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EQUITY RESEARCH
Company Report

May 20, 2014

Repros Therapeutics (RPRX - $ 16.13)

Healthcare/Biotechnology

TRT Impact on Cardiovascular Events Could Remain Uncertain.

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

Last Friday at a late breaker session of the American Association of Clinical Endocrinologists meeting, Dr. Robert Tan and colleagues from Texas presented analysis (Abstract# 1353) suggesting testosterone therapy could have a protective effect against occurrence of myocardial infarction (MI) and stroke events.

- **Details** From a retrospective analysis titled "Testosterone therapy is not associated with higher risk of myocardial infarction or stroke: the Low T experience", researchers identified a total of 6 MI cases (4 nonfatal and 2 fatal) from ~20,000 TRT treated hypogonadism patients (or rate of ~ 0.03%). Data were collected from 40 U.S. treatment centers from 2009 to 2014. The study is based on ICD-9 codes extracted from the electronic health record (Advanced MD) and selected family interviews. The general population reference figure is based on data from Kaiser Permanente and Northern Manhattan Registry database and indicated MI rate of ~0.2% (208/100,000). For stroke, occurrence rate of TRT-treated and general population was 0.01% (2/20,000) and 0.09% (93/100,000), respectively. Together, the data suggested that risks for developing MI and stroke in TRT-treated patients were 7x and 9x **lower than** that of general population, respectively ($p<0.0001$). Further, 46 MI and 12 stroke pre-existing patients prior to TRT treatment did not experience any additional adverse outcomes after treatment.

- **Implications**. With several recent analyses that suggested TRT could cause increased risks of CV complications and led to a FDA investigation on TRT's CV safety, the Tan and colleagues analysis makes the debate much less one-sided. Although it remains unclear as how the agency would resolve the debate on TRT's CV impact of their investigation; we view the analysis presented at the AACE is positive to TRT manufacturers and RPRX. Recent negative news might have placed some damper on the future growth of the overall testosterone restoration therapy market; a perception of greater CV safety profile of TRT, if further validated, could change such outlook. As such, we believe such development could lead to increased interests from prospective partner for Androxal given it is a better product (maintain sperm production) situated in a growing market.

- **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.

Trading Data:

Last Price (05/19/2014)	$ 16.13
52–Week High (9/24/2013)	$ 29.79
52–Week Low (4/15/2014)	$ 13.93
Market Cap. (MM)	$ 373
Shares Out. (MM)	23

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.37A	-0.38	-0.35	-0.30	-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 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 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	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	7.3	7.4	6.9	5.6	27.1	16.8	17.3	19.0	20.8
General and administrative	3.8	4.8	4.8	1.2	1.3	1.4	1.4	5.4	6.5	9.7	10.7	10.8
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	$8.3	$7.0	$32.5	$28.3	$51.7	$29.7	$31.5
Operating Income (loss)	($12.5)	($18.2)	($27.7)	($8.5)	($8.7)	($8.3)	($7.0)	($32.5)	($28.3)	$13.5	$103.0	$213.2
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)	(8.3)	(7.0)	(32.5)	(28.3)	13.5	103.0	213.2
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(27.7)	(8.5)	(8.7)	(8.3)	(7.0)	(32.5)	(28.3)	13.5	103.0	213.2
Income tax expense	-	-	-	-	-	-	-	-	-	4.6	35.0	72.5
Net Incomes (Losses)	($12.5)	($18.2)	($27.7)	($8.5)	($8.7)	($8.3)	($7.0)	($32.5)	($28.3)	$8.9	$68.0	$140.7
Net Earnings (Losses) Per Share—Basic	($1.04)	($1.18)	($1.33)	($0.37)	($0.38)	($0.35)	($0.30)	($1.40)	($1.20)	$0.37	$2.78	$5.66
Net Earnings (Losses) Per Share—Diluted	($1.04)	($1.18)	($1.33)	($0.37)	($0.38)	($0.35)	($0.30)	($1.40)	($1.20)	$0.37	$2.78	$5.66
Shares outstanding—basic	12.0	15.3	20.8	23.0	23.1	23.3	23.5	23.3	23.7	24.1	24.5	24.9
Shares outstanding—diluted	12.0	15.3	20.8	23.0	23.1	23.3	23.5	23.3	23.7	24.1	24.5	24.9
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%	N.A.	N.A.	N.A.	N.A.	N.A.	24%	13%	8%
SG&A	190550%	160900%	53533%	61300%	N.A.	N.A.	N.A.	N.A.	N.A.	14%	7%	4%
Operating Income (loss)	-624550%	-605567%	-308011%	-427450%	N.A.	N.A.	N.A.	N.A.	N.A.	19%	70%	79%
Pretax	0%	0%	0%	-427450%	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%	-427450%	N.A.	N.A.	N.A.	N.A.	N.A.	13%	46%	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%	16%	22%	43%	-4%	18%	-38%	3%	10%	9%
General and administrative	67%	27%	0%	15%	15%	15%	4%	12%	20%	50%	10%	1%
Sales and marketing								N.A.	0%	393%	15%	15%
Operating incomes	162%	45%	53%	16%	21%	38%	-2%	17%	-13%	-148%	661%	107%
Total Other Income, net	162%	45%	53%	16%	21%	38%	-2%	17%	-13%	-148%	661%	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%	16%	21%	38%	-2%	17%	-13%	-132%	661%	107%
EPS - Basic	76%	13%	13%	-8%	-1%	36%	-5%	5%	-14%	-131%	648%	104%
EPS - Diluted	76%	13%	13%	-8%	-1%	36%	-5%	5%	-14%	-131%	648%	104%
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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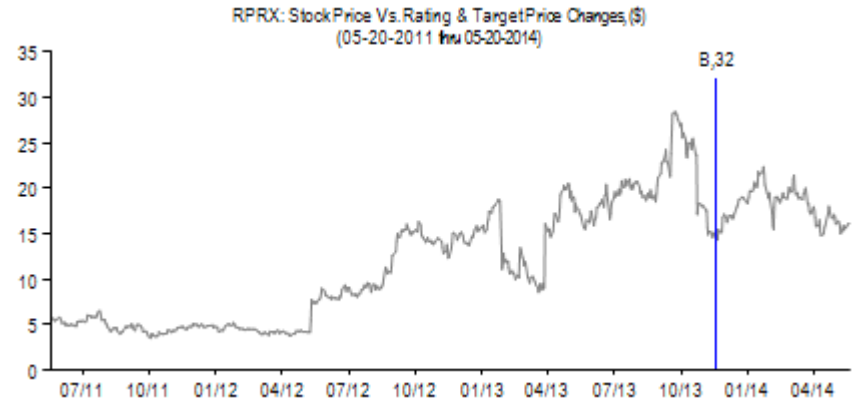

3 Year Rating Change History

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.	92.86%	35.71%	14.29%
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