Morgan Stanley

MORGAN STANLEY RESEARCH
NORTH AMERICA

Morgan Stanley & Co. Incorporated

Steven Harr, M.D.
Steven.Harr@morganstanley.com
+1 (1)212 761 3805

Sara Slifka
Sara.Slifka@morganstanley.com
+1 (1)212 761 3920

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Stock Rating
Overweight

Industry View
In-Line

Ironwood Pharmaceuticals

Quick Comment: Guidelines Validate Linaclotide Phase III

Impact on our views: FDA's draft guidance on clinical trials in irritable bowel syndrome with constipation (IBS-C) are consistent with Ironwood's Phase III trials, increasing our confidence that Phase III endpoints will be adequate for approval and highlighting why some competitive drugs may need more data. The guidelines do highlight that drugs in IBS-C will need to be positive on a dual primary endpoint (constipation **and** pain), decreasing the potential for an indication if linaclotide only improved constipation (an endpoint where efficacy is nearly certain). Phase IIb data on **both** endpoints were solid, with 48% pain responders and 31% CSMB responders, giving us confidence linaclotide will meet its Phase III endpoints and, based on the new FDA guidance, that these endpoints are sufficient for approval.

What's new: The FDA issued draft guidance on the design of clinical trials for diarrhea- or constipation-predominant IBS. The guidance calls for a co-primary endpoint of pain (30% reduction vs. baseline) and stool frequency (≥1 increase in complete spontaneous bowel movements (CSBM) vs. baseline). Ironwood's Phase III trials match these guidelines. The guidelines indicate a single item patient reported endpoint (e.g. "adequate relief of IBS symptoms") is inadequate, and for now, FDA recommends a co-primary endpoint consisting of pain intensity and stool frequency for IBS-C trials. The guidelines can be viewed at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM205269.pdf.

Investment thesis: We see a high chance of clinical and regulatory success as well as blockbuster sales potential for linaclotide, which is likely to be the first IBS-C drug with a significant pain benefit. Key potential catalysts include: 1) Phase III IBS-C data (2H10); 2) IBS-C & CC NDA filing (1H11); 3) linaclotide approval (late 2011/early 2012).

Key Ratios and Statistics

Reuters: IRWD.O Bloomberg: IRWD US
Biotechnology / United States of America

Price target	**$19.00**
Shr price, close (Mar 22, 2010)	$14.49
Mkt cap, curr (mm)	$1,412,292
52-Week Range	$14.65-11.20

Company Description
Ironwood is a pharmaceutical company that discovers, develops, and intends to commercialize innovative medicines targeting important therapeutic needs. Ironwood's lead drug candidate Linacloide, a first-in-class compound for treatment of patients with irritable bowel syndrome with constipation or chronic constipation, is currently in Phase III development.

Biotechnology/United States of America

Industry View: In-Line

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(as of February 28, 2010)

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Stock Rating Category	Count	% of Total	Count	% of Total IBC	% of Rating Category
Overweight/Buy	**1035**	**41%**	**316**	**42%**	**31%**
Equal-weight/Hold	**1091**	**43%**	**341**	**45%**	**31%**
Not-Rated/Hold	**22**	**1%**	**5**	**1%**	**23%**
Underweight/Sell	**382**	**15%**	**89**	**12%**	**23%**
Total	**2,530**		**751**		

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The Americas
1585 Broadway
New York, NY 10036-8293
United States
Tel: +1 (1) 212 761 4000

Europe
20 Bank Street, Canary Wharf
London E14 4AD
United Kingdom
Tel: +44 (0) 20 7 425 8000

Japan
4-20-3 Ebisu, Shibuya-ku
Tokyo 150-6008
Japan
Tel: +81 (0) 3 5424 5000

Asia/Pacific
1 Austin Road West
Kowloon
Hong Kong
Tel: +852 2848 5200

Industry Coverage:Biotechnology

Company (Ticker)	Rating (as of)	Price* (03/22/2010)
Steven Harr, M.D.		
Affymax Inc (AFFY.O)	E (01/29/2009)	$20.74
Amgen (AMGN.O)	O (07/28/2008)	$60.09
Amicus (FOLD.O)	E (12/20/2007)	$3.33
Amylin Pharmaceuticals (AMLN.O)	E (10/27/2008)	$22.94
Biocryst Pharmaceuticals, Inc. (BCRX.O)	E (12/21/2009)	$6.82
Biogen Idec (BIIB.O)	U (07/30/2007)	$59.82
Celgene Corporation (CELG.O)	O (09/10/2009)	$64.4
Genzyme Corporation (GENZ.O)	U (12/21/2009)	$59.07
Gilead Sciences, Inc. (GILD.O)	E (09/10/2009)	$48.15
Human Genome Sciences Inc. (HGSI.O)	O (12/21/2009)	$31.16
Ironwood Pharmaceuticals (IRWD.O)	O (03/15/2010)	$14.49
OSI Pharmaceuticals (OSIP.O)	O (08/13/2002)	$59.36
Onyx Pharmaceuticals (ONXX.O)	U (10/27/2008)	$32.29
Regeneron (REGN.O)	E (06/05/2008)	$24.36
Vertex Pharmaceuticals (VRTX.O)	O (11/04/2009)	$42.48
XenoPort (XNPT.O)	E (02/18/2010)	$9.07
Marshall Urist, M.D., Ph.D.		
AMAG Pharmaceuticals, Inc. (AMAG.O)	E (11/16/2007)	$37.85
Auxilium Pharmaceuticals (AUXL.O)	O (11/16/2007)	$34.03

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