

## Repros Therapeutics (RPRX - \$ 0.82)

### Robust Results of Proellex-V in Uterine Fibroids (UF) First Treatment Cycle Phase IIb Trial Reported

Yesterday after the market close, RPRX reported positive vaginal-delivered Proellex in uterine fibroids (UF) first treatment cycle results, which met the primary endpoint of induction of amenorrhea for both vaginal doses vs. placebo ( $p < 0.0011$ ).

- Details.** The Phase II results demonstrated that 52% of the Proellex-treated patients became amenorrheic, while placebo treated patients continued their menstruation throughout the 18-week dosing period ( $p < 0.0011$ ). By using PBAC (Pictorial Blood Assessment Chart) to evaluate bleeding via tallying patients' sanitary product usage and stain size and measured by alkaline hematin assay, median PBAC reduction of the Proellex- and placebo-treated groups is 100% and 25.4%, respectively ( $p = 0.0033$ ). Further, fibroids volume (measured by MRI) of Proellex-treated arms was reduced by 18%, while the placebo group showed a continued increase ( $p = 0.0437$ ). Patients had been asked to withdraw from the drug to allow for menses and are currently undergoing a second course (18 weeks) of treatment, with the results expected possibly in late September. 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  $> 255$  mL on average ( $> 80$  mL are considered to be menorrhagia). The study tested 6 and 12mg of Proellex and placebo ( $n = 13, 15$  and  $14$ ). Further, RPRX expects to report oral low dose Proellex in UF first treatment cycle Phase II results in 2Q16 (possibly in May) and second cycle data possibly in October 2016.
- Implications.** We view the news as a major positive for RPRX shares given Proellex currently is a major value driver, in our opinion. Coupled with an earlier report that RPRX had decided to stop patient enrollment of the oral low dose Proellex in endometriosis Phase II trial ( $n = 41$ ) after encouraging interim results [statistically significant reduction in pain scores (61% vs. 17%) and analgesic usage (77% vs. 0%) from the baseline between the treatment and placebo groups], we believe Proellex could potentially become an important treatment in women's healthcare. RPRX plans to conduct a meeting with the FDA to discuss Phase III study design, possibly in 1Q17.
- 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.

Healthcare/Biotechnology

Ticker:	<b>RPRX</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$ 3.50</b>

#### Trading Data:

Last Price (04/12/2016)	\$ 0.82
52-Week High (4/14/2015)	\$ 9.65
52-Week Low (2/11/2016)	\$ 0.80
Market Cap. (MM)	\$ 20
Shares Out. (MM)	24

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	-0.21	-0.22	-0.19	-0.18	-0.80	NM
<b>FY-15A</b>	-0.35	-0.32	-0.27	-0.26	-1.20	NM
<b>FY-14A</b>	-0.37	-0.38	-0.32	-0.31	-1.37	NM
<b>FY-13A</b>	-0.41	-0.38	-0.26	-0.31	-1.33	NM

#### Yale Jen, Ph.D.

Managing Director /  
Senior Biotechnology Analyst  
(212) 953-4978  
yjen@laidlawltd.com

Source: Laidlaw & Company estimates

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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 one cycle treatment from oral low dose Proellex Phase II study	2Q16 (May)	****
		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.

## Major risks

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**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.

Figure 1: Income Statement

<b>Repros Therapeutics – Income Statement</b>										
(\$ MM)	2013	2014	2015	2016E				2016E	2017E	2018E
				1Q16E	2Q16E	3Q16E	4Q16E			
<b>Revenue</b>										
Licensing fees	-	-	-	-	-	-	-	-	0.0	0.0
Product revenue	-	-	-	-	-	-	-	-	-	-
Research and development grants	-	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>
Research and development	22.9	26.7	24.1	4.1	4.2	3.5	3.4	15.2	16.7	18.2
General and administrative	4.8	5.4	5.1	1.1	1.1	1.1	1.1	4.4	4.8	4.9
Sales and marketing	-	0.0	0.0	-	-	-	-	0.0	0.0	0.0
Interest expense and amortization of intangibles	-	-	0.0	-	-	-	-	-	-	-
<b>Total Operating Expenses</b>	<b>\$27.7</b>	<b>\$32.1</b>	<b>\$29.2</b>	<b>\$5.2</b>	<b>\$5.2</b>	<b>\$4.6</b>	<b>\$4.5</b>	<b>\$19.5</b>	<b>\$21.5</b>	<b>\$23.0</b>
<b>Operating Income (loss)</b>	<b>(\$27.7)</b>	<b>(\$32.1)</b>	<b>(\$29.2)</b>	<b>(\$5.2)</b>	<b>(\$5.2)</b>	<b>(\$4.6)</b>	<b>(\$4.5)</b>	<b>(\$19.5)</b>	<b>(\$21.5)</b>	<b>(\$23.0)</b>
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)	(5.2)	(5.2)	(4.6)	(4.5)	(19.5)	(21.5)	(23.0)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(29.2)	(5.2)	(5.2)	(4.6)	(4.5)	(19.5)	(21.5)	(23.0)
Income tax expense	-	-	-	-	-	-	-	0.0	0.0	0.0
<b>Net Incomes (Losses)</b>	<b>(\$27.7)</b>	<b>(\$32.1)</b>	<b>(\$29.2)</b>	<b>(\$5.2)</b>	<b>(\$5.2)</b>	<b>(\$4.6)</b>	<b>(\$4.5)</b>	<b>(\$19.5)</b>	<b>(\$21.5)</b>	<b>(\$23.0)</b>
Net Earnings (Losses) Per Share—Basic	(\$1.33)	(\$1.37)	(\$1.20)	(\$0.21)	(\$0.22)	(\$0.19)	(\$0.18)	(\$0.80)	(\$0.86)	(\$0.91)
Net Earnings (Losses) Per Share—Diluted	(\$1.33)	(\$1.37)	(\$1.20)	(\$0.21)	(\$0.22)	(\$0.19)	(\$0.18)	(\$0.80)	(\$0.86)	(\$0.91)
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
<b>Margin Analysis (% of Revenue)</b>										
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.	411315%	415428%	353114%	335458%	378829%	N.A.	N.A.
SG&A	53533%	181233%	N.A.	108000%	109080%	110171%	111273%	109631%	N.A.	N.A.
Operating Income (loss)	-308011%	-1069567%	N.A.	-519215%	-524408%	-463185%	-446631%	-488360%	N.A.	N.A.
Net Income	-308011%	-1069567%	N.A.	-519215%	-524408%	-463185%	-446631%	-488360%	N.A.	N.A.
<b>Financial Indicator Growth Analysis (Y/Y)</b>										
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%	0%	0%	-50%	-88%	N.A.	-100%	N.A.
Research and development	72%	16%	-10%	-44%	-36%	-36%	-31%	-37%	10%	9%
General and administrative	0%	13%	-6%	-10%	-19%	0%	-23%	-14%	10%	1%
Sales and marketing		N.A.	N.A.					N.A.	0%	15%
Operating incomes	53%	16%	-9%	-39%	-33%	-30%	-29%	-33%	10%	7%
Total Other Income, net	53%	16%	-9%	-39%	-33%	-30%	-29%	-33%	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%	-39%	-33%	-30%	-29%	-33%	10%	7%
EPS - Basic	13%	3%	-12%	-39%	-33%	-30%	-29%	-34%	8%	6%
EPS - Diluted	13%	3%	-12%	-39%	-33%	-30%	-29%	-34%	8%	6%
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%

Yale Jen, Ph.D. 212-953-4978

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

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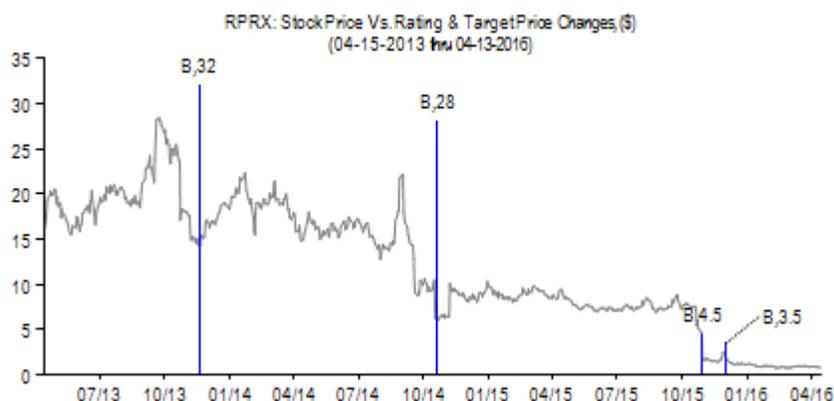
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#### Rating and Price Target Change History



#### 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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	66.67%	27.78%	2.78%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
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