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EQUITY RESEARCH
Company Report

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Repros Therapeutics (RPRX - $ 18.95)

Healthcare/Biotechnology

FDA Guidance on Low Dose Oral Proellex in UF Phase II Studies

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

This morning, RPRX reported the FDA's guidance for the proposed Phase II studies of low dose oral Proellex in uterine fibroids (UF) and endometriosis.

- **Details.** The agency indicated that low dose oral Proellex in UF and endometriosis (the study is already underway) Phase I or II studies would be under two separate INDs and remained on partial clinical hold. The highest allowed dose is 12 mg daily. For the proposed UF Phase II study, the FDA suggested that preferred efficacy endpoint is the reduction in excessive menstrual bleeding associated with UF; and the preferred methodology to determine changes in bleeding, of which we believe is alkaline hematin assay. Additional efficacy outcomes would include tumor size and other symptomatic relief. Accordingly, RPRX is scheduled to conduct a three-arm (6, 12 mg daily dosages and placebo), parallel design and double blind trial with up to 75 women and the study is > 90% powered to achieve efficacy endpoints. We estimate the study could start in mid-2014 and might take ~3 quarters to complete with top-line data possible in 2H15. Given the company already completed a vaginally-delivered Proellex (Proellex-V) in UF Phase II study (ZPV-200) with robust outcome, RPRX would have the option to move forward with either the low dose oral or the vaginally-delivered Proellex forward in UF once the oral data become available.

- **Implications.** The expected advancement of second Proellex in UF program is a positive, in our opinion. Given that the majority of current RPRX share value is on Androxal development, the lion's share of Proellex progress upside, in our assessment, has not been accounted for at the current valuation. Proellex in endometriosis Phase II study is underway with ~1/3 patient enrollment completed and we anticipate top-line results possibly in 2H15. Together, we anticipate major catalysts for RPRX shareholder in 2015 could include a decision on Proellex in UF and endometriosis; and a potential FDA expert panel meeting decision on Androxal in secondary hypogonadism approval.

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

Trading Data:

Last Price (03/17/2014)	$ 18.95
52–Week High (9/24/2013)	$ 29.79
52–Week Low (3/20/2013)	$ 8.42
Market Cap. (MM)	$ 436
Shares Out. (MM)	23

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.32	-0.33	-0.33	-0.28	-1.27	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 on 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 task; could significantly reduce RPRX share value. As such, we view the outcome from the FDA discussion and report 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 coupling with 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 well-entrenched TRT treatment paradigm, substantial and effective education effects, in our opinion, are necessary to change physician's 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 dynamic 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 despite Proellex only accounts for a minor portion of the RPRX valuation.

Potential financing could dilute shareholders. Despite the company's cash position could support operation, including R&D and M&S expenses, into 2016; the possibility exists as additional cash could be needed for other un-expected 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	1Q14E	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	6.0	6.2	6.2	5.0	23.3	14.5	14.9	16.4	17.9
General and administrative	3.8	4.8	4.8	1.5	1.7	1.7	1.7	6.6	7.9	11.9	13.1	13.2
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	$7.5	$7.8	$7.9	$6.7	$29.9	$27.4	$51.4	$29.5	$31.1
Operating Income (loss)	($12.5)	($18.2)	($27.7)	($7.5)	($7.8)	($7.9)	($6.7)	($29.9)	($27.4)	$13.8	$103.3	$213.7
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)	(7.5)	(7.8)	(7.9)	(6.7)	(29.9)	(27.4)	13.8	103.3	213.7
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(27.7)	(7.5)	(7.8)	(7.9)	(6.7)	(29.9)	(27.4)	13.8	103.3	213.7
Income tax expense	-	-	-	-	-	-	-	-	-	4.7	35.1	72.6
Net Incomes (Losses)	($12.5)	($18.2)	($27.7)	($7.5)	($7.8)	($7.9)	($6.7)	($29.9)	($27.4)	$9.1	$68.2	$141.0
Net Earnings (Losses) Per Share—Basic	($1.04)	($1.18)	($1.33)	($0.32)	($0.33)	($0.33)	($0.28)	($1.27)	($1.15)	$0.37	$2.76	$5.62
Net Earnings (Losses) Per Share—Diluted	($1.04)	($1.18)	($1.33)	($0.32)	($0.33)	($0.33)	($0.28)	($1.27)	($1.15)	$0.37	$2.76	$5.62
Shares outstanding—basic	12.0	15.3	20.8	23.2	23.4	23.6	23.8	23.5	23.9	24.3	24.7	25.1
Shares outstanding—diluted	12.0	15.3	20.8	23.2	23.4	23.6	23.8	23.5	23.9	24.3	24.7	25.1
Margin Analysis (% of Revenue)												
COGS				N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%	10%
R&D	434100%	444767%	254578%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	21%	11%	7%
SG&A	190550%	160900%	53533%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	17%	9%	5%
Operating Income (loss)	-624550%	-605567%	-308011%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	19%	71%	79%
Pretax	0%	0%	0%	N.A.	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%	N.A.	N.A.	N.A.	N.A.	N.A.	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%	-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%	-4%	2%	29%	-14%	2%	-38%	3%	10%	9%
General and administrative	67%	27%	0%	41%	41%	41%	27%	37%	20%	50%	10%	1%
Sales and marketing								N.A.	0%	393%	15%	15%
Operating incomes	162%	45%	53%	2%	8%	31%	-6%	8%	-9%	-150%	650%	107%
Total Other Income, net	162%	45%	53%	2%	8%	31%	-6%	8%	-9%	-150%	650%	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%	2%	8%	31%	-6%	8%	-9%	-133%	650%	107%
EPS - Basic	76%	13%	13%	-20%	-12%	28%	-9%	-5%	-10%	-133%	638%	104%
EPS - Diluted	76%	13%	13%	-20%	-12%	28%	-9%	-5%	-10%	-133%	638%	104%
Shares outstanding—basic	48%	28%	36%	28%	23%	3%	3%	13%	2%	2%	2%	2%
Shares outstanding—diluted	48%	28%	36%	28%	23%	3%	3%	13%	2%	2%	2%	2%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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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**

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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.	85.71%	28.57%	14.29%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	7.14%	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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