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EQUITY RESEARCH
Company Report

September 29, 2014

Repros Therapeutics (RPRX - $ 10.48)

Healthcare/Biotechnology

Robust ZA-304 Results and a Type-B Pre-NDA Meeting with FDA is Scheduled in November 2014

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

Late last week, RPRX reported robust ZA-304 top-line results as the study met all primary endpoints and several secondary endpoints. RPRX is scheduled to conduct a type-B pre-NDA meeting with the FDA in the first half of November, 2014.

- **Details.** RPRX reported robust top-line results of the ZA-304 study, which were similar to that of prior reported ZA-305 study. The ZA-304 study met its primary endpoints demonstrating Androxal is superior to a topical gel (AndroGel) in the percent change from baseline in average sperm concentration and the percent of subjects considered to be responders. For the average sperm concentration changes from baseline, the 304 study demonstrated a greater reduction compared to the 305 study in AndroGel (-71% vs. -33%); while differences of Androxal changes in the two studies were less (-1% vs. 6%). The results for all secondary endpoints including LH, FSH, and morning testosterone were similar between the two studies. The safety profile is satisfactory. Four SAEs have been identified and none were considered related to the study drug. RPRX is scheduled to conduct a type-B pre-NDA meeting with the FDA in the first half of November 2014 to seek guidance on the planned NDA for Androxal in secondary hypogonadism with preservation of testicular function.
- **Implications.** As anticipated, the ZA-304 study exhibited robust results similar to that of ZA-305 trial reported earlier. Management indicated that it would file the NDA in late 4Q14, with the package which includes the 301, 302, 304, and 305 studies. We view the pre-NDA meeting to be critical for the Androxal regulatory path. It would be the first time RPRX is to present full clinical data, differentiated attributes, and the value of Androxal to the agency, after a rather negative AdCom meeting on the potential restriction of TRT use. RPRX has requested an AdCom expert panel meeting prior to the possible PDUFA date in 2015 and, if granted, we believe the meeting outcome could also be critical to the near term outlook for Androxal advancement. We also anticipate more visibility at the Analyst Day (Oct. 31st) to illustrate RPRX's NDA filing tactics.
- **Action.** We are reiterating our Buy rating and our $32 target price to reflect the 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 (09/26/2014)	$ 10.48
52–Week High (9/27/2013)	$ 28.99
52–Week Low (9/22/2014)	$ 8.46
Market Cap. (MM)	$ 242
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-304 Study

ZA-304 is a randomized, double blind; placebo-controlled Phase III study that enrolled 129 secondary hypogonadism patients with 114 completing the study. In the study, 41, 43 and 45 patients were randomized to Androxal, AndroGel 1.62, and a placebo, respectively. The mean age of the three groups was 49, 47 and 47 years; and baseline BMI was 33.1, 34.0 and 32.6, 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	98 (87)	71 (18, 472)	102 (95)	69 (0, 466)	11 (78)	**-1** (-100, 353)	0.9128	
Topical T	79 (69)	51 (17, 280)	40 (59)	18 (0, 219)	(53) (49)	**-71** (-100, 83)	< 0.0001	< 0.0001
Placebo	95 (91)	63 (17, 493)	79 (46)	60 (13, 198)	4 (54)	**-9** (-74, 216)	0.3328	0.558

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 of different measurements.

Figure 2: Composite responder endpoint in ITT population

	Success n (%)	Failure n (%)	p-value vs Androxal
Androxal	25 **(61.0)**	16 **(39.0)**	
Topical T	7 **(16.3)**	36 **(83.7)**	< 0.0001
Placebo	2 (4.4)	43 (95.6)	< 0.0001

Source: Company presentation

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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	203 (52)	198 (116, 298)	435 (184)	401 [1] (148, 931)	377 (176)	327 [1] (138, 854)
Topical T	209 (54)	214 (85, 298)	339 (320)	233 [1,2] (112, 1686)	173 (94)	160 [1,2] (46, 571)
Placebo	200 (43)	200 (119, 291)	231 (136)	198 [2] (51, 976)	229 (78)	219 [1,2] (60, 484)

[1]Change from baseline is statistically significantly different from no change (within group test) $p < 0.05$.

[2]Change from baseline is statistically significantly different from subjects treated with Androxal (between group test) $p < 0.05$.

Source: Company presentation

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	385 (169)	349 (155, 819)	
Topical T	347 (180)	290 (155, 932)	
Placebo	193 (50)	187 (124, 337)	< 0.0001

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	**4Q (Nov.) '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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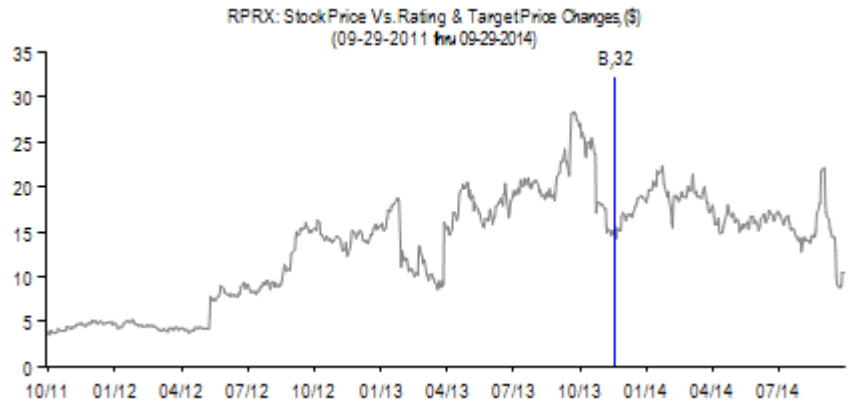

3 Year Rating Change History

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.	95.00%	30.00%	10.00%
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