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EQUITY RESEARCH
Company Report

May 19, 2016

Repros Therapeutics (RPRX - $ 2.15)

Healthcare/Biotechnology

Positive Results of Low Dose Oral Proellex in Uterine Fibroids (UF) Phase IIb Trial Reported

Ticker:	**RPRX**
Rating:	**Buy**
Price Target:	**$ 5.00**

Yesterday after the market close, RPRX reported positive results from its low dose oral Proellex in uterine fibroids (UF) Phase IIb study. It met the primary endpoint of induction of amenorrhea for both doses vs. placebo (p=0.0004).

- **Details.** The Phase IIb results demonstrated that 79% of the Proellex-treated patients vs. 17% of placebo-treated patients became amenorrheic at the end of the 1st treatment cycle (p=0.0004). In the Proellex-treated patient arm, 78% of patients became amenorrheic in the first 6 weeks. Bleeding was evaluated by using a PBAC (Pictorial Blood Assessment Chart) to tally sanitary product usage and stain size in addition to alkaline hematin assay. Median PBAC reduction was 100% and 62% for Proellex- and placebo-treated patients, respectively (p=0.0001). Moreover, changes in fibroids volume (measured by MRI) displayed a 28% volume reduction in Proellex-treated arms, whereas the placebo-treated group continued to increase in size by 3% (p=0.0007). Upon completion of the first 18-week treatment cycle, patients stopped the treatment to allow for menses and are currently undergoing a second cycle (18 weeks) of treatment, with the results expected in October 2016. The study tested 6 and 12mg of Proellex and placebo (n=12, 17, and 14). Patients under the study are with severe UF (Biberoglu Berman Symptom Survey Score > 7) and their mean amount of blood lost for one menstrual cycle at baseline was 177mL, 251mL, and 260mL for each arm, respectively (>80mL are considered to be menorrhagia). Vaginal delivered Proellex in UF second treatment cycle data are expected in August 2016.
- **Implications.** We view the continued robust results from the low dose oral Proellex in UF (after first treatment cycle) Phase IIb study after the recently reported similar results from the vaginal delivered version as a strong support that the drug could become an important treatment in UF and endometriosis, in our opinion. We view results from both forms of Proellex are equally impressive with very minor edge in favor of the low dose oral drug (Figure 1). Further, oral medication in general is more preferable in the U.S., while European are seems more acceptable for drug delivered by various methods. After the reporting of the second treatment cycle results, RPRX plans to conduct a meeting with the FDA, potentially in 1Q17 to discuss its Phase III study design.
- **Action.** We are reiterating our Buy rating, and target price of $5.00 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 (05/18/2016)	$ 2.15
52–Week High (9/25/2015)	$ 8.96
52–Week Low (2/11/2016)	$ 0.80
Market Cap. (MM)	$ 52
Shares Out. (MM)	24

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.20A	-0.20	-0.19	-0.18	-0.76	NM
FY-15A	-0.35	-0.32	-0.27	-0.26	-1.20	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

Source: Laidlaw & Company estimates

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Figure 1: Comparison of low dose oral and vaginal-delivered Proellex results

	Vaginal-delivered Proellex			Low dose oral Proellex		
Treatment arm	6-mg	12-mg	Placebo	6-mg	12-mg	Placebo
Patient size	13	15	14	12	17	14
Mean blood loss/menstrual cycle (baseline)	255mL	274mL	238mL	177mL	251mL	260mL
Blood loss range	94mL - 654 mL			82mL - 769mL		
% achieved amenorrhea at end of 1st treatment cycle	52%		0%	79%		17%
P value	<0.0011			0.0004		
PBAC score reduction (median)	100%		25.4%	100%		62%
P value	0.0033			0.0001		
Change in fibroids volume	18% reduction		Continued to increase	28% reduction		3% increase
P value	0.0437			0.0007		

Source: Laidlaw and Co. equity research

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Anticipated milestones in 2016 and beyond

Program	Indication	Event	Timing	Importance
Enclomiphene	Secondary hypogonadism	MAA filing for Europe	**3Q16**	***
		Report interim (3 and 6 month) results of metabolic syndrome improvement Phase II study	**2Q & 3Q16**	****
		FDA AdCom meeting on secondary hypogonadism management	**2H16**	****
		Potential EU approval	**4Q17**	****
		Potential ex-U.S. partnership or other business development activities	**2017**	****
		Potential determine future clinical path in the U.S.	**2016**	****
Proellex	Uterine Fibroids	Potentially to report top-line results after two cycle treatment from oral low and vaginal Proellex Phase II study	**3Q/4Q16**	****
		Potentially to schedule a type C meeting with the FDA to discuss Proellex Phase III study	**1Q17**	****
		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 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	2015	1Q16	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E
Revenue										
Licensing fees	-	-	-	-	-	-	-	-	0.0	0.0
Product revenue	-	-	-	-	-	-	-	-	-	-
Research and development grants	-	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-
Total Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research and development	22.9	26.7	24.1	3.8	3.8	3.4	3.3	14.2	15.7	17.1
General and administrative	4.8	5.4	5.1	1.1	1.1	1.1	1.1	4.5	4.9	4.9
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	$29.2	$4.9	$4.9	$4.5	$4.4	$18.7	$20.6	$22.0
Operating Income (loss)	($27.7)	($32.1)	($29.2)	($4.8)	($4.9)	($4.5)	($4.4)	($18.7)	($20.6)	($22.0)
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(27.7)	(32.1)	(29.2)	(4.8)	(4.9)	(4.5)	(4.4)	(18.7)	(20.6)	(22.0)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(29.2)	(4.8)	(4.9)	(4.5)	(4.4)	(18.7)	(20.6)	(22.0)
Income tax expense	-	-	-	-	-	-	-	0.0	0.0	0.0
Net Incomes (Losses)	($27.7)	($32.1)	($29.2)	($4.8)	($4.9)	($4.5)	($4.4)	($18.7)	($20.6)	($22.0)
Net Earnings (Losses) Per Share—Basic	($1.33)	($1.37)	($1.20)	($0.20)	($0.20)	($0.19)	($0.18)	($0.76)	($0.83)	($0.87)
Net Earnings (Losses) Per Share—Diluted	($1.33)	($1.37)	($1.20)	($0.20)	($0.20)	($0.19)	($0.18)	($0.76)	($0.83)	($0.87)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.3	24.4	24.4	24.5	24.9	25.3
Shares outstanding—diluted	20.8	23.4	24.3	24.3	24.3	24.4	24.4	24.5	24.9	25.3
Margin Analysis (% of Revenue)										
COGS		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
R&D	254578%	888433%	N.A.	22147%	380265%	342239%	325127%	71207%	N.A.	N.A.
SG&A	53533%	181233%	N.A.	6447%	110696%	111803%	112921%	22251%	N.A.	N.A.
Operating Income (loss)	-308011%	-1069567%	N.A.	-28494%	-490861%	-453941%	-437948%	-93358%	N.A.	N.A.
Net Income	-308011%	-1069567%	N.A.	-28494%	-490861%	-453941%	-437948%	-93358%	N.A.	N.A.
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.
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%	-100%	1600%	0%	-50%	-88%	N.A.	-100%	N.A.
Research and development	72%	16%	-10%	-49%	-41%	-38%	-33%	-41%	10%	9%
General and administrative	0%	13%	-6%	-9%	-18%	2%	-22%	-13%	10%	1%
Sales and marketing		N.A.	N.A.					N.A.	0%	15%
Operating incomes	53%	16%	-9%	-43%	-37%	-31%	-30%	-36%	10%	7%
Total Other Income, net	53%	16%	-9%	-43%	-37%	-31%	-30%	-36%	10%	7%
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%	-9%	-43%	-37%	-31%	-30%	-36%	10%	7%
EPS - Basic	13%	3%	-12%	-43%	-37%	-31%	-30%	-37%	8%	5%
EPS - Diluted	13%	3%	-12%	-43%	-37%	-31%	-30%	-37%	8%	5%
Shares outstanding—basic	36%	13%	4%	0%	0%	0%	0%	1%	2%	2%
Shares outstanding—diluted	36%	13%	4%	0%	0%	0%	0%	1%	2%	2%

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

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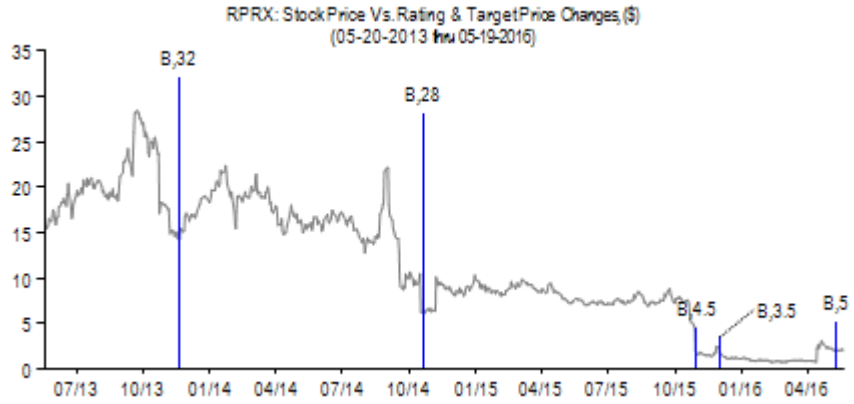
Rating and Price Target Change History



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
05/10/2016	5.00	2.16

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.	66.67%	27.78%	2.78%
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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