Research Note

Biotechnology / Biopharmaceuticals

Ironwood Pharmaceuticals, Inc. (IRWD)

August 18, 2010

Q2:10 Update – IRWD to Add a New Co-Primary Endpoint to the IBS-C Phase III Studies

- **Ironwood has amended the two IBS-C Phase III study protocols by adding another co-primary endpoint to the previous three primary endpoints.** The new endpoint is IBS-C responder analysis defined in the March 2010 IBS FDA guidance documents as abdominal pain reduction of ≥30% for 6 of the 12 weeks and an increase of ≥1 CSBM per week from baseline for 6 of the 12 weeks. The company has discussed the proposed endpoint with the FDA and we believe it will be acceptable to the Agency because it is reflective of the IBS-C endpoint in the guidance documents.
- **The original co-primary endpoints are: (1) patients achieving both a ≥30% reduction in abdominal pain relative to baseline for at least 9 of the 12 weeks, and ≥3 CSBMs and an increase ≥1 CSBM per week over baseline for at least 9 of the 12 weeks (2) patients achieving ≥3 CSBMs per week and ≥1 CSBM per week over baseline for at least 9 of the 12 weeks (3) patients achieving both a ≥30% reduction in abdominal pain relative to baseline for at least 9 of the 12 weeks.** The combined responder endpoint, the CSBM responder and the abdominal pain responder endpoints will be evaluated in a sequential manner, followed by the new co-primary endpoint. Importantly, all 4 endpoints are >95% powered to demonstrate statistical significance.
- **The proposed endpoint is hierarchical and does not require any alpha-spend.** In our opinion, this additional co-primary endpoint is not a significant revision to the protocol, primarily because the additional endpoint is a 6 of the 12 weeks responder analysis requiring just one increase in CSBM per week above baseline, a lower hurdle than the 9 of the 12 weeks combination responder analysis requiring ≥3 CSBMs per week and an increase ≥1 CSBM per week over baseline.
- **This primary endpoint data may be included in a potential linaclotide label, making potential comparisons future IBS-C products much more straightforward.**
- **Both IBS-C Phase III studies are fully enrolled and top-line data from the studies are expected in Q4:10.** Forest Laboratories (FRX) is conducting one study and is expected to report out their study first; IRWD and Almirall are conducting the second study and are expected to report the data shortly after FRX.
- **IRWD expects to finish 2010 with about $220 million in cash and equivalents.**
- **We reiterate our OUTPERFORM rating and our $24/share price target.** We estimate that US linaclotide sales will peak at approximately $2.4 billion in 2019 in the CC and IBS-C settings. We arrive at our valuation by discounting back the product of the net present value of losses and profits through 2015 plus 18X 2016 linaclotide royalties and US revenues (25% discount rate, estimated current diluted share count of 119.8 million).

FYE Dec	2009E	2010E			2011E		
REV. ($m)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	$9.1	--	NA	$14.5	--	NA
Q2 Jun	--	$11.0	--	NA	$14.5	--	NA
Q3 Sep	--	$9.8	--	NA	$14.5	--	NA
Q4 Dec	--	$9.8	--	NA	$14.5	--	NA
Year*	**$36.8**	**$39.5**	**--**	**NA**	**$58.0**	**--**	**NA**
Change	NA	NA	NA	NA	NA	NA	NA
	2009E	**2010E**			**2011E**		
EPS	**ACTUAL**	**CURR.**	**PREV.**	**CONS.**	**CURR.**	**PREV.**	**CONS.**
Q1 Mar	--	(0.25)	--	NA	(0.04)	--	NA
Q2 Jun	--	(0.18)	--	NA	(0.06)	--	NA
Q3 Sep	--	(0.11)	--	NA	(0.10)	--	NA
Q4 Dec	--	(0.06)	--	NA	(0.12)	--	NA
Year*	**($0.84)**	**(0.55)**	**--**	**NA**	**(0.32)**	**--**	**NA**
P/E	NA	NA	NA	NA	NA	NA	NA
Change	NA	NA	NA	NA	NA	NA	NA

Consensus estimates are from Thomson First Call.
** Numbers may not add up due to rounding.*

Price (intraday 08/18/10)
$9.65

Rating
OUTPERFORM

Price target
$24

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Company Information

52-Week Range	$11.20-$14.50
Shares/Diluted	98.0M / 119.8M
Cash (Q2)	$271.6 M
FY:10 Burn	$60.4 M
Market Cap.	$946 M
ST/LT Debt	$1.0 M / $1.3 M
Debt/Capital	1.3%
ROE	NM
Cash & Inv/Share	$2.77
Book Value/Share	$1.77

Company Description

Ironwood is developing linaclotide, an agonist of guanylate cyclase type-C receptors that line the intestinal tract, for the treatment of chronic constipation (CC) and irritable bowel syndrome with constipation (IBS-C).

Nasdaq.com

Risks
Risks to the attainment of our price target include potential negative data from the IBS-C Phase III studies, regulatory risk associated with the NDA expected to be filed with the FDA and failure to achieve meaningful sales penetration of linaclotide in the IBS-C and/or CC settings.

Upcoming milestones
Q4:10 Expected data for the two linaclotide Phase III studies in the IBS-C setting
H1:11 Potential NDA filing for linaclotide in the CC and IBS-C settings
H1:12 Potential FDA approval of linaclotide for the treatment of CC and IBS-C
H1:12 Possible launch of linaclotide for CC and IBS-C in the US
H2:12 Potential EMEA approval of linaclotide for CC and IBS-C
H2:12 Possible launch of linaclotide for CC and IBS-C in the EU

Ongoing Phase III IBS-C Trials
In July 2009 Ironwood and FRX initiated 2 Phase III, randomized, double-blind, placebo-controlled trials with IBS-C patients in the US and Canada. Each trial is scheduled to enroll about 800 patients. Patients enrolled in the study are required to have fewer than 3 CSBMs, no more than 5 SBMs per week during the pretreatment period, and an average abdominal pain score of at least 3.0 on an 11-point pain scale (0-10). Patients in the study are randomized to receive placebo or 266 mcg of linaclotide.

The primary endpoints are 1) 12-week CSBM (≥3 CSBMs per week and an increase ≥1 CSBM per week over baseline for 9 of the 12 weeks) and 12-week abdominal pain responder (≥30% reduction in abdominal pain relative to baseline for 9 of the 12 weeks), 2) 12-week abdominal pain responder, 3) 12-week CSBM responder, and 4) an IBS-C responder analysis from the March 2010 FDA IBS draft guidance documents defined as abdominal pain reduction of ≥30% for 6 of the 12 weeks and an increase of ≥1 CSBM per week from baseline for 6 of the 12 weeks.

The studies are designed to include about 400 patients per treatment arm to provide a >95% powering for the primary endpoints in the study. Also, the measurement of the abdominal symptoms is now measured with an 11-point pain scale, instead of a 5-point scale, which is thought to detect changes in symptoms with greater precision.

IBS-C Phase IIb Trials and Results
IRWD analyzed the complete data set from the Phase IIb IBS-C study using the first 3 planned Phase III primary endpoints, 12-week abdominal pain and 12-week Complete Spontaneous Bowel Movement (CSBM) responder rate. This analysis determined the responder rates for the placebo, pooled linaclotide group and 300 mcg linaclotide groups. The responder rate for the 12-week abdominal pain and CSBM responder was 10% for the placebo group, 20% for the pooled group and 27% for the 300 mcg linaclotide group. The responder rate for the 12-week CSBM responder was 13% in the placebo group, 26% for the pooled group and 31% for the 300 mcg group. The responder rate for the 12-week abdominal pain responder was 30% for the placebo group, 44% for the pooled group and 48% for the 300 mcg group.

Phase IIb IBS-C Results
Ironwood conducted a 420 patient, multicenter study in patients with IBS-C (mild to moderate abdominal discomfort, fewer than 3 CSBM's per week, no more than 6 SBM per week during the pre-treatment period). Patients received placebo or 1 of 4 doses of linaclotide (75, 150, 300 or 600 mcg per day) once daily and the primary endpoint of the study was change from baseline in CSBM's for the evaluable patient population. The clinical results from this study are described below:

Primary and Secondary Efficacy Results

Primary Endpoint	Placebo (N=85)	75 mcg linaclotide (N=79)	150 mcg linaclotide (N=82)	300 mcg linaclotide (N=84)	600 mcg linaclotide (N=89)
Baseline/treatment CSBM/wk (ITT)	0.3/1.3	0.3/3.2 (p<0.001)	0.3/2.8 (p<0.01)	0.3/3.9 (p<0.001)	0.3/3.1 (p<0.001)
Secondary Endpoints					
Abdominal Pain	25.6%	37.1%	36.9%	46.8%	44.4%
Abdominal Discomfort	22.1%	31.3%	32.5%	42.7%	38.6%
Bloating	16.1%	27.3%	25.5%	37.3%	31.6%
IBS Severity	22.2%	35.0%	34.1%	42.1%	41.0%
Constipation Severity	23.3%	42.3%	41.1%	53.8%	48.8%

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

Treatment Emergent Adverse Events

Adverse Event	Placebo (N=85)	75 mcg linaclotide (N=79)	150 mcg linaclotide (N=82)	300 mcg linaclotide (N=85)	600 mcg linaclotide (N=89)	All (N=335)
Any	41%	52%	49%	59%	69%	57%
Diarrhea	1%	11%	12%	16%	18%	15%
Abdominal Pain	4%	5%	4%	5%	8%	5%
UTI	2%	9%	1%	6%	1%	4%
Nausea	6%	1%	10%	1%	3%	4%
Nasopharyngitis	6%	4%	7%	1%	1%	3%
Upper Resp. Inf.	4%	0%	2%	5%	6%	3%
Sinusitis	2%	4%	2%	4%	2%	3%
Bronchitis	0%	3%	1%	1%	3%	2%
Back pain	1%	0%	5%	1%	1%	2%
Fecal incontinence	0%	0%	1%	0%	3%	1%

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

Model

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8/17/2010

WEDBUSH
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Ironwood Pharmaceuticals, Inc.
Annual Financial Results & Projections
($ in thousands except per share data)
Ticker: IRWD (Nasdaq)

	FY:07A	FY:08A	FY:09E	FY:10E	FY:11E	FY:12E	FY:13E	FY:14E
Revenue:								
US profit share	0	0	0	0	0	0	0	17,766
Royalties	0	0	0	0	0	0	6,143	37,815
Contracts and grants	10,464	22,216	36,798	39,511	58,000	133,000	17,000	41,000
Total Revenues	**$10,464**	**$22,216**	**$36,798**	**$39,511**	**$58,000**	**$133,000**	**$23,143**	**$96,581**
Cost and Expenses:								
Research and development	57,246	59,809	78,235	64,590	50,000	48,020	56,863	43,532
Sales, general, and administrative	10,833	18,328	23,020	25,968	42,000	127,712	161,176	82,606
Cost of goods	0	0	0	0	0	0	0	0
Total Costs and Expenses	**$68,079**	**$78,137**	**$101,255**	**$90,558**	**$92,000**	**$175,732**	**$218,039**	**$126,138**
Other Income (Expense):	600	(900)	(133)	1,586	2,417	2,092	1,093	152
Income before taxes	(57,015)	(56,821)	(64,590)	(49,461)	(31,583)	(40,640)	(193,803)	(29,405)
Provision for income taxes (expense)	0	0	(203)	0	0	948	0	800
Net loss	**(57,015)**	**(56,821)**	**(64,797)**	**(49,461)**	**(31,583)**	**(40,640)**	**(193,803)**	**(30,205)**
GAAP EPS	**(0.77)**	**(0.76)**	**(0.84)**	**(0.55)**	**(0.32)**	**(0.42)**	**(1.98)**	**(0.30)**
Basic weighted shares outstanding	74,500	75,000	77,038	89,240	97,755	97,855	97,955	98,055
Fully diluted shares outstanding	74,500	75,000	77,038	89,240	97,755	97,855	97,955	98,055

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

Clinical Trials

Product Candidate (Indication/ Study name)	Trial Design/Results
linaclotide (ongoing; CC and IBS-C/ MCP-103-305)	**Phase III – study design:** (N≈1300) interventional, treatment, non-randomized, open label, single group assignment to examine the safety and tolerability of 300 mcg of linaclotide in patients with CC or IBS-C; **primary endpoint:** safety assessed by AEs, clinical laboratory test results, vital sign measurements and ECG measurements for up to 52 weeks; **secondary endpoint:** treatment satisfaction; estimated completion per ClinicalTrials.gov: August 2011.
linaclotide (ongoing; CC and IBS-C/ LIN-MD-02)	**Phase III – study design:** (N≈1200) interventional, treatment, non-randomized, open label, single group assignment to examine the safety and tolerability of 300 mcg of linaclotide in patients with CC or IBS-C; safety assessed by AEs, clinical laboratory test results, vital sign measurements and ECG measurements for up to 52 weeks; estimated completion per ClinicalTrials.gov: April 2010.
linaclotide (ongoing; IBS-C/ LIN-MD-31)	**Phase III – study design:** (N≈800) interventional, treatment, randomized, double blind, placebo controlled, parallel assignment study to examine the safety and efficacy of 300 mcg of linaclotide in patients with IBS-C, followed by a 4-week randomized withdrawal period; **primary endpoints: 1)** abdominal pain and complete spontaneous bowel movement responder, **2)** complete spontaneous bowel movement responder **3)** abdominal pain responder **4)** IBS-C responder as defined by March 2010 FDA IBS draft guidance; **secondary endpoints:** CSBM frequency, SBM frequency, stool consistency, severity of straining, abdominal pain, abdominal pain-free days, abdominal discomfort, bloating and adverse events.
linaclotide (ongoing; IBS-C/ MCP-103-302)	**Phase III – study design:** (N≈800) interventional, treatment, randomized, double blind, placebo controlled, parallel assignment study to examine the safety and efficacy of 300 mcg of linaclotide in patients with IBS-C; **primary endpoints: 1)** abdominal pain and complete spontaneous bowel movement responder, **2)** complete spontaneous bowel movement responder **3)** abdominal pain responder **4)** IBS-C responder as defined by March 2010 FDA IBS draft guidance; **secondary endpoints:** CSBM frequency, SBM frequency, stool consistency, severity of straining, abdominal pain, abdominal pain-free days, abdominal discomfort, bloating and adverse events.
linaclotide (completed; CC/MCP-103-303)	**Phase III – study design:** (N=643) interventional, treatment, randomized, double blind, placebo controlled, parallel assignment study to examine the safety and efficacy of 150 mcg and 300 mcg of linaclotide in patients with CC, followed by a 4-week randomized withdrawal period; **primary endpoint:** complete spontaneous bowel movement (CSBM) overall responder; **secondary endpoints:** change from baseline in 12-week CSBM frequency, 12-week spontaneous bowel movement, 12-week stool consistency, 12-week severity of straining, 12-week abdominal discomfort, 12-week bloating and 12-week constipation severity.
linaclotide (completed; CC/LIN-MD-01)	**Phase III – study design:** (N=630) interventional, treatment, randomized, double blind, placebo controlled, parallel assignment study to examine the safety and efficacy of 150 mcg and 300 mcg of linaclotide in patients with CC; **primary endpoint:** complete spontaneous bowel movement (CSBM) overall responder; **secondary endpoints:** change from baseline in 12-week CSBM frequency, 12-week spontaneous bowel movement, 12-week stool consistency, 12-week severity of straining, 12-week abdominal discomfort, 12-week bloating and 12-week constipation severity.
linaclotide (completed; IBS-C/MCP-103-202)	**Phase IIb – study design:** (N=420) interventional, treatment, randomized, double blind, placebo controlled, parallel assignment study to examine the safety and efficacy of linaclotide (75 mcg, 150 mcg, 300 mcg and 600 mcg) in patients with IBS-C; **primary endpoint:** change in the complete spontaneous bowel movement frequency (CSBM); **secondary endpoints:** CSBM weekly responder and CSBM complete responder, SBM weekly responder, daily bowel habits, symptom severity, patient assessment of constipation severity, patient assessment of IBS symptoms, use of rescue medication, disease specific quality of life, IBS symptom severity score, end of treatment satisfaction, physical exams, vital signs, weight, ECGs, clinical laboratory tests and adverse events.
linaclotide (completed; CC/MCP-103-201)	**Phase IIb – study design:** (N=310) interventional, treatment, randomized, double blind, placebo controlled, parallel assignment study to examine the safety and efficacy of linaclotide (75 mcg, 150 mcg, 300 mcg and 600 mcg) in patients with CC; **primary endpoint:** change in the mean spontaneous bowel movement frequency (SBM); **secondary endpoints:** CSBM weekly responder, daily bowel habits, daily patient symptom severity, patient assessment of constipation severity, patient global assessment of relief of constipation symptoms, use of rescue medication, end of treatment satisfaction, patient assessment of constipation - QOL.

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

Product Candidate (Indication/ Study name)	Trial Design/Results
linaclotide (completed; IBS-C/MCP-103-005)	**Phase IIa – study design:** (N=36) interventional, treatment, randomized, double blind, placebo controlled, parallel assignment study to examine the pharmacodynamics of linaclotide (100 mcg and 1000 mcg) in patients with IBS-C; **primary endpoint:** AEs, clinical chemistry, hematology and urinalyses before and after treatment period, cardiac safety measured by ECG, primary endpoints for analysis of efficacy are the colonic geometric center (GC) at 24 hours and ascending colon $t_{1/2}$ values; **secondary endpoints:** $t_{1/2}$ gastric emptying, colonic filing at 6 hours, colonic GC at additional time points including 48 hours, and time to first bowel movement after the first dose of medication.
linaclotide (completed; CC/MCP-103-005)	**Phase IIa – study design:** (N=42) interventional, treatment, randomized, double blind, placebo controlled, parallel assignment study to examine the safety and efficacy of linaclotide (100 mcg, 300 mcg and 1000 mcg) versus placebo in patients with CC; **primary endpoint:** safety will be evaluated by physical examinations, ECGs, laboratory tests, adverse events; **secondary endpoints:** stool frequency (reported daily), stool consistency (reported daily), stool ease of passage (reported daily), stool completeness of evacuation (reported daily), patient assessment of abdominal discomfort (reported weekly), patient assessment of constipation (reported weekly), patient assessment of overall relief (reported weekly) and part 1 of IBS severity scale once pre-dose and once post-dose.

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

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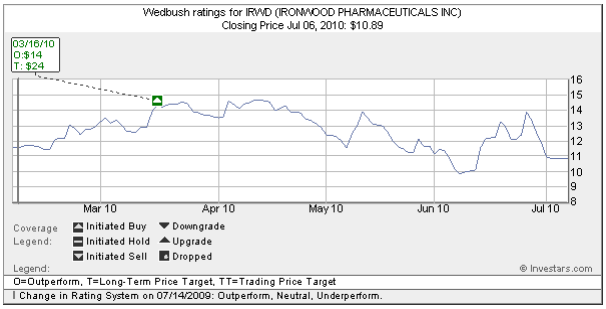

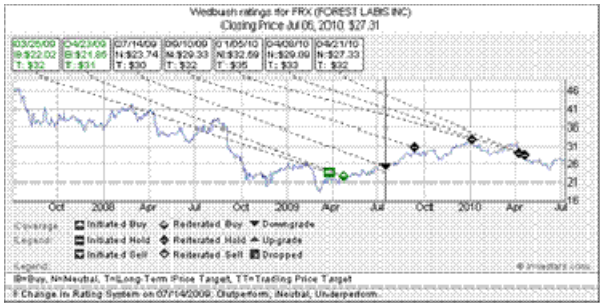

Disclosure information regarding historical ratings and price targets is available at
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OUTPERFORM – Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

NEUTRAL – Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

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OUTPERFORM – 51% (10% of this rating category were investment banking clients within the last 12 months).

NEUTRAL – 38% (1% of this rating category were investment banking clients within the last 12 months).

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WS co-managed a public offering of securities for BioMimetic Therapeutics (BMTI), Clinical Data (CLDA), Delcath Systems (DCTH), Ironwood Pharmaceuticals (IRWD) and ZymoGenetics (ZGEN) within the last 12 months.

WS has received compensation for investment banking services from BioMimetic Therapeutics (BMTI), Clinical Data (CLDA), CombinatoRx (CRXX), Delcath Systems (DCTH), Emergent BioSolutions (EBS), Ironwood Pharmaceuticals (IRWD) and ZymoGenetics (ZGEN) within the last 12 months.

WS provided investment banking services to BioMimetic Therapeutics (BMTI), Clinical Data (CLDA), CombinatoRx (CRXX), Delcath Systems (DCTH), Emergent BioSolutions (EBS), Ironwood Pharmaceuticals (IRWD), Pharmacyclics (PCYC) and ZymoGenetics (ZGEN) within the last 12 months.

WS is acting as financial advisor to Emergent BioSolutions (EBS) and Pharmacyclics (PCYC).

WS expects to receive compensation for investment banking services from BioMimetic Therapeutics (BMTI), Emergent BioSolutions (EBS) and Pharmacyclics (PCYC) within the next 3 months.

Greg Wade, the analyst providing research coverage of Adolor (ADLR), BioMimetic (BMTI), Cubist (CBST), CombinatoRx (CRXX), OncoGenex Pharmaceuticals (OGXI) and ZymoGenetics (ZGEN), maintains long positions in the common stocks.

Jeremiah Shepard, the associate providing research coverage of Ironwood Pharmaceuticals (IRWD) and Xenoport (XNPT) maintains a long position in the common stocks.

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.

Please access the attached hyperlink for WS' Coverage Universe: http://www.wedbush.com/inside/CapitalMarkets/CoverageList.asp

Applicable disclosure information is also available upon request by contacting Ellen Kang in the Research Department at (213) 688-4529, by email to ellen.kang@wedbush.com, or the Business Conduct Department at (213) 688-8090. You may also submit a written request to the following: Business Conduct Department, 1000 Wilshire Blvd., Los Angeles, CA 90017.

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