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EQUITY RESEARCH
Company Report

July 18, 2017

Repros Therapeutics (RPRX - $0.58)

Healthcare/Biotechnology

Ticker:		**RPRX**
Rating:	↓ lower	**Neutral**
Price Target:		

Preliminary FDA Feedback Dictates the Need for a Large Safety Database to Support Future Proellex Development

Yesterday, RPRX reported the preliminary feedback from the FDA indicating that Proellex will remain on partial clinical hold and RPRX would need to compile a large pre-approval safety database to support future development of Proellex, especially the oral low dose version.

- **Details.** Based on the existing liver function safety data, the FDA indicated that a large pre-approval safety database would be necessary to support future Proellex development. We believe such information will be gained from patients instead of healthy volunteers. The agency also indicated that Proellex will remain on partial clinical hold. RPRX indicated that they could potentially lean to developing vaginal Proellex in uterine fibroids (UF) and endometriosis. Prior clinical data showed comparable but slightly lower efficacy of the vaginal vs. oral Proellex in UF. For instance, at the end of the first treatment cycle (18 weeks), the relative percentage of treated patients over placebo achieved amenorrhea was 52% of vaginal (52% vs. 0%, p<0.0011) and 62% of low dose oral (79% vs. 17%, p=0.0004). Management also indicated more optimization work on vaginal Proellex is needed in the future. RPRX also received notice that expects a European patent to be granted on August 2, 2017 for the use of Proellex with an off-drug interval (ODI) for the treatment of estrogen-dependent hyperproliferative uterine conditions, including UF and endometriosis. This patent is related to recently granted U.S. patent (#: 9,616,074). RPRX could file responses to the EMA for its MAA for enclomiphene in 3Q17 with a potential EMA decision to occur possibly in late 4Q17 or 1Q18.
- **Implications.** We are disappointed with the FDA's preliminary feedback requiring a large safety database for advancing low dose oral Proellex forward, since this would incur substantially greater costs and time. We also believe additional work (both safety and efficacy) is needed for the development of vaginal Proellex before it can reach Phase III-ready status. The need for more cash for development in our opinion, is another overhang for the shares. We however are convinced that Proellex remains a valuable asset since SPRM is a clinically validated modality for UF and endometriosis treatment based on clinical advancements of competing programs. We anticipate more visibility provided by management near-term could potentially clarify the possible clinical path for Proellex.
- **Action.** We are downgrading RPRX shares to Neutral from our prior Buy rating, and withdrawing our target price to reflect the increased hurdle for Proellex development despite the promising fundamental of this asset.

Trading Data:

Last Price (7/17/2017)	$0.58
52–Week High (8/15/2016)	$2.48
52–Week Low (7/17/2017)	$0.30
Market Cap. (MM)	$11
Shares Out. (MM)	24.660

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.22A	-0.22	-0.28	-0.32	-1.07	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

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Anticipated milestones in 2017 and beyond

Program	Indication	Event	Timing	Importance
Proellex	Uterine Fibroids	Potentially to finalize the clinical development details	**2H17**	****
		Potentially to start a Phase II 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.

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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 in 2017; 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.

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Figure 1: Income Statement

Repros Therapeutics – Income Statement

($ MM)	2015	2016	1Q17	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E
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	2.1	2.0	5.0	6.0	15.1	17.2	18.9
General and administrative	5.1	4.6	3.8	3.9	3.9	4.0	15.6	15.8	15.9
Sales and marketing	0.0	0.0	-	-	-	-	-	-	-
Interest expense and amortization of intangibles	0.0	-	-	-	-	-	-	-	-
Total Operating Expenses	$29.2	$17.3	$5.9	$5.9	$8.9	$10.0	$30.7	$33.0	$34.9
Operating Income (loss)	($29.2)	($17.3)	($5.9)	($5.9)	($8.9)	($10.0)	($30.7)	($33.0)	($34.9)
Loss from continuing operations	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(29.2)	(17.3)	(5.9)	(5.9)	(8.9)	(10.0)	(30.7)	(33.0)	(34.9)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(29.2)	(17.3)	(5.9)	(5.9)	(8.9)	(10.0)	(30.7)	(33.0)	(34.9)
Income tax expense	-	0.0	-	-	-	-	0.0	0.0	0.0
Net Incomes (Losses)	($29.2)	($17.2)	($5.9)	($5.9)	($8.9)	($10.0)	($30.7)	($33.0)	($34.9)
Net Earnings (Losses) Per Share—Basic	($1.20)	($0.70)	($0.22)	($0.22)	($0.28)	($0.32)	($1.07)	($1.01)	($1.05)
Net Earnings (Losses) Per Share—Diluted	($1.20)	($0.70)	($0.22)	($0.22)	($0.28)	($0.32)	($1.07)	($1.01)	($1.05)
Shares outstanding—basic	24.3	24.7	26.3	26.3	31.3	31.3	28.8	32.8	33.2
Shares outstanding—diluted	24.3	24.7	26.3	26.3	31.3	31.3	28.8	32.8	33.2
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%	29629%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
SG&A	N.A.	9717%	54900%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Operating Income (loss)	N.A.	-36751%	-84429%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	N.A.	-36651%	-84429%	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.	-59%	-100%	-100%	-100%	-100%	N.A.	N.A.
Research and development	-10%	-47%	-45%	-37%	57%	134%	18%	14%	10%
General and administrative	-6%	-10%	251%	269%	293%	178%	242%	1%	1%
Sales and marketing	N.A.	N.A.					N.A.	N.A.	N.A.
Operating incomes	-9%	-41%	22%	38%	114%	150%	78%	7%	6%
Total Other Income, net	-9%	-41%	22%	38%	114%	150%	78%	7%	6%
Pretax Income	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	-9%	-41%	22%	39%	114%	151%	78%	7%	6%
EPS - Basic	-12%	-42%	13%	28%	68%	104%	53%	-6%	4%
EPS - Diluted	-12%	-42%	13%	28%	68%	104%	53%	-6%	4%
Shares outstanding—basic	4%	1%	8%	8%	28%	23%	17%	14%	1%
Shares outstanding—diluted	4%	1%	8%	8%	28%	23%	17%	14%	1%

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

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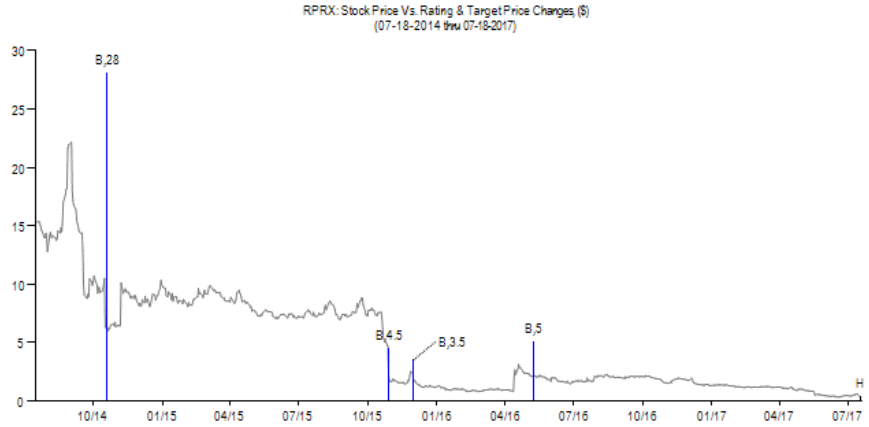

3 Year Rating Change History

Date	Rating	Closing Price ($)
10/20/2...	Buy (B)	6.23
07/18/2...	Hold (H)	0.39*

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
07/18/2...		0.39*

** Previous Close7/17/2017*

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	62.22%	31.11%	2.22%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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