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EQUITY RESEARCH
Company Report

March 27, 2017

Repros Therapeutics (RPRX - $1.18)

Healthcare/Biotechnology

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

New CEO Update Reaffirms RPRX Priority is on Advancing Proellex Development

We recently met the new CEO, Dr. Larry Dillaha, for an update regarding his plan for the future direction of RPRX. We walked away encouraged that the company is in the hands of a veteran experienced with late stage drug development. RPRX has a strong commitment to advance Proellex development starting with an FDA meeting scheduled in April.

- **Advancing Proellex development IS the sole focus.** Management indicated that the major focus from both the operational and financial perspective is solely on advancing Proellex development. As such, enclomiphene development expenditure in the U.S. would remain halted. After the enclomiphene MAA filing in 4Q16, RPRX believes a potential EU approval decision could occur in 4Q17.
- **Outcome of the April EOP2 meeting could be a critical near term catalyst, providing visibility on Proellex Phase III trial.** RPRX and the FDA are scheduled to conduct an EOP2 meeting before the end of April. They are likely to discuss the potential requirements of the low dose oral Proellex in uterine fibroids (UF) Phase III trial. Possible subjects could include study design, primary and secondary endpoints, and trial size; which also include the scope needed for demonstrating sufficient safety exposure and partial clinical hold. Data from Proellex in endometriosis Phase II trial would also be part of the discussions, though we believe development priority of Proellex will initially on UF. Following the EOP2 meeting, we anticipate RPRX could potentially commence a Proellex in UF Phase III study later in 2017. We view the potential EOP2 meeting feedback and FDA green lighting the advancement into pivotal studies as a very critical catalyst for RPRX shares. In addition to gaining greater visibility on the Phase III study design, it could help investors assess the developmental timeline. Potentially it could afford Proellex an earlier market entry to complete with other products.
- **Clinical operations could be further optimized.** Management. indicated that RPRX will continue its clinical operations optimization, potentially with greater leverage through external CROs.
- **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.

Trading Data:

Last Price (3/24/2017)	$1.18
52–Week High (4/14/2016)	$3.48
52–Week Low (4/12/2016)	$0.81
Market Cap. (MM)	$29
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

Source: Laidlaw & Company estimates

Yale Jen, Ph.D.
Managing Director /
Senior Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

- **Our major investment thesis is that Proellex clinical risk is well-mitigated.** We believe the low dose oral Proellex in UF development is well de-risked clinically given 1) the recently reported robust UF Phase II study readout, and 2) two other like-minded selective progesterone receptor modulators (SPRMs) with similar MOAs also exhibited good efficacy and safety in UF development. For Proellex, the Phase II study met the primary endpoint of induction of amenorrhea over the placebo (80% vs. 18%, p=0.0043). Further, Proellex treatment vs. placebo provided statistically significant fibroids volume reduction from baseline (40% vs. -3% with p=0.0002) measured by MRI. 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). Proellex in endometriosis Phase II trial also exhibited benefits over placebo in pain reduction assessed by BBSS (85% vs. 38% p=0.0008) and reduced analgesics use.

  Including Proellex (telapristone acetate), there are four late clinical stage oral products in development for treating UF. Three are SPRM which include Esmya (ulipristal acetate) and Vilaprisan, while Elagolix is a GnRH antagonist. Although Proellex would not likely be the first or even the second to reach the market, we believe the commercial outlook could still be encouraging given the large market size (potential over 10 million patients in the U.S. and EU combined) and significant unmet need. With the caveat of comparing clinical data across different clinical trials, we believe the overall outcome (for example, reduction of bleeding or achieving amenorrhea) of all three SPRMs are generally on par with each other as they have reached ~60% improvement over placebo.

  Here is a summary of highlights from some of the competitors:

  - Esmya (ulipristal acetate): an SPRM developed by Allergan is undergoing two pivotal trials (Venus I and II) for approval. The company reported positive outcome of the first Phase III (Venus I) study in 2Q16, meeting all co-primary and secondary endpoints with statistical significance. AGN recently also reported positive results from the second Phase III trial (Venus II) (n=432) which met co-primary endpoint of percentage of patients with absence of uterine bleeding and time to absence of uterine bleeding [54.8% of 10 mg ($p<0.0001$) and 42.0% of 5 mg ($p<0.0001$) vs. placebo (0%)]. AGN is schedule to file an NDA in 2H17 with potential Esmya approval in 2018.

  - Elagolix: a GnRH antagonist developed by Neurocrine and AbbVie. The drug has demonstrated positive Phase III results in moderate-to-severe endometriosis. ABBV plans to file an NDA in 2H17 with potential approval in endometriosis in 2018. For UF, Elagolix (300mg BID) also showed encouraging results in reducing heavy menstrual bleeding (HMB) vs. placebo (86% vs. 27%, $p<0.001$) in a Phase IIb trial. ABBV guided the ongoing Phase III trials in UF to potentially report interim data (6 month and 12 month) in 2H17 and 2018 and topline data in 2019 with sNDA filing (if endometriosis indication is approved) shortly thereafter.

  - Vilaprisan (BAY 1002670): an SPRM developed by Bayer. We believe the program is potentially Phase III ready for UF treatment. BAYN conducted two Phase II trials (ASTEROID 1 and 2) and recently reported encouraging ASTEROID 1 (n=286) results at the 2016 ASRM (American Society for Reproductive Medicine) meeting demonstrated that 97-100% of patients achieved controlled bleeding, while 87%-92% achieved amenorrhea by the end of the treatment course. The company could potentially report ASTEROID 2 (n=120) study results in 2017, and this study also include 3 comparator arms of Esmya.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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%

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

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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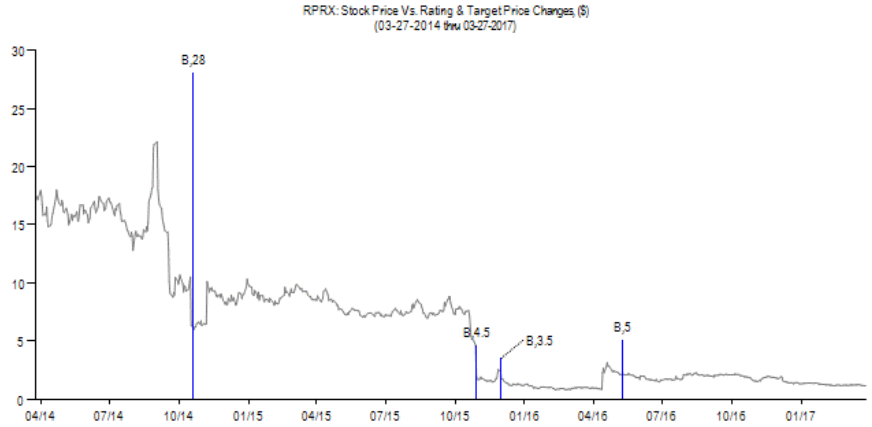
Rating and Price Target Change History



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 **Created by: Blue-Compass.net**

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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%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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Allergan, Inc. (AGN – Not Rated)
Neurocrine Biosciences, Inc. (NBIX – Not Rated)
AbbVie (ABBV – Not Rated)
Bayer AG (BAYN – Not Rated)

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Yale Jen, Ph.D.
yjen@laidlawltd.com

NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com