

Repros Therapeutics (RPRX - \$1.20)

4Q16: April EOP2 Meeting Could Pave Path to Commence Proellex Phase III Study

RPRX recently reported 4Q16 financial results with a net loss of (\$4.0MM), matching Laidlaw, vs. the Street (\$4.2MM) estimates. Net loss per share was (\$0.16), the same as Laidlaw, vs. (\$0.18) estimates of the Street. The company ended 4Q16 with ~\$8.7MM cash, enough to support its operations into 2H17, in our opinion.

- April EOP2 meeting discussions could shape Proellex Phase III study.** The upcoming EOP2 meeting with the FDA, scheduled to occur before the end of April, is an important near-term catalyst for establishing the critical next steps for Proellex development. We anticipate RPRX could walk away from the meeting with greater visibility for how to implement a Phase III study of low dose oral Proellex in uterine fibroids (UF). Discussions could include the necessary requirements for demonstrating both safety and efficacy such as primary and secondary endpoints and trial size. Aside from enabling RPRX to formulate a study design and commence the trial, greater visibility would enable investors to better assess the Proellex developmental timeline. We anticipate that following the EOP2 meeting, RPRX could start a Proellex in UF Phase III study later in 2017 – a critical step especially given the comparable late clinical stage of competitor oral products in development for treating UF (see our 2017-03-27 note).
- Encouraging Proellex commercial outlook exists even with later entry to the market.** Our major investment thesis for RPRX is that Proellex is clinically well de-risked, mainly because: 1) robust UF Phase II study data; and 2) two other selective progesterone receptor modulator (SPRM) oral products in development for treating UF with similar MOAs exhibited good efficacy and safety. As a reminder, Proellex in UF Phase II study met its primary endpoint of induction of amenorrhea over the placebo (80% vs. 18%, p=0.0043). Proellex vs. placebo also achieved fibroids volume reduction from baseline (40% vs. -3% with p=0.0002). Further, an improvement in the Uterine Fibroid Symptom Quality of Life (UFSQOL) survey was achieved in 71% of Proellex treated patients vs. 38% for placebo (p=0.0211). Although Proellex would not likely be the first oral UF treatment to reach the market (among its current competitors are Esmya, Vilaprisan, and Elagolix); we believe the commercial outlook remains encouraging given the large market size and significant unmet need.
- 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-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

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (3/31/2017)	\$1.20
52-Week High (4/14/2016)	\$3.48
52-Week Low (4/12/2016)	\$0.81
Market Cap. (MM)	\$32
Shares Out. (MM)	24.660

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Anticipated milestones in 2017 and beyond

Program	Indication	Event	Timing	Importance
Proellex	Uterine Fibroids	Potentially to conduct a type B meeting with the FDA to discuss Proellex Phase III study	April, 2017	****
		Potentially to start a Phase III study	2H17	*****
	Endometriosis	Possible EOP2 meeting with the FDA	April, 2017	***
Enclomiphene	Secondary hypogonadism	Report interim (12 month) results of metabolic syndrome improvement Phase II study	1H17	***
		Potential EU approval	4Q17	****
		Potential ex-U.S. partnership or other business development activities	2017	****
		Potential determine future clinical path in the U.S.	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)	2013	2014	2015	1Q16	2Q16	3Q16	4Q16	2016	1Q17E	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E
Revenue															
Licensing fees	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Research and development grants	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	0.0	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	\$0.0	\$0.0	\$0.0	\$0.0
Research and development	22.9	26.7	24.1	3.8	3.2	3.2	2.6	12.8	2.3	2.2	5.0	6.0	15.5	17.6	19.4
General and administrative	4.8	5.4	5.1	1.1	1.1	1.0	1.4	4.6	1.4	1.5	1.5	1.5	5.8	5.9	5.9
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	\$17.3	\$3.7	\$3.7	\$6.5	\$7.5	\$21.3	\$23.5	\$25.3
Operating Income (loss)	(\$27.7)	(\$32.1)	(\$29.2)	(\$4.8)	(\$4.3)	(\$4.2)	(\$4.0)	(\$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	(27.7)	(32.1)	(29.2)	(4.8)	(4.3)	(4.2)	(4.0)	(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	(27.7)	(32.1)	(29.2)	(4.8)	(4.3)	(4.2)	(4.0)	(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)	(\$27.7)	(\$32.1)	(\$29.2)	(\$4.8)	(\$4.3)	(\$4.2)	(\$4.0)	(\$17.2)	(\$3.7)	(\$3.7)	(\$6.5)	(\$7.5)	(\$21.3)	(\$23.5)	(\$25.3)
Net Earnings (Losses) Per Share—Basic	(\$1.33)	(\$1.37)	(\$1.20)	(\$0.20)	(\$0.18)	(\$0.17)	(\$0.16)	(\$0.70)	(\$0.14)	(\$0.14)	(\$0.21)	(\$0.24)	(\$0.76)	(\$0.73)	(\$0.78)
Net Earnings (Losses) Per Share—Diluted	(\$1.33)	(\$1.37)	(\$1.20)	(\$0.20)	(\$0.18)	(\$0.17)	(\$0.16)	(\$0.70)	(\$0.14)	(\$0.14)	(\$0.21)	(\$0.24)	(\$0.76)	(\$0.73)	(\$0.78)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.3	24.5	25.5	24.7	25.6	25.6	30.6	30.6	28.1	32.1	32.5
Shares outstanding—diluted	20.8	23.4	24.3	24.3	24.3	24.5	25.5	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.	N.A.	N.A.	N.A.	N.A.	N.A.
R&D	254578%	888433%	N.A.	22147%	21620%	31820%	51260%	27134%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
SG&A	53533%	181233%	N.A.	6447%	7013%	9970%	28440%	9717%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Operating Income (loss)	-308011%	-1069567%	N.A.	-28494%	-28533%	-41690%	-79600%	-36751%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	-308011%	-1069567%	N.A.	-28394%	-28433%	-41590%	-79500%	-36651%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Financial Indicator Growth Analysis (YY)															
Licensing fees	N.A.	N.A.	N.A.	N.A.	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.	N.A.	N.A.	N.A.	N.A.
Total Revenue	200%	-67%	-100%	1600%	1400%	400%	-38%	N.A.	-100%	-100%	-100%	-100%	-100%	N.A.	N.A.
Research and development	72%	16%	-10%	-49%	-50%	-42%	-47%	-47%	-40%	-32%	57%	134%	21%	14%	10%
General and administrative	0%	13%	-6%	-9%	-22%	-9%	-1%	-10%	31%	38%	47%	4%	28%	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%	-37%	-41%	-24%	-14%	55%	88%	23%	10%	8%
Total Other Income, net	53%	16%	-9%	-43%	-45%	-37%	-37%	-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.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	53%	16%	-9%	-43%	-45%	-37%	-37%	-41%	-24%	-14%	55%	88%	24%	10%	8%
EPS - Basic	13%	3%	-12%	-43%	-45%	-37%	-40%	-42%	-27%	-18%	24%	57%	8%	-3%	6%
EPS - Diluted	13%	3%	-12%	-43%	-45%	-37%	-40%	-42%	-27%	-18%	24%	57%	8%	-3%	6%
Shares outstanding—basic	36%	13%	4%	0%	0%	1%	5%	1%	5%	5%	25%	20%	14%	14%	1%
Shares outstanding—diluted	36%	13%	4%	0%	0%	1%	5%	1%	5%	5%	25%	20%	14%	14%	1%

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

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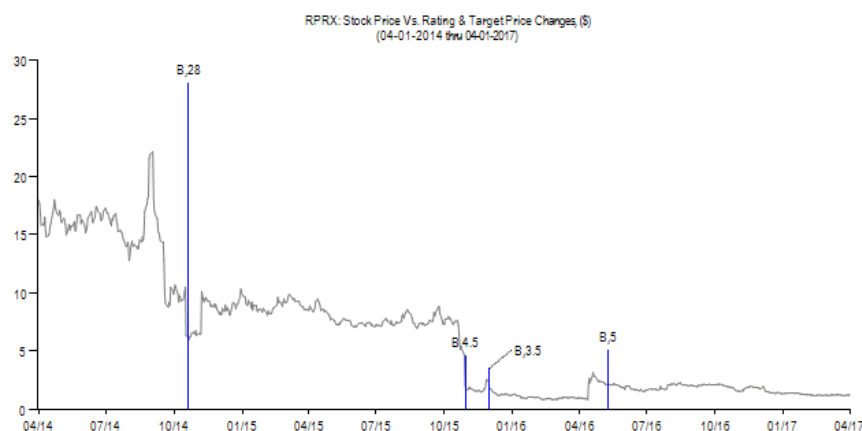
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3 Year Rating Change History

Date	Rating	Closing Price (\$)
10/20/2...	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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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.38%	2.38%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	64.29%	28.57%	2.38%
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