

Recro Pharma, Inc.

(REPH/ NASDAQ)

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Starts Revised Phase 2 Post-Op Pain Trial - Success Far More Likely

Buy
TP: \$26.00

Investment Summary

Yesterday, Recro announced the start of its revised Phase 2 trial of Dex-IN for acute pain on day 1 following bunionectomy surgery. Compared to the recently discontinued Phase 2 trial, the revised trial evaluates Dex-IN over 48 hours in the day 1 post-op setting, instead of the day 0 post-op setting. A total of 200-250 patients will be randomized to receive 50mcg Dex-IN or placebo every 6 hours starting on post-op day 1. Oral opioid rescue treatment will be provided if needed. After treatment begins, patients will remain under observation for 48 hours at study centers and will be followed for 7 days, with the summed pain intensity difference over 48 hours (SPID48) being the primary efficacy endpoint. Pain is generally stable or declining on post-op day 1 while pain is rapidly escalating on post-op day 0, and therefore we are more confident in Dex-IN's ability to effectively manage pain in the revised Phase 2 trial. Additional efficacy endpoints include use of opioid rescue medication and opioid related side effects, and Patient Global Assessment of pain control. Recro expects to report top-line results by mid-2015, and the company plans to conduct an interim analysis for any necessary sample size adjustment when half of the evaluable patients have been enrolled. Trading below cash value, we see a highly favorable risk reward profile for Recro.

Discussion

Dosing started in the Phase 2 post-operative pain trial. Yesterday, Recro announced the start of its revised Phase 2 trial of Dex-IN for acute pain on day 1 following bunionectomy surgery. Compared to the recently discontinued Phase 2 trial, the revised trial evaluates Dex-IN over 48 hours in the day 1 post-op setting, instead of the day 0 post-op setting. A total of 200-250 patients will be randomized to receive 50mcg Dex-IN or placebo every 6 hours starting on post-op day 1. Oral opioid rescue treatment will be provided if needed. After treatment begins, patients will remain under observation for 48 hours at study centers and will be followed for 7 days, with the summed pain intensity difference over 48 hours (SPID48) being the primary efficacy endpoint. Pain is generally stable or declining on post-op day 1 while pain is rapidly escalating on post-op day 0, and therefore we are more confident in Dex-IN's ability to effectively manage pain in the revised Phase 2 trial. Additional efficacy endpoints include use of opioid rescue medication and opioid related side effects, and Patient Global Assessment of pain control. Recro expects to report top-line results by mid-2015, and the company plans to conduct an interim analysis for any necessary sample size adjustment when half of the evaluable patients have been enrolled. Trading below cash value, we see a highly favorable risk reward profile for Recro.

Final results were provided from the Phase 2 post-op day 0 pain trial. Data from 23 additional patients who were enrolled after the cutoff for the prespecified interim analysis now became available. With the additional efficacy data in hand, the post-op day 0 pain trial would still not have been expected to reach statistical significance for pain control. A total of 95 patients received treatment, and 85 patients with any baseline pain intensity were evaluable for SPID48 (2/3 on either 35mcg or 50mcg Dex-IN). Of the 23 additional patients, 8 patients had baseline pain intensity scores of 6 or below, increasing the size of this subgroup of patients to 42 from 34. With the addition of these 8 patients (3 in placebo, 3 in 50mcg Dex-IN and 2 in 35mcg Dex-IN), the effect size and the differences in opioid consumption were further reduced. Despite the lack of efficacy, Dex-IN was well tolerated with no serious adverse events reported. Four patients (3 in 50mcg Dex-IN and 1 in 35mcg Dex-IN) discontinued due to symptomatic hypotension and one subject (35mcg Dex-IN) due to fever. No other symptomatic hypotension events were seen in the 95 patients treated. Asymptomatic hypotension was observed in 10 Dex-IN patients (6 in 50mcg Dex-IN and 4 in 35mcg Dex-IN). In addition, only one patient in the Dex-IN 50mcg arm and two patients in the placebo arm had reduced heart rate. Lastly, no clinically significant changes were seen in electrocardiograms and in clinical laboratory studies.

Valuation / Target Price

We derive our target price of \$26 through a DCF analysis, assuming a 25% discount rate that is applied to all cash flows and the terminal value, which is based on a 5 multiple of the projected 2020 EBITDA of \$101 million.

Price	\$2.77
52-Week High/Low	\$9.88-\$2.65
Shares Out (mm)	7.7
Market Cap (mm)	\$21
Avg. Daily Vol (000)	52,550
Short Interest	0.7%
EV (mm)	NA

	FY13A	FY14E	FY15E
EPS			
Mar	--	\$(3.67)A	--
June	--	\$(0.36)A	--
Sept	--	\$(0.57)	--
Dec	--	\$(0.86)	--
FY (Dec)	\$(15.41)	\$(3.25)	\$(2.44)
P/E (x)	NM	NM	NM
Revenue (\$M)			
Mar	--	\$0.0A	--
June	--	\$0.0A	--
Sept	--	\$0.0	--
Dec	--	\$0.0	--
FY (Dec)	\$0.0	\$0.0	\$0.0



Source: Bloomberg

Exhibit 1: Summary of key safety data of interest REC-13-012

Event	Dex-IN 50mcg Group N (%)	Placebo Group N (%)
Drowsiness	17 (53%)	17 (53%)
Nausea	8 (25%)	14 (44%)
Vomiting	2 (6%)	6 (19%)
Dizziness	3 (9%)	5 (16%)
Nasal Irritation	2 (6%)	3 (9%)
Epistaxis	2 (6%)	3 (9%)

Source: Company documents

RECRO PHARMA, INC Income Statement Fiscal Year ends December (All amounts in 000s except per share items)														
	2011A	2012A	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Dex-IN for post-operative pain (US)								-	-	-	52,983	110,787	173,742	222,014
Total revenues				-	-	-	-	-	-	-	52,983	110,787	173,742	222,014
COGS											10,597	22,157	34,748	44,403
R&D	1,828	542	544	227	1,837	3,123	4,997	10,184	19,350	20,318	22,350	24,585	27,043	29,748
SG&A	485	339	546	647	959	1,342	1,745	4,692	7,507	12,012	24,023	33,633	47,086	56,503
Total operating expenses	2,313	881	1,090	874	2,796	4,465	6,742	14,877	26,858	32,330	56,970	80,375	108,877	130,653
Operating income (EBIT)	(2,313)	(881)	(1,090)	(874)	(2,796)	(4,465)	(6,742)	(14,877)	(26,858)	(32,330)	(3,987)	30,413	64,865	91,361
Interest income		0	0	0	2	2	2	6	7	8	8	9	14	21
Grant income		85						-	-	-	-	-	-	
Interest expense	(558)	(740)	(868)	(4,273)				(4,273)						
Income before taxes	(2,871)	(1,537)	(1,958)	(5,146)	(2,794)	(4,463)	(6,740)	(19,143)	(26,851)	(32,322)	(3,978)	30,422	64,879	91,382
Provision for income taxes			-					-	-	-	-	-	6,488	27,415
Net income, GAAP	(2,871)	(1,537)	(1,958)	(5,146)	(2,794)	(4,463)	(6,740)	(19,143)	(26,851)	(32,322)	(3,978)	30,422	58,391	63,967
Accretion of redeemable convertible preferred stock	(383)	(413)	(440)	(1,270)				(1,270)						
Net income to common shareholders	(3,254)	(1,949)	(2,398)	(6,416)	(2,794)	(4,463)	(6,740)	(20,413)	(26,851)	(32,322)	(3,978)	30,422	58,391	63,967
EPS basic	\$ (20.91)	\$ (12.53)	\$ (15.41)	\$ (3.67)	\$ (0.36)	\$ (0.57)	\$ (0.86)	\$ (3.25)	\$ (2.44)	\$ (2.88)	\$ (0.35)	\$ 2.60	\$ 4.90	\$ 5.26
EPS diluted, GAAP	\$ (20.91)	\$ (12.53)	\$ (15.41)	\$ (3.67)	\$ (0.36)	\$ (0.57)	\$ (0.86)	\$ (3.25)	\$ (2.44)	\$ (2.88)	\$ (0.35)	\$ 2.44	\$ 4.59	\$ 4.94
Basic shares outstanding	156	156	156	1,750	7,708	7,785	7,863	6,276	11,008	11,228	11,452	11,681	11,915	12,153
Diluted shares outstanding	156	156	156	1,750	7,708	8,590	8,668	6,679	11,813	12,033	12,257	12,486	12,720	12,958

Source: Company documents and Brean Capital, LLC. estimates

RELATED COMPANIES

Company	Ticker	Rating	Price
Recro Pharma, Inc.	REPH	Buy	\$2.77

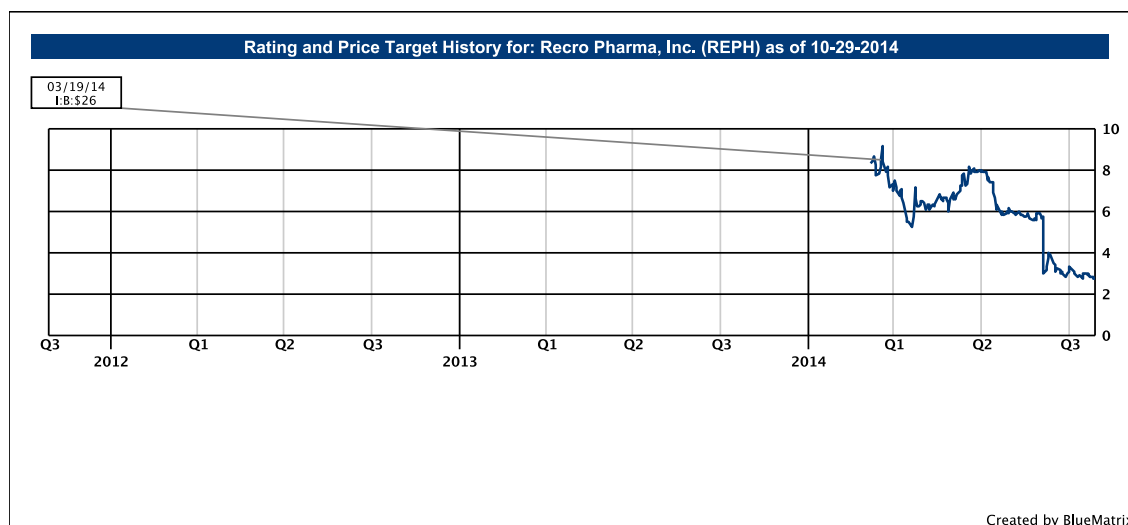
Risks

Recro Pharma, Inc. (REPH)

Risks to the achievement of our target price include market adoption risks, business development risks, competition, and high share price volatility.

Important Disclosures

Ratings and Target Price History



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Rating Category	Count	Percent	IB Serv./ Past 12Mos.	
			Count	Percent
BUY	136	76.40%	19	13.97%
HOLD	37	20.79%	1	2.70%
SELL	5	2.81%	0	0.00%
NOT RATED				

Note: Stock price volatility may cause temporary non-alignment of some ratings with some target prices.

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