

Repros Therapeutics (RPRX - \$1.28)

Proellex in Uterine Fibroids EOP2 Meeting to Come Before the End of April 2017

This morning, RPRX announced that the FDA has granted an end of Phase II (EOP2) meeting to discuss requirements for an oral Proellex in uterine fibroids (UF) Phase III study. The meeting intends to cover requirements necessary for demonstrating both safety and efficacy.

- Details.** Following the positive Phase II study results of Proellex (both oral and vaginal) in UF, RPRX has decided to advance the oral formulation into a Phase III study given the potential ease-of-use and slightly more robust outcome. We believe the EOP2 meeting will likely focus on the Phase III study design, including primary and secondary outcome measures for demonstrating treatment safety and efficacy. As a reminder, the orally-delivered Proellex in UF Phase II study met the primary endpoint of induction of amenorrhea over the placebo with 93% ($p < 0.0001$) and patients experienced statistically significant reduction in fibroids volume from baseline vs. placebo (42% vs. 0% with $p = 0.0004$) measured by MRI. Fibroid size reduction of the 12mg and 6mg were 58% and 33%, respectively. Additionally, Proellex treated patients vs. placebo showed an improvement of the Uterine Fibroid Symptom Quality of Life (UFSQOL) survey (71% vs. 38% with $p = 0.0211$). We anticipate RPRX could commence a Phase III study of Proellex in UF following the EOP2 meeting, possibly later in 2017. We believe the EOP2 meeting might also discuss data from Proellex in endometriosis Phase II trial.
- Implications.** We view today's news as an important step for advancing Proellex development in UF. Based on the potential feedback from the EOP2 meeting, we anticipate gaining a much clearer picture about the Phase III design, such as the scope of patient size for the trial and for the safety exposure database, plus specifics of the primary and secondary endpoints. Given Proellex is the key driver for RPRX share value, we view the visibility of the Phase III trial design would be important for investors as well as potential prospective partners.
- 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.

Healthcare/Biotechnology

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

Trading Data:

Last Price (1/27/2017)	\$1.28
52-Week High (4/14/2016)	\$3.48
52-Week Low (2/11/2016)	\$0.80
Market Cap. (MM)	\$30
Shares Out. (MM)	24.298

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.16	-0.16	-0.20	-0.24	-0.78	NM
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

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Source: Laidlaw & Company estimates

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Anticipated milestones in 2017 and beyond

Program	Indication	Event	Timing	Importance
Enclomiphene	Secondary hypogonadism	Report interim (12 month) results of metabolic syndrome improvement Phase II study	1Q17	***
		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 conduct a type C meeting with the FDA to discuss Proellex Phase III study	1H17	****
		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.

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	3Q16	4Q16E	2016E	2017E	2018E	2019E
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	\$0.0
Research and development	22.9	26.7	24.1	3.8	3.2	3.2	3.0	13.2	16.9	18.4	20.3
General and administrative	4.8	5.4	5.1	1.1	1.1	1.0	1.0	4.2	4.1	4.2	4.2
Sales and marketing	-	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	\$21.1	\$22.6	\$24.5
Operating Income (loss)	(\$27.7)	(\$32.1)	(\$29.2)	(\$4.8)	(\$4.3)	(\$4.2)	(\$4.0)	(\$17.3)	(\$21.1)	(\$22.6)	(\$24.5)
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)	(21.1)	(22.6)	(24.5)
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)	(21.1)	(22.6)	(24.5)
Income tax expense	-	-	-	-	-	-	-	0.0	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)	(\$21.1)	(\$22.6)	(\$24.5)
Net Earnings (Losses) Per Share—Basic	(\$1.33)	(\$1.37)	(\$1.20)	(\$0.20)	(\$0.18)	(\$0.17)	(\$0.16)	(\$0.71)	(\$0.78)	(\$0.73)	(\$0.78)
Net Earnings (Losses) Per Share—Diluted	(\$1.33)	(\$1.37)	(\$1.20)	(\$0.20)	(\$0.18)	(\$0.17)	(\$0.16)	(\$0.71)	(\$0.78)	(\$0.73)	(\$0.78)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.3	24.5	24.5	24.4	27.1	31.1	31.5
Shares outstanding—diluted	20.8	23.4	24.3	24.3	24.3	24.5	24.5	24.4	27.1	31.1	31.5
Margin Analysis (% of Revenue)											
COGS		N.A.	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.	N.A.
SG&A	53533%	181233%	N.A.	6447%	105200%	9970%	100697%	14317%	N.A.	N.A.	N.A.
Operating Income (loss)	-308011%	-1069567%	N.A.	-28494%	-429400%	-41690%	-402887%	-59779%	N.A.	N.A.	N.A.
Net Income	-308011%	-1069567%	N.A.	-28494%	-429400%	-41690%	-402887%	-59779%	N.A.	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.	N.A.
Product royalties	N.A.	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.	N.A.
Research and development	72%	16%	-10%	-49%	-50%	-42%	-38%	-45%	28%	9%	10%
General and administrative	0%	13%	-6%	-9%	-22%	-9%	-30%	-18%	-1%	1%	1%
Sales and marketing		N.A.	N.A.					N.A.	N.A.	N.A.	N.A.
Operating incomes	53%	16%	-9%	-43%	-45%	-37%	-36%	-41%	21%	7%	8%
Total Other Income, net	53%	16%	-9%	-43%	-45%	-37%	-36%	-41%	21%	7%	8%
Pretax Income	N.A.	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%	21%	7%	8%
EPS - Basic	13%	3%	-12%	-43%	-45%	-37%	-36%	-41%	9%	-6%	7%
EPS - Diluted	13%	3%	-12%	-43%	-45%	-37%	-36%	-41%	9%	-6%	7%
Shares outstanding—basic	36%	13%	4%	0%	0%	1%	1%	0%	11%	15%	1%
Shares outstanding—diluted	36%	13%	4%	0%	0%	1%	1%	0%	11%	15%	1%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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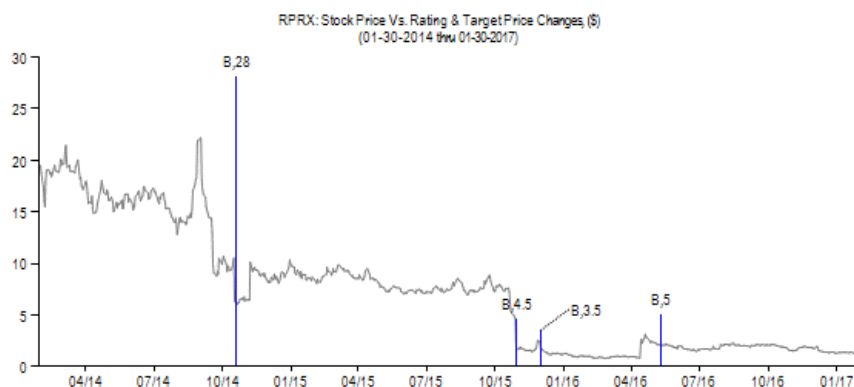
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3 Year Rating Change History

Date	Rating	Closing Price (\$)
10/20/2014	Buy (B)	6.23

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
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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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
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