

## FRX and IRWD

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### INCREASE TARGET PRICE

## First Phase III IBS-C Data Bodes Well for Linacotide's Approvability, Although Commercial Challenges Keep Us Cautious on Drug's Potential

- **Impressive data in IBS-C confirms Street's optimism.** We expect FRX and IRWD shares to react positively to the release of positive data from their first Phase III study for linacotide in irritable bowel syndrome with constipation (IBS-C). While the results are in-line with most investors' expectations, today's data reinforces the clinical profile for the product and suggests that the second IBS-C study may be positive as well. Given the strength of today's data, we raise our probability of success for the product coming to the market from 75% to 85%. Our IRWD target price is based on a probability-adjusted NPV and increases from \$11 to \$12 while our FRX target price is a 70/30 blend of DCF and relative valuation and increases from \$28 to \$29. Our relative conservatism on the product remains unchanged, due to the challenges the constipation market brings, and we maintain our Neutral rating on both names.
- **Expect positive results from remaining linacotide studies.** The overall response rates and the persistence of the treatment effect on both abdominal pain and complete spontaneous bowel movements (CSBMs) in this 12-week study are encouraging (Exhibit 1 - Exhibit 4), as we await the top-line data in 4Q 2010 from study MCP-103-302, which had a 26-week treatment period. The minimal systemic absorption of the drug also leaves us confident in the data that will emerge from the ongoing long-term safety studies with the drug. All of these studies will need to come back positive before linacotide can be approved for use in chronic constipation (CC) or IBS-C but data available to date suggests that the drug will be able to meet these upcoming hurdles.
- **Compliance issues and over-the-counter (OTC) competitors make success in constipation markets a challenge.** Despite the strength of the data for linacotide in both CC and IBS-C, we remain relatively guarded on the drug's commercial potential given our previous due diligence into this market. Our 100-physician survey revealed how dominant OTC medications are in this market and suggested that, for patients who do receive prescription medications, 80% stop therapy for reasons other than symptom resolution and about half of them complete less than 60% of the prescription that they are given (Exhibit 5 - Exhibit 8). The size of the constipation markets and the overall clinical profile of linacotide, however, still leaves us expecting US sales to surpass \$1 Bn by 2020.

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Exhibit 1: Top-Line Efficacy Data from Phase III LIN-MD-31 Study (US Endpoints)

Primary Endpoints	Responder Rates (%)		P-value
	266 mcg	Placebo	
• Composite responder 1 (abdominal pain 30, CSBM 3+1, 9/12)	12	5	=0.0004
• CSBM responder 1 (CSBM 3+1, 9/12)	20	6	<0.0001
• Abdominal pain responder 1 (abdominal pain 30, 9/12)	34	27	=0.0262
• Composite responder 2 (abdominal pain 30, CSBM +1, 6/12)	34	21	<0.0001
<b>Secondary Endpoints</b>			
• CSBM+1 responder 2 (CSBM +1, 6/12)	49	30	<0.0001
• Abdominal pain responder 2 (abdominal pain 30, 6/12)	50	37	=0.0003
• Abdominal pain (12-week)	Yes		<0.0001
• Percent of abdominal pain-free days (12-week)	Yes		=0.0014
• Abdominal discomfort (12-week)	Yes		<0.0001
• Bloating (12-week)	Yes		<0.0001
• CSBM frequency rate (12-week)	Yes		<0.0001
• SBM frequency rate (12-week)	Yes		<0.0001
• Stool consistency (12-week)	Yes		<0.0001
• Severity of straining (12-week)	Yes		<0.0001

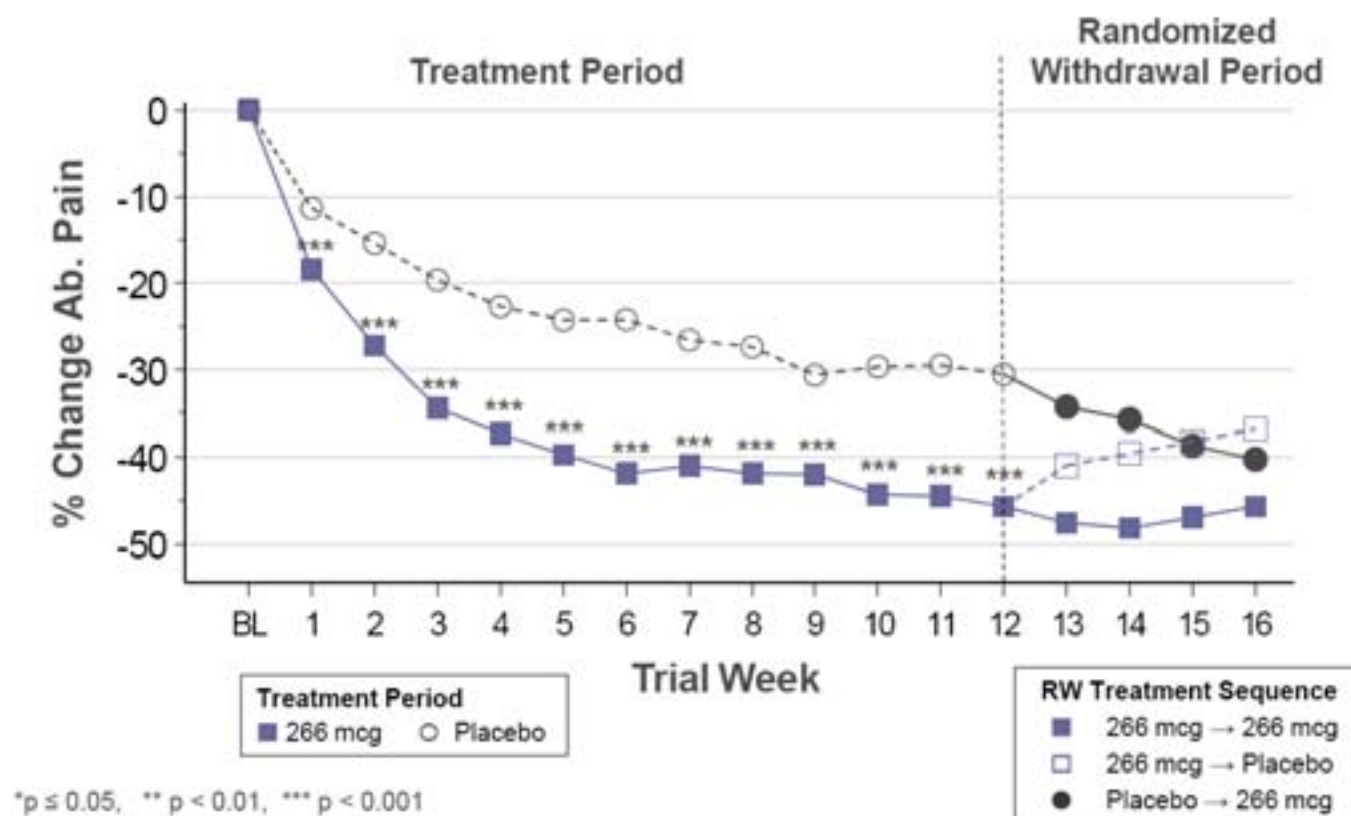
Source: Company data.

Exhibit 2: Top-Line Efficacy Data from Phase III LIN-MD-31 Study (EU Endpoints)

Co-Primary Endpoints	Responder Rates (%)		Nominal p-value
	266 mcg	Placebo	
• 12-week abdominal pain / abdominal discomfort responder	55	42	=0.0002
• 12-week IBS degree of relief responder	37	18	<0.0001
<b>Secondary Endpoints</b>			
• Bloating (12-week)	Yes		<0.0001
• CSBM frequency rate (12-week)	Yes		<0.0001
• Stool consistency (12-week)	Yes		<0.0001
• Severity of straining (12-week)	Yes		<0.0001

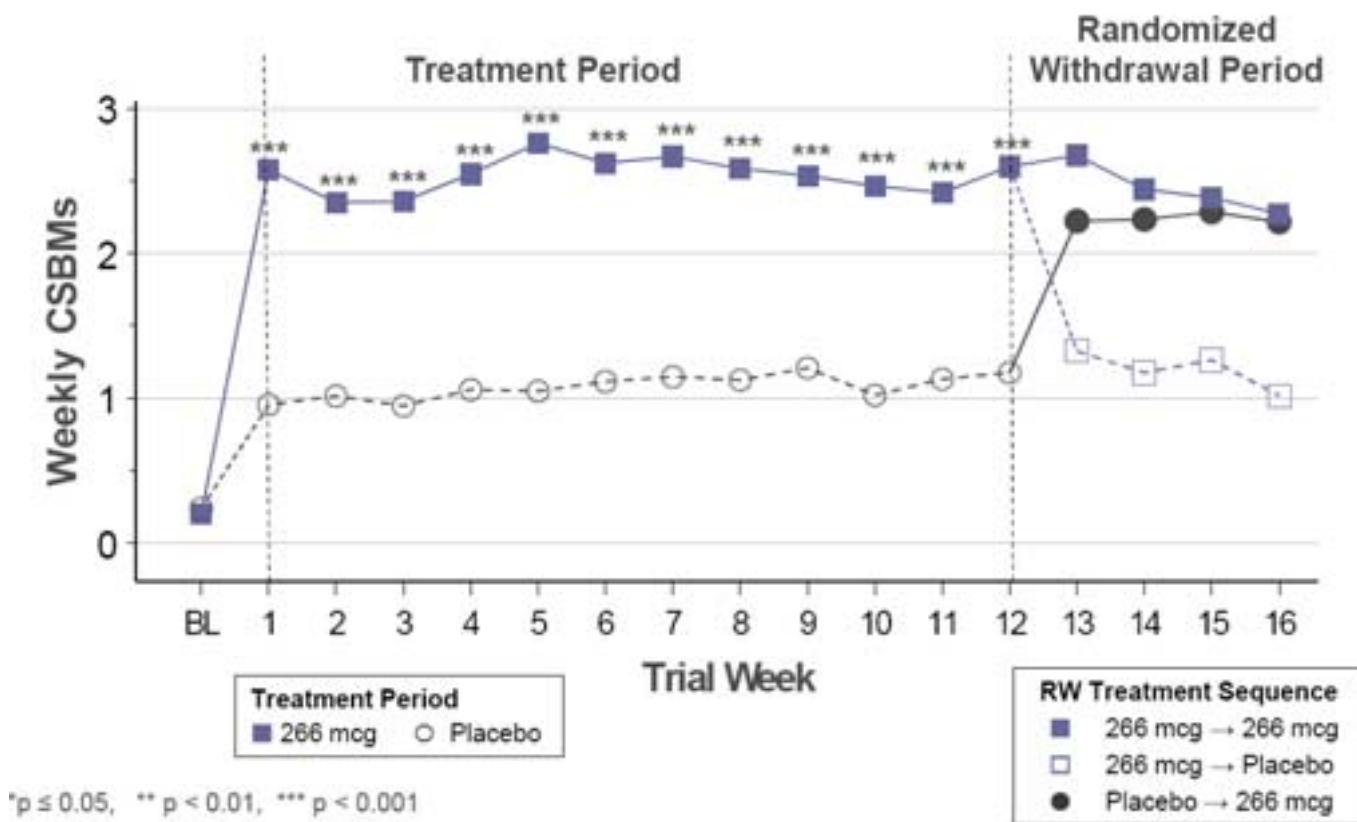
Source: Company data.

Exhibit 3: Abdominal Pain Reduction through 16 Weeks in Phase III LIN-MD-31 Study



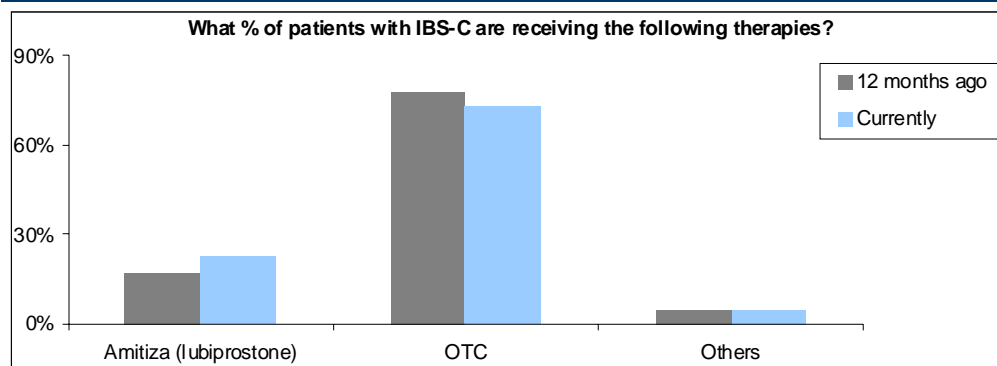
Source: Company data.

Exhibit 4: Improvement in CSBMs through 16 Weeks in Phase III LIN-MD-31 Study

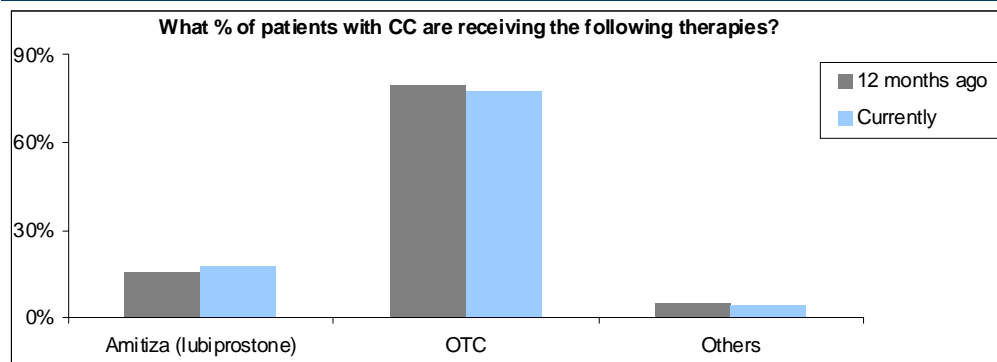


Source: Company data.

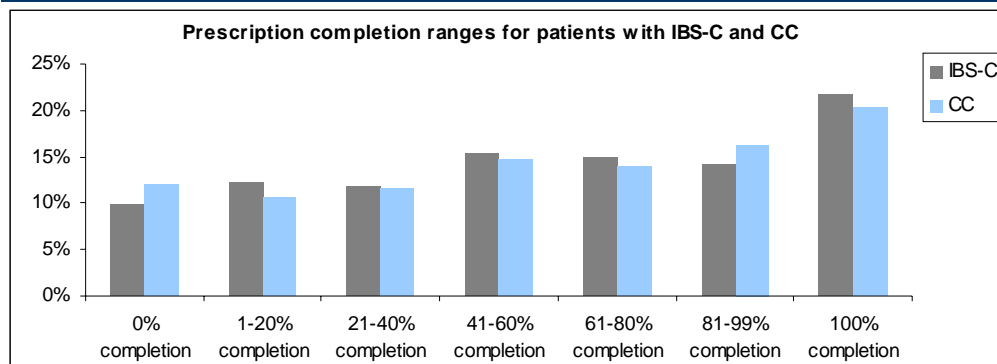
Exhibit 5: CS Survey results highlights dominance of OTC meds in IBS-C market



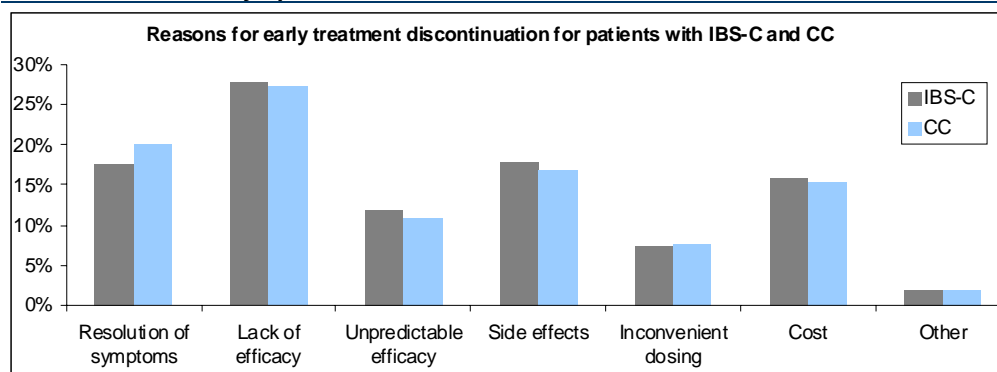
Source: Credit Suisse proprietary survey.

**Exhibit 6: OTC medications also dominate the CC market**

Source: Credit Suisse proprietary survey.

**Exhibit 7: Survey Respondents Believe that About Half of Their Patients with IBS-C and CC Complete Less than 60% of the Prescription That They Are Given for Their Illness**

Source: Credit Suisse proprietary survey.

**Exhibit 8: 80% of Patients Stop Therapy for IBS-C and CC for Reasons other Than Resolution of Their Symptoms**

Source: Credit Suisse proprietary survey.

Company	Price ccy	Price 10 Sep 10	Rating*		Target Price		Year End	EPS Ccy	EPS FY1E		EPS FY2E		EPS FY3E	
			Prev.	Cur.	Prev.	Cur.			Prev.	Cur.	Prev.	Cur.	Prev.	Cur.
Forest Laboratories Inc. (FRX)	US\$	29.86	—	N	28.00	29.00	Mar 10	US\$	—	3.73	—	4.11	1.33	1.30
Ironwood Pharmaceuticals (IRWD)	US\$	9.74	—	N [V]	11.00	12.00	Dec 09	US\$	—	(0.66)	—	(0.56)	—	(0.04)

\*O – Outperform, N – Neutral, U – Underperform, R – Restricted  
Source: Company data, Credit Suisse estimates.

[V] = Stock considered volatile (see Disclosure Appendix).

### Companies Mentioned (Price as of 13 Sep 10)

Forest Laboratories Inc. (FRX, \$29.86, NEUTRAL, TP \$29.00)

Ironwood Pharmaceuticals (IRWD, \$9.74, NEUTRAL [V], TP \$12.00)

## Disclosure Appendix

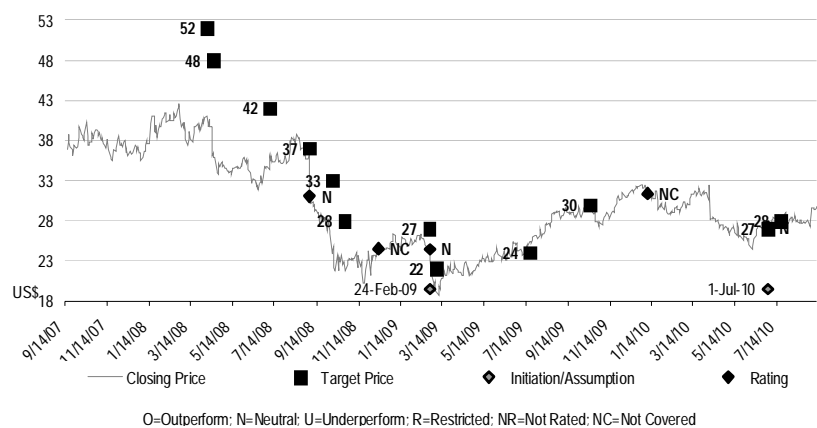
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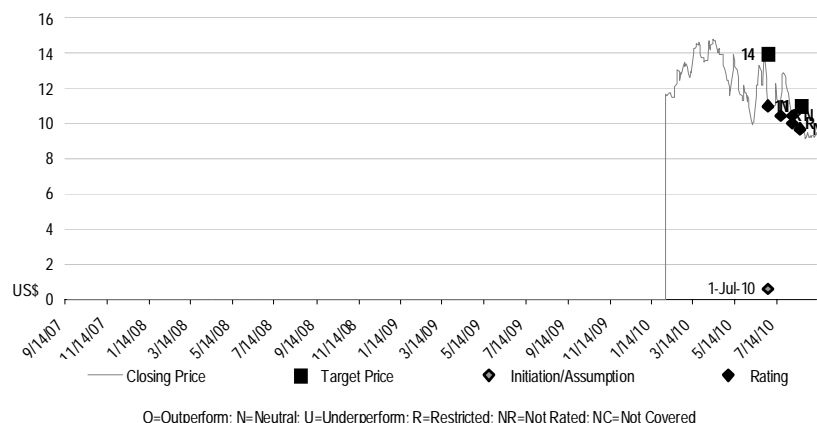
### 3-Year Price, Target Price and Rating Change History Chart for FRX

FRX	Closing Price	Target Price	Initiation/	
Date	(US\$)	(US\$)	Rating	Assumption
4/7/08	41.13	52		
4/16/08	36.52	48		
7/8/08	36.11	42		
9/3/08	31.08	37	N	
10/7/08	24.26	33		
10/24/08	21.86	28		
12/12/08	24.54		NC	
2/24/09	24.43	27	N	X
3/6/09	19.12	22		
7/20/09	25.4	24		
10/15/09	30.18	30		
1/7/10	31.37		NC	
7/1/10	27.17	27	N	X
7/20/10	28.1	28		



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

IRWD	Closing Price	Target Price	Initiation/	
Date	(US\$)	(US\$)	Rating	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	
8/19/10	9.58	11		



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**Price Target:** (12 months) for (FRX)

**Method:** Our \$29 target price for Forest is based on a 70/30% blend of (DCF) valuation of \$31 and relative valuation of \$25. Our DCF uses a 11.0% WACC (weighted average cost of capital) and a terminal EBITDA multiple of 4.0x. For our P/E valuation, we place FRX at a 10% premium to its Speciality Pharma peers, giving it a multiple of 11.6x applied to its FY 2014 EPS estimate of \$2.07.

**Risks:** Risks to our \$29 target price for Forest include: (1) development pipeline risks, (2) unexpected declines in key products sales growth, and (3) earlier than expected generic entry for key products.

**Price Target:** (12 months) for (IRWD)

**Method:** Our \$12 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 \$12 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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