

Ironwood Pharmaceuticals

3Q Results Uneventful; Reiterating OW Rating On Back Of Robust Linaclotide Clinical Data Package

After the close, Ironwood reported 3Q10 earnings of (\$0.08), ahead of our and consensus estimates (JPMe: -\$0.25; consensus: -\$0.21), mostly related to net income benefit from discontinued operations. With Ironwood already hosting a conference call to discuss results from the second phase 3 trial of linaclotide in IBS-C earlier in the week, 3Q results were largely uneventful. Ironwood did note that Japanese partner Astellas has started a phase 1 single dose safety/tolerability study of linaclotide in healthy volunteers. We expect incremental linaclotide data points from the long-term safety studies (expected 1H11) and the full data sets of the IBS-C studies (perhaps at DDW; Chicago, 5/7/11-5/10/11) to keep investors interested in the story ahead of regional regulatory filings. Recall, Ironwood has guided to a US and EU regulatory filing in 3Q11 and 2H11, respectively. Given the robust clinical package for linaclotide in both IBS-C and CC, we believe there is a high probability for regulatory approval. We continue to believe shares are undervalued, given the ultimate market potential of linaclotide (\$3 billion estimated peak potential in the US alone). Reiterate Overweight rating.

- **Linaclotide clinical profile is impressive.** Recall, linaclotide has shown robust efficacy in 4 phase 3 registrational clinical trials (2 in CC and 2 in IBS-C). Related to IBS-C, linaclotide has provided rapid and sustained benefits on the key endpoint of abdominal pain. The safety profile across the 4 clinical trials has been generally consistent, and we are comfortable with the overall clinical profile of the drug.
- **Linaclotide approval pathway is low risk, in our opinion.** 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. NDA and EMEA filing is expected 3Q11 and 2H11, respectively.
- **Reiterate Overweight rating.** We continue to believe IRWD shares are undervalued, given the clinical data for linaclotide to date, the low-risk regulatory path forward, and ultimate market potential of linaclotide.

Overweight

IRWD, IRWD US

Price: \$10.68

Price Target: \$18.00

US Biotechnology

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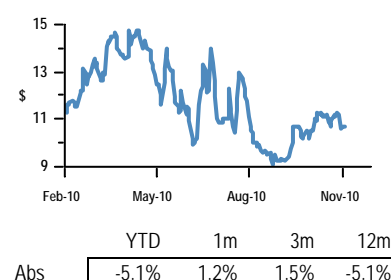
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Price Performance



Ironwood Pharmaceuticals, Inc. (IRWD;IRWD US)

	2009A	2010E (Old)	2010E (New)	2011E	2012E
EPS - Recurring (\$)					
Q1 (Mar)		(0.25)A	(0.25)A		
Q2 (Jun)		(0.18)A	(0.18)A		
Q3 (Sep)		(0.25)	(0.08)A		
Q4 (Dec)		(0.28)	(0.18)		
FY	(0.83)	(0.94)	(0.66)	(0.26)	(0.72)

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

Company Data

Price (\$)	10.68
Date Of Price	04 Nov 10
52-week Range (\$)	15.03 - 8.90
Mkt Cap (\$ mn)	1,040.23
Fiscal Year End	Dec
Shares O/S (mn)	97
Price Target (\$)	18.00
Price Target End Date	31 Dec 11

See page 4 for analyst certification and important disclosures.

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Changes to Our Model

Based on 3Q10 results, we have updated our model. We adjusted 4Q10 expenses and share count to reflect company run rate. As a result of these changes, our full year 2010 EPS estimate changes to (\$0.66) from (\$0.94).

Table 1: IRWD: Changes to Our Model

	2010E	2010E	2011E	2011E	2012E	2012E
	OLD	NEW	OLD	NEW	OLD	NEW
Total Revenue	37.5	37.8	112.5	112.8	97.0	97.3
R&D	85.0	78.0	65.0	65.0	63.0	63.0
SG&A	35.0	28.0	75.0	75.0	110.0	110.0
Total Op Ex	120.0	106.0	140.0	140.0	174.4	174.4
Net income	(80.7)	(59.2)	(25.9)	(25.6)	(75.9)	(75.6)
EPS	(0.94)	(0.66)	(0.26)	(0.26)	(0.72)	(0.72)
<i>fully diluted shares</i>	<i>85.8</i>	<i>89.6</i>	<i>100.0</i>	<i>100.0</i>	<i>105.0</i>	<i>105.0</i>

Source: Company reports, Bloomberg, and J.P. Morgan estimates.

Valuation, Rating, and Price Target Analysis

Our December 2011 price target of \$18 for IRWD is based on 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 discount rate of ~13% 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 and Price Target

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 phase 3 data in IBS-C studies as it has shown in phase 2 – 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; and 4) financing risk: the company may need to raise capital in the public markets, diluting current shareholders.

Ironwood Pharmaceuticals: Summary of Financials

Income Statement - Annual	FY09A	FY10E	FY11E	FY12E	Income Statement - Quarterly	1Q10A	2Q10A	3Q10A	4Q10E
Revenues	37	38	113	97	Revenues	9	11	9	9
Cost of products sold	-	-	-	1	Cost of products sold	-	-	-	-
Gross profit	0	0	0	0	Gross profit	0	0	0	0
SG&A	23	28	75	110	SG&A	7	7	6	8
R&D	78	78	65	63	R&D	19	21	19	20
Operating Income	(65)	(68)	(27)	(77)	Operating income	(16)	(17)	(16)	(18)
Note: EBITDA	0	0	0	0	Note: EBITDA	0	0	0	0
Net interest income / (expense)	0	0	0	0	Net interest income / (expense)	0	0	0	0
Other income / (expense)	(0)	0	0	0	Other income / (expense)	0	0	0	0
Pretax income	(65)	(67)	(26)	(76)	Pretax income	(16)	(17)	(16)	(18)
Income taxes	0	0	0	0	Income taxes	0	0	0	0
Net income - GAAP	-	-	-	-	Net income - GAAP	-	-	-	-
Net income - recurring	(65)	(59)	(26)	(76)	Net income - recurring	(16)	(17)	(8)	(18)
Diluted shares outstanding	78	90	100	105	Diluted shares outstanding	64	98	98	99
EPS - excluding non-recurring	-	-	-	-	EPS - excluding non-recurring	-	-	-	-
EPS - recurring	(0.83)	(0.66)	(0.26)	(0.72)	EPS - recurring	(0.25)	(0.18)	(0.08)	(0.18)
Balance Sheet and Cash Flow Data	FY09A	FY10E	FY11E	FY12E	Ratio Analysis	FY09A	FY10E	FY11E	FY12E
Cash and cash equivalents	123	-	-	-	Sales growth	-	-	-	-
Accounts receivable	5	10	10	10	EBIT growth	16.0%	5.2%	(60.1%)	183.9%
Inventories	-	-	-	-	EPS growth	12.8%	(20.7%)	(61.2%)	181.2%
Other current assets	3	3	3	3	Gross margin	0.0%	0.0%	0.0%	0.0%
Current assets	131	275	260	201	EBIT margin	(176.7%)	(180.3%)	(24.1%)	(79.3%)
PP&E	23	28	33	38	EBITDA margin	0.0%	0.0%	0.0%	0.0%
Total assets	162	311	301	247	Tax rate	0.0%	0.0%	0.0%	0.0%
Total debt	3	2	2	2	Net margin	(177.6%)	(156.4%)	(22.7%)	(77.7%)
Total liabilities	461	134	134	134	Debt / EBITDA	-	-	-	-
Shareholders' equity	(298)	177	167	113	Debt / Capital (book)	(1.0%)	1.1%	1.2%	1.7%
Net income (including charges)	(73)	(59)	(26)	(76)	Return on assets (ROA)	(40.1%)	(19.0%)	(8.5%)	(30.6%)
D&A	5	5	8	10	Return on equity (ROE)	-	-	-	-
Change in working capital	58	0	0	0	Return on invested capital (ROIC)	3363.2%	3260.4%	1093.0%	1267.4%
Other	-	-	-	-	Enterprise value / sales	0.0	0.0	0.0	0.0
Cash flow from operations	(4)	(49)	(10)	(54)	Enterprise value / EBITDA	0.0	0.0	0.0	0.0
Capex	(4)	(15)	(5)	(5)	Free cash flow yield	0.0%	0.0%	0.0%	0.0%
Free cash flow	0	0	0	0					
Cash flow from investing activities	18	(15)	(5)	(5)					
Cash flow from financing activities	42	203	0	0					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.

Note: \$ in millions (except per-share data). Fiscal year ends Dec

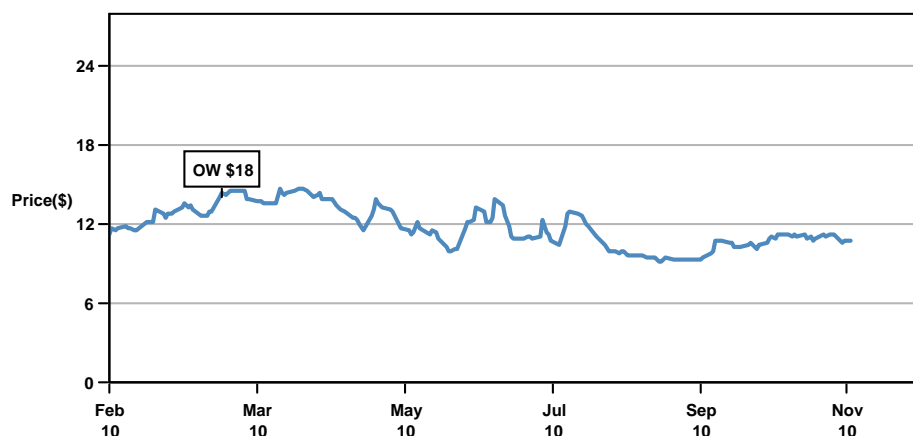
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Ironwood Pharmaceuticals (IRWD) Price Chart



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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04 November 2010

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