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EQUITY RESEARCH
Company Report

November 15, 2016

Repros Therapeutics (RPRX - $ 1.88)

Healthcare/Biotechnology

Positive Top-line Results Enable Proellex as Phase III-Ready Asset for Uterine Fibroids and Endometriosis

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

Yesterday after the market close, RPRX reported positive top-line results from its Proellex in UF second treatment cycle (both vaginally and orally administered) Phase II study. RPRX also recently reported 3Q16 financial results with a net loss of ($4.2MM) or ($0.17) per share, and the company ended the quarter with ~$10.5MM cash, enough to support its operations into 2H17, in our opinion.

- **Proellex in UF Phase II study results.** Both the orally- (n=41) and vaginally- (n=42) delivered Proellex in the uterine fibroids (UF) Phase II studies exhibited positive results following the second 18-week treatment cycle (Last Observation Carried Forward or LOCF). Two studies met the primary endpoint of induction of amenorrhea over the placebo with 93% ($p<0.0001$) in the oral group and 50% ($p=0.0071$) in the vaginal group. Patients took 12mg or 6mg oral-Proellex achieved 100% and 88.9% induction of amenorrhea, respectively. Oral Proellex treated patients experienced a statistically significant reduction in fibroids volume (measured by MRI) from baseline vs. placebo (42% vs. 0% with $p=0.0004$). The Uterine Fibroid Symptom Quality of Life (UFSQOL) survey, which assesses distress from both bleeding and bulk symptoms of UF, demonstrated an improvement for the Proellex-treated patients vs. placebo (71% vs. 38% with $p=0.0211$). Fibroid size reduction of the 12mg and 6 mg (both oral) were 58.2% and 32.9%, respectively. Accordingly, RPRX intends to advance the oral Proellex into a Phase III study after a potential EOP2 meeting with the FDA to be scheduled in YE16 or early 1Q17.
- **Implications.** We believe the robust Proellex in UF Phase II results at LOCF provided additional confirmation that the drug is active especially after both formats have achieved statistically significant induction of amenorrhea during the first treatment cycle (delta of 62% with $p=0.0004$ of oral, and 52% with $p<0.0011$ of vaginal). Proellex is of a similar drug class (SPRM) to Allergan's Esmya (ulipristal acetate), which has met the primary endpoint of its first Phase III study in UF with a second Phase III study (Venus II) ongoing. Given that, we believe Proellex could be a de-risked Phase III ready asset for UF and endometriosis treatment.
- **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 (11/14/2016)	$ 1.88
52–Week High (4/14/2016)	$ 3.48
52–Week Low (2/11/2016)	$ 0.80
Market Cap. (MM)	$ 48
Shares Out. (MM)	25

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.20A	-0.18A	-0.17A	-0.16	-0.71	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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Anticipated milestones in 2016 and beyond

Program	Indication	Event	Timing	Importance
Enclomiphene	Secondary hypogonadism	Report interim (12 month) results of metabolic syndrome improvement Phase II study	**1Q17**	***
		FDA AdCom meeting on secondary hypogonadism management	**Dec. 6, 2016**	***
		Potential EU approval	**1H18**	****
		Potential ex-U.S. partnership or other business development activities	**2017**	****
		Potential determine future clinical path in the U.S.	**2016/2017**	***
Proellex	Uterine Fibroids	Potentially to schedule a type C meeting with the FDA to discuss Proellex Phase III study	**1Q17**	****
		Potentially to start a Phase III study	**2017**	*****
	Endometriosis	Possible EOP2 meeting with the FDA	**4Q16/1H17**	***

***** / ***** 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	2Q16	3Q16	4Q16E	2016E	2017E	2018E
Revenue										
Licensing fees	-	-	-	-	-	-	-	-	-	-
Product revenue	-	-	-	-	-	-	-	-	-	-
Research and development grants	-	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	0.0	0.0	-	0.0	-	-
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	3.2	3.2	3.0	13.2	14.5	15.8
General and administrative	4.8	5.4	5.1	1.1	1.1	1.0	1.0	4.2	4.6	4.6
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	$4.3	$4.2	$4.0	$17.4	$19.1	$20.5
Operating Income (loss)	($27.7)	($32.1)	($29.2)	($4.8)	($4.3)	($4.2)	($4.0)	($17.3)	($19.1)	($20.5)
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(27.7)	(32.1)	(29.2)	(4.8)	(4.3)	(4.2)	(4.0)	(17.3)	(19.1)	(20.5)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(29.2)	(4.8)	(4.3)	(4.2)	(4.0)	(17.3)	(19.1)	(20.5)
Income tax expense	-	-	-	-	-	-	-	0.0	0.0	0.0
Net Incomes (Losses)	($27.7)	($32.1)	($29.2)	($4.8)	($4.3)	($4.2)	($4.0)	($17.3)	($19.1)	($20.5)
Net Earnings (Losses) Per Share—Basic	($1.33)	($1.37)	($1.20)	($0.20)	($0.18)	($0.17)	($0.16)	($0.71)	($0.77)	($0.81)
Net Earnings (Losses) Per Share—Diluted	($1.33)	($1.37)	($1.20)	($0.20)	($0.18)	($0.17)	($0.16)	($0.71)	($0.77)	($0.81)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.3	24.5	24.5	24.5	24.9	25.3
Shares outstanding—diluted	20.8	23.4	24.3	24.3	24.3	24.5	24.5	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%	324300%	31820%	302290%	45562%	N.A.	N.A.
SG&A	53533%	181233%	N.A.	6447%	105200%	9970%	100697%	14317%	N.A.	N.A.
Operating Income (loss)	-308011%	-1069567%	N.A.	-28494%	-429400%	-41690%	-402887%	-59779%	N.A.	N.A.
Net Income	-308011%	-1069567%	N.A.	-28494%	-429400%	-41690%	-402887%	-59779%	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%	400%	-88%	N.A.	-100%	N.A.
Research and development	72%	16%	-10%	-49%	-50%	-42%	-38%	-45%	10%	9%
General and administrative	0%	13%	-6%	-9%	-22%	-9%	-30%	-18%	10%	1%
Sales and marketing		N.A.	N.A.					N.A.	0%	15%
Operating incomes	53%	16%	-9%	-43%	-45%	-37%	-36%	-41%	10%	7%
Total Other Income, net	53%	16%	-9%	-43%	-45%	-37%	-36%	-41%	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%	-45%	-37%	-36%	-41%	10%	7%
EPS - Basic	13%	3%	-12%	-43%	-45%	-37%	-36%	-41%	8%	5%
EPS - Diluted	13%	3%	-12%	-43%	-45%	-37%	-36%	-41%	8%	5%
Shares outstanding—basic	36%	13%	4%	0%	0%	1%	1%	1%	2%	2%
Shares outstanding—diluted	36%	13%	4%	0%	0%	1%	1%	1%	2%	2%

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

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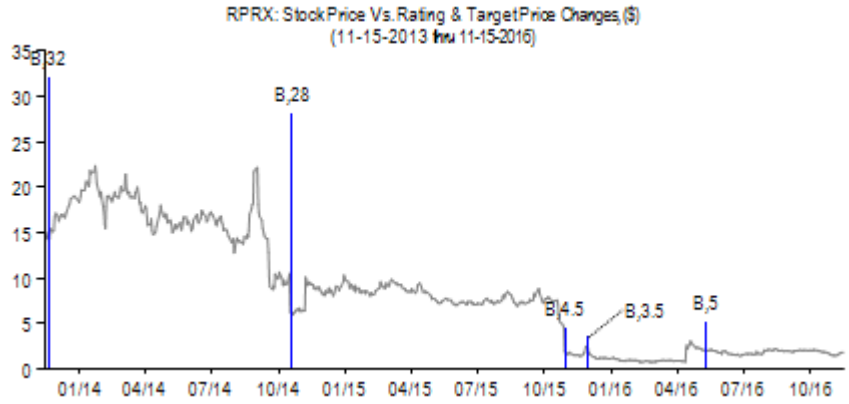
Rating and Price Target Change History



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.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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Allergan, Inc. (AGN – Not Rated)

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