

Repros Therapeutics (RPRX -\$15.01)

FDA Meeting in Feb. 2014 to Clarify Phase III Clinical Path

RPRX announced this morning the FDA will conduct a face to face meeting with the company to discuss the pivotal Androxal efficacy studies. RPRX is expected to submit the final clinical study reports to the agency prior to the meeting.

- Details:** Given the issues raised by the FDA in Oct. '13 regarding the sperm count data from one of the clinical site (site 9) of the 301 study, RPRX would likely to gain more guidance from the Feb. 2014 meeting for the value of the two completed studies (301 and 302) and the proposed comparative studies (vs. marketed testosterone gel). Discussion is likely within a context of unmet need in testosterone levels restoration and spermatogenesis suppression by marketed TRT products; and what could be the best clinical approach addressing these issues. RPRX will invite two KOLs, Drs. Wayne Hellstrom and Edward Kim from the Tulane University and University of Tennessee, respectively to participate for discussing current hypogonadism treatment issues. RPRX expects to report the outcome of the meeting before the end of February 2014.
- Implications:** This highly expected meeting with the FDA, in our opinion, could potentially clarify Androxal's clinical path via assessing the potential value of the completed studies (301 and 302), the proposed comparative studies, and all safety studies (300 and 303) within final potential approval package. We believe positive comparative studies (which we believe is with lower hurdle based on positive outcome from multiple prior studies) would likely provide Androxal a superiority claim on sperm production preservation on its product label. Such scenario could have high commercial value regarding market potential and sales ramp up. Further, we believe agency's potential clearer opinion (or expectation) on Androxal pivotal trial could provide prospective partners a better understanding in making their future decisions.
- Action:** We are reiterating our Buy rating and target price of \$32 which reflects 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.

Healthcare/Biotechnology

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

Trading Data:

Last Price (11/24/2013)	\$ 15.18.
52-Week High (9/24/2013)	\$ 29.79.
52-Week Low (3/20/2013)	\$ 8.42.
Market Cap. (MM)	\$344
Shares Out. (MM)	23

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.28	-0.28	-0.28	-0.24	-1.08	NM
FY-13E	-0.41A	-0.38A	-0.26A	-0.26	-1.28	NM
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

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Source: Laidlaw & Company estimates

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Income Statement

Repros 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	3.8	4.8	1.1	1.2	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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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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