

Repros Therapeutics (RPRX - \$1.11)

Meeting with the FDA Provided More Specific Guidance for Moving Proellex Development Forward

Yesterday, RPRX reported that last week, the FDA at the last minute has changed the scheduled meeting to a type C/guidance meeting for discussing the specific criteria necessary for moving Proellex forward, instead of the originally anticipated type B/EOP2 meeting. The agency also indicated that the current partial clinical hold remains in effect while they consult with internal liver experts regarding previously disclosed AEs on the liver.

- Details.** The objective of the meeting was to discuss the potential upcoming clinical development path for advancing Proellex in uterine fibroids (UF). During the meeting, the FDA indicated that Proellex would remain on partial clinical hold while the agency discusses with liver experts and reviews previously disclosed AEs in liver from prior high dose Proellex clinical studies. RPRX indicated that they also have conducted liver AEs analysis with relevant KOLs but were not able to submit information to the agency in time for the scheduled meeting. RPRX indicated it would submit the analysis from its commissioned liver experts along with existing clinical data, and the proposed study design of a possible Phase II or Phase III study to the agency, possibly within a month. RPRX will request for another meeting with the FDA once the agency has reviewed the submission. No additional clinical studies are needed for liver AEs analysis. We anticipate more details on the next steps for Proellex following additional conversations with the FDA, possibly in 2H17. Further, RPRX announced that its interim President and CEO, Dr. Dillaha, will continue on in these same roles on a permanent basis.
- Implications.** We are slightly disappointed with the reclassification of the meeting with the focus was on liver AEs rather than discussing the future clinical path. However we remain encouraged by the FDA's specific direction, which could potentially help RPRX to take the proper steps to move towards the FDA lifting partial clinical hold. Overall it is an overhang for advancing the drug into pivotal studies. Following the submission and the review by the FDA, we view the outcome from the subsequent discussions could be critical for investors as well as 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 (4/10/2017)	\$1.11
52-Week High (4/14/2016)	\$3.48
52-Week Low (4/12/2016)	\$0.81
Market Cap. (MM)	\$29
Shares Out. (MM)	24.660

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.14	-0.14	-0.21	-0.24	-0.76	NM
FY-16A	-0.20	-0.18	-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

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 2017 and beyond

Program	Indication	Event	Timing	Importance
Proellex	Uterine Fibroids	Potentially to conduct a meeting with the FDA to discuss Proellex Phase III study	2H17	****
		Potentially to start a Phase III study	2018	*****
Enclomiphene	Secondary hypogonadism	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	***

**** / ***** 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)	2015	2016					2017E	2018E	2019E
			1Q17E	2Q17E	3Q17E	4Q17E			
Revenue									
Licensing fees	-	-	-	-	-	-	-	-	-
Product revenue	-	-	-	-	-	-	-	-	-
Research and development grants	-	-	-	-	-	-	-	-	-
Other Income	-	0.0	-	-	-	-	-	-	-
Total Revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Research and development	24.1	12.8	2.3	2.2	5.0	6.0	15.5	17.6	19.4
General and administrative	5.1	4.6	1.4	1.5	1.5	1.5	5.8	5.9	5.9
Sales and marketing	0.0	0.0	-	-	-	-	-	-	-
Interest expense and amortization of intangibles	0.0	-	-	-	-	-	-	-	-
Total Operating Expenses	\$29.2	\$17.3	\$3.7	\$3.7	\$6.5	\$7.5	\$21.3	\$23.5	\$25.3
Operating Income (loss)	(\$29.2)	(\$17.3)	(\$3.7)	(\$3.7)	(\$6.5)	(\$7.5)	(\$21.3)	(\$23.5)	(\$25.3)
Loss from continuing operations	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(29.2)	(17.3)	(3.7)	(3.7)	(6.5)	(7.5)	(21.3)	(23.5)	(25.3)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(29.2)	(17.3)	(3.7)	(3.7)	(6.5)	(7.5)	(21.3)	(23.5)	(25.3)
Income tax expense	-	0.0	-	-	-	-	0.0	0.0	0.0
Net Incomes (Losses)	(\$29.2)	(\$17.2)	(\$3.7)	(\$3.7)	(\$6.5)	(\$7.5)	(\$21.3)	(\$23.5)	(\$25.3)
Net Earnings (Losses) Per Share—Basic	(\$1.20)	(\$0.70)	(\$0.14)	(\$0.14)	(\$0.21)	(\$0.24)	(\$0.76)	(\$0.73)	(\$0.78)
Net Earnings (Losses) Per Share—Diluted	(\$1.20)	(\$0.70)	(\$0.14)	(\$0.14)	(\$0.21)	(\$0.24)	(\$0.76)	(\$0.73)	(\$0.78)
Shares outstanding—basic	24.3	24.7	25.6	25.6	30.6	30.6	28.1	32.1	32.5
Shares outstanding—diluted	24.3	24.7	25.6	25.6	30.6	30.6	28.1	32.1	32.5
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	N.A.	27134%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
SG&A	N.A.	9717%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Operating Income (loss)	N.A.	-36751%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	N.A.	-36651%	N.A.	N.A.	N.A.	N.A.	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.
Product royalties	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Total Revenue	-100%	N.A.	-100%	-100%	-100%	-100%	-100%	N.A.	N.A.
Research and development	-10%	-47%	-40%	-32%	57%	134%	21%	14%	10%
General and administrative	-6%	-10%	31%	38%	47%	4%	28%	1%	1%
Sales and marketing	N.A.	N.A.					N.A.	N.A.	N.A.
Operating incomes	-9%	-41%	-24%	-14%	55%	88%	23%	10%	8%
Total Other Income, net	-9%	-41%	-24%	-14%	55%	88%	23%	10%	8%
Pretax Income	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	-9%	-41%	-24%	-14%	55%	88%	24%	10%	8%
EPS - Basic	-12%	-42%	-27%	-18%	24%	57%	8%	-3%	6%
EPS - Diluted	-12%	-42%	-27%	-18%	24%	57%	8%	-3%	6%
Shares outstanding—basic	4%	1%	5%	5%	25%	20%	14%	14%	1%
Shares outstanding—diluted	4%	1%	5%	5%	25%	20%	14%	14%	1%

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

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

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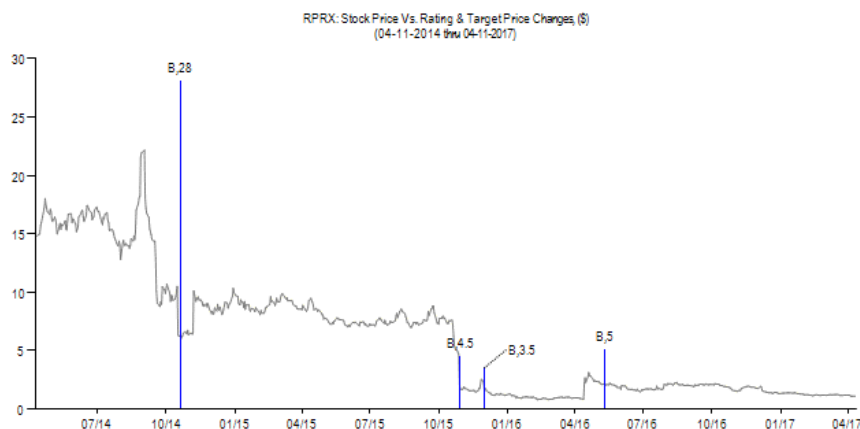
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3 Year Rating Change History

Date	Rating	Closing Price (\$)
10/20/2...	Buy (B)	6.23

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
10/20/2...	28.00	6.23
10/30/2...	4.50	1.71
12/01/2...	3.50	1.74
05/10/2...	5.00	2.16

Source: Laidlaw & Company

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