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EQUITY RESEARCH
Company Report

August 28, 2014

Repros Therapeutics (RPRX - $ 18.21)

Healthcare/Biotechnology

Robust ZA-305 Results Bode Well for 304 Study Outcome and Potential Approval Going Forward.

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

Yesterday after market close, RPRX reported robust ZA-305 top-line results as the study met all primary endpoints and several secondary endpoints. RPRX is scheduled to host a conference call today at 9:00am for more details (dial-in #: 855-218-1790).

- **Details.** RPRX reported robust top-line results of the ZA-305 study as the study met primary endpoints demonstrating Androxal is superior to a topical gel (AndroGel) in percent change from baseline in average sperm concentration and percent of subjects considered to be responders. Specifically, for the average sperm concentration changes from baseline, both Androxal and placebo demonstrated no changes (6% increase and 2% reduction, respectively); while AndroGel group exhibited a 33% reduction. P values were 0.0007 and 0.0004 by comparing baseline and Androxal, respectively. As for the responder analysis, the proportion of subjects responding to Androxal was statistically significantly greater than the proportion responding to both AndroGel and placebo (successful responders were 66% vs. 33% and 7%, respectively) with p=0.0047 (vs. AndroGel) and <0.0001 (vs. placebo). Patients were deemed a failure if their mean sperm concentration was under 10 million/mL or their average 24 hour serial T did not fall within the normal range. In addition, testosterone elevation by Androxal is slightly better than AndroGel and the positive effect by Androxal treatment were maintained one week post treatment. The safety profile is satisfactory and single SAE was deemed not associated with study medication.

- **Implications.** We are very encouraged by the robust results and believe this bodes well for a positive outcome of the 304 trial and potential approval going forward. We are particularly impressed by the study meeting the responder composite endpoint as it potentially implies that Androxal is overall better than TRT with a possibly more compelling commercial outlook.

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

Trading Data:

Last Price (08/27/2014)	$ 18.21
52–Week High (9/24/2013)	$ 29.79
52–Week Low (8/1/2014)	$ 12.61
Market Cap. (MM)	$ 421
Shares Out. (MM)	23

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.37A	-0.38A	-0.35	-0.29	-1.40	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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- ZA-305 is a randomized, double blind; placebo-controlled Phase III study that expects to enroll 127 secondary hypogonadism patients with 117 completing the study. In the study, 44, 42 and 41 patients were randomized to Androxal, AndroGel 1.62, and placebo, respectively. The mean age of the three groups was 47, 45 and 48 years; and baseline BMI was 33.8, 33.1 and 33.5, respectively. Eligible patients are men (⩽ 60 years of age) that exhibited sperm counts in the normal range at baseline (> 15 million/mL) on two separate days separated by at least two days; and also exhibited morning testosterones of < 300 ng/dL on both of those days. Figure 1 illustrates results of first primary efficacy endpoint of the percent change from baseline in sperm concentration.

Figure 1: Sperm concentration in ITT population

	Baseline Concentration (million/mL)		End of Study Concentration (million/mL)		Percentage Change from Baseline (%)		Different from Baseline	Different from Androxal
	Mean (SD)	Median (Min, Max)	Mean (SD)	Median (Min, Max)	Mean (SD)	Median (Min, Max)	p-value	p-value
Androxal	79 (55)	61 (20, 245)	87 (71)	68 (9, 355)	14 (55)	**6** (-74, 197)	0.182	
Topical T	75 (46)	65 (23, 226)	45 (42)	39 (0, 176)	-30 (61)	**-33** (-100, 174)	0.0007	0.0004
Placebo	80 (62)	54 (27, 343)	71 (48)	69 (9, 235)	7 (87)	**-2** (78, 479)	0.5834	0.2042

Source: Company presentation

- The second primary efficacy endpoint was a comparison of the proportion of subjects deemed a success for both testosterone and sperm concentration (Figure 2). Figure 3 and 4 illustrate the impact of testosterone elevation by different treatment group.

Figure 2: Composite responder endpoint in ITT population

	Success n (%)	Failure n (%)	p-value vs Androxal
Androxal	29 (**65.9**)	15 (**34.1**)	
Topical T	14 (**33.3**)	28 (**66.7**)	0.0047
Placebo	3 (7.3)	38 (92.7)	< 0.0001

Source: Company presentation

Figure 3: Morning testosterone in the ITT population

	Baseline		Week 16		One Week Post Dosing	
	Mean (SD)	Median (Min, Max)	Mean (SD)	Median (Min, Max)	Mean (SD)	Median (Min, Max)
Androxal	213 (48)	**208** (79, 297)	416 (149)	**390** (168, 896)	371 (123)	**360** (81, 654)
Topical T	230 (44)	**237** (147, 299)	373 (238)	**284** (117, 1150)	183 (77)	**180** (38, 416)
Placebo	206 (48)	**197** (110, 299)	214 (58)	**211** (120, 353)	246 (135)	**226** (121, 984)

Source: Company presentation

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Figure 4: 24-hour average testosterone concentration in the ITT population

	Week 16 24-hour Average T (ng/dL)		
	Mean (SD)	**Median (Min, Max)**	**p-value vs Androxal**
Androxal	376 (134)	382 (167, 896)	
Topical T	385 (244)	308 (153, 1,534)	
Placebo	202 (53)	190 (113, 346)	< 0.0001

Source: Company presentation

- In addition, the change of FSH (follicle stimulating hormone) and LH (luteinizing hormone) is consistent with the mechanism of action of Androxal by comparing to the results from study group of AndroGel 1.62, and placebo (Figure 5). The size of testes change is also consistent with negative impact of AndroGel (Figure 6).

Figure 5: Impact of treatment on LH and FSH

	Baseline (mIU/mL)		End of 16 Week Dosing (mIU/mL)		
	LH Median (Min, Max)	**FSH Median (Min, Max)**	**LH Median (Min, Max)**	**FSH Median (Min, Max)**	**p-value vs. Androxal LH / FSH**
Androxal	3.2 (1.0, 7.5)	4.7 (1.0, 14.5)	6.7 (2.7, 34.7)	8.8 (2.9, 28.9)	
Topical T	3.4 (1.2, 6.8)	3.8 (0.9, 11.0)	1.4 (0.0, 6.1)	2.1 (0.0, 5.9)	< 0.0001 / < 0.0001
Placebo	3.1 (1.2, 9.5)	4.3 (1.0, 9.6)	3.3 (1.3, 11.7)	4.0 (1.2, 10.5)	

Source: Company presentation

Figure 6: Testicular volume by Orchidometry

	Testicular Volume by Orchidometry (cm^3)		
	Baseline Volume Mean (SD)	**End of 16 Week Volume Mean (SD)**	**p-value vs. Androxal**
Androxal	19.1 (5.5)	19.4 (5.2)	
Topical T	19.6 (6.5)	18.6 (6.3)	0.026
Placebo	19.3 (5.7)	19.8 (5.4)	

Source: Company presentation

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Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	Potential to release 2nd Phase III (304) 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	**3Q14**	***
		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**	****
		Analyst Day	**Oct. 31, 2014**	***

***** / ***** 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 although 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	1Q14	2Q14	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	-	-	-	-	-	-	-	-	-
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	7.3	7.5	6.9	5.6	27.3	16.9	17.4	19.2	20.9
General and administrative	3.8	4.8	4.8	1.2	1.3	1.3	1.3	5.1	6.1	9.2	10.1	10.2
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	$8.6	$8.7	$8.2	$6.9	$32.4	$28.1	$51.3	$29.3	$31.1
Operating Income (loss)	($12.5)	($18.2)	($27.7)	($8.5)	($8.7)	($8.2)	($6.9)	($32.4)	($28.1)	$13.9	$103.5	$213.6
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)	(8.5)	(8.7)	(8.2)	(6.9)	(32.4)	(28.1)	13.9	103.5	213.6
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(27.7)	(8.5)	(8.7)	(8.2)	(6.9)	(32.4)	(28.1)	13.9	103.5	213.6
Income tax expense	-	-	-	-	-	-	-	-	-	4.7	35.2	72.6
Net Incomes (Losses)	($12.5)	($18.2)	($27.7)	($8.5)	($8.7)	($8.2)	($6.9)	($32.4)	($28.1)	$9.2	$68.3	$141.0
Net Earnings (Losses) Per Share—Basic	($1.04)	($1.18)	($1.33)	($0.37)	($0.38)	($0.35)	($0.29)	($1.40)	($1.19)	$0.38	$2.79	$5.68
Net Earnings (Losses) Per Share—Diluted	($1.04)	($1.18)	($1.33)	($0.37)	($0.38)	($0.35)	($0.29)	($1.40)	($1.19)	$0.38	$2.79	$5.68
Shares outstanding—basic	12.0	15.3	20.8	23.0	23.1	23.3	23.5	23.2	23.6	24.0	24.4	24.8
Shares outstanding—diluted	12.0	15.3	20.8	23.0	23.1	23.3	23.5	23.2	23.6	24.0	24.4	24.8
Margin Analysis (% of Revenue)												
COGS				N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%	10%
R&D	434100%	444767%	254578%	366250%	372500%	N.A.	N.A.	1365779%	N.A.	24%	13%	8%
SG&A	190550%	160900%	53533%	61300%	62800%	N.A.	N.A.	255377%	N.A.	13%	7%	4%
Operating Income (loss)	-624550%	-605567%	-308011%	-427450%	-435200%	N.A.	N.A.	-1621056%	N.A.	20%	71%	79%
Pretax	0%	0%	0%	-427450%	-435200%	N.A.	N.A.	-1621056%	N.A.	0%	0%	0%
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	34%	34%	34%
Net Income	-624550%	-605567%	-308011%	-427450%	-435200%	N.A.	N.A.	-1621056%	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%	-75%	0%	0%	0%	0%
Total Revenue	-100%	50%	200%	100%	100%	-100%	-100%	-78%	-100%	N.A.	105%	85%
Research and development	199%	54%	72%	16%	23%	45%	-3%	19%	-38%	3%	10%	9%
General and administrative	67%	27%	0%	15%	7%	8%	-3%	6%	20%	50%	10%	1%
Sales and marketing								N.A.	0%	393%	15%	15%
Operating incomes	162%	45%	53%	16%	21%	37%	-3%	17%	-13%	-150%	643%	106%
Total Other Income, net	162%	45%	53%	16%	21%	37%	-3%	17%	-13%	-150%	643%	106%
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%	16%	21%	37%	-3%	17%	-13%	-133%	643%	106%
EPS - Basic	76%	13%	13%	-8%	-1%	36%	-5%	5%	-15%	-132%	630%	103%
EPS - Diluted	76%	13%	13%	-8%	-1%	36%	-5%	5%	-15%	-132%	630%	103%
Shares outstanding—basic	48%	28%	36%	27%	22%	1%	2%	12%	2%	2%	2%	2%
Shares outstanding—diluted	48%	28%	36%	27%	22%	1%	2%	12%	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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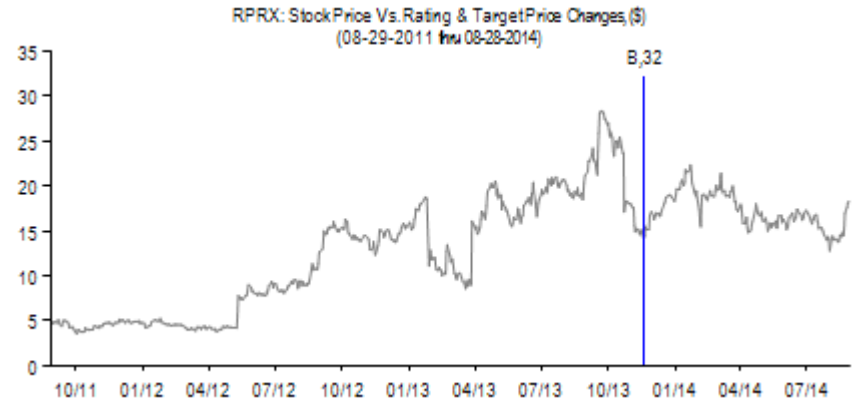
Rating and Price Target Change History



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.	94.74%	31.58%	10.53%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.26%	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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NOTES:

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