

## Repros Therapeutics (RPRX - \$ 2.08)

### Androxal Development Risks Increased Substantially After AdCom Meeting Cancellation; Reducing TP to \$4.50

Yesterday, the FDA cancelled the Nov. 3, 2015 AdCom meeting for reviewing Androxal in secondary hypogonadism (2<sup>nd</sup> HG) due to issues related to the validation of the bioanalytical method used for pivotal studies. RPRX shares dropped ~56% and closed at \$2.08 with a market cap of ~\$50MM.

- Details.** The agency indicated that the lack of bioanalytical method validation could affect interpretability of certain study data; and the FDA will work with RPRX to address these questions. RPRX suggested at the conference call that an additional reason for this decision could be that the FDA has not established the approach for medically managing 2<sup>nd</sup> HG patients who are not classified as “classic”. The AdCom meeting (Sep. 2014) seemed to define “classic HG” as primary and secondary HG patients with only specific and well-recognized medical conditions. All other HGs are considered as “age related” and the FDA had not issued any guidance as how or even whether to treat them. Two questions from the briefing document revealed by RPRX, which include whether the sponsor a) studied the intended patient population; and b) identified clinical benefit from the study; appear to support RPRX’s speculation. RPRX plans to work with the FDA over the next year to hopefully identify a clinical path moving Androxal development forward. It is likely that additional clinical studies may be needed. RPRX is scheduled to file for Androxal approval in Europe in 1H16.
- Implication.** We are very surprised and disappointed on the FDA’s decision since the agency did not even offer an opportunity for RPRX to present their case. It is also very unusual to cancel an AdCom meeting at the very last minute. We continue to view Androxal as an effective and better HG treatment. The FDA, in our opinion, should develop workable guidelines for medically managing the dominant majority of “non-classic” HG patients. Due to great uncertainty for the clinical path forward, we have removed the value of Androxal in 2<sup>nd</sup> HG in the U.S. from our model until greater visibility is available. We believe the Androxal EU opportunity remains intact given Europeans have a different view on testosterone restoration.
- Action.** We are reiterating our Buy rating, and reducing our target price to \$4.50 from \$28 to reflect the value of Androxal (Europe) and promising Proellex in development. Our valuation is based on our P/E and probability-adjusted sum-of-the-parts analyses.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-15E</b>	-0.35A	-0.32A	-0.25	-0.25	-1.17	NM
<b>FY-14A</b>	-0.37	-0.38	-0.32	-0.31	-1.37	NM
<b>FY-13A</b>	-0.41	-0.38	-0.26	-0.31	-1.33	NM
<b>FY-12A</b>	-0.17	-0.21	-0.30	-0.47	-1.18	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **RPRX**  
 Rating: **Buy**  
 Price Target: ↓ lower **\$ 4.50**

#### Trading Data:

Last Price (10/29/2015)	\$ 2.08
52-Week High (11/13/2014)	\$ 10.72
52-Week Low (10/29/2015)	\$ 1.90
Market Cap. (MM)	\$ 51
Shares Out. (MM)	24

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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.

## Major risks

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**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,

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.

Figure 1: Income Statement

<b>Repros Therapeutics – Income Statement</b>										
<b>(\$ MM)</b>	<b>2013</b>	<b>2014</b>	<b>1Q15</b>	<b>2Q15</b>	<b>3Q15E</b>	<b>4Q15E</b>	<b>2015E</b>	<b>2016E</b>	<b>2017E</b>	<b>2018E</b>
<b>Revenue</b>										
Licensing fees	-	-	-	-	-	-	-	10.0	10.0	10.0
Product revenue	-	-	-	-	-	-	-	0.0	2.0	3.5
Research and development grants	-	-	-	-	-	-	-	-	-	-
Interest income	0.0	0.0	-	-	-	-	-	-	-	-
Gain on disposal of fixed assets	0.0	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$10.0</b>	<b>\$12.0</b>	<b>\$13.5</b>
<b>Costs of goods</b>										
Gross revenue	-	-	-	-	-	-	-	0.0	0.2	0.3
Research and development	22.9	26.7	7.3	6.5	4.7	4.8	23.2	23.9	26.3	28.7
General and administrative	4.8	5.4	1.2	1.3	1.4	1.4	5.3	6.9	7.5	7.6
Sales and marketing	-	0.0	-	-	-	-	0.0	0.0	0.0	0.0
Interest expense and amortization of intangibles	-	-	-	-	-	-	0.0	-	-	-
<b>Total Operating Expenses</b>	<b>\$27.7</b>	<b>\$32.1</b>	<b>\$8.5</b>	<b>\$7.8</b>	<b>\$6.1</b>	<b>\$6.1</b>	<b>\$28.5</b>	<b>\$30.8</b>	<b>\$33.9</b>	<b>\$36.3</b>
<b>Operating Income (loss)</b>	<b>(\$27.7)</b>	<b>(\$32.1)</b>	<b>(\$8.5)</b>	<b>(\$7.8)</b>	<b>(\$6.1)</b>	<b>(\$6.1)</b>	<b>(\$28.5)</b>	<b>(\$20.8)</b>	<b>(\$22.1)</b>	<b>(\$23.2)</b>
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)	(6.1)	(6.1)	(28.5)	(20.8)	(22.1)	(23.2)
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(8.5)	(7.8)	(6.1)	(6.1)	(28.5)	(20.8)	(22.1)	(23.2)
Income tax expense	-	-	-	-	-	-	-	0.0	0.0	0.0
<b>Net Incomes (Losses)</b>	<b>(\$27.7)</b>	<b>(\$32.1)</b>	<b>(\$8.5)</b>	<b>(\$7.8)</b>	<b>(\$6.1)</b>	<b>(\$6.1)</b>	<b>(\$28.5)</b>	<b>(\$20.8)</b>	<b>(\$22.1)</b>	<b>(\$23.2)</b>
Net Earnings (Losses) Per Share—Basic	(\$1.33)	(\$1.37)	(\$0.35)	(\$0.32)	(\$0.25)	(\$0.25)	(\$1.17)	(\$0.84)	(\$0.88)	(\$0.91)
Net Earnings (Losses) Per Share—Diluted	(\$1.33)	(\$1.37)	(\$0.35)	(\$0.32)	(\$0.25)	(\$0.25)	(\$1.17)	(\$0.84)	(\$0.88)	(\$0.91)
Shares outstanding—basic	20.8	23.4	24.3	24.3	24.4	24.5	24.4	24.8	25.2	25.6
Shares outstanding—diluted	20.8	23.4	24.3	24.3	24.4	24.5	24.4	24.8	25.2	25.6
<b>Margin Analysis (% of Revenue)</b>										
COGS		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%
R&D	254578%	888433%	732100%	645000%	235425%	237779%	N.A.	239%	220%	213%
SG&A	53533%	181233%	120500%	134200%	67771%	68449%	N.A.	69%	63%	56%
Operating Income (loss)	-308011%	-1069567%	-852500%	-779100%	-303096%	-306128%	N.A.	-208%	-185%	-172%
Net Income	-308011%	-1069567%	-852500%	-779100%	-303096%	-306128%	N.A.	-208%	-185%	-172%
<b>Financial Indicator Growth Analysis (Y/Y)</b>										
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.	76%
Total Revenue	200%	-67%	-50%	N.A.	N.A.	-33%	-100%	N.A.	20%	13%
Research and development	72%	16%	0%	-13%	-23%	-18%	-13%	3%	10%	9%
General and administrative	0%	13%	-2%	7%	6%	-18%	-3%	30%	10%	1%
Sales and marketing		N.A.					N.A.	N.A.	0%	15%
Operating incomes	53%	16%	0%	-11%	-18%	-18%	-11%	-27%	6%	5%
Total Other Income, net	53%	16%	0%	-11%	-18%	-18%	-11%	-27%	6%	5%
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%	-18%	-18%	-11%	-27%	6%	5%
EPS - Basic	13%	3%	-5%	-15%	-21%	-19%	-15%	-28%	5%	3%
EPS - Diluted	13%	3%	-5%	-15%	-21%	-19%	-15%	-28%	5%	3%
Shares outstanding—basic	36%	13%	5%	5%	4%	1%	4%	2%	2%	2%
Shares outstanding—diluted	36%	13%	5%	5%	4%	1%	4%	2%	2%	2%

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

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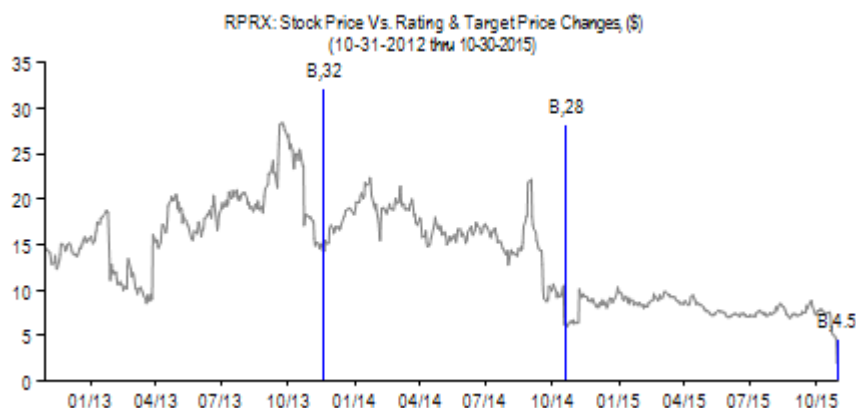
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#### Rating and Price Target Change History



#### 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	2.08*

\* Previous Close 10/29/2015

Source: Laidlaw & Company

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			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	74.19%	25.81%	6.45%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	3.23%	0.00%	0.00%
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