

Repros Therapeutics (RPRX - \$ 2.10)

1Q16: Anticipating More Proellex in Uterine Fibroids (UF) Phase IIb Trial Results and Increasing TP to \$5.00 from \$3.50

RPRX reported 1Q16 financial results this morning with a net loss of (\$4.8MM) or (\$0.20)/share. The company ended 1Q16 with ~\$16MM cash, enough to support its operations into 2017, in our opinion.

- Increasing our bullish view on Proellex in UF Phase II study clinical data.**

RPRX is scheduled to report the low dose oral Proellex in Uterine Fibroids (UF) Phase II results in mid- to late 2Q16. This is after an earlier report of positive Phase IIa study results (from first treatment cycle of 18 weeks) that vaginal-delivered Proellex in UF achieved 52% of amenorrheic in UF patients ($p < 0.0011$). Proellex also demonstrated reduction of blood loss ($p = 0.0033$) and shrinkage of fibroids volume ($p = 0.0437$) compared to placebo. Patients under the study are with severe UF. Prior Phase II studies also demonstrated that low dose oral Proellex has significantly reduced menses in milder UF patients. In addition, Allergan recently reported positive results from their Esmya (ulipristal acetate) in UF Phase III (Venus I) trial ($n = 157$). The study met the co-primary endpoint of percentage of patients with absence of uterine bleeding and time to absence of uterine bleeding [58.3% of 10 mg ($p < 0.0001$) and 47.2% of 5 mg ($p < 0.0001$) vs. placebo (1.8%)]. AGN is conducting second Phase III (Venus II) study ($n = 400$) with top-line results expected in 2017 and potential approval in 2018. Like Proellex (telapristone acetate), Esmya is also an anti-progesterone compound or selective progesterone receptor modulator (SPRM); and the chemical structures of both compounds are very similar (Figure 1). Further, RPRX had showed encouraging interim results from an oral low dose Proellex in endometriosis Phase II trial ($n = 41$). The results showed statistically significant reduction in pain scores (61% vs. 17%) and analgesic usage (77% vs. 0%) from the baseline between the treatment and placebo groups. Together, we believe the likelihood that Proellex could achieve positive Phase II results from the ongoing UF and advance into Phase III pivotal studies could be substantially improved. RPRX plans to conduct a meeting with the FDA to discuss Phase III study design, possibly in 1Q17 and potentially with Phase III study to start later in 2017. Despite that Esmya might reach the market first, commercial outlooks of Proellex, in our opinion, remain significant given the large market size and unmet medical need.

- Action.** With an improved outlook and potentially reduced clinical risks for Proellex development, we are increasing our 12-month target price to \$5.00 from \$3.50 and reiterating our Buy rating, 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.

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

Healthcare/Biotechnology

Ticker:	RPRX
Rating:	Buy
Price Target: ↑ raise	\$ 5.00

Trading Data:

Last Price (05/10/2016)	\$ 2.10
52-Week High (9/25/2015)	\$ 8.96
52-Week Low (2/11/2016)	\$ 0.80
Market Cap. (MM)	\$ 51
Shares Out. (MM)	24

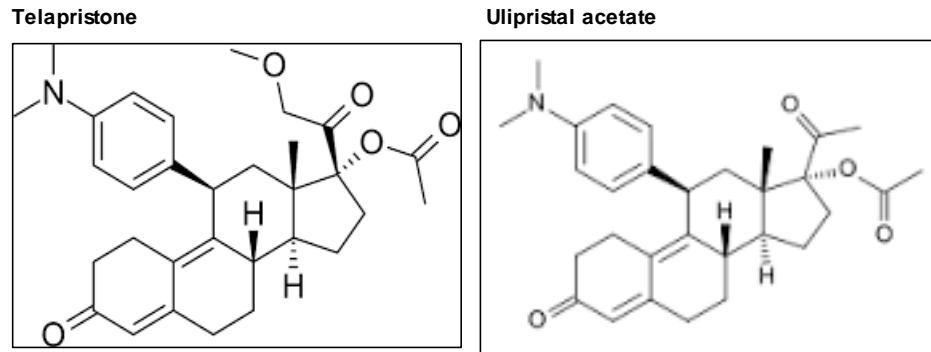
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- Other updates.** The POC Phase II study that assesses enclomiphene’s impact on metabolic syndromes and quality of life on top of rigorous diet and exercise regimen in obese 2nd HG men is underway. The 3- and 6-month interim data are expected in June and August 2016 – potentially ahead of the anticipated FDA AdCom meeting for discussing medical management of 2nd HG patients.

Figure 1: Chemical structures of telapristone and Ulipristal acetate



Source: Wikipedia

Table 1: Estimated and reported 1Q16 results

1Q16 Estimates and Reported Results			
(\$ MM)	Laidlaw Estimate	Actual	Consensus
Total revenue	\$0.0	\$0.0	\$0.0
Total op. profit (loss)	(\$5.2)	(\$4.8)	(\$5.3)
R&D	\$4.1	\$3.8	
SG&A	\$1.1	\$1.1	
EPS	(\$0.21)	(\$0.20)	(\$0.22)
Net income (loss)	(\$5.2)	(\$4.8)	(\$5.3)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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/June)	****
		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

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

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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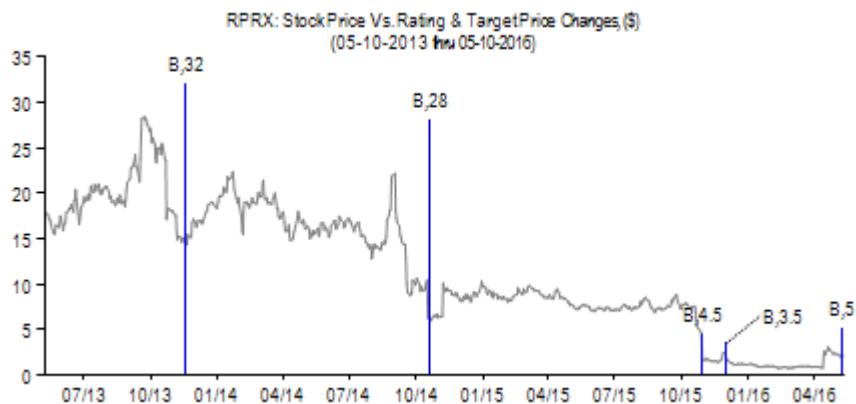
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3 Year Rating Change History

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	2.15*

* Previous Close 5/9/2016

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%
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Allergan (AGN – Not Rated)

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