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EQUITY RESEARCH
Company Report

September 18, 2014

Repros Therapeutics (RPRX - $ 9.31)

Healthcare/Biotechnology

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

Modest Risks Increase But We Do Not Believe It Will Derail Potential Androxal Approval.

Yesterday, the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) panel voted 20 – 1 in favor that the agency should revise approval uses of testosterone replacement therapy (TRT) as a way to potentially reduce the use in patients who did not fulfill diagnostic guidelines or patients with age or obesity related low-testosterone. The panel also recommended drug developers to study potential cardiovascular (CV) risks of TRT in certain indications.

- **Details.** The major purpose of the meeting was to discuss two controversial issues regarding TRT for: 1) identifying the appropriate patient population for whom TRT should be indicated; and 2) assessing potential risk of major adverse cardiovascular events associated with TRT use.
- **Implications.** Given that the clinical evidence for the causality between CV risks and TRT have not been strongly confirmed, the AdCom panel vote, in our opinion, may have very limited impact on the future use of TRT. For eligible patients, the panel recommendation, if accepted by the FDA, could potentially curb the use of TRT in patients who did not fulfill the diagnostic guidelines for hypogonadism and age and obesity related hypogonadism. We also view any possible new labelling regarding the lack of proof on reversing common aging issues like low libido and fatigue, could also have negative impact on TRT prescriptions for patients who did not truly suffer from hypogonadism. As such, we believe total scripts and hence market size might be reduced; as only a smaller group of eligible patients would be treated by TRT or other T restoration therapies. Despite some increased risks, we believe the outlook for Androxal's potential approval remains encouraging; as the drug functions via a very different mechanism of action, by restoring patient's own ability to produce testosterone endogenously instead of supplying it exogenously, like TRT. At the pre-NDA discussion, we anticipate RPRX to emphasize the therapeutic value of self-generating testosterone and coupling with exercises in hypogonadotropic hypogonadism patients. We think RPRX is likely to report robust results from the second Phase III (304) study, possibly in Oct. and conduct pre-NDA meeting in 4Q14.
- **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 (09/18/2014)	$ 9.31
52–Week High (9/24/2013)	$ 29.79
52–Week Low (9/18/2014)	$ 8.88
Market Cap. (MM)	$ 215
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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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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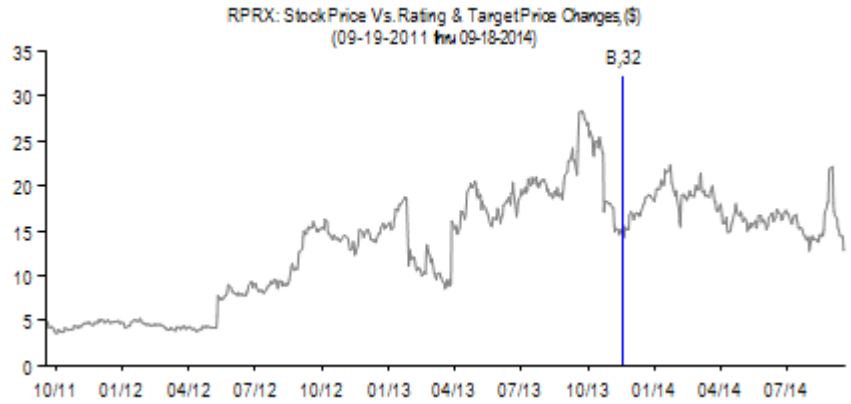

3 Year Rating Change History

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**

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			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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