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EQUITY RESEARCH
Company Report

December 1, 2015

Repros Therapeutics (RPRX - $ 1.73)

Healthcare/Biotechnology

Complete Response Letter from the FDA for Androxal in Secondary Hypogonadism

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

This morning, RPRX reported that the FDA issued a Complete Response Letter (CRL) for its NDA of Androxal as a treatment of secondary hypogonadism in overweight men wishing to restore normal testicular function.

- **Details.** The agency indicated that RPRX needs to conduct an additional Phase III study to support approval in the target population since the design of earlier Phase III studies is no longer adequate to demonstrate clinical benefit. The major concerns of the agency are the study entry criteria, titration and bioanalytical method validation in the submitted Phase III trials. The FDA considers the "classic" hypogonadism (the one with an absence or deficiency of testosterone due to documented testicular or hypothalamic/pituitary disease, such as Klinefelter's syndrome) as target patients that need treatment. Other types of hypogonadism, which have been categorized as so-called "age-related" and its management from a testosterone restoration perspective remains controversial. RPRX plans to work with the FDA in 2016 hopefully to identify a clinical path toward moving Androxal development forward. RPRX is scheduled to file for Androxal approval in Europe in 1H16.
- **Implication**. Given the abrupt cancellation of the AdCom meeting by the FDA at the very last minute on October 30, we are not surprised with the CRL decision since the agency appeared to have already made up its mind on which kinds of hypogonadism require treatment. Due to great uncertainty for the clinical path forward, we will wait for more feedback from the discussions between RPRX and the FDA before assessing the Androxal U.S. outlook. We believe currently the majority of RPRX share value is on Proellex in uterine fibroids (UF) and endometriosis developments, and the possible Androxal EU opportunity. Two Proellex in UF Phase II trials (low dose oral and vaginally-delivered) are underway with top-line results potentially in mid-2016. If positive, RPRX is scheduled to conduct a meeting with the FDA (possibly in 2H16) to discuss the path forward. Proellex in endometriosis Phase II results could be available in late 2016 or 2017.
- **Action.** We are reiterating our Buy rating, and reducing our target price to $3.50 from $4.50 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 (12/01/2015)	$ 1.73
52–Week High (12/30/2014)	$ 10.55
52–Week Low (12/1/2015)	$ 1.18
Market Cap. (MM)	$ 41
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	**1H16**	****
		Potentially to schedule a type C meeting with the FDA to discuss Proellex Phase III study	**2016**	****
		Potentially to determine low dose oral vs. vaginal Proellex as final format for Phase III trial	**2016**	****
		Potentially to start a Phase III study	**2016**	*****
	Endometriosis	Possible to complete patient enrollment for Phase II study	**2016**	***
		Possible to report Phase II study top-line results	**1H16**	***

***** / ***** 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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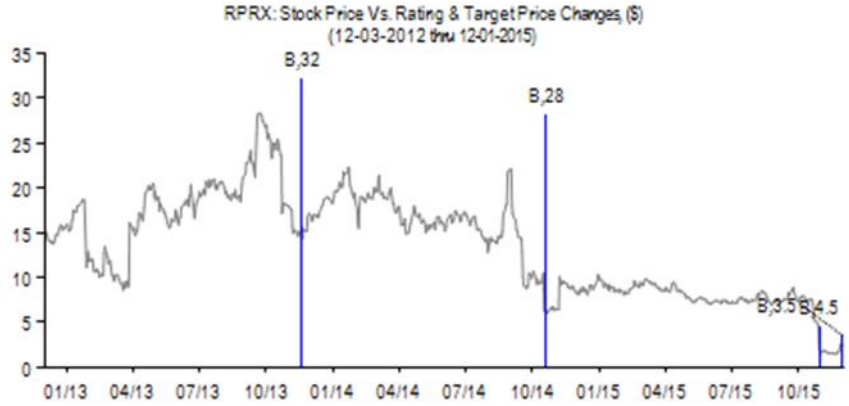
Rating and Price Target Change History



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	2.40*

** Previous Close11/30/2015*

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.	62.50%	25.00%	3.13%
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%

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