

Repros Therapeutics (RPRX -\$19.62)

Commencement of Androxal Comparative Phase III Studies

RPRX announced this morning the commencement of two identical head to head, placebo-controlled Phase III studies (304 and 305) of Androxal versus a leading topical testosterone gel (we believe it is AndroGel 1.62%).

- Details:** Each study will enroll 120 men and randomize equally (40/each) into three parallel arms: Androxal, AndroGel and placebo. All three arms will be blinded and "double dummied" as all patient will receive both an active dose and a placebo mimicking the other active; while placebo will receive two placebos, one for each active. Study duration is 17 weeks (16 weeks dosing and 1 week follow-up). Androxal group will receive 12.5 mg initially and could be up titrated to 25mg on week 4 if T level does not reach 450 ng/dl. AndroGel group could also be re-adjusted on week 2 (<350 ng/dl) and/or week 4. Eligible patient must exhibit morning T level of <300 ng/dl. Primary endpoint is the comparison of Androxal vs. AndroGel on 1) normalized testicular function based on 24 hour average T levels in the normal range (300-1040 ng/dL); and 2) sperm counts at the end of the study remain above the lower bound of the 95% confidence interval for normal male fertility (15 million/mL). The study is 90% powered for an alpha=0.05, with assumption on responder analysis of 20%, 35% and 70% for placebo AndroGel and Androxal, respectively. The studies are conducted at 23 clinical sites across the U.S. (301 and 302 were with ~40% from Florida) Topline results are expected by October 2014 (without interim data reporting) with NDA filing scheduled in Q4 2014.
- Implications:** We view the initiation of the two comparative studies a major positive event as potential success could provide possible superiority claim of sperm restoration over other TRTs on product label. We believe study design of the two trials is appropriate and with lower hurdle based on positive outcome from multiple prior studies (especially study 203).
- Action:** We are reiterating our Buy rating and reiterating our \$32 target price to reflect the improved outlook of Androxal and maturation of Proellex development. Valuation is based on our P/E, and NPV-driven-and-probability adjusted sum-of-the-parts analyses.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.28	-0.28	-0.28	-0.24	-1.08	-18.3
FY-13E	-0.41A	-0.38A	-0.26A	-0.26	-1.28	-15.4
FY-12A	-0.17	-0.21	-0.30	-0.47	-1.18	NM
FY-11A	-0.20	-0.30	-0.32	-0.22	-1.04	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **RPRX**
 Rating: **Buy**
 Price Target: **\$ 32.00**

Trading Data:

Last Price (1/8/2014)	\$ 19.74
52-Week High (9/24/2013)	\$ 29.79
52-Week Low (3/20/2013)	\$ 8.42
Market Cap. (MM)	\$344
Shares Out. (MM)	23

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Income Statement

Repos Therapeutics – Income Statement

(\$ MM)	2011	2012	1Q13	2Q13	3Q13	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E
Revenue																
Licensing fees	-	-	-	-	-	-	-	-	-	-	-	-	-	10.0	10.0	10.0
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	61.4	136.4	260.8
Research and development grants	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest income	0.0	0.0	-	0.0	0.0	-	0.0	-	-	-	-	-	-	-	-	-
Gain on disposal of fixed assets	-	-	0.0	-	-	-	0.0	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$71.4	\$146.4	\$270.8
Costs of goods																
Gross revenue													0.0	6.1	13.6	26.1
Research and development	8.7	13.3	6.3	6.0	4.8	4.9	22.0	5.1	5.2	5.2	4.2	19.6	12.2	12.5	13.8	15.0
General and administrative					1.2	1.2	4.7	1.4	1.5	1.6	1.6	6.0	7.2	10.8	11.9	12.0
Sales and marketing										0.0	0.0	0.0	5.0	24.7	28.3	32.6
Interest expense and amortization of intangibles																
Total Operating Expenses	\$12.5	\$18.2	\$7.4	\$7.2	\$6.0	\$6.1	\$26.7	\$6.4	\$6.7	\$6.7	\$5.8	\$25.6	\$24.4	\$48.0	\$25.7	\$27.0
Operating Income (loss)	(\$12.5)	(\$18.2)	(\$7.4)	(\$7.2)	(\$6.0)	(\$6.1)	(\$26.7)	(\$6.4)	(\$6.7)	(\$6.7)	(\$5.8)	(\$25.6)	(\$24.4)	\$17.2	\$107.1	\$217.7
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(12.5)	(18.2)	(7.4)	(7.2)	(6.0)	(6.1)	(26.7)	(6.4)	(6.7)	(6.7)	(5.8)	(25.6)	(24.4)	17.2	107.1	217.7
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(7.4)	(7.2)	(6.0)	(6.1)	(26.7)	(6.4)	(6.7)	(6.7)	(5.8)	(25.6)	(24.4)	17.2	107.1	217.7
Income tax expense	-	-	-	-	-	-	-	-	-	-	-	-	-	5.9	36.4	74.0
Net Incomes (Losses)	(\$12.5)	(\$18.2)	(\$7.4)	(\$7.2)	(\$6.0)	(\$6.1)	(\$26.7)	(\$6.4)	(\$6.7)	(\$6.7)	(\$5.8)	(\$25.6)	(\$24.4)	\$11.4	\$70.7	\$143.7
Net Earnings (Losses) Per Share—Basic	(\$1.04)	(\$1.18)	(\$0.41)	(\$0.38)	(\$0.26)	(\$0.26)	(\$1.28)	(\$0.28)	(\$0.28)	(\$0.28)	(\$0.24)	(\$1.08)	(\$1.01)	\$0.46	\$2.84	\$5.68
Net Earnings (Losses) Per Share—Diluted	(\$1.04)	(\$1.18)	(\$0.41)	(\$0.38)	(\$0.26)	(\$0.26)	(\$1.28)	(\$0.28)	(\$0.28)	(\$0.28)	(\$0.24)	(\$1.08)	(\$1.01)	\$0.46	\$2.84	\$5.68
Shares outstanding—basic	12.0	15.3	18.2	19.0	23.0	23.2	20.8	23.4	23.6	23.8	24.0	23.7	24.1	24.5	24.9	25.3
Shares outstanding—diluted	12.0	15.3	18.2	19.0	23.0	23.2	20.8	23.4	23.6	23.8	24.0	23.7	24.1	24.5	24.9	25.3
Margin Analysis (% of Revenue)																
COGS								N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%	10%
R&D	434100%	444767%	630800%	603700%	159533%	N.A.	440254%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	18%	9%	6%
SG&A	190550%	160900%	106700%	117100%	40500%	N.A.	93846%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	15%	8%	4%
Operating Income (loss)	-624550%	-605567%	-737400%	-720700%	-199933%	N.A.	-534000%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	24%	73%	80%
Pretax	0%	0%	-737400%	-720700%	-199933%	N.A.	0%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	0%	0%	0%
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	34%	34%	34%
Net Income	-624550%	-605567%	-737400%	-720700%	-199933%	N.A.	-534000%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	16%	48%	53%
Financial Indicator Growth Analysis (Y/Y)																
Licensing fees	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	0%	0%
Product royalties	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	122%	91%
Research and development grants	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	0%	0%	0%	0%
Interest income	N.A.	50%	N.A.	N.A.	200%	-100%	33%	N.A.	-100%	-100%	N.A.	-100%	0%	0%	0%	0%
Total Revenue	-100%	50%	N.A.	N.A.	200%	-100%	67%	-100%	-100%	-100%	N.A.	-100%	N.A.	N.A.	105%	85%
Research and development	199%	54%	330%	177%	53%	-26%	65%	-20%	-14%	8%	-14%	-11%	-38%	3%	10%	9%
General and administrative	67%	27%	10%	27%	-16%	-16%	-3%	28%	28%	28%	27%	28%	20%	50%	10%	1%
Sales and marketing												N.A.	0%	393%	15%	15%
Operating incomes	162%	45%	202%	132%	31%	-24%	47%	-13%	-7%	13%	-6%	-4%	-5%	-171%	522%	103%
Total Other Income, net	162%	45%	202%	132%	31%	-24%	47%	-13%	-7%	13%	-6%	-4%	-5%	-171%	522%	103%
Pretax Income	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	162%	45%	202%	132%	31%	-24%	47%	-13%	-7%	13%	-6%	-4%	-5%	-147%	522%	103%
EPS - Basic	76%	13%	133%	82%	-12%	-44%	8%	-32%	-26%	9%	-9%	-16%	-7%	-146%	512%	100%
EPS - Diluted	76%	13%	133%	82%	-12%	-44%	8%	-32%	-26%	9%	-9%	-16%	-7%	-146%	512%	100%
Shares outstanding—basic	48%	28%	30%	28%	49%	35%	36%	29%	25%	3%	3%	14%	2%	2%	2%	2%
Shares outstanding—diluted	48%	28%	30%	28%	49%	35%	36%	29%	25%	3%	3%	14%	2%	2%	2%	2%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
11/19/2013	Buy (B)	14.59

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
11/19/2013	32.00	14.59

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	90.91%	36.36%	9.09%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	9.09%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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