

## Repros Therapeutics (RPRX - \$ 1.06)

### 4Q15: Proellex in Uterine Fibroids (UF) and Endometriosis Phase II Results Expected in 2016 Could Be Major Catalysts

RPRX reported 4Q15 financial results this morning with a net loss of (\$6.3MM) or (\$0.26)/share. The company ended 2015 with ~\$21MM cash, enough to support its operations into 2017, in our opinion.

- **Uneventful quarter.** Overall, 4Q15 financial reporting was uneventful as the major activity for the company was the continued Phase II advancement of Proellex in uterine fibroids (UF) and endometriosis studies.
- **Proellex is under three Phase II clinical trials with results expected in 2Q -- 3Q16.** Proellex is under three Phase IIb studies in UF (low dose oral and vaginal-delivered) and severe (Biberoglu Berman Symptom Survey Score > 7) endometriosis (low dose oral). The trial design for all studies (n~45) is overall identical with either two doses (6mg and 12mg) of treatment or a placebo. The UF study uses the alkaline-hematin method to measure the menstrual blood losses. We estimate the top-line results of the vaginal-delivered UF Phase II study could be available in 2Q16 (possibly in May), while low dose oral study results in 3Q16 (possibly in July). RPRX has decided to stop patient enrollment of the endometriosis trial after they have reported encouraging interim results (n=41). They demonstrated statistically significant reduction in pain scores (61% vs. 17%) and analgesic usage (77% vs. 0%) from the baseline between the treatment and placebo groups. RPRX expects to report detailed top-line results in early 4Q16. If all positive, RPRX plans to conduct a meeting with the FDA to discuss a Phase III study, possibly in 4Q16. We believe the reporting of positive Proellex in UF and endometriosis results would potentially afford substantial upside for RPRX shares given the current low valuation (~\$5MM enterprise value).
- **Enclomiphene 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 2<sup>nd</sup> HG men is underway. The 3- and 6-month interim data are expected in May and August 2016 – potentially ahead of the anticipated FDA AdCom meeting for discussing medical management of 2<sup>nd</sup> HG patients.
- **Action.** We are reiterating our Buy rating, and target price of \$3.50 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
<b>FY-16E</b>	-0.21	-0.22	-0.19	-0.18	-0.80	NM
<b>FY-15A</b>	-0.35	-0.32	-0.27	-0.26	-1.20	NM
<b>FY-14A</b>	-0.37	-0.38	-0.32	-0.31	-1.37	NM
<b>FY-13A</b>	-0.41	-0.38	-0.26	-0.31	-1.33	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	<b>RPRX</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$ 3.50</b>

#### Trading Data:

Last Price (03/14/2016)	\$ 1.06
52-Week High (4/2/2015)	\$ 10.05
52-Week Low (2/11/2016)	\$ 0.80
Market Cap. (MM)	\$ 25
Shares Out. (MM)	24

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### Anticipated milestones in 2016 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	MAA filing for Europe	3Q16	***
		Report interim (3 and 6 month) results of metabolic syndrome improvement Phase II study	3Q16	****
		FDA AdCom meeting on secondary hypogonadism management	2H16	****
		Potential ex-U.S. partnership or other business development activities	2017	****
		Potential determine future clinical path	2016	****
Proellex	Uterine Fibroids	Potentially to report top-line results after one cycle treatment from low dose Proellex Phase II study	2Q16 (May)	****
		Potentially to report top-line results after one cycle treatment from low dose Proellex Phase II study	3Q16 (July)	****
		Potentially to schedule a type C meeting with the FDA to discuss Proellex Phase III study	4Q16	****
		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	4Q16	****

\*\*\*\* / \*\*\*\*\* Major catalyst event that could impact share price very significantly while \*\*\* event is more informative

Source: Laidlaw & Company estimates and company presentation.

## Major risks

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**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	1Q15	2Q15	3Q15	4Q15	2015	1Q16E	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E
<b>Revenue</b>														
Licensing fees	-	-	-	-	-	-	-	-	-	-	-	-	0.0	0.0
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Research and development grants	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>
Research and development	22.9	26.7	7.3	6.5	5.5	4.8	24.1	4.1	4.2	3.5	3.4	15.2	16.7	18.2
General and administrative	4.8	5.4	1.2	1.3	1.1	1.4	5.1	1.1	1.1	1.1	1.1	4.4	4.8	4.9
Sales and marketing	-	0.0	-	-	-	-	0.0	-	-	-	-	0.0	0.0	0.0
Interest expense and amortization of intangibles	-	-	-	-	-	-	0.0	-	-	-	-	-	-	-
<b>Total Operating Expenses</b>	<b>\$27.7</b>	<b>\$32.1</b>	<b>\$8.5</b>	<b>\$7.8</b>	<b>\$6.6</b>	<b>\$6.3</b>	<b>\$29.2</b>	<b>\$5.2</b>	<b>\$5.2</b>	<b>\$4.6</b>	<b>\$4.5</b>	<b>\$19.5</b>	<b>\$21.5</b>	<b>\$23.0</b>
<b>Operating Income (loss)</b>	<b>(\$27.7)</b>	<b>(\$32.1)</b>	<b>(\$8.5)</b>	<b>(\$7.8)</b>	<b>(\$6.6)</b>	<b>(\$6.3)</b>	<b>(\$29.2)</b>	<b>(\$5.2)</b>	<b>(\$5.2)</b>	<b>(\$4.6)</b>	<b>(\$4.5)</b>	<b>(\$19.5)</b>	<b>(\$21.5)</b>	<b>(\$23.0)</b>
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(27.7)	(32.1)	(8.5)	(7.8)	(6.6)	(6.3)	(29.2)	(5.2)	(5.2)	(4.6)	(4.5)	(19.5)	(21.5)	(23.0)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(8.5)	(7.8)	(6.6)	(6.3)	(29.2)	(5.2)	(5.2)	(4.6)	(4.5)	(19.5)	(21.5)	(23.0)
Income tax expense	-	-	-	-	-	-	-	-	-	-	-	0.0	0.0	0.0
<b>Net Incomes (Losses)</b>	<b>(\$27.7)</b>	<b>(\$32.1)</b>	<b>(\$8.5)</b>	<b>(\$7.8)</b>	<b>(\$6.6)</b>	<b>(\$6.3)</b>	<b>(\$29.2)</b>	<b>(\$5.2)</b>	<b>(\$5.2)</b>	<b>(\$4.6)</b>	<b>(\$4.5)</b>	<b>(\$19.5)</b>	<b>(\$21.5)</b>	<b>(\$23.0)</b>
Net Earnings (Losses) Per Share—Basic	(\$1.33)	(\$1.37)	(\$0.35)	(\$0.32)	(\$0.27)	(\$0.26)	(\$1.20)	(\$0.21)	(\$0.22)	(\$0.19)	(\$0.18)	(\$0.80)	(\$0.86)	(\$0.91)
Net Earnings (Losses) Per Share—Diluted	(\$1.33)	(\$1.37)	(\$0.35)	(\$0.32)	(\$0.27)	(\$0.26)	(\$1.20)	(\$0.21)	(\$0.22)	(\$0.19)	(\$0.18)	(\$0.80)	(\$0.86)	(\$0.91)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.3	24.3	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	24.3	24.3	24.3	24.3	24.4	24.4	24.5	24.9	25.3
<b>Margin Analysis (% of Revenue)</b>														
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.
R&D	254578%	888433%	732100%	645000%	275300%	60488%	N.A.	411315%	415428%	353114%	335458%	378829%	N.A.	N.A.
SG&A	53533%	181233%	120500%	134200%	55000%	18000%	N.A.	108000%	109080%	110171%	111273%	109631%	N.A.	N.A.
Operating Income (loss)	-308011%	-1069567%	-852500%	-779100%	-330200%	-78388%	N.A.	-519215%	-524408%	-463185%	-446631%	-488360%	N.A.	N.A.
Net Income	-308011%	-1069567%	-852500%	-779100%	-330200%	-78388%	N.A.	-519215%	-524408%	-463185%	-446631%	-488360%	N.A.	N.A.
<b>Financial Indicator Growth Analysis (Y/Y)</b>														
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.
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.
Total Revenue	200%	-67%	-50%	N.A.	N.A.	167%	-100%	0%	0%	-50%	-88%	N.A.	-100%	N.A.
Research and development	72%	16%	0%	-13%	-10%	-16%	-10%	-44%	-36%	-36%	-31%	-37%	10%	9%
General and administrative	0%	13%	-2%	7%	-14%	-14%	-6%	-10%	-19%	0%	-23%	-14%	10%	1%
Sales and marketing		N.A.					N.A.					N.A.	0%	15%
Operating incomes	53%	16%	0%	-11%	-11%	-16%	-9%	-39%	-33%	-30%	-29%	-33%	10%	7%
Total Other Income, net	53%	16%	0%	-11%	-11%	-16%	-9%	-39%	-33%	-30%	-29%	-33%	10%	7%
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.
Net Income	53%	16%	0%	-11%	-11%	-16%	-9%	-39%	-33%	-30%	-29%	-33%	10%	7%
EPS - Basic	13%	3%	-5%	-15%	-14%	-16%	-12%	-39%	-33%	-30%	-29%	-34%	8%	6%
EPS - Diluted	13%	3%	-5%	-15%	-14%	-16%	-12%	-39%	-33%	-30%	-29%	-34%	8%	6%
Shares outstanding—basic	36%	13%	5%	5%	4%	0%	4%	0%	0%	0%	0%	1%	2%	2%
Shares outstanding—diluted	36%	13%	5%	5%	4%	0%	4%	0%	0%	0%	0%	1%	2%	2%

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

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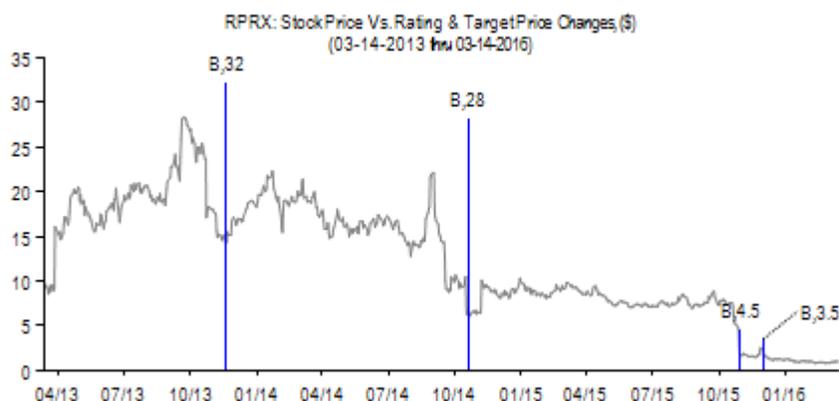
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#### 3 Year Rating Change History

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

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	65.71%	25.71%	2.86%
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