0105  
anupam.rama@jpmchase.com

**G Krishna Gorti, MD**  
(1-212) 622-4986  
krishna.gorti@jpmchase.com

**Michael E Ulz**  
(1-212) 622-0900  
michael.e.ulz@jpmorgan.com

J.P. Morgan Securities LLC

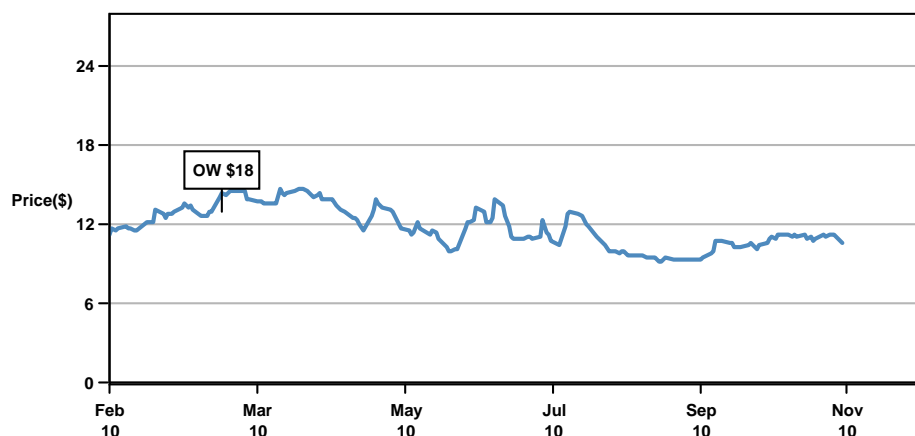
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### Ironwood Pharmaceuticals (IRWD) Price Chart



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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Geoffrey Meacham, Ph.D.  
(1-212) 622-6531  
geoffrey.c.meacham@jpmorgan.com

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J.P.Morgan