Recro Pharma, Inc. May 27, 2014 (REPH/ NASDAQ)



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Management Meeting Highlights - Clinical Timelines Intact

Investment Summary

Regarding the central event for Recro, its Phase 2b bunionectomy trial, Recro reaffirmed its commitment to its 2Q14 start and 4Q14 completion, and will conduct the trial at 3 sites. An interim look (alpha spend only 0.001) will indicate whether the trial needs to enroll closer to the 200 patient range or if 150 is fine. The trial would be set up with a 90% power to see a 10% difference in SPID scores over 48 hours post-surgery, but the company indicated it should see at least a 20% difference. Given the subjectivity inherent within pain endpoints, Recro is committed to reduce variability by taking control of many trial particulars. The company will fund the bunionectomy procedures in an effort to make all 3 trial sites conform to the same surgical procedure using the same materials including everything from suture materials to the frequency of wound dressing changes. There is also a stipulated dosing regimen for intranasal dex to reduce variability.

Before Phase 2b is even complete, Recro will request its EOP2 meeting such that it can more likely have a 1Q15 meeting and start and finish both Phase 3 trials in 2015, enabling an early 2016 filing. The key intellectual property for dex has had early office actions already but it is still likely a year or 2 for patent issuances. Recro has enough cash to carry it through both Phase 3 intranasal dex trials and NDA filing in early 2016.

Discussion

Regarding the central event for Recro, its Phase 2b bunionectomy trial, Recro reaffirmed its commitment to its 2Q14 start and 4Q14 completion, and will conduct the trial at 3 sites. An interim look (alpha spend only 0.001) will indicate whether the trial (based mostly on patient response variability) needs to enroll closer to the 200 patient range or if enrollment can stay closer to 150. The trial would be set up with a 90% power to see a 10% difference in SPID scores over 48 hours post-surgery, but the company indicated it should see at least a 20% difference. There will be no background pain medication use, but rescue therapy is allowed. Use of rescue therapy will censure that patient's SPID 48 data for a few hours, and we expect there to be a clear difference in the number of rescue med administrations between the arms. There is no LOCF for such a short trial, and there would not be any sense in using LOCF because the SPID 48 is a cumulative pain score and thus the cumulative SPID value at the point of any dropout is what will be entered. Given the subjectivity inherent within pain endpoints, Recro is committed to reduce variability by taking control of many trial particulars. The company will fund the bunionectomy procedures in an effort to make all 3 trial sites conform to the same surgical procedure using the same materials including everything from suture materials to the frequency of wound dressing changes. There is also a stipulated dosing regimen for intranasal dex to reduce variability. The FDA wanted Recro to do 2 doses and placebo, and while a 50mg dose group is known, the exact lower dose is not known, but we believe it will be 40mg.

Before Phase 2b is even complete, Recro will request its EOP2 meeting such that it can more likely have a 1Q15 meeting and start and finish both Phase 3 trials in 2015, enabling an early 2016 filing. The Phase 3 trials with be comprised of one intra-abdominal soft tissue trial and another in either bunionectomy or knee replacement. Six and 9 month rat and dog studies also need to be conducted for preclinical safety requirements, as well as additional clinical trials to have enough patients on drug for an acute pain label with hopefully a 7 day treatment duration in the label. Much like is being done with great success at Pacira (PCRX \$76.22, Buy), Recro will generate generous amounts of clinical data demonstrating the benefits of intranasal dex from a pharmacoeconomic and safety perspective (no IV, no nurse, lower hospital readmission, less opioid, etc). Recro already determined in late 2012 that Orion and the FDA agreed that Precedex is not a likeability risk and thus no abuse liability trials are required. We take comfort in the fact that Precedex delivers 8-10x the dose of dex versus Recro's intranasal dex, and thus would not suspect such a lower dose to have any likeability concerns. Marketing intranasal dex would still require some P&T work, but at least Precedex has paved the way such that no new drug category need be created.

Buy

PT: \$26.00

Price \$5.6.67 52-Week High/Low \$9.88-\$5.01 Shares Out (mm) 7.7 Market Cap (mm) \$551 Avg. Daily Vol (000) NA Short Interest 0.4% EV (mm) NA EPS FY13A FY14E FY15E Mar \$(3.67)A June \$(0.25) Sept \$(0.49) Dec \$(0.86) FY (Dec) \$(15.41) \$(3.00) \$(2.19) P/E (x) NM NM NM Revenue (\$M) Mar \$0.0 Sept \$0.0 Sept \$0.0 FY (Dec) \$0.0 \$0.0 Sept \$0.0 \$ FY (Dec) \$0.0 \$0.0 Sept \$0.0 \$ FY (Dec) \$0.0 \$0.0 Source: Bloomberg								
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Source: Bloomberg		Apr	May					
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The key intellectual property for dex has had early office actions already but it is still likely a year or 2 for patent issuances. It took more than 50 formulation attempts to arrive at an effective intranasal formulation and the key patents cover formulation, PK, method of use, and analgesia without sedation, among other things. The intranasal delivery device is already approved and is used for Afrin and other drugs, so we see very little risk there. We also see negligible risk from hypotension, as mean BP drops only by 10mmHg after the first dose in healthy volunteers and only for about 15 minutes, and drops only 6mmHg in post-surgical patients (surgical procedures tend to raise BP a little). The BP drops did not require any clinical intervention.

Recro has enough cash to carry the company through both Phase 3 intranasal dex trials and NDA filing in early 2016. We believe that Phase 2b success in 4Q14 would create such a valuation inflection that Recro would capitalize upon it and raise money for dex label expansion and development of other drugs like fadolmidine. Recro's COGS at scale should approach that which is typical in spec pharma. Recro owes Orion low double digit royalties on net dex sales, and if Orion chooses to commercialize dex in its territories (Europe, Turkey, former USSR), then Orion would have to reimburse Recro almost half the clinical cost of developing dex.

RECRO PHARMA, INC															
Income Statement															
Fiscal Year ends December															
(All amounts in 000s except per share items)															
	2	011A :	2012A	2013A	1Q14A	2Q14E	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	1,021	2,554	5,107	8,910	16,928	17,775	19,552	21,507	23,658	26,024
SG&A		485	339	546	647	970	1,358	1,765	4,740	7,584	12,134	24,268	33,975	47,565	57,078
Total operating expenses		2,313	881	1,090	874	1,991	3,912	6,873	13,649	24,512	29,909	54,416	77,640	105,971	127,504
Operating income (EBIT)		(2,313)	(881)	(1,090)	(874)	(1,991)	(3,912)	(6,873)	(13,649)	(24,512)	(29,909)	(1,433)	33,148	67,771	94,510
Interest income			0	0	0	79	71	64	214	235	258	284	313	469	704
Grant income			85						-	-	-	-	-	-	
Interest expense		(558)	(740)	(868)	(4,273)				(4,273)						
Income before taxes		(2,871)	(1,537)	(1,958)	(5,146)	(1,913)	(3,841)	(6,809)	(17,709)	(24,277)	(29,650)	(1,149)	33,461	68,240	95,213
Provision for income taxes				-					-	-	-	-	-	6,824	28,564
Net income, GAAP		(2,871)	(1,537)	(1,958)	(5,146)	(1,913)	(3,841)	(6,809)	(17,709)	(24,277)	(29,650)	(1,149)	33,461	61,416	66,649
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)	(1,913)	(3,841)	(6,809)	(18,979)	(24,277)	(29,650)	(1,149)	33,461	61,416	66,649
EPS basic	\$	(20.91) \$	(12.53) \$	(15.41)	\$ (3.67)	(0.25) \$	(0.49) \$	(0.86)	\$ (3.00) \$	(2.19) \$	(2.62) \$	(0.10) \$	2.84 \$	5.12 \$	5.45
EPS diluted, GAAP	\$	(20.91) \$	(12.53) \$	(15.41)	\$ (3.67)	(0.25) \$	(0.49) \$	(0.86)	\$ (3.00) \$	(2.19) \$	(2.62) \$	(0.10) \$	2.66 \$	4.80 \$	5.11
Basic shares outstanding		156	156	156	1,750	7,763	7,840	7,919	6,318	11,086	11,308	11,534	11,764	12,000	12,240
Diluted shares outstanding		156	156	156	1,750	8,568	8,645	8,724	6,922	11,891	12,113	12,339	12,569	12,805	13,045
Source: Company documents and Brean Capital, LLC. estimates															

RELATED COMPANIES			
Company	Ticker	Rating	Price
Pacira Pharmaceuticals Inc.	PCRX	Buy	76.22
Recro Pharma, Inc.	REPH	Buy	\$6.67

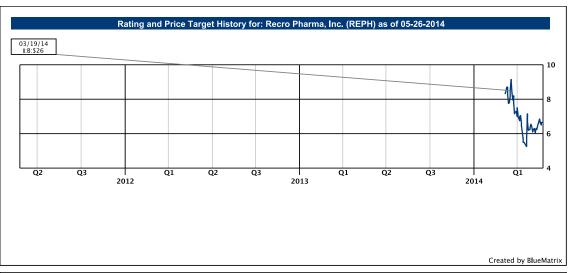
Risks

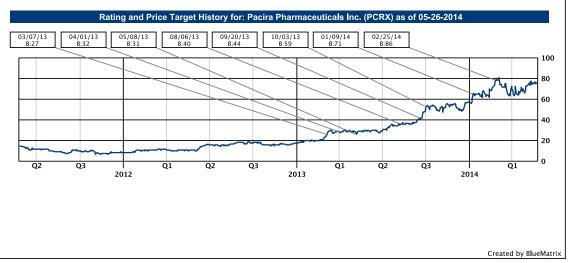
Recro Pharma, Inc. (REPH)

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





At the time this report was published, Brean Capital, LLC made a market in the securities of Recro Pharma, Inc. and Pacira Pharmaceuticals Inc. .

Recro Pharma, Inc. and Pacira Pharmaceuticals Inc. is, or within the last 12 months has been, a client of Brean Capital, LLC, and investment banking and/or advisory services are being, or have been provided.

Brean Capital, LLC has managed or co-managed a public offering or placement of securities of Recro Pharma, Inc. and Pacira Pharmaceuticals Inc. within the past 12 months.

Brean Capital, LLC expects to receive compensation for investment banking and/or advisory services from Pacira Pharmaceuticals Inc. within the next 3 months.

Brean Capital, LLC has received compensation for investment banking and/or advisory services from Recro Pharma, Inc. within the past 12 months.

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Buy - Expected to appreciate by at least 10% within the next 12 months.

Hold - Fully valued, not expected to appreciate or decline materially within the next 12 months.

Sell - Expected to decline by at least 10% within the next 12 months.

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Rating Category	Count	Percent	Count	Percent
BUY	145	72.86%	21	14.48%
HOLD	49	24.62%	3	6.12%
SELL	5	2.51%	0	0.00%
NOT RATED				

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

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.

Analyst Certification

We, Jonathan Aschoff and Yi Cheng, hereby certify that the views expressed in this research report accurately reflect our personal views about any and all of the subject securities or issuers referred to in this document. The analyst and associate analyst further certify that they have not received and will not be receiving direct or indirect compensation in exchange for expressing the recommendation contained in this publication.

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