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EQUITY RESEARCH
Company Report

December 22, 2015

Repros Therapeutics (RPRX - $ 1.23)

Healthcare/Biotechnology

Proellex Development Updates with Three Phase II Clinical Trial Results Expected in 3Q16

Ticker:	**RPRX**
Rating:	**Buy**
Price Target:	**$ 3.50**

Yesterday after market close, RPRX updated investors the progress of Proellex Phase II trials with topline results of all three studies expected by the end of 3Q16.

- **Details.** Proellex is under three Phase IIb studies in uterine fibroids (UF) (low dose oral and vaginal-delivered) and severe (Biberoglu Berman Symptom Survey Score > 7) endometriosis (low dose oral). The overall study design is identical for all studies (n~45) with either two doses (6mg and 12mg) of treatment or a placebo. Patients are treated for four months, followed by a follow-up to allow the return of menses. The UF study uses the alkaline-hematin method to measure the menstrual blood losses. RPRX expects the last patient of the low dose oral study to be randomized by the end of Jan. 2016. RPRX reported encouraging interim results of the endometriosis study (n=41) with reduction from the baseline of treatment vs. placebo in pain scores (61% vs. 17%) and analgesic usage (77% vs. 0%) – both outcomes are statistically significant. As such, RPRX decided to stop patient enrollment and will conclude the study by the end of Jan. 2016.

- **Implication**. These updates, especially the promising endometriosis interim analysis results, are very encouraging given potentially positive Proellex developments drive the majority of the near term RPRX share value, in our opinion. Should the outcomes reported in 3Q16 be positive, RPRX is scheduled to conduct a meeting with the FDA to discuss appropriate Phase III programs for an NDA filing of the two indications. RPRX is also likely to make a decision to advance one of the Proellex formulations into pivotal studies in UF. The market potential of both indications is large with substantial unmet need. One of the leading competitors is elagolix (an orally-administered GnRH antagonist) developed by Neurocrine and AbbVie. ABBV conducted two Phase III studies (Violet Petal and Solstice) evaluating Elagolix in moderate-to-severe endometriosis and will start a Phase III study in UF in 1Q16. The Violet Petal trial has met its co-primary endpoints of reductions in dysmenorrhea and non-menstrual pelvic pain ($p<0.001$). The topline results of the Solstice study is expected in 1Q16.

- **Action.** We are reiterating our Buy rating, and target price of $3.50 to reflect the promising Proellex development and potential Androxal value in Europe. Our valuation is based on our probability-adjusted sum-of-the-parts analysis.

Trading Data:

Last Price (12/21/2015)	$ 1.23
52–Week High (12/30/2014)	$ 10.55
52–Week Low (12/15/2015)	$ 1.09
Market Cap. (MM)	$ 30
Shares Out. (MM)	24

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.35A	-0.32A	-0.27A	-0.27	-1.22	NM
FY-14A	-0.37	-0.38	-0.32	-0.31	-1.37	NM
FY-13A	-0.41	-0.38	-0.26	-0.31	-1.33	NM
FY-12A	-0.17	-0.21	-0.30	-0.47	-1.18	NM

Source: Laidlaw & Company estimates

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Anticipated milestones in 2015 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	Potential ex-U.S. partnership or other business development activities	**2016**	****
		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	**3Q16**	****
		Potentially to schedule a type C meeting with the FDA to discuss Proellex Phase III study	**2H16**	****
		Potentially to determine low dose oral vs. vaginal Proellex as final format for Phase III trial	**2H16**	****
		Potentially to start a Phase III study	**2016/2017**	*****
	Endometriosis	Possible to complete Phase II study	**1Q16**	***
		Possible to report Phase II study top-line results	**3Q16**	****

***** / ***** 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

Clinical risks of trial study failure could have a significantly negative impact on RPRX share value. Given that Androxal in secondary hypogonadism is the most advanced and most promising program in Repros' product portfolio, we believe the majority of RPRX share value (assessed by both us and the Street) resides in the potential clinical and regulatory success of this program. Even with a greater probability of clinical failure, a scenario where the FDA requests significantly more difficult Phase III studies at the upcoming meeting, should the company be unable to accomplish such a task; could significantly reduce RPRX share value.

Market potential of Androxal in secondary hypogonadism is lower than projected. With well-differentiated attributes, such as retaining spermatogenesis compared to marketed testosterone replacement products, coupled with the trend of increased prescription, and substantial unmet medical need; we believe the commercial outlook of Androxal could be substantial. However, given Androxal is a non-testosterone and competes in an environment of a well-entrenched TRT treatment paradigm, substantial and effective education efforts, in our opinion, are necessary to change physicians' prescribing habits and expand Androxal sales. The potential patent expiration of AndroGel could be an opportunity for Androxal but it also could become a challenge that limits Androxal's pricing flexibility. Overall, if our projection for the future market dynamics is incorrect, or the execution by the company (given the current management team has limited product commercialization experience), or potential licensing partner is inadequate; the revenue outlook for Androxal could disappoint.

Androxal patent dispute could potentially affect the economics RPRX receives. The company is currently in a legal dispute with Dr. Harry Fisch, who claims the two patents encompassing clomid as a treatment for hypogonadism. Despite the fact that the U.S. Patent and Trademark Office (PTO) recently reversed the rejections of Dr. Fisch's patent infringement claims, it might be too early or too uncertain, in our opinion, to determine the ultimate resolution. If such patents are not invalidated by the PTO or a court of competent jurisdiction, the company may be required to obtain a license, potentially for a fee, from the holder of such patents in order to develop Androxal further. Although we do not anticipate such a scenario would derail the development or commercial outlook of Androxal, we believe the economic reward to the company would be reduced modestly.

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 be too early to fully project the product's future in endometriosis and in uterine fibroids. In addition,

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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 a setback although Proellex only accounts for a minor portion of the RPRX valuation.

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.

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Figure 1: Income Statement

Repros Therapeutics – Income Statement

($ MM)	2013	2014	1Q15	2Q15	3Q15	4Q15E	2015E	2016E	2017E	2018E
Revenue										
Licensing fees	-	-	-	-	-	-	-	5.0	5.0	5.0
Product revenue	-	-	-	-	-	-	-	-	-	-
Research and development grants	-	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-
Total Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$5.0	$5.0	$5.0
Research and development	22.9	26.7	7.3	6.5	5.5	5.6	24.8	25.6	28.1	30.7
General and administrative	4.8	5.4	1.2	1.3	1.1	1.1	4.8	6.2	6.8	6.9
Sales and marketing		0.0	-	-	-	-	0.0	0.0	0.0	0.0
Interest expense and amortization of intangibles	-	-	-	-	-	-	0.0	-	-	-
Total Operating Expenses	$27.7	$32.1	$8.5	$7.8	$6.6	$6.7	$29.6	$31.8	$34.9	$37.5
Operating Income (loss)	($27.7)	($32.1)	($8.5)	($7.8)	($6.6)	($6.7)	($29.6)	($26.8)	($29.9)	($32.5)
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(27.7)	(32.1)	(8.5)	(7.8)	(6.6)	(6.7)	(29.6)	(26.8)	(29.9)	(32.5)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(8.5)	(7.8)	(6.6)	(6.7)	(29.6)	(26.8)	(29.9)	(32.5)
Income tax expense	-	-	-	-	-	-	-	0.0	0.0	0.0
Net Incomes (Losses)	($27.7)	($32.1)	($8.5)	($7.8)	($6.6)	($6.7)	($29.6)	($26.8)	($29.9)	($32.5)
Net Earnings (Losses) Per Share—Basic	($1.33)	($1.37)	($0.35)	($0.32)	($0.27)	($0.27)	($1.22)	($1.09)	($1.20)	($1.29)
Net Earnings (Losses) Per Share—Diluted	($1.33)	($1.37)	($0.35)	($0.32)	($0.27)	($0.27)	($1.22)	($1.09)	($1.20)	($1.29)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.3	24.3	24.3	24.5	24.9	25.3
Shares outstanding—diluted	20.8	23.4	24.3	24.3	24.3	24.3	24.3	24.5	24.9	25.3
Margin Analysis (% of Revenue)										
COGS		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%
R&D	254578%	888433%	732100%	645000%	275300%	278053%	N.A.	512%	563%	613%
SG&A	53533%	181233%	120500%	134200%	55000%	55550%	N.A.	124%	136%	137%
Operating Income (loss)	-308011%	-1069567%	-852500%	-779100%	-330200%	-333503%	N.A.	-535%	-599%	-651%
Net Income	-308011%	-1069567%	-852500%	-779100%	-330200%	-333503%	N.A.	-535%	-599%	-651%
Financial Indicator Growth Analysis (Y/Y)										
Licensing fees	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	0%	0%
Product royalties	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.	-33%	-100%	N.A.	0%	0%
Research and development	72%	16%	0%	-13%	-10%	-4%	-7%	3%	10%	9%
General and administrative	0%	13%	-2%	7%	-14%	-34%	-12%	30%	10%	1%
Sales and marketing		N.A.					N.A.	N.A.	0%	15%
Operating incomes	53%	16%	0%	-11%	-11%	-10%	-8%	-10%	12%	9%
Total Other Income, net	53%	16%	0%	-11%	-11%	-10%	-8%	-10%	12%	9%
Pretax Income	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%	-10%	-8%	-10%	12%	9%
EPS - Basic	13%	3%	-5%	-15%	-14%	-11%	-11%	-10%	10%	7%
EPS - Diluted	13%	3%	-5%	-15%	-14%	-11%	-11%	-10%	10%	7%
Shares outstanding—basic	36%	13%	5%	5%	4%	0%	4%	1%	2%	2%
Shares outstanding—diluted	36%	13%	5%	5%	4%	0%	4%	1%	2%	2%

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

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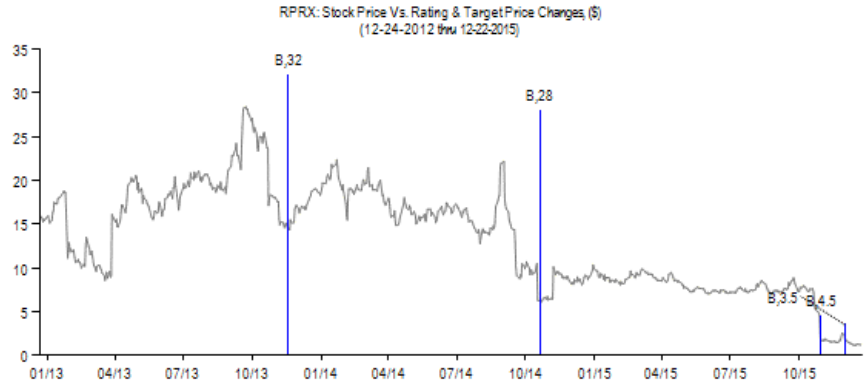
Rating and Price Target Change History



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**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			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.	64.71%	26.47%	2.94%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

AbbVie (ABBV – Not Rated)
Neurocrine Biosciences (NBIV – Not Rated)

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