Ironwood Pharmaceuticals (IRWD)

REINSTATEMENT

Rating	**NEUTRAL* [V]**
Price (17 Aug 10, US$)	9.70
Target price (US$)	(from 14.00) 11.00[1]
52-week price range	14.78 - 0
Market cap. (US$ m)	866.77
Enterprise value (US$ m)	623.67

**Stock ratings are relative to the relevant country benchmark.*
[1]Target price is for 12 months.
[V] = Stock considered volatile (see Disclosure Appendix).

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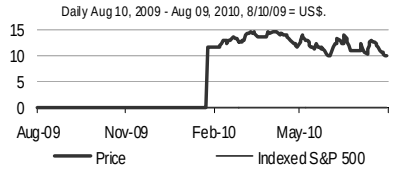
Reinstating Coverage, Awaiting Phase III Data

- **Coming off restriction, we reinstate coverage of IRWD with a Neutral rating and $11 price target.** We await the Phase III data in IBS-C (expected in 4Q 10) to gain further insights on linaclotide's potential but believe it could be a best-in-class drug with better efficacy and a more convenient once-daily dosing schedule as compared to Amitiza, its primary branded competition. However, the constipation market is a challenging one, leading to our linaclotide forecasts being below the Street.
- **2Q performance unremarkable.** Higher expenses offset higher revenues and led to a one cent EPS miss in 2Q (-$0.18 actual vs. -$0.17 CS forecast). Adjusting our model accordingly, and accounting for a greater than expected share count, leads to minor EPS changes (Exhibit 1). We also now use a more conservative WACC assumption of 15% for IRWD, which we believe better reflects the cost of capital for IRWD following the end of the pre-IPO investors' lockup period. Our overall view on linaclotide and IRWD are unchanged, but these model changes do lead to our target price coming down from $14 to $11.
- **Fourth endpoint in IBS-C studies does not add significant risk.** IRWD used its 2Q earnings call to announce the addition of a 4th co-primary endpoint to their two ongoing Phase III IBS-C studies. The 4th endpoint will measure 6-out-of-12-week abdominal pain and CSBM response rates (Exhibit 2), as requested in the new draft FDA guidelines for these types of studies. Given that the endpoints in both studies will be assessed sequentially, with the new endpoint being the last one measured, there is no material risk added by this change.
- **Slight timeline delays possible.** The introduction of the new endpoint does require the companies to obtain FDA acceptance of the amended protocols, which could lead to a small delay in timelines, although IRWD still guides to top-line data being available in 4Q 2010 and FDA submission in the middle of 2011.

Share price performance



On 08/09/10 the S&P 500 index closed at 1127.79

Quarterly EPS	Q1	Q2	Q3	Q4
2009A	-2.56	-2.61	-1.53	-3.30
2010E	-0.18	-0.18	-0.17	-0.14
2011E	-0.13	-0.10	-0.16	-0.16

Financial and valuation metrics

Year	12/09A	12/10E	12/11E	12/12E
EPS (CS adj.) (US$)	-10.00	-0.66	-0.56	-0.04
Prev. EPS (US$)	—	-0.69	-0.55	0.00
P/E (x)	NM	NM	NM	NM
P/E rel. (%)	NM	NM	NM	NM
Revenue (US$ m)	36.1	38.6	50.4	136.7
EBITDA (US$ m)	-67.5	-59.0	-54.5	-2.7
OCFPS (US$)	-0.56	-0.72	-0.19	-0.76
P/OCF (x)	—	-13.5	-50.2	-12.7
EV/EBITDA (current)	-11.1	-10.6	-11.9	-272.8
Net debt (US$ m)	-120	-243	-219	-132
ROIC (%)	—	—	—	—

Number of shares (m)	89.36	IC (12/09A, US$ m)	—
BV/share (current, US$)	-3.7	EV/IC (x)	—
Net debt (current, US$ m)	-295.7	Dividend (12/09A, US$)	—
Net debt/tot. cap. (12/09A, %)	—	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates.

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Exhibit 1: Changes to Credit Suisse EPS Estimates for IRWD (2010-2015)

	2010	2011	2012	2013	2014	2015
Pro Forma EPS						
Old	($0.69)	($0.55)	$0.00	($1.13)	($0.24)	$0.32
Revised	(0.66)	(0.56)	(0.04)	(1.09)	(0.24)	0.26
Change	***0.03***	***(0.01)***	***(0.05)***	***0.04***	***(0.00)***	***(0.06)***

Source: Company data, Credit Suisse estimates

New Endpoint to Phase III IBS-C Studies Does Not Add Material Risk

IRWD used its 2Q earnings call to announce the addition of a 4th co-primary endpoint to their two ongoing Phase III IBS-C studies. The 4th endpoint will assess 6-out-of-12 week abdominal pain and CSBM response rates (Exhibit 2), as requested in the new draft FDA guidelines for these types of studies. The endpoints in both studies will be assessed sequentially, however, with the new endpoint being the last one measured. If a study misses one endpoint, there will be no analysis of the subsequent endpoints. Therefore, each study must meet the three endpoints looking at 9-out-of-12 week response rates of abdominal pain, CSBM or both before the new endpoint is even evaluated. In addition, considering that the 6-out-of-12 week endpoint is technically an easier endpoint to meet that the first 9-out-of-12-week one, we do not see how adding this new endpoint adds any significant new risk.

The introduction of the new endpoint does require the companies to get FDA acceptance of the amended protocols. Given that the new endpoint is consistent with FDA guidance we believe the FDA will agree to the changes, but admit that this is an additional step that could lead to a slight delay in the timelines for data release and/or regulatory filing. IRWD has reiterated, however, that they believe top-line data will be available in 4Q 2010 and FDA submission should take place in the middle of 2011.

Exhibit 2: Addition of 4th Co-Primary Endpoint Does Not Add Material Risk to Phase III Linaclotide IBS-C Trials

Endpoint	Measure	Description
First	9/12 week abdominal pain and CSBM responder	For at least nine out of 12 weeks 1) A patient has three or more CSBMs (complete spontaneous bowel movement) per week and an increase of one or more CSBMs per week from baseline 2) A patient has at least 30 percent average weekly reduction in abdominal pain from baseline
Second	9/12 week CSBM responder	For at least nine out of 12 weeks 1) A patient has three or more CSBMs (complete spontaneous bowel movement) per week and an increase of one or more CSBMs per week from baseline
Third	9/12 week abdominal pain	For at least nine out of 12 weeks 1) A patient has at least 30 percent average weekly reduction in abdominal pain from baseline
Fourth	**6/12 week abdominal pain and CSBM responder**	For at least six out of 12 weeks 1) A patient has three or more CSBMs (complete spontaneous bowel movement) per week and an increase of one or more CSBMs per week from baseline 2) A patient has at least 30 percent average weekly reduction in abdominal pain from baseline

Source: Company data

Linaclotide Has Best-in-Class Potential

We have applied a segment framework to compare the branded therapies across common drug characteristics. Our segment framework seeks to measure the branded therapies approved for constipation across six product attributes including: dosing, CSBM, pain alleviation, cardiac risk, nausea, and diarrhea.

Overall, we believe linaclotide has the best profile among the prescription therapies for CC and IBS-C (Exhibit 3). Looking across improvement in bowel movements, pain relief, dosing convenience, and safety, we believe linaclotide is well positioned to become a market leading treatment.

Exhibit 3: Branded Constipation Therapy—Comparison of Product Attributes

	Linaclotide	Amitiza	Zelnorm
Dosing schedule	✓		
Improvement in bowel movement (per CSBM)	✓		
Pain allevation	✓		
Cardiac risk	✓	✓	
Nausea	✓		
Diarrhea		✓	✓

Source: Credit Suisse analysis.

- **Dosing.** In a patient population with traditionally low compliance, we like the once-a-day dosing of linaclotide as opposed to twice-a-day Amitiza.
- **Improvement in bowel movement.** CSBMs are a gold standard for measuring the effectiveness, degree of evacuation, ease, and satisfaction of a bowel movement. In Phase III chronic constipation trials for linaclotide, 2.1 placebo-adjusted increases in CSBMs were reported. While both Zelnorm and Amitiza are both effective and result in increase of bowel movements, the use of CSBM as a study endpoint is a harder measurement for efficacy than bowel movements. Furthermore, our conversations with treating physicians have led us to take a view that linaclotide is more effective than the other two in improving bowel movement frequency.
- **Pain relief.** One of the main characteristics that makes IBS-C a relatively more serious disease than chronic constipation is the abdominal pain associated with IBS-C. After analysis of available clinical data, we believe that greater pain-relief was provided by linaclotide in Phase IIb studies with patients reporting 21.2% placebo-adjusted improvement in pain as compared with 5.0%, 6.0%, and 4.4% in two Zelnorm Phase III and one Amitiza Phase III studies, respectively.
- **Cardiac Risk.** Linaclotide is a locally acting molecule with no systemic exposure and data to date does not suggest the presence of any cardiac toxicity. We await longer term linaclotide safety data expected in 2011 but we feel comfortable about its safety profile based on existing data. The data available to date also appears to be favorable for Amitiza from a cardiac safety perspective. Recall that Zelnorm was withdrawn from the market in 2007 owing to the cardiovascular adverse events observed in 0.11% patients from a meta-analysis of 29 clinical trials. Given that IBS-C is not a life-threatening disease; the FDA deemed the risk-benefit profile of Zelnorm to be unfavorable.

- **Nausea.** While up to 29% of patients complained of nausea upon consuming Amitiza twice daily, there were no cases of severe nausea reported in the clinical trials. Linaclotide and Zelnorm cause less nausea than Amitiza. However, a certain level of nausea is reported in almost all laxative treatments.
- **Diarrhea.** In comparing the drugs for diarrhea incidence, linaclotide stood out with 16.5% patients suffering from diarrhea compared with 6-9% in the Zelnorm and Amitiza studies. This is the only attribute out of six for which linaclotide appears to be less favorable than the other agents.

Limited Number of Near-Term Competitors Should Also Benefit Linaclotide

The competitive landscape of treatment for CC and IBS-C is summarized in Exhibit 4. The bottom-line conclusion from our analysis of the competitive environment for linaclotide is that the drug faces a relatively benign competitive threat, with most pipeline products at least two years behind in development.

Exhibit 4: Selected Competitive Drugs on the Market or in Development

Compound	Company	Mechanism of Action	Development Stage	Comment
Chloride channel activators				
Amitiza (lubiprostone)	Sucampo/ Takeda (US)	Chloride Channel Agonist	Marketed	FDA approved for the treatment of chronic idiopathic constipation and for IBS-C. Phase III data generated in OBD with mixed results. Sucampo had submitted a CTD through the decentralised procedure in Europe but the Marketing Authorisation Application was withdrawn by Sucampo in September 2009.
Guanylate cyclase agonists				
SP-304	Synergy Pharmaceuticals/ Callisto	Cytokine modulators, Guanylate cyclase stimulants	Phase II	Phase II studies started in early 2010. Results expected in late 2010.
5HT4 agonists				
Resolor (prucalopride)	Movetis/Johnson and Johnson	Serotonin receptor agonist	Marketed (EU)	EMEA approved for the treatment of chronic constipation in October 2009. JNJ retains the US and ROW rights. Unclear if they will look to file the product in the US.
TD-5108	Theravance	Selective oral 5-HT4 receptor agonist	Phase II	Phase III to be started. No recent developments reported but likely waiting partnership.
ATI-7505	Aryx	5-HT4 receptor agonist	Phase II	Rights were returned to Aryx by Procter&Gamble after latest trial results became available. In April 2010, the FDA provided guidance on the outline for phase III clinical trials of ATI 7505 in the treatment of Chronic Ideopathic Constipation.
Sodium-bile acid co-tranporter inhibitors				
A3309	Albireo/ AstraZeneca	Apical sodium dependent bile acid transporter (ASBT) inhibitor	Phase II	Once-daily, oral compound. In a multiple ascending-dose Phase II study for chronic constipation. Albireo plans to move A 3309 into phase III in chronic constipations during 2011
Opioid antagonists				
Relistor (methylnaltrexone)	Progenics	Subcutaneous mu-opioid receptor antagonist	Approved (OBD)	Approved in US and EU (SC formulation) for opioid-induced constipation only (not competitive in the chronic constipation market). World-wide marketing rights were returned to Progenics by Pfizer/Wyeth in October 2009. Progenics received a positive opinion issued by the EMEA for pre-filled syringes in Aug 2010.
NKTR-118	Astra Zeneca/ Nectar	Peripheral opioid antagonist	Phase II/III	Potential competitive threat for OIC. Phase IIb completed with positive results, but significant degree of abdominal pain. Designing Phase III, planned filing 2013.
TD-1211	Theravance	Opioid receptor antagonist	Phase II	Once-daily treatment for constipation in patients treated with opioids. A multiple ascending-dose Phase II study for OBD is ongoing.
ALKS 37	Alkermes	Opioid receptor antagonist	Phase II	An orally active, peripherally-restricted opioid antagonist with potential to block the effects of opioid agonists on gastrointestinal motility. In May 2010, Alkermes initiated phase 2 study of ALKS 37 for the treatment of opioid-induced constipation.
ADL5945	Adolor/GSK	Opioid receptor antagonist	Phase I	Potential competitive threat for OIC only. Both a Phase I single and multiple, escalating dose placebo-controlled safety study have been conducted with ADL5945. Adolor intends to initiate Phase I exploratory efficacy clinical studies in early 2010.

Source: ADIS, Company data, Credit Suisse estimates.

Companies Mentioned *(Price as of 17 Aug 10)*
Adolor Corporation (ADLR, $1.11)
Alkermes Inc. (ALKS, $13.89)
Astellas Pharma (4503, ¥2,934, NEUTRAL, TP ¥3,000, MARKET WEIGHT)
AstraZeneca (AZN.L, 3317.50 p, NEUTRAL, TP 3100.00 p, OVERWEIGHT)
Forest Laboratories Inc. (FRX, $28.04, NEUTRAL, TP $28.00)
GlaxoSmithKline (GSK.L, 1217.00 p, UNDERPERFORM, TP 1225.00 p, OVERWEIGHT)
Ironwood Pharmaceuticals (IRWD, $9.70, NEUTRAL [V], TP $11.00)
Johnson & Johnson (JNJ, $59.22, NEUTRAL, TP $66.00)
Movetis (MOVET.BR, Eu18.82, OUTPERFORM [V], TP Eu17.50, OVERWEIGHT)
Novartis (NOVN.VX, SFr53.05, NEUTRAL, TP SFr59.00, OVERWEIGHT)
Progenics Pharmaceuticals (PGNX, $4.53)
Sucampo Pharmaceuticals (SCMP, $3.42)
Takeda Pharmaceutical (4502, ¥3,955, NEUTRAL, TP ¥3,900, MARKET WEIGHT)
Theravance, Inc. (THRX, $15.41)

Disclosure Appendix

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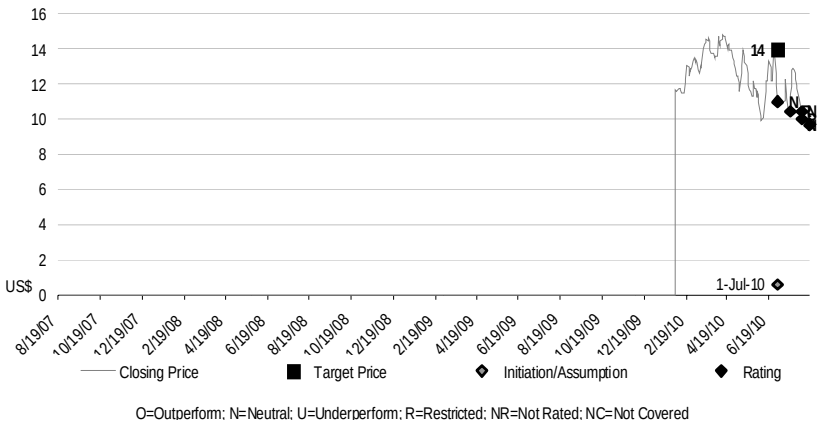
3-Year Price, Target Price and Rating Change History Chart for IRWD

IRWD Date	Closing Price (US$)	Target Price (US$)	Rating	Initiation/ Assumption
7/1/10	11	14	N	X
7/19/10	10.47		R	
8/5/10	10.45		N	
8/6/10	10		R	
8/17/10	9.7		N	



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Price Target: (12 months) for (IRWD)
Method: Our $11 target price for IRWD is based on a probability weighted net present value (NPV) analysis. We have used a 15% WACC (weighted average cost of capital) for our analysis. Major sources of cash inflow for Ironwood include: (1) Future US linaclotide profit share income, (2) linaclotide ex-US royalty income, and (3) milestones-based revenues.
Risks: Risk to our $11 target price include: (1) Regulatory risks related to linaclotide approval, (2) single product risk, (3) unexpected change in competitive landscape, and (4) the company's financing risk, due to the potential need to raise additional funds to fund spend related to linaclotide launch.

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