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EQUITY RESEARCH
Company Report

December 8, 2016

Repros Therapeutics (RPRX - $ 1.62)

Healthcare/Biotechnology

A Buying Opportunity after the AdCom Vote on Obesity-Related Hypogonadism Approval Criterion Decision

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

The Bone, Reproductive and Urologic Drugs AdCom of the FDA on December 6 held a meeting on the clinical and regulatory path for approving products in obesity-related hypogonadism patients who wish to maintain spermatogenesis. The panel voted 16 to 5 indicating that the achievement of testosterone improvement and maintaining evidence of spermatogenesis was not sufficient to provide evidence of clinical benefit.

- **Details.** Several panel members during the meeting also suggested that an additional endpoint related to symptoms should be assessed for potential approval in this indication. RPRX indicated it would develop a symptom-related assessment tool after the completion and review of the ongoing enclomiphene plus diet and exercise Phase II study; and intends to discuss with the FDA for a potential Phase III study design in 2017.
- **Implications.** We are not surprised by the AdCom panel's consensus given that achieving the testosterone restoration and spermatogenesis maintaining endpoints did not gain an approval for enclomiphene at first in late 2015. With the ongoing Phase II study, RPRX could potentially find a path to advance enclomiphene forward for possible approval. However, we believe the majority of the RPRX share value is relying on the potential success of Proellex in endometriosis and in uterine fibroids (UF). In our opinion, enclomiphene development in Europe (potential approval decision in 1H18) and the U.S. could be a free call option at the current valuation. Proellex achieved robust Phase II study results in both indications, and is of the same drug class (selective progesterone receptor modulator or SPRM) as Allergan's Esmya (ulipristal acetate). Esmya already met the primary endpoint of its first Phase III study in UF, thus we believe Proellex is a de-risked Phase III ready asset for endometriosis and UF. Esmya's second Phase III study (Venus II) is ongoing with top-line results expected in 2017 and potential approval in 2018. As such, we view RPRX shares were oversold (~15% drop) yesterday after the news, and the current valuation represents a good buying opportunity for investors who want to own a late stage and mitigated risk drug developer prospect.
- **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 (12/07/2016)	$ 1.62
52–Week High (4/14/2016)	$ 3.48
52–Week Low (2/11/2016)	$ 0.80
Market Cap. (MM)	$ 41
Shares Out. (MM)	25

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
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
FY-13A	-0.41	-0.38	-0.26	-0.31	-1.33	NM

Source: Laidlaw & Company estimates

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Anticipated milestones in 2016 and beyond

Program	Indication	Event	Timing	Importance
Enclomiphene	Secondary hypogonadism	Report interim (12 month) results of metabolic syndrome improvement Phase II study	**1Q17**	***
		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**	***
Proellex	Uterine Fibroids	Potentially to schedule a type C meeting with the FDA to discuss Proellex Phase III study	**1Q17**	****
		Potentially to start a Phase III study	**2017**	*****
	Endometriosis	Possible EOP2 meeting with the FDA	**4Q16/1H17**	***

***** / ***** 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, 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	2015	1Q16	2Q16	3Q16	4Q16E	2016E	2017E	2018E
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
Research and development	22.9	26.7	24.1	3.8	3.2	3.2	3.0	13.2	14.5	15.8
General and administrative	4.8	5.4	5.1	1.1	1.1	1.0	1.0	4.2	4.6	4.6
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	$29.2	$4.9	$4.3	$4.2	$4.0	$17.4	$19.1	$20.5
Operating Income (loss)	($27.7)	($32.1)	($29.2)	($4.8)	($4.3)	($4.2)	($4.0)	($17.3)	($19.1)	($20.5)
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)	(19.1)	(20.5)
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)	(19.1)	(20.5)
Income tax expense	-	-	-	-	-	-	-	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)	($19.1)	($20.5)
Net Earnings (Losses) Per Share—Basic	($1.33)	($1.37)	($1.20)	($0.20)	($0.18)	($0.17)	($0.16)	($0.71)	($0.77)	($0.81)
Net Earnings (Losses) Per Share—Diluted	($1.33)	($1.37)	($1.20)	($0.20)	($0.18)	($0.17)	($0.16)	($0.71)	($0.77)	($0.81)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.3	24.5	24.5	24.5	24.9	25.3
Shares outstanding—diluted	20.8	23.4	24.3	24.3	24.3	24.5	24.5	24.5	24.9	25.3
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	254578%	888433%	N.A.	22147%	324300%	31820%	302290%	45562%	N.A.	N.A.
SG&A	53533%	181233%	N.A.	6447%	105200%	9970%	100697%	14317%	N.A.	N.A.
Operating Income (loss)	-308011%	-1069567%	N.A.	-28494%	-429400%	-41690%	-402887%	-59779%	N.A.	N.A.
Net Income	-308011%	-1069567%	N.A.	-28494%	-429400%	-41690%	-402887%	-59779%	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.
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%	-100%	1600%	0%	400%	-88%	N.A.	-100%	N.A.
Research and development	72%	16%	-10%	-49%	-50%	-42%	-38%	-45%	10%	9%
General and administrative	0%	13%	-6%	-9%	-22%	-9%	-30%	-18%	10%	1%
Sales and marketing		N.A.	N.A.					N.A.	0%	15%
Operating incomes	53%	16%	-9%	-43%	-45%	-37%	-36%	-41%	10%	7%
Total Other Income, net	53%	16%	-9%	-43%	-45%	-37%	-36%	-41%	10%	7%
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%	-9%	-43%	-45%	-37%	-36%	-41%	10%	7%
EPS - Basic	13%	3%	-12%	-43%	-45%	-37%	-36%	-41%	8%	5%
EPS - Diluted	13%	3%	-12%	-43%	-45%	-37%	-36%	-41%	8%	5%
Shares outstanding—basic	36%	13%	4%	0%	0%	1%	1%	1%	2%	2%
Shares outstanding—diluted	36%	13%	4%	0%	0%	1%	1%	1%	2%	2%

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

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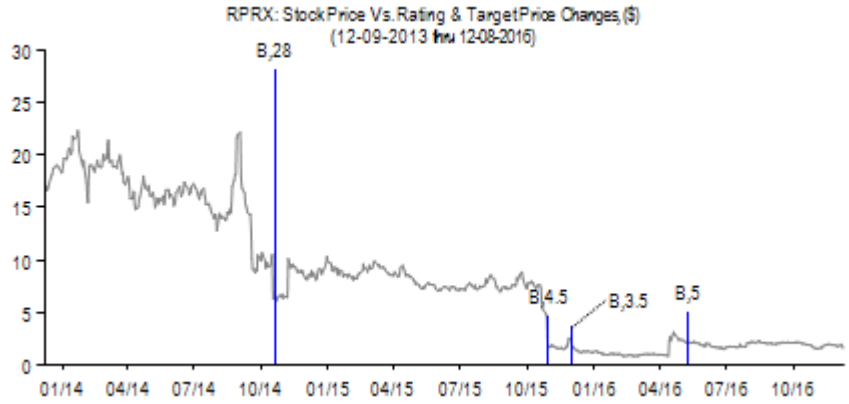
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
10/20/2014	Buy (B)	6.23

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
10/20/2014	28.00	6.23
10/30/2015	4.50	1.71
12/01/2015	3.50	1.74
05/10/2016	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.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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Allergan, Inc. (AGN – Not Rated)

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