

Repros Therapeutics (RPRX - \$ 2.09)

2Q16: Uneventful with Focus on Proellex Phase II Results

RPRX yesterday reported 2Q16 financial results with a net loss of (\$4.3MM) or (\$0.18) per share. The company ended 2Q16 with ~\$12.5MM cash, enough to support its operations into 2H17, in our opinion.

- Proellex Phase IIb clinical trial results main focus.** Investor focus remains on the 2nd treatment cycle results from two Phase IIb trials testing Proellex in severe UF. The first is of Proellex-V (vaginally delivered) and we believe the results are expected in late September. As a reminder, results from the first 18-week treatment cycle (first) met primary endpoint of induction of amenorrhea for both vaginal doses vs. placebo (p<0.0011). The second is of a low-dose oral Proellex and the results are expected in October 2016. Similar to that of Proellex-V, results from the low-dose oral Proellex from the first 18-week treatment also met primary endpoint with 79% (Proellex) vs. 17% (placebo) achieved amenorrhea (p=0.0004). Following completion of these trials (~early 4Q16) RPRX is expected to choose one of the two forms and advance it into the Phase III study, which could start in 2017. We believe the oral form could have certain advantages given it is the most commonly used format for drug administration. The overall clinical risks of Proellex in UF treatment might be mitigated given another selective progesterone receptor modulator (SPRM) called Esmya (ulipristal acetate) from Allergan met the primary endpoint of its first Phase III study. Another Phase III study of Esmya in UF (Venus II) is underway with top-line results expected in 2017 and potential approval in 2018. RPRX showed encouraging interim results from the oral low-dose Proellex in endometriosis Phase II trial with statistically significant reduction in pain scores (61% vs. 17%) and analgesic usage (77% vs. 0%) from the baseline between treatment and placebo groups. Together, we are bullish on the likelihood that Proellex could achieve positive Phase IIb results and advance into Phase III pivotal studies. Should the Phase IIb results be positive, RPRX plans to conduct a meeting with the FDA to discuss Phase III study design potentially in 1Q17 with a subsequent Phase III study to start shortly thereafter.
- Enclomiphene program on track.** The EU submission of Enclomiphene for the treatment of 2nd hypogonadism is expected to occur in 3Q/early 4Q16 with potential EU approval in 4Q17. RPRX recently reported 3-month interim results of testosterone levels in obese men participating in a Phase II diet and exercise study, and the 6-month data are expected potentially in late 3Q16.
- 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.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.20A	-0.18A	-0.17	-0.16	-0.70	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:	\$ 5.00

Trading Data:

Last Price (08/09/2016)	\$ 2.09
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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Table 1: Estimated and reported 2Q16 results

2Q16 Estimates and Reported Results			
(\$ MM)	Laidlaw Estimate	Actual	Consensus
Total revenue	\$0.0	\$0.0	\$0.0
Total op. profit (loss)	(\$4.9)	(\$4.3)	(\$4.8)
R&D	\$3.8	\$3.2	
SG&A	\$1.1	\$1.1	
EPS	(\$0.20)	(\$0.18)	(\$0.19)
Net income (loss)	(\$4.9)	(\$4.3)	(\$4.8)

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 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	2Q16	3Q16E	4Q16E	2016E	2017E	2018E
Revenue										
Licensing fees	-	-	-	-	-	-	-	-	0.0	0.0
Product revenue	-	-	-	-	-	-	-	-	-	-
Research and development grants	-	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	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	3.0	2.9	12.9	14.2	15.5
General and administrative	4.8	5.4	5.1	1.1	1.1	1.1	1.1	4.3	4.7	4.8
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	\$4.1	\$3.9	\$17.2	\$18.9	\$20.2
Operating Income (loss)	(\$27.7)	(\$32.1)	(\$29.2)	(\$4.8)	(\$4.3)	(\$4.1)	(\$3.9)	(\$17.2)	(\$18.9)	(\$20.2)
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)	(4.1)	(3.9)	(17.2)	(18.9)	(20.2)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(29.2)	(4.8)	(4.3)	(4.1)	(3.9)	(17.2)	(18.9)	(20.2)
Income tax expense	-	-	-	-	-	-	-	0.0	0.0	0.0
Net Incomes (Losses)	(\$27.7)	(\$32.1)	(\$29.2)	(\$4.8)	(\$4.3)	(\$4.1)	(\$3.9)	(\$17.2)	(\$18.9)	(\$20.2)
Net Earnings (Losses) Per Share—Basic	(\$1.33)	(\$1.37)	(\$1.20)	(\$0.20)	(\$0.18)	(\$0.17)	(\$0.16)	(\$0.70)	(\$0.76)	(\$0.80)
Net Earnings (Losses) Per Share—Diluted	(\$1.33)	(\$1.37)	(\$1.20)	(\$0.20)	(\$0.18)	(\$0.17)	(\$0.16)	(\$0.70)	(\$0.76)	(\$0.80)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.3	24.3	24.4	24.5	24.9	25.3
Shares outstanding—diluted	20.8	23.4	24.3	24.3	24.3	24.3	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%	324300%	301599%	286519%	64446%	N.A.	N.A.
SG&A	53533%	181233%	N.A.	6447%	105200%	106252%	107315%	21418%	N.A.	N.A.
Operating Income (loss)	-308011%	-1069567%	N.A.	-28494%	-429400%	-407751%	-393734%	-85764%	N.A.	N.A.
Net Income	-308011%	-1069567%	N.A.	-28494%	-429400%	-407751%	-393734%	-85764%	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%	-50%	-45%	-41%	-47%	10%	9%
General and administrative	0%	13%	-6%	-9%	-22%	-3%	-25%	-16%	10%	1%
Sales and marketing		N.A.	N.A.					N.A.	0%	15%
Operating incomes	53%	16%	-9%	-43%	-45%	-38%	-37%	-41%	10%	7%
Total Other Income, net	53%	16%	-9%	-43%	-45%	-38%	-37%	-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%	-38%	-37%	-41%	10%	7%
EPS - Basic	13%	3%	-12%	-43%	-45%	-38%	-37%	-42%	8%	5%
EPS - Diluted	13%	3%	-12%	-43%	-45%	-38%	-37%	-42%	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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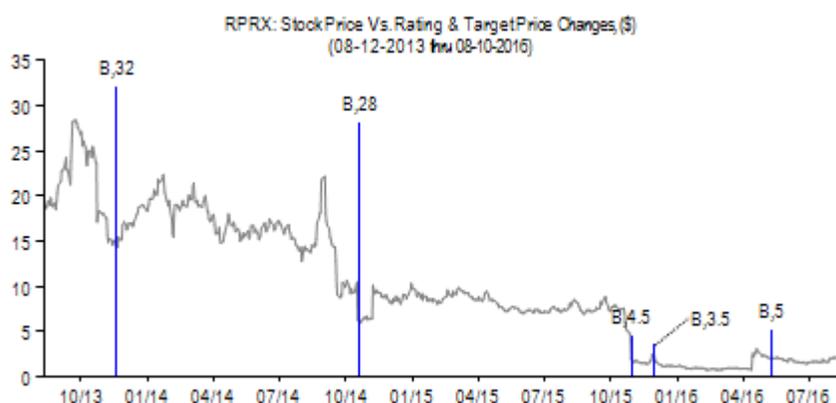
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Rating and Price Target Change History



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

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