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EQUITY RESEARCH
Company Report

May 8, 2014

Repros Therapeutics (RPRX - $ 15.72)

Healthcare/Biotechnology

Additional Trial Design Information Reported Regarding the ZA-304 / 305 Phase III Studies.

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

RPRX reported additional information regarding the ongoing ZA-304 / 305 Phase III study at an investor conference meeting today to provide more details on the powering assumption of both the primary and secondary endpoints.

- **Details.** The two sperm co-primary endpoints are to compare Androxal vs. AndroGel after 16 weeks of treatment; and both endpoints are expected to demonstrate superiority of Androxal over AndroGel. The first is the proportion of subjects whose semen concentrations are below 10 $X10^6$/mL with 10% vs. 50% assumption and powered at 98.6%. The second is the percentage change from baseline in semen concentration with -5% vs. -65% assumption and powered at 80% (Figure 1). Secondary efficacy comparison endpoints include change in LH and FSH from baseline; 24-hr average T level of Androxal vs. placebo; impact on testosterone levels one week after treatment stoppage; and impact on hematocrit. RPRX reiterated being on track for reporting top-line results and NDA filing in mid- (Oct.) and late 4Q14, respectively. For the fully enrolled ZA-305 study (n=127), the mean and median baseline morning testosterone level were 216.2 and 214 ng/dL, respectively; and mean and median baseline sperm concentration were 78 and 61.3 million/mL, respectively.

- **Implications.** We view the more detailed information regarding the 304/305 study endpoint is informative and affords more visibility of the ongoing studies. A comparison of percentages of sperm concentration changes from prior Androxal clinical studies (ZA-301, 302 and 203) also afford a good perspective (Figure 3). We reiterate our positive outlook for successful 304/305 study based on prior studies that have consistently demonstrated the disparity of sperm impact between Androxal and TRTs.

- **Action.** We are reiterating our Buy rating and our $32 target price to reflect the continued improved outlook of Androxal and the maturation of Proellex development. Our valuation is based on our P/E, and NPV-driven-and-probability adjusted sum-of-the-parts analyses

Trading Data:

Last Price (05/08/2014)	$ 15.72
52–Week High (9/24/2013)	$ 29.79
52–Week Low (4/15/2014)	$ 13.93
Market Cap. (MM)	$ 363
Shares Out. (MM)	23

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.32	-0.33	-0.33	-0.28	-1.27	NM
FY-13A	-0.41	-0.38	-0.26	-0.31	-1.33	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

Source: Laidlaw & Company estimates

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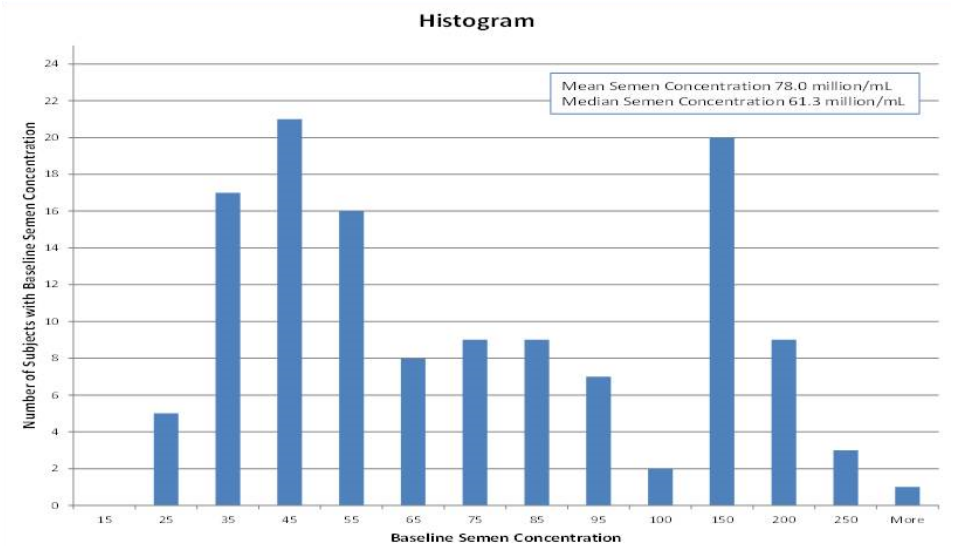
Figure 1: ZA /305 efficacy endponts

Endpoint Class	Endpoint	Goal	Powering
Primary	% of subjects with sperm concentration <10X10^6/mL Comparing Androxal to Androgel 1.62%	Show Androxal superior to Androgel	10% vs 50% 98.6%
	% change from baseline comparing Androxal to Androgel 1.62%	Show Androxal superior to Androgel	-5% vs -65%, SD=85 80% power
Secondary	change from baseline for LH comparing Androxal to Androgel 1.62%	Show Androxal superior to Androgel from perspective of no negative effect on pituitary secretions. One of two mechanisms of exogenous T suppression of pituitary and testicular function	3.6 vs -2.4, SD=5 100% power
	change from baseline for FSH comparing Androxal to Androgel 1.62%	Show Androxal superior to Androgel from perspective of no negative effect on pituitary secretions. One of two mechanisms of exogenous T suppression of pituitary and testicular function	3.7 vs -4, SD=5 100% power
	Responder analysis assessing % of men within normal range for 24-hr avg T and sperm count >15X10^6/mL comparing Androxal to Androgel 1.62%	Show Androxal superior to Androgel in normalizing testicular function	30% vs 70% 95.7% power
	Comparison of Androxal to placebo for 24 hr average T	Androxal to be superior	400 vs 245, SD=160 99%
	Comparison of Androxal to Androgel 1.62% regarding morning T one week post end of active dosing period	Show suppression of testicular function by Androgel as a result of suppressed pituitary function. Androxal expected to be superior to Androgel	440 vs 300, SD = 180 93% power
	Comparison of Androxal to Androgel 1.62% for effect on raising hematocrit by end of study	Show Androxal is superior to Androgel regarding elevations of hematocrit. This is a key safety parameter and demonstrates less risk for Androxal in clinical practice	1.2 vs 2.6, SD=2.9 Power = 56.8, 80% power if Androxal is 1.06 instead

Source: Company presentation

Figure 2: ZA /305 baseline sperm concentration



Source: Company presentation

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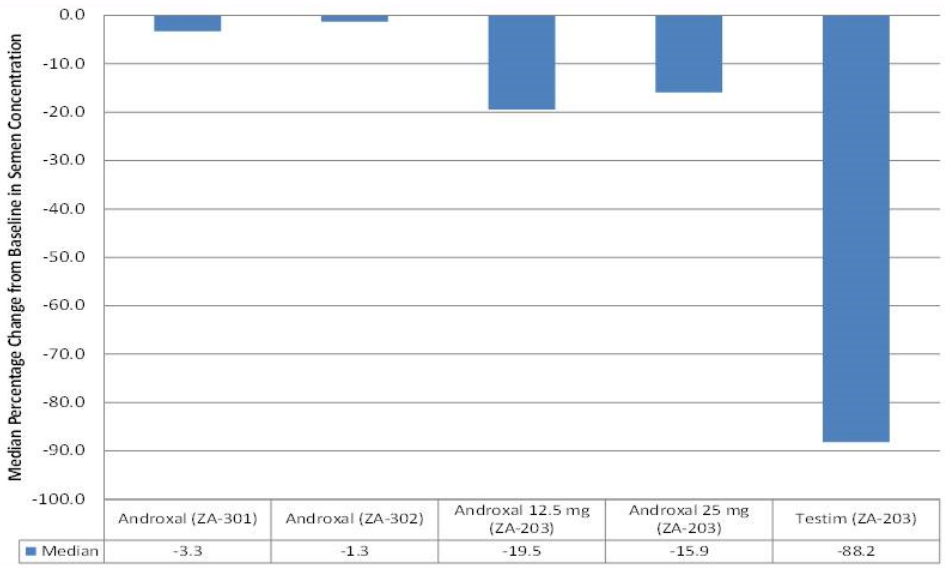
Figure 3: Percentages of sperm concentration changes of prior clinical studies



Source: Company presentation

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Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	Potential pre-NDA meeting with the FDA	**June '14**	****
		Potential report ZA-303 DEXA safety study data	**4Q14**	****
		Potential report ZA-300 12 months safety study data	**3Q14**	****
		Potential to release Phase III comparative studies results	**4Q (Oct.) '14**	*****
		Potential NDA filing	**4Q14**	****
		FDA expert panel meeting	**3Q15**	*****
		Potential partnership or other business development activities	**2014 / 2015**	*****
		Potential approval for 2nd hypogonadism	**4Q15 / 1Q16**	*****
Proellex	Uterine Fibroids	Potentially to commence low dose oral Proellex Phase II study	**Mid-14**	***
		Potentially to report top-line results from low dose oral Proellex Phase II study	**2H15**	***
		Potentially to determine low dose oral vs. vaginal Proellex as final format for Phase III trial	**2H15**	****
		Potentially to start a Phase III study	**2015**	*****
	Endometriosis	Possible to complete patient enrollment for Phase II study	**Late 14 / 2015**	***
		Possible to report Phase II study top-line results	**2H15**	****

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation

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Major risks

Clinical risks of trial study failure could have significantly negative impact on RPRX share value. Given that Androxal in secondary hypogonadism is the most advanced and most promising program in Repros' product portfolio, we believe the majority of RPRX share valuation (both assessed by us and the Street) resides in the potential clinical and regulatory success of this program. Despite a lower probability of clinical failure, in our opinion, a scenario that if the FDA requests significantly more difficult Phase III studies at the upcoming meeting and the company cannot accomplish such a task; could significantly reduce RPRX share value. As such, we view the outcome from the FDA discussion and report of the top-line results from the pivotal comparative trials (possibly in 4Q14) could be important binary events for RPRX shares.

Market potential of Androxal in secondary hypogonadism is lower than projected. With well-differentiated attributes, such as retaining spermatogenesis compared to marketed testosterone replacement products, coupled with the trend of increased prescription, and substantial unmet medical need; we believe the commercial outlook of Androxal could be substantial. However, given Androxal is a non-testosterone and competes in an environment of a well-entrenched TRT treatment paradigm, substantial and effective education efforts, in our opinion, are necessary to change physicians' prescribing habits and expand Androxal sales. The potential patent expiration of AndroGel could be an opportunity for Androxal but it also could become a challenge that limits Androxal's pricing flexibility. Overall, if our projection for the future market dynamics is incorrect, or the execution by the company (given the current management team has limited product commercialization experience), or potential licensing partner is inadequate; the revenue outlook for Androxal could disappoint.

Androxal patent dispute could potentially affect the economics RPRX receives. The company is currently in a legal dispute with Dr. Harry Fisch, who claims the two patents encompassing clomid as a treatment for hypogonadism. Despite the fact that the U.S. Patent and Trademark Office (PTO) recently reversed the rejections of Dr. Fisch's patent infringement claims, it might be too early or too uncertain, in our opinion, to determine the ultimate resolution. If such patents are not invalidated by the PTO or a court of competent jurisdiction, the company may be required to obtain a license, potentially for a fee, from the holder of such patents in order to develop Androxal further. Although we do not anticipate such a scenario would derail the development or commercial outlook of Androxal, we believe the economic reward to the company would be reduced modestly.

Although promising, low dose Proellex and Proellex-V must still demonstrate proof-of-concept results. Although the current clinical data regarding efficacy and safety from the low-dose oral Proellex and newly-

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developed Proellex-V study are encouraging, it is still be too early to fully project the product's future in endometriosis and in uterine fibroids. In addition, it is still uncertain as which format of Proellex would be used for UF development going forward. Further, low dose oral Proellex in endometriosis Phase II study is still ongoing and we believe a positive efficacy and satisfactory safety profile are needed from the study to potentially to fully lift the clinical hold by the FDA to advance the program. Any negative outcomes could also a setback despite Proellex only accounts for a minor portion of the RPRX valuation.

Potential financing could dilute shareholders. Although we estimate that the company's cash position could support operations, including R&D and M&S expenses, into 2016; the possibility exists that additional cash could be needed for other unexpected corporate development activities. If not from the non-dilutive sources, options could include a potentially-dilutive equity offering, of which could potentially affect current shareholders negatively due to dilution. However, we view such risk could be offset by the substantial value increase of the company's assets due to clinical advancement leading to commercialization.

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Figure 1: Income Statement

Repros Therapeutics – Income Statement

($ MM)	2011	2012	2013	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	-	-	-	-	-	-	-	-	-
Gain on disposal of fixed assets	-	-	0.0	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	$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									0.0	6.1	13.6	26.1
Gross revenue									0.0	65.2	132.8	244.7
Research and development	8.7	13.3	22.9	6.0	6.2	6.2	5.0	23.3	14.5	14.9	16.4	17.9
General and administrative	3.8	4.8	4.8	1.5	1.7	1.7	1.7	6.6	7.9	11.9	13.1	13.2
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	$27.7	$7.5	$7.8	$7.9	$6.7	$29.9	$27.4	$51.4	$29.5	$31.1
Operating Income (loss)	($12.5)	($18.2)	($27.7)	($7.5)	($7.8)	($7.9)	($6.7)	($29.9)	($27.4)	$13.8	$103.3	$213.7
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(12.5)	(18.2)	(27.7)	(7.5)	(7.8)	(7.9)	(6.7)	(29.9)	(27.4)	13.8	103.3	213.7
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(27.7)	(7.5)	(7.8)	(7.9)	(6.7)	(29.9)	(27.4)	13.8	103.3	213.7
Income tax expense	-	-	-	-	-	-	-	-	-	4.7	35.1	72.6
Net Incomes (Losses)	($12.5)	($18.2)	($27.7)	($7.5)	($7.8)	($7.9)	($6.7)	($29.9)	($27.4)	$9.1	$68.2	$141.0
Net Earnings (Losses) Per Share—Basic	($1.04)	($1.18)	($1.33)	($0.32)	($0.33)	($0.33)	($0.28)	($1.27)	($1.15)	$0.37	$2.76	$5.62
Net Earnings (Losses) Per Share—Diluted	($1.04)	($1.18)	($1.33)	($0.32)	($0.33)	($0.33)	($0.28)	($1.27)	($1.15)	$0.37	$2.76	$5.62
Shares outstanding—basic	12.0	15.3	20.8	23.2	23.4	23.6	23.8	23.5	23.9	24.3	24.7	25.1
Shares outstanding—diluted	12.0	15.3	20.8	23.2	23.4	23.6	23.8	23.5	23.9	24.3	24.7	25.1
Margin Analysis (% of Revenue)												
COGS				N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%	10%
R&D	434100%	444767%	254578%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	21%	11%	7%
SG&A	190550%	160900%	53533%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	17%	9%	5%
Operating Income (loss)	-624550%	-605567%	-308011%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	19%	71%	79%
Pretax	0%	0%	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%	34%	34%	34%
Net Income	-624550%	-605567%	-308011%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	13%	47%	52%
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.	0%	0%
Product royalties	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.	0%	0%	0%	0%
Interest income	N.A.	50%	167%	N.A.	-100%	-100%	-100%	-100%	0%	0%	0%	0%
Total Revenue	-100%	50%	200%	-100%	-100%	-100%	-100%	-100%	N.A.	N.A.	105%	85%
Research and development	199%	54%	72%	-4%	2%	29%	-14%	2%	-38%	3%	10%	9%
General and administrative	67%	27%	0%	41%	41%	41%	27%	37%	20%	50%	10%	1%
Sales and marketing								N.A.	0%	393%	15%	15%
Operating incomes	162%	45%	53%	2%	8%	31%	-6%	8%	-9%	-150%	650%	107%
Total Other Income, net	162%	45%	53%	2%	8%	31%	-6%	8%	-9%	-150%	650%	107%
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.
Net Income	162%	45%	53%	2%	8%	31%	-6%	8%	-9%	-133%	650%	107%
EPS - Basic	76%	13%	13%	-20%	-12%	28%	-9%	-5%	-10%	-133%	638%	104%
EPS - Diluted	76%	13%	13%	-20%	-12%	28%	-9%	-5%	-10%	-133%	638%	104%
Shares outstanding—basic	48%	28%	36%	28%	23%	3%	3%	13%	2%	2%	2%	2%
Shares outstanding—diluted	48%	28%	36%	28%	23%	3%	3%	13%	2%	2%	2%	2%

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

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Additional information available upon request.

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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.	86.67%	33.33%	13.33%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	6.67%	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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