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EQUITY RESEARCH
Company Report

February 17, 2016

Repros Therapeutics (RPRX - $ 0.86)

Healthcare/Biotechnology

Enclomiphene in Obese Secondary Hypogonadal Men Phase II POC Study Details Revealed.

Ticker:	**RPRX**
Rating:	**Buy**
Price Target:	**$ 3.50**

Yesterday after market close, RPRX reported the completion of patient randomization and the study design of enclomiphene in obese secondary hypogonadal (2nd HG) men Phase II proof of concept (POC) trial.

- **Details.** It is a POC Phase II to assess enclomiphene's impact on metabolic syndromes and quality of life on top of rigorous diet and exercise regimen in obese 2nd HG men. It is a double-blind and placebo controlled study with 15 months study duration, which consists of three phases: **Phase 1**, during the first six-months, patients will receive either enclomiphene or placebo with all of them taking a commercially prepared diet and enrolled in a trainer-based exercise program. Clinical outcomes including changes in waist circumference, lean body mass, BMI and quality of life will be assessed at the end of the sixth month. **Phase 2**, for the next six months, all patients will be treated the same way as in the first phase except the commercial diet will not be provided. All clinical parameters will be re-assessed. **Phase 3**, which will last for three months as patients will not receive any treatment; only remain enrolled in the exercise program. The objective is to determine the durability of effects due to diet and exercise alone vs. the addition of enclomiphene. RPRX expects the 3- and 6-month interim data should be available before the end of summer 2016, potentially ahead of the anticipated FDA AdCom meeting for discussing medical management of 2nd HG patients.

- **Implication**. We view this study as a novel approach to explore enclomiphene's potential to have a positive impact on metabolic syndrome improvements in 2nd HG patients. It could be a high risk but potentially high reward approach given there are limited precedents for these types of studies. Further, we also view the outcomes of the Phase II study together with the FDA AdCom discussions could play a critical role setting the potential of enclomiphene in the U.S. As such, we would further evaluate enclomiphene's value in the U.S. once we gain more visibility later in 2016.

- **Action.** We are reiterating our Buy rating, and target price of $3.50 to reflect the promising Proellex development and potential enclomiphene value in Europe. Our valuation is based on our probability-adjusted sum-of-the-parts analysis.

Trading Data:

Last Price (02/16/2016)	$ 0.86
52–Week High (4/2/2015)	$ 10.05
52–Week Low (2/12/2016)	$ 0.80
Market Cap. (MM)	$ 21
Shares Out. (MM)	24

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.35A	-0.32A	-0.27A	-0.27	-1.22	NM
FY-14A	-0.37	-0.38	-0.32	-0.31	-1.37	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

Source: Laidlaw & Company estimates

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Anticipated milestones in 2016 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	MAA filing for Europe	**Mid-2016**	***
		Report interim (3 and 6 month) results of metabolic syndrome improvement Phase II study	**3Q16**	****
		FDA AdCom meeting on secondary hypogonadism management	**2H16**	****
		Potential ex-U.S. partnership or other business development activities	**2017**	****
		Potential determine future clinical path	**2016**	****
Proellex	Uterine Fibroids	Potentially to report top-line results after one cycle treatment from low dose Proellex Phase II study	**3Q16**	****
		Potentially to schedule a type C meeting with the FDA to discuss Proellex Phase III study	**4Q16**	****
		Potentially to determine low dose oral vs. vaginal Proellex as final format for Phase III trial	**2H16**	****
		Potentially to start a Phase III study	**2017**	*****
	Endometriosis	Possible to complete exploratory Phase II study	**1Q16**	***
		Possible to report Phase II study top-line results	**3Q16**	****

***** / ***** 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

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-developed Proellex-V study are encouraging, it is still 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 be a setback for the RPRX valuation as we view the Proellex program as RPRX's main value driver.

Clinical risks of trial study failure could have a significantly negative impact on RPRX share value. Given that the current study of enclomiphene in obese secondary hypogonadism is a novel approach to potentially demonstrate the drug's effects in a metabolic disease and that there are very limited precedence for these type of studies, we believe this is a high risk trial and the majority of RPRX share value (assessed by both us and the Street) resides in the potential clinical and regulatory success of this program. Another challenge is if under a scenario that the FDA might request significantly more difficult Phase III studies at the future meeting and should the company be unable to accomplish such a task; RPRX share value could also significantly reduce.

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)	2013	2014	1Q15	2Q15	3Q15	4Q15E	2015E	2016E	2017E	2018E
Revenue										
Licensing fees	-	-	-	-	-	-	-	5.0	5.0	5.0
Product revenue	-	-	-	-	-	-	-	-	-	-
Research and development grants	-	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-
Total Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$5.0	$5.0	$5.0
Research and development	22.9	26.7	7.3	6.5	5.5	5.6	24.8	25.6	28.1	30.7
General and administrative	4.8	5.4	1.2	1.3	1.1	1.1	4.8	6.2	6.8	6.9
Sales and marketing		0.0	-	-	-	-	0.0	0.0	0.0	0.0
Interest expense and amortization of intangibles	-	-	-	-	-	-	0.0	-	-	-
Total Operating Expenses	$27.7	$32.1	$8.5	$7.8	$6.6	$6.7	$29.6	$31.8	$34.9	$37.5
Operating Income (loss)	($27.7)	($32.1)	($8.5)	($7.8)	($6.6)	($6.7)	($29.6)	($26.8)	($29.9)	($32.5)
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(27.7)	(32.1)	(8.5)	(7.8)	(6.6)	(6.7)	(29.6)	(26.8)	(29.9)	(32.5)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(8.5)	(7.8)	(6.6)	(6.7)	(29.6)	(26.8)	(29.9)	(32.5)
Income tax expense	-	-	-	-	-	-	-	0.0	0.0	0.0
Net Incomes (Losses)	($27.7)	($32.1)	($8.5)	($7.8)	($6.6)	($6.7)	($29.6)	($26.8)	($29.9)	($32.5)
Net Earnings (Losses) Per Share—Basic	($1.33)	($1.37)	($0.35)	($0.32)	($0.27)	($0.27)	($1.22)	($1.09)	($1.20)	($1.29)
Net Earnings (Losses) Per Share—Diluted	($1.33)	($1.37)	($0.35)	($0.32)	($0.27)	($0.27)	($1.22)	($1.09)	($1.20)	($1.29)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.3	24.3	24.3	24.5	24.9	25.3
Shares outstanding—diluted	20.8	23.4	24.3	24.3	24.3	24.3	24.3	24.5	24.9	25.3
Margin Analysis (% of Revenue)										
COGS		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%
R&D	254578%	888433%	732100%	645000%	275300%	278053%	N.A.	512%	563%	613%
SG&A	53533%	181233%	120500%	134200%	55000%	55550%	N.A.	124%	136%	137%
Operating Income (loss)	-308011%	-1069567%	-852500%	-779100%	-330200%	-333503%	N.A.	-535%	-599%	-651%
Net Income	-308011%	-1069567%	-852500%	-779100%	-330200%	-333503%	N.A.	-535%	-599%	-651%
Financial Indicator Growth Analysis (Y/Y)										
Licensing fees	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.
Total Revenue	200%	-67%	-50%	N.A.	N.A.	-33%	-100%	N.A.	0%	0%
Research and development	72%	16%	0%	-13%	-10%	-4%	-7%	3%	10%	9%
General and administrative	0%	13%	-2%	7%	-14%	-34%	-12%	30%	10%	1%
Sales and marketing		N.A.					N.A.	N.A.	0%	15%
Operating incomes	53%	16%	0%	-11%	-11%	-10%	-8%	-10%	12%	9%
Total Other Income, net	53%	16%	0%	-11%	-11%	-10%	-8%	-10%	12%	9%
Pretax Income	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	53%	16%	0%	-11%	-11%	-10%	-8%	-10%	12%	9%
EPS - Basic	13%	3%	-5%	-15%	-14%	-11%	-11%	-10%	10%	7%
EPS - Diluted	13%	3%	-5%	-15%	-14%	-11%	-11%	-10%	10%	7%
Shares outstanding—basic	36%	13%	5%	5%	4%	0%	4%	1%	2%	2%
Shares outstanding—diluted	36%	13%	5%	5%	4%	0%	4%	1%	2%	2%

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

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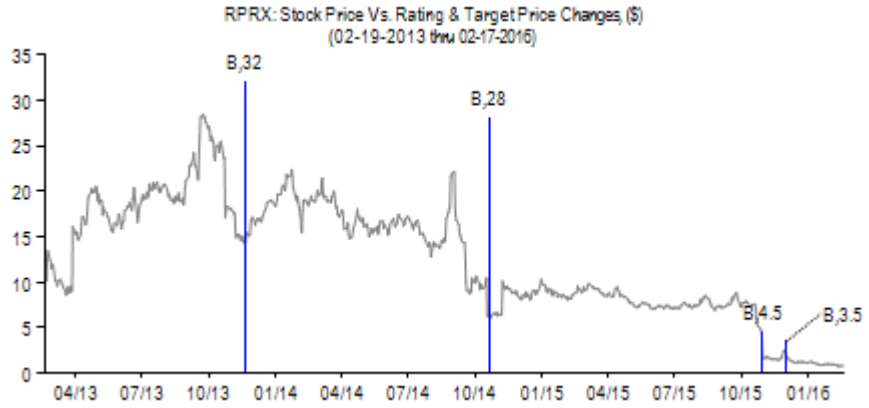
Rating and Price Target Change History



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
10/20/2014	28.00	6.23
10/30/2015	4.50	1.71
12/01/2015	3.50	1.74

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.	64.71%	26.47%	2.94%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	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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