Research Note

Biotechnology / Biopharmaceuticals

Ironwood Pharmaceuticals, Inc. (IRWD)

March 16, 2010

Play Ironwood to Reach Green – Initiating with OUTPERFORM and $24 price target

- **Ironwood's lead product linaclotide, an oral, 14 amino acid agonist of guanylate cyclase type-C receptors that line the gastrointestinal tract, has achieved positive results in two Phase III studies in the chronic constipation (CC) setting.** We anticipate positive data in the constipation predominant irritable bowel syndrome (IBS-C) setting anticipated in H2:10 will lead to a sharp move in the stock. The drug's favorable tolerability profile, robust effect on bowel habit frequency and quality, and potential to address the painful symptoms of CC and IBS-C are anticipated to make it the front-line choice for the management of these indications for which there are 23 million and 12 million people in the US, respectively.
- **It is estimated that over 40% of the 12 million IBS-C patients suffer from some related symptoms daily and that only 25% of the 23 million people that suffer from CC seek medical treatment for their condition.** It is estimated that about 70% of patients taking the OTC and prescription laxatives report that they are not satisfied with their therapy.
- **The drug's favorable tolerability profile, robust effect on bowel habit frequency and quality, and potential to address the painful symptoms of CC and IBS-C are anticipated to make it the front-line choice for the management of these indications.** We anticipate linaclotide's favorable safety profile will make physicians comfortable providing their IBS-C and CC patients with samples; combined, relief of pain, bloating, cramping and constipation during the sampling period will ensure patients fill prescriptions and stick with their therapy.
- **Ironwood has struck a 50/50 co-development/commercialization collaboration with Forest Laboratories in the US, licensed the European rights to Almirall and licensed Asian rights to Astellas.**
- **Ironwood expects to contribute approximately 35% of the estimated 1,000 sales personnel that will participate in the anticipated launch of linaclotide in the US, seeing the company emerge from a discovery and development organization to a fully-integrated pharmaceutical company, and offering the opportunity for the acquisition of additional products targeting the gastrointestinal specialist setting.**
- **We are initiating on Ironwood Pharmaceuticals with an OUTPERFORM rating with a $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	--	$9.8	--	NA	$14.5	--	NA
Q2 Jun	--	$9.8	--	NA	$14.5	--	NA
Q3 Sep	--	$9.8	--	NA	$14.5	--	NA
Q4 Dec	--	$9.8	--	NA	$14.5	--	NA
Year*	**$36.8**	**$39.0**	**--**	**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	--	(0.18)	--	NA	(0.04)	--	NA
Q2 Jun	--	(0.16)	--	NA	(0.07)	--	NA
Q3 Sep	--	(0.11)	--	NA	(0.10)	--	NA
Q4 Dec	--	(0.06)	--	NA	(0.12)	--	NA
Year*	**($0.84)**	**(0.50)**	**--**	**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 03/16/10)
$14.09

Rating
OUTPERFORM

Price target
$24

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Company Information

52-Week Range	$11.20-$14.50
Shares/Diluted	97.4M / 119.8M
Est. Cash	$310.7M
FY:10 Burn	$47.0 M
Market Cap.	$1.34B
ST/LT Debt	$1.4 M / $2.0 M
Debt/Capital	$3.4 M / $228.2 M
ROE	NM
Cash & Inv/Share	$3.19
Book Value/Share	$2.31

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

Investment thesis and valuation

IBS-C and CC patients typically attempt to self-treat with over-the-counter medications such as laxatives, stool softeners or fiber supplementation, which can make certain symptoms, such as bloating and abdominal pain, worse. We estimate that about 12 million people over the age of 18 suffer from IBS-C, and it is believed that over 40% of all IBS-C patients suffer from some related symptoms daily (Talley et al, Am Jour of Epid, (142):76-83, 1995). We estimate that 23 million people suffer from CC, with only approximately 25% seeking medical treatment for their condition (Johanson et al, Alim Pharm and Thera, (25):599-608, 2007). It is estimated that about 70% of patients taking the OTC and prescription laxatives report that they are not satisfied with their therapy.

We believe that linaclotide will be a successful product because, in our opinion, physicians will likely recommend the drug for patients due to the clinical results and strong safety profile in IBS-C and CC settings, which have very limited therapeutic options. We believe a five day sample should be sufficient to demonstrate efficacy for the average patient, leading that patient to filling a script for linaclotide. Together, the clinical results and the quick onset of efficacy, in our opinion, will lead to rapid market penetration of linaclotide into the IBS-C and CC settings. Our peak sales US estimate in 2019 for IBS-C and CC are $1.58 billion and $878.5 million, respectively.

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.

Key points

- Linaclotide is a poorly absorbed 14 amino acid agonist of guanylate cyclase type-C receptor, which is located on the surface of epithelial cells that line the intestine. The drug causes elevation of the cellular second messenger cyclic GMP, leading to increased movement of water into the intestine (by means of increased hydration of intestinal contents, which stimulates both gut motility and content transit via peristalsis). Additionally, activation of this pathway causes inhibition of GI pain likely via activation of inhibitory potassium channels on GI pain afferent nerves.
- Linaclotide has achieved positive results in two Phase III studies in the chronic constipation setting, with positive data in the constipation predominant irritable bowel syndrome (IBS-C) setting anticipated in H2:10.
- The drug's favorable tolerability profile, robust effect on bowel habit frequency and quality, and potential to address the painful symptoms of CC and IBS-C are anticipated to make it the front-line choice for the management of these indications for which there are 23 million and 12 million people in the United States, respectively.
- Ironwood has struck a 50/50 co-development/commercialization collaboration with Forest Laboratories in the US (includes remaining $105 million pre-commercialization milestones and $100 million in commercialization milestones), licensed the European rights to Almirall (received $53 million in license fees, milestone payments and equity investments to date, and is eligible for up to $40 million in pre-commercialization milestone payments) and licensed Asian rights (Japan, South Korea, Taiwan, Thailand, the Philippines and Indonesia) to Astellas (received $30 million upfront license fee, and is eligible to receive up to $43 million in pre-commercial milestone payments).

Company overview

Ironwood Pharmaceuticals is located in Cambridge, MA and was incorporated in 1998. Ironwood's lead product candidate, linaclotide, is being developed for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). In two Phase III studies in the chronic constipation setting, linaclotide demonstrated statistically significant improvement all 32 primary and secondary endpoints in 2 Phase III CC trials involving 1287 patients. Ironwood is currently conducting two Phase III studies for linaclotide in the IBS-C setting, and data from these two studies is expected in H2:10. Ironwood expects to file an NDA for linaclotide in the IBS-C and CC settings for patients 18 and older in H1:11, potentially allowing for approval in H1:12.

Upcoming milestones

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

Ironwood's lead product candidate, linaclotide

Linaclotide is a 14 amino acid agonist of the guanylate cyclase type-C (GC-C) receptor located on the surface of epithelial cells that line the intestine. Activation of the GC-C receptor causes both increased fluid secretion into the bowel leading to increased gut motility which facilitates the movement of gut contents, and, local inhibition of visceral pain signaling. This allows for relief of the symptoms associated with constipation and the pain associated with IBS-C. The drug is formulated into a pill suitable for once daily dosing.

Irritable Bowel Syndrome with Constipation and Chronic Constipation Conditions

Bowel movements in healthy subjects occur spontaneously, cause minimal pain or discomfort, lead to the sense of complete evacuation and normally occur at frequencies between three-times a day to three times a week. IBS-C is characterized by recurrent abdominal discomfort (bloating, pain) along with disturbed bowel function (hard stools, straining during defecation, and a sense of incomplete evacuation). It is estimated that about 12 million people in the US over the age of 18 suffer from IBS-C, with over 40% of all IBS-C patients suffering from some daily symptoms (Talley et al, Am Jour of Epid, (142):76-83, 1995). The International Foundation of Functional Gastrointestinal Disorders in 2007 reported that 92% of IBS-C patients are not fully satisfied with their treatments and that 77% of patients were unsatisfied with overall care by their physician. The prevalence rates of IBS-C in Japan and Europe are believed to be similar to those in the US.

Chronic constipation (CC) is characterized by hard stools, straining during defecation and a sense of incomplete evacuation. It is estimated that 23 million people suffer from CC, with only approximately 25% seeking medical treatment for their condition. Furthermore, 9% of CC patients included in the survey, conducted by Johanson et al, reported that 9% of respondents reported missing work or school despite taking a therapeutic for their condition (Johanson et al, Alim Pharm and Thera, (25):599-608, 2007). It is thought that about 70% of those patients taking OTC and prescription laxatives are not satisfied with their therapy. CC is more common in women than men, and the incidence increases with age (Joshston et al, Am Jour of Gastro, (104); 125-132; 2009).

IBS-C and CC Markets

Disease Burden Estimates and Market	IBS-C	CC
US Prevalence	12M	23-34M
Seek care	7M	6-8.5M
Fully Satisfied with Treatment	8%	23%
Average # of Days Affected	166 per year or 40%	97 per year or 27%
Ambulatory Care Visits	3M (all IBS)	6.3M
Unsatisfied, seeking medical attention	6.4M	4.2-6.0M
Days of Treatment (rescue / chronic)	1.1B / 2.4B	37.8M / 2.2B
Total Market opportunity at $6/day	$6.4B / $14.1B	$3.5B / $13.1B

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

IBS-C and CC treatments

IBS-C and CC patients typically attempt to self-treat with over-the-counter medications such as laxatives, stool softeners or fiber supplementation. These, paradoxically, can actually make certain symptoms such as bloating and abdominal pain worse. Polyethylene glycol (MiraLAX) and lactulose are the most commonly used therapies. While these agents can improve bowel movement frequency and stool consistency, they typically do not improve bloating or abdominal discomfort. In order to treat more severe conditions, physicians will prescribe medications not approved for the two indications, such as antidepressants and antispasmodic agents.

Clinical trials with polyethylene glycol and lactulose reveal evidence these therapies cause bloating, cramping and up to a 40% incidence of diarrhea. It is estimated that up to 75% of patients taking prescription laxatives are not completely satisfied with the predictability of their bowel movements on treatment and 47% were not completely satisfied with the relief of their constipation symptoms (Johanson et al, Alim Pharm and Thera, (25):599-608, 2007).

The only approved prescription therapy for IBS-C and CC in the US is Amitiza, which as approved for CC in 2006 and IBS-C in 2008. Amitiza sales have been weak relative to Zelnorm and sales in 2008 were $193 million. We believe Amitiza sales are lagging primarily because the drug does not cause an improvement in the bloating and pain, and laxatives can readily address constipation, without the nausea commonly caused by Amitiza at doses that lead to efficacy. Resolor (prucalopride), a serotonin 5-HT_4 receptor agonist, was recently approved in the EU for CC in women that have taken laxatives and failed to experience relief. Resolor is J&J has US rights to prucalopride. There is unmet medical need for a proven therapeutic for the treatment of IBS-C.

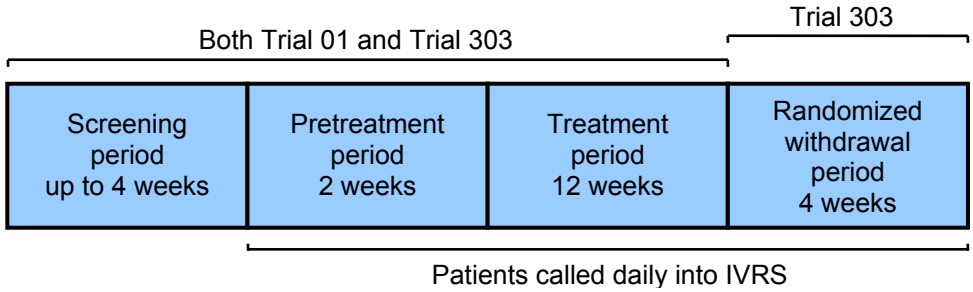
Zelnorm sales are indicative of potential IBS-C and CC market

In 2002 the FDA approved Zelnorm for the treatment of IBS-C. The serotonin 5-HT_4 receptor agonist mechanism of action for this drug was novel for the treatment of IBS-C. Zelnorm raised the awareness of the IBS-C and CC conditions, and 5 years after its approval, the total prescriptions for these conditions grew three fold to over 16 million prescriptions written for IBS-C and CC patients. In 2007 Zelnorm was withdrawn from the market due to a meta-analysis that suggested patients taking the drug had a higher chance of heart attack, stroke and chest pains. In the year before being removed from the market, Zelnorm total sales were approximately $561 million. Zelnorm highlighted the need, as well as available market opportunity, for an effective therapy.

Phase III linaclotide CC trials

In November 2009, Ironwood announced statistically significant top-line results from two pivotal Phase III linaclotide CC trials. Both studies were randomized, double-blind, placebo-controlled, parallel group, multi-center studies, and all the patients had CC according to the modified Rome II criteria. There were three treatment groups, placebo, linaclotide 150 mcg and 300 mcg. The primary endpoint for both studies was 12-week complete spontaneous bowel movement (CSBM) overall responder rate at the 2 doses studied in each trial. CSBM overall responder rate was defined as a patient that had 3 or more CSBM per week and an increase of at least one CSBM per week relative to baseline for 9 of the 12 weeks during treatment. The secondary endpoints were CSBM frequency rate (weekly rate), SBM frequency rate (weekly rate), stool consistency (7-point BSFS), severity of straining (5-point scale), constipation severity (5-point scale), abdominal discomfort (5-point scale) and bloating (5-point scale). Statistical significance was also reached for all pre-specified secondary endpoints.

Trial 01 and Trial 303 Protocol Design



Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

Phase III linaclotide CC trial (Trial 01) results

Trial 01 enrolled 630 patients that were ≥18 years old and had fewer than three CSBMs per week with no more than six spontaneous bowel movements (SBM) per week during the pretreatment period. At baseline, patients averaged 0.3 CSBM per week and 72% had no CSBMs during the run-in period. The efficacy results for Trial 01 are summarized below:

Primary Endpoint	Placebo (N=215)	133 mcg linaclotide (N=213)	266 mcg linaclotide (N=202)
12-week CSBM overall responder	6.0%	16.0% (p=0.0012)	21.3% (p=0.0001)
Other responder and efficacy measurements			
CSBM rate change ≥1 responder	13.0%	31.0% (p<0.0001)	40.1% (p<0.0001)
CSBM rate ≥3 responder	6.0%	16.0% (p=0.0012)	21.8% (p<0.0001)
12-week CSBM mean change ≥1 responder	25.6%	49.3% (p<0.0001)	56.9% (p<0.0001)
Average Weekly CSBMs	0.6	2.0 (p<0.0001)	2.7 (p<0.0001)
Average Weekly SBMs	1.1	3.4 (p<0.0001)	3.7 (p<0.0001)
Abdominal discomfort (IFB)	19.5%	31.1%	33.5%
Bloating (IFB)	13.0%	24.3%	27.3%
Constipation severity (IFB)	14.4%	40.2%	42.7%

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences; IFB – improvement from baseline

In 5/6 Phase II and the 2 Phase III studies, diarrhea was the most common adverse event (5%-20% of the subjects) and was the most common reason for discontinuing the study. The diarrhea reported was mild to moderate in occurrence. Consistent with this observation, the most common side effect reported in the first Phase III was diarrhea.

Trial 01 Treatment Emergent Adverse Events:

Adverse Event	Placebo (N=215)	133 mcg linaclotide (N=213)	266 mcg linaclotide (N=205)	All (N=418)
Diarrhea	6 (3%)	42 (20%)	30 (15%)	72 (17%)
Flatulence	13 (6%)	16 (8%)	13 (6%)	29 (7%)
Upper respiratory tract infection	14 (7%)	16 (8%)	9 (4%)	25 (6%)
Abdominal pain	5 (2%)	11 (5%)	11 (5%)	22 (5%)
Nausea	7 (3%)	8 (4%)	9 (4%)	17 (4%)
Abdominal distension	7 (3%)	7 (3%)	8 (4%)	15 (4%)
Urinary tract infection	8 (4%)	8 (4%)	6 (3%)	14 (3%)
Sinusitis	5 (2%)	8 (4%)	4 (2%)	12 (3%)
Nasopharyngitis	7 (3%)	3 (1%)	8 (4%)	11 (3%)

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

The most common treatment emergent adverse event was diarrhea, and this side effect lead to the discontinuation of 5% to 6% of the linaclotide treated patients versus 0.5% of the patients that received placebo. Serious adverse events, which occurred in 2% of the patients, were evenly distributed between the placebo and linaclotide treatment groups.

Second linaclotide CC Phase III trial (Trial 303)

The second CC trial (Trial 303) enrolled 643 patients and had an identical design as Trial 01. Patients were ≥18 years old and had fewer than three CSBMs per week and no more than six SBMs per week during the pretreatment period. At baseline, the average CSBM was also 0.3 CSBM per week (identical to Trial 01) and 68% had no CSBMs during the period (versus 72% in Trial 01). The efficacy results for Trial 01 are summarized below:

Primary Endpoint	Placebo (N=209)	133 mcg linaclotide (N=217)	266 mcg linaclotide (N=216)
12-week CSBM overall responder	3.3%	21.2% (p<0.0001)	19.4% (p<0.0001)
Other responder and efficacy measurements			
CSBM rate change ≥1 responder	11.0%	39.2% (p<0.0001)	37.0% (p<0.0001)
CSBM rate ≥3 responder	3.8%	21.7% (p<0.0001)	19.4% (p<0.0001)
12-week CSBM mean change ≥1 responder	22.5%	55.8% (p<0.0001)	52.8% (p<0.0001)
Average Weekly CSBMs	0.5	1.9 (p<0.0001)	2.0 (p<0.0001)
Average Weekly SBMs	1.1	3.0 (p<0.0001)	3.0 (p<0.0001)
Abdominal discomfort (IFB)	21.1%	32.9%	30.3%
Bloating (IFB)	13.2%	26.9%	22.0%
Constipation severity (IFB)	13.9%	40.5%	37.2%

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences; IFB – improvement from baseline

Trial 303 Treatment Emergent Adverse Events:

Adverse Event	Placebo (N=209)	133 mcg linaclotide (N=217)	266 mcg linaclotide (N=217)	All (N=434)
Diarrhea	14 (7%)	27 (12%)	30 (14%)	57 (13%)
Headache	8 (4%)	7 (3%)	10 (5%)	17 (4%)
Flatulence	9 (4%)	8 (4%)	8 (4%)	16 (4%)
Nausea	8 (4%)	7 (3%)	9 (4%)	16 (4%)
Abdominal distension	3 (1%)	8 (4%)	7 (3%)	15 (3%)
Abdominal pain	8 (4%)	6 (3%)	9 (4%)	15 (3%)
Nasopharyngitis	6 (3%)	6 (3%)	9 (4%)	15 (3%)
Sinusitis	3 (1%)	5 (2%)	7 (3%)	12 (3%)
Abdominal pain upper	3 (1%)	7 (3%)	7 (1%)	10 (2%)

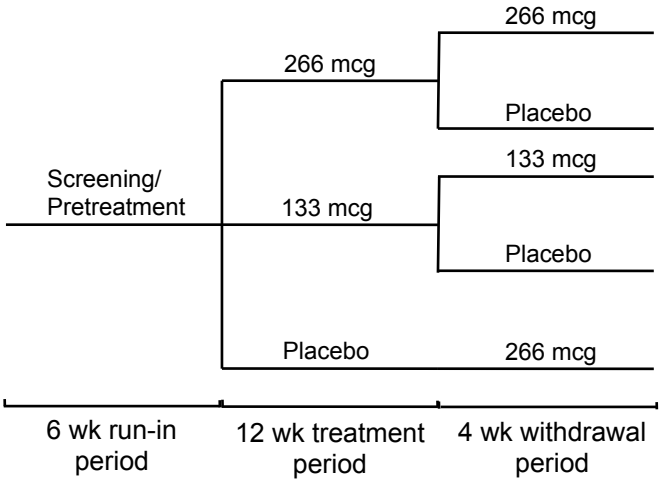
Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

The most common treatment emergent adverse event was diarrhea, and this side effect lead to the discontinuation of 3% of the linaclotide treated patients versus 0.5% of the patients that received placebo. Similar to Trial 01, serious adverse events occurred in 2% of the patients, and were evenly distributed between the placebo and linaclotide treatment groups.

We note that incidence rates are not, in our opinion, informative as to the potential competitive position of drugs broadly speaking. The prevalence and degree of diarrhea would be more informative however in its absence, the discontinuation rate due to diarrhea of 5-6% (of the 15-20% who reported it in Study 01), and 3% (of the 12-14% of who reported it in Study 02) suggests to us no impairment to the opportunity for linaclotide.

Trial 303 Randomized withdrawal period

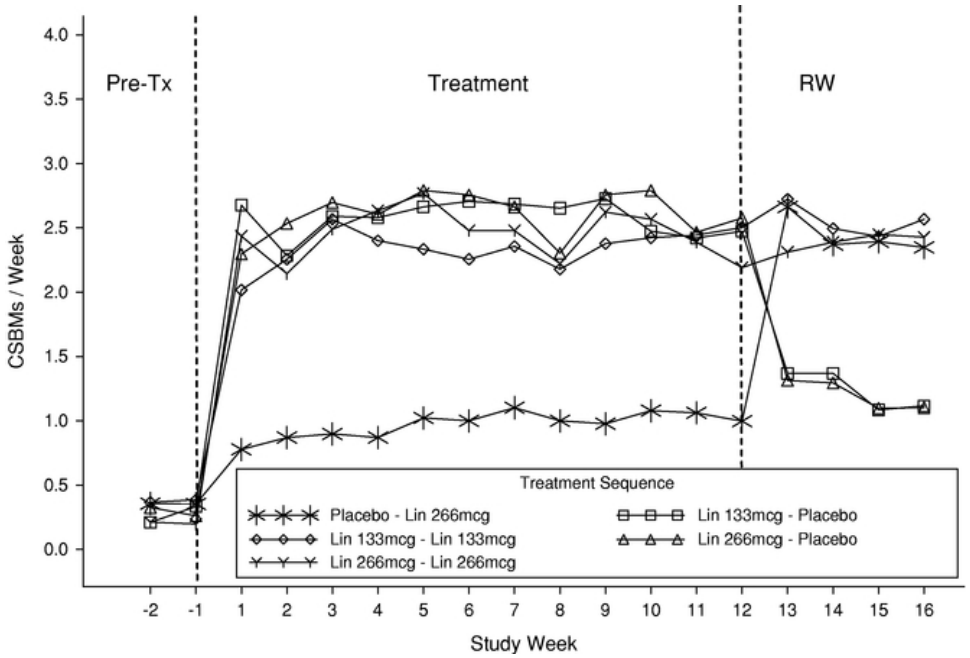
Trial 303 included a randomized withdrawal period to examine the effect of linaclotide treatment on the patients' original symptoms. During the 12 week treatment period, patients were re-randomized into one of five treatment groups, as outlined below:



Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

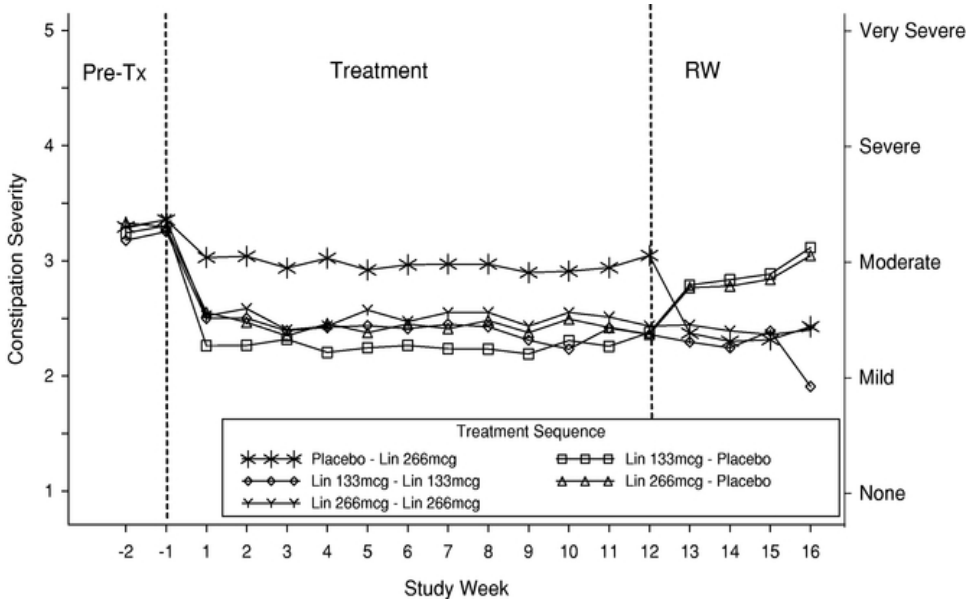
Significantly, the patients in the linaclotide treated groups exhibited similar bowel and abdominal symptoms prior to treatment, suggesting that discontinuing linaclotide treatment did not make their symptoms worse. Also, the patients in the placebo group, when treated with the 300 mcg of linaclotide, showed similar improvements in symptoms that were noted in the 300 mcg linaclotide treated group, and the groups that continued treatment with the same dose of linaclotide demonstrated sustained relief of their symptoms. The results of the randomization period are highlighted below.

Mean weekly CSBMs



Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

Mean weekly constipation severity



Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

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Male and elderly patient subpopulation analysis

A pre-specified analysis of the male and elderly patients (65 years and older) in the two Phase III studies indicated that both populations demonstrated a significant increase in the primary endpoint, the 12-week CSBM overall responder rate. Below is the combined data from both studies:

Male patients

Primary Endpoint	Placebo (N=46)	133 mcg linaclotide (N=44)	266 mcg linaclotide (N=51)
12-week CSBM overall responder	4.3%	29.5% (p=0.0028)	29.4% (p=0.0014)

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

Elderly patients (65 years and older)

Primary Endpoint	Placebo (N=55)	133 mcg linaclotide (N=51)	266 mcg linaclotide (N=48)
12-week CSBM overall responder	5.5%	33.3% (p=0.0004)	20.8% (p=0.0312)

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

Long-term safety studies

Two ongoing long-term safety studies examining the safety and tolerability of the 266 mcg linaclotide dose for 6 to 12 months, and longer, were initiated in September 2008. Patients that complete any of the linaclotide Phase II and Phase III trials are eligible to enroll in the studies, as well as patients enrolled in the Phase III efficacy studies, but were not randomized into the treatment phase of the study for reasons not related to their CC or IBS-C classifications. The target enrollment is 2,500 and approximately 1,500 patients have been enrolled.

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 one of 3 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 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

Design of ongoing IBS-C Phase III Trials

IRWD analyzed the complete data set from the Phase IIb IBS-C study using the 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.

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

Ongoing Phase III IBS-C Trials

In July 2009 Ironwood 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 three CSBMs and 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 endpoint is patients achieving both the 12-week abdominal pain (at least 30% reduction in abdominal pain relative to baseline for at least nine out of the 12 weeks in the treatment period) and 12-week Complete Spontaneous Bowel Movement (CSBM) responder (three or more CSBMs per week and an increase of at least on CSBM per week over baseline for at least nine of the 12 weeks of the treatment period). The 12-week Complete Spontaneous Bowel Movement (CSBM) responder and 12-week abdominal pain responder endpoints will be evaluated in a sequential manner

The data from these two trials is expected to be available in H2:10.

Marketing plans following potential linaclotide approval

Ironwood will contribute approximately 35% of the estimated 1,000 sales personnel that will participate in the anticipated launch of linaclotide in the US, seeing the company emerge from a discovery and development organization to a fully-integrated pharmaceutical company and offering the opportunity for the acquisition of additional products targeting the gastrointestinal specialist setting. Ironwood and Forest plan to initiate a direct-to-patient and provide education program prior to potential launch of linaclotide. This effort, by our estimates, will require approximately.

Additional indications

Ironwood may seek to gain approval in additional gastrointestinal indications or in pediatric populations. Significant overlap among GI disorders and their symptoms, with 29% of GERD patients believed to have chronic constipation and 23-50% of dyspepsia patients have IBS. Another potential indication is opioid bowl dysfunction.

Microbia, Inc.

Microbia, Inc. was spun out of Ironwood in 2006 and the company focuses on developing specialty biochemicals from specialized microbes. The company working on developing a range of compounds from bacteria, including carotenoids, high octane biofuels and industrial chemicals. Ironwood is the majority shareholder in Microbia.

Intellectual Property

The linaclotide patent portfolio includes two issued US patents, on granted EU patent, four additional international patents, as well as numerous pending patent applications. Significantly, both US patents will expire in 2025, and have claims for the linaclotide molecule, pharmaceutical composition, method of using the drug to treat GI disorders and processes of making the molecule. Additionally, there is one US patent that will expire in 2024 that covers other GC-C agonist molecules for the treatment of other diseases and disorders, as well as the process for their manufacture. The EU patent will expire in 2024 and contains claims for the linaclotide molecule, pharmaceutical composition and use of linaclotide for GI disorders.

Partnerships

Ironwood entered into a co-development and co-marketing collaboration with Forest Laboratories for linaclotide in 2007. It is a 50/50 partnership in the US, while Forest has full rights to Mexico and Canada (and will pay Ironwood Pharmaceuticals a royalty on net sales). Ironwood retains all rights outside of the US. To date, greater than $250 million has been received from Forest Laboratories for the licensing fees, milestone payments, equity investments and development costs. IRWD has received $125 million in license fees and milestones to date, and the remaining pre-commercialization milestones are $105 million and is eligible for $100 million in milestones.

In April 2009 Ironwood entered into license agreement with Almirall for the development and commercialization of linaclotide in Europe for IBS-C and other GI conditions. Almirall has paid IRWD $53 million in license fees, milestone payments and equity investments to date, and IRWD is eligible for up to $40 million in pre-commercialization milestone payments. Almirall is responsible for activities and expenses associated with the regulatory approval process in Europe. IRWD will receive escalating royalties on linaclotide sales volumes.

In November 2009, Ironwood entered into an agreement with Astellas Pharma to develop and commercialize linaclotide for IBS-C and other GI conditions for Japan, South Korea, Taiwan, Thailand, the Philippines and Indonesia. IRWD has received a $30 million upfront license fee, and is eligible to receive up to $43 million in pre-commercial milestone payments.

Management

Name, Position	Previous positions
Peter M. Hecht, Ph.D., Chief Executive Officer, co-founder	Research fellow at Whitehead Institute for Biomedical Research, B.S. in Mathematics and an M.S. in Biology from Stanford University, and a Ph.D. in Molecular Biology from the University of California at Berkeley, serves on the boards of directors of Whitehead Institute and Microbia, Inc, serves on the Leadership Council for the Koch Institute for Integrative Cancer Research at MIT and the advisory board of Infante Sano.
Michael J. Higgins Chief Operating Officer and Chief Financial Officer	Senior business positions at Genzyme Corporation, including Vice President of Corporate Finance, B.S. from Cornell University and an M.B.A. from the Amos Tuck School of Business Administration at Dartmouth College. He serves on the board of directors of Microbia, Inc.
Mark G. Currie, Ph.D. Senior Vice President, R&D and Chief Scientific Officer	Vice President of Discovery Research at Sepracor, Director of arthritis and inflammation at Monsanto/Searle, B.S. in Biology from the University of South Alabama and Ph.D. in Cell Biology from the Bowman-Gray School of Medicine of Wake Forest University.
Jeffrey M. Johnston, M.D., F.A.C.P. Vice President, Clinical Development and Chief Medical Officer	Chief Medical Officer and Vice President of Drug Development at Critical Therapeutics, Vice President of clinical research at Triangle Pharmaceuticals, Clinical Development at GlaxoSmithKline, B.S. in Biology from Davidson College and M.D. from the Duke University School of Medicine, completed internal medicine residency at Vanderbilt and infectious diseases fellowship at the University of Utah School of Medicine.
Thomas McCourt Chief Commercial Officer and Senior Vice President, Marketing and Sales	Led the U.S. brand team for denosumab at Amgen, Directed the launch and growth of Zelnorm for the treatment of patients with IBS-C and chronic constipation and held a number of senior commercial roles, including vice president of strategic marketing and operations at Novartis, part of the founding team at Astra Merck and led the development of the medical affairs and science liaison group and then served as brand manager for Prilosec®. Pharmacy degree from the University of Wisconsin.
James J. O'Mara Vice President, Business Development	Vice President of Corporate Development at Cozint Interactive, a healthcare marketing services company, Vice President for MPM Capital where he managed business development strategies, different sales and marketing positions at both Merck and Centocor.

Source: Ironwood Pharmaceuticals and Wedbush PacGrow Life Sciences

Model

Gregory R. Wade, Ph.D.
Jeremiah B. Shepard, Ph.D.
3/16/2010

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	39,000	58,000	133,000	17,000	41,000
Total Revenues	**$10,464**	**$22,216**	**$36,798**	**$39,000**	**$58,000**	**$133,000**	**$23,143**	**$96,581**
Cost and Expenses:								
Research and development	57,246	59,809	78,235	65,000	50,000	48,020	56,863	43,532
Sales, general, and administrative	10,833	18,328	23,020	24,000	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**	**$89,000**	**$92,000**	**$175,732**	**$218,039**	**$126,138**
Other Income (Expense):	600	(900)	(133)	2,109	2,551	2,228	1,230	152
Income before taxes	(57,015)	(56,821)	(64,590)	(47,891)	(31,449)	(40,504)	(193,665)	(29,405)
Provision for income taxes (expense)	0	0	(203)	0	0	951	0	800
Net Income	**(57,015)**	**(56,821)**	**(64,797)**	**(47,891)**	**(31,449)**	**(40,504)**	**(193,665)**	**(30,205)**
GAAP EPS	**(0.77)**	**(0.76)**	**(0.84)**	**(0.50)**	**(0.32)**	**(0.42)**	**(1.98)**	**(0.31)**
Basic weighted shares outstanding	74,500	75,000	77,038	95,672	97,483	97,583	97,683	97,783
Fully diluted shares outstanding	74,500	75,000	77,038	119,823	119,923	120,023	120,123	120,223

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; **primary endpoint:** 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 (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 (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 endpoint:** abdominal pain and complete spontaneous bowel movement responder, complete spontaneous bowel movement responder and abdominal pain responder; **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 endpoint:** abdominal pain and complete spontaneous bowel movement responder, complete spontaneous bowel movement responder and abdominal pain responder; **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; 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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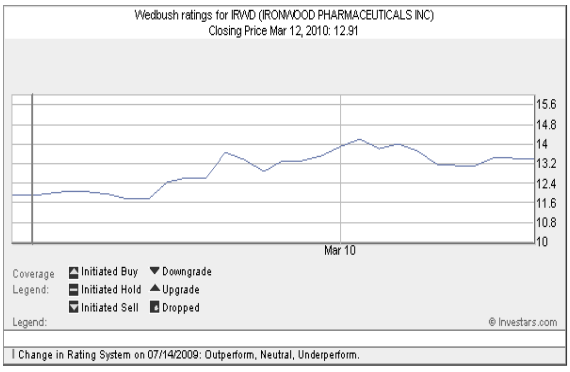

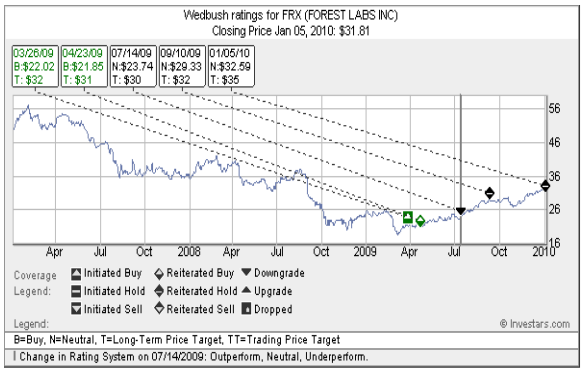

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Jeremiah Shepard, the associate providing research coverage of Ironwood Pharmaceuticals (IRWD) and Xenoport (XNPT), maintains a long position in the common stocks.

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

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