# J.P.Morgan

# **Ironwood Pharmaceuticals**

1Q Uneventful; IBS-C Data on Track for 4Q10

IRWD reported 1Q loss per share of \$0.25 (JPMe: (\$0.23)) with \$9M (JPMe: \$8.8M) in revenues. The company highlighted the recent presentation of phase 3 data at DDW from two trials of linaclotide in chronic constipation (CC). Recall that these studies met all primary and secondary endpoints with a clean safety profile. Top-line data from two phase 3 trials in irritable bowel syndrome with constipation (IBS-C) remains on track for 4Q10 followed by a regulatory filing expected in mid 2011. Overall we believe that IRWD's first reported quarter following the IPO in early February, was largely uneventful. We continue to believe that the significant unmet medical need in a large population of ~17M patients for CC and IBS-C supports a \$3B peak penitential for linaclotide in the US. We're maintaining our Overweight rating on IRWD shares.

- Phase 3 linaclotide data in IBS-C on track for 4Q10. According to management, two ongoing Phase 3 trials of linaclotide in IBS-C are now fully enrolled (800 patients each) with base disease severity that is representative of the general IBS-C population. Top-line data remains on track for 4Q10. As a reminder, phase 2b data were robust in a large trial (419 patients) and should be predictive of positive data in the ongoing phase 3 trials. We continue to believe linaclotide is likely to lead to a benefit in pain, which in our view is a key differentiating factor.
- Long term safety, clinical and CMC data key to timing of regulatory filing. Management reiterated expectations to submit a regulatory filing for linaclotide in CC and IBS-C in mid 2011. The key remaining gating factors for a timely filing include long term safety data, clinical data, and CMC data. Importantly based on agreement with regulators no additional EU phase 3 trials in IBS-C will be required, but different primary endpoints and statistical analysis plans will be applied in the US and EU.
- **Reiterate Overweight rating.** We reiterate our Overweight rating on IRWD and YE10 price target of \$18 PT (implying 29% upside potential) based on a conservative NPV analysis. We value US linaclotide at \$11/sh, EU linaclotide at \$4/sh and have added \$3/sh in cash. Our model assumes profitability in 2014 with EPS of \$0.18 and acceleration in 2015 with EPS of \$1.46.

## **Overweight**

IRWD, IRWD US
Price: \$13.95

Price Target: \$18.00

## **Biotech**

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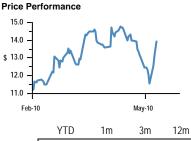
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J.P. Morgan Securities Inc.



	YTD	1m	3m	12m
Abs	24.0%	-4.0%	21.3%	24.0%

Ironwood Pharmaceuticals, Inc. (IRWD;IRWD US)

	2009A	2010E	2010E	2011E	2011E
		(Old)	(New)	(Old)	(New)
EPS Reported (\$)					
Q1 (Mar)		(0.23)	(0.25)A		
Q2 (Jun)		(0.22)	(0.24)		
Q3 (Sep)		(0.20)	(0.25)		
Q4 (Dec)		(0.18)	(0.27)		
FY ` ´	(0.83)	(0.83)	(1.01)	(0.28)	(0.28)

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data	
Price (\$)	13.95
Date Of Price	12 May 10
52-week Range (\$)	15.03 - 11.20
Mkt Cap (\$ mn)	1,358.73
Fiscal Year End	Dec
Shares O/S (mn)	97
Price Target (\$)	18.00
Price Target End Date	31 Dec 10

## See page 3 for analyst certification and important disclosures.

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## **Changes to Our Model**

Following IRWD's first reported quarter (1Q10) we have adjusted our model. Specifically, we have adjusted our shares outstanding in 2010, while our revenue and operating expenses remain unchanged. Our 2010 GAAP EPS estimates decreases to (\$1.01). We have not made changes to 2011 and 2012. Please see Table 1 for details.

Table 1: IRWD: Changes to Our Model

	2010E	2010E	2011E	2011E	2012E	2012E
	OLD	NEW	OLD	NEW	OLD	NEW
Total Revenue	35.0	35.3	110.0	110.3	94.5	94.8
R&D	85.0	85.0	65.0	65.0	63.0	63.0
SG&A	35.0	35.0	75.0	75.0	110.0	110.0
Total Op Ex	120.0	120.0	140.0	140.0	174.4	174.4
Net income	(82.5)	(82.5)	(28.5)	(28.1)	(78.5)	(78.0)
EPS	(0.83)	(1.01)	(0.28)	(0.28)	(0.74)	(0.74)
fully diluted shares	99.9	82.0	103.4	100.0	105.4	105.0

Source: JPMorgan estimates, Bloomberg, and Company data.

# Valuation

Our \$18 PT for IRWD shares is supported by our sum-of-the-parts analysis, which is based on the NPV of linaclotide profits in the US and future royalties from Almirall in Europe. We conducted DCF analyses using a 12% discount rate and probability adjusted our analysis by the risk we feel is associated with the linaclotide program. In our analysis, we assume a 75% probability of success for linaclotide, which we feel is appropriate given that the two phase 3 studies in CC are already complete, and the phase 3 studies in IBS-C are supported by strong phase 2b data. We assume the IP for linaclotide runs out in 2025 in the US and 2024 in the EU, and we assume no terminal value in our analysis. Under this analysis we derive a value of \$18/share, which justifies our Overweight rating.

## **Risks to Our Rating**

We see four primary risks to our Overweight rating on Ironwood. 1) Commercial Risk: IBS-C and CC markets are still undeveloped for branded pharmaceuticals and in our view require a significant marketing effort to increase disease awareness. 2) Clinical Risk: Linaclotide may not show similar ph 3 data in IBS-C studies as it has shown in ph2. Failure to show a pain benefit could be key clinical risk. 3) Regulatory risk: Linaclotide could face regulatory risk for both the IBS-C and CC indications, where there may be uncertainty as to whether the clinical data are supportive of FDA approval. Lastly, 4) there is financing risk: the company may need to raise capital in the public markets, diluting current shareholders.

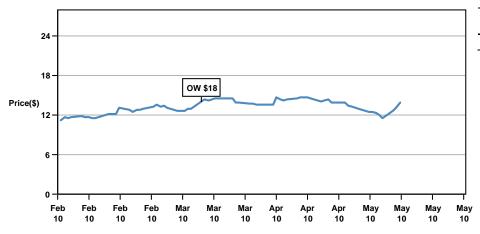
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#### Ironwood Pharmaceuticals (IRWD) Price Chart



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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