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EQUITY RESEARCH
Company Report

September 4, 2014

Repros Therapeutics (RPRX - $ 18.05)

Healthcare/Biotechnology

Maybe Too Early to Panic About the AdCom Meeting Outcome.

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

Yesterday, RPRX shares lost ~18.5% after the release of the FDA AdCom (BRUDAC) meeting briefing document for the discussion of TRT on two subjects: appropriate indicated population for TRT, and potential for adverse cardiovascular outcome associated with use of TRT. The meeting is on Sep. 17.

- **Details.** The major purpose of the meeting is to discuss two controversial issues regarding testosterone replacement therapy (TRT) that have important public health implications: 1) to identify the appropriate patient population for whom TRT should be indicated, and 2) potential risk of major adverse cardiovascular events associated with TRT use.
- **Implications.** Although the AdCom meeting discussing TRT eligibility and potential CV risks could always add risks to all TRTs, we think the risks to Androxal could be much more limited. Regarding the appropriate patient population, the FDA's concern is about age-related hypogonadism and younger patients without laboratory testing for serum T levels. If the FDA were to issue more restrictions on patient eligibility, we believe it might have more limited impact on Androxal than other TRTs. Given that it could preserve sperm production, Androxal could be more welcomed, in our opinion, than TRT in younger patients. Further, since Androxal stimulates the body to produce its own testosterone, and is not a "replacement" therapy, the drug could demonstrate improvement of other hypogonadal signs such as increase of LH and FSH; and possibly improve the likelihood of approval. As such, regardless the impact, if any, on the overall hypogonadism patient profile, we remain optimistic on Androxal's market potential. Regarding the CV risk, the FDA's research was inconclusive; while the two publications that triggered an alert by the agency in 1Q14 were both associated with patients potentially having higher propensity of CV risks (either the one undergoing coronary angiography for the assessment of coronary artery disease; or men with pre-existing heart diseases). As such, we view the FDA's overall tone for this subject as rather benign. Although we cannot predict the voting outcome, the risk/benefit of restoring T level to normal, in our assessment, remains favorable with the addition of mild to moderate warning language on the label if CV risks can be established as a possibility.
- **Action.** We reiterate our Buy rating and our $32 target price based on our P/E, peer comparable and NPV-driven and probability adjusted sum-of-the-part analyses. We view the current price level as a buying opportunity.

Trading Data:

Last Price (09/03/2014)	$ 18.05
52–Week High (9/24/2013)	$ 29.79
52–Week Low (8/1/2014)	$ 12.61
Market Cap. (MM)	$ 417
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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- Following are Voting questions for the Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM AC) on testosterone replacement therapy (TRT) on September 17, 2014:

1. a. The current approach to establishing the efficacy and safety of testosterone products for marketing approval is based upon pharmacokinetic assessments of serum testosterone concentrations and an acceptable safety profile. The product must be able to reliably raise low serum testosterone concentrations into the normal range for young, healthy men. FDA does not require a demonstration that testosterone products ameliorate or improve any specific hypogonadal sign or symptom. Describe the populations for which approval would be supported based on data generated from this current approach.

   b. Discuss what changes, if any, would be needed to the current clinical development paradigm to support an indication for TRT in men with "age-related" hypogonadism.

2. Discuss whether the totality of the data indicates a cardiovascular safety signal associated with the use of testosterone therapy. Include in your discussion:

   a. The strength of the signal

   b. The biologic plausibility of the signal

   c. Whether you believe there is a signal that is restricted to a certain subset of the population using testosterone products or whether there is a signal that applies to all users.

   d. Whether the evidence on major adverse cardiovascular events associated with TRT is sufficiently informative to warrant inclusion of such information in labeling.

3. The current indication for TRT is:

   "DRUG X is an androgen indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone"

   - Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range.
   - Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations, but have gonadotropins in the normal or low range."

   Should the FDA revise the current indication for testosterone therapies?

   Provide a rationale for your vote. If you vote to change the indication, describe the specific changes you are recommending to the indication statement.

4. Should FDA require sponsors of testosterone products to conduct a post-marketing study (e.g. observational study, controlled clinical trial) to further assess a potential cardiovascular risk with the use of TRT?

   a. No, a postmarket study should not be required

   b. Yes, but only if TRT is also approved for age-related hypogonadism

   c. Yes, regardless of the indication for testosterone therapy

   Provide a rationale for your answer. If you vote yes, discuss the type of study that should be required (e.g., observational study, controlled clinical trial). Include a discussion of the study population that should be enrolled as well as an acceptable degree of risk that would need to be excluded.

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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**	*****
		FDA AdCom meeting on TRT	**Sep. 17, 2014**	*****
		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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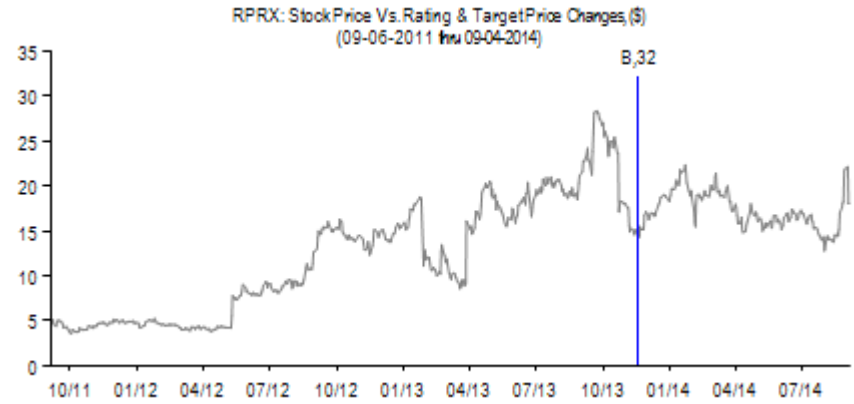

3 Year Rating Change History

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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