

## Repros Therapeutics (RPRX - \$ 20.12)

### ZA-305 Results Conference Call Updates.

We are providing highlights of RPRX's conference call this morning focusing on the robust ZA-305 top-line results.

- Details.** During this morning's conference call, management afforded several more insights on the robust ZA-305 results. Key highlights of the call are: 1) the change of the primary endpoints from three to two occurred several days after the company issued the press release of three co-primary endpoints in July. The change was requested by the FDA; 2) an Advisory Committees (Adcom) meeting is scheduled on September 17 to provide more information to the FDA. The company also plans to schedule a pre-NDA meeting in October; 3) given the 305 data release is slightly ahead of schedule, it is possible that the 304 data release could occur earlier as well, although the management did not commit to a potentially early timeline; 4) regarding the better testosterone data (both the morning and 24-hour average readings) outcome of Androxal vs. AndroGel, management speculated that the reason could be due to patients treated with exogenous testosterone (such as AndroGel) might have further impaired their ability in producing testosterone, resulting in lower circulating testosterone reported; 4) with the novel mechanism of action and robust comparative clinical outcome, the company might have applied more patents to further protect Androxal although management provided limited information on this issue; 5) 304 study design is identical to that of the 305 with more academic clinical sites; and 6) major presentation of 304/305 results at the 2015 AUA meeting is expected.
- Implications.** We concurred with management's comment that the study meeting the responder composite endpoint is critical since it indicated that Androxal is overall better than TRT as a treatment for secondary hypogonadism. We also believe robust clinical 305 study results afford positive commercial implication. We believe the results of the 304 study are likely being positive and robust and the company could file NDA in 4Q14 with potential FDA expert meeting and potential approval in 2H15.
- Action.** We are reiterating our Buy rating and our \$32 target price to reflect the very positive outlook of Androxal and the maturation of Proellex development. Our valuation is based on our P/E, and NPV-driven-and-probability adjusted sum-of-the-parts analyses.

### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-14E</b>	-0.37A	-0.38A	-0.35	-0.29	-1.40	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
<b>FY-11A</b>	-0.20	-0.30	-0.32	-0.22	-1.04	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **RPRX**  
 Rating: **Buy**  
 Price Target: **\$ 32.00**

### Trading Data:

Last Price (08/28/2014)	\$ 20.12
52-Week High (9/24/2013)	\$ 29.79
52-Week Low (8/1/2014)	\$ 12.61
Market Cap. (MM)	\$ 465
Shares Out. (MM)	23

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## Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	Potential to release 2nd Phase III (304) comparative studies results	4Q (Oct.) '14	*****
		Potential NDA filing	4Q14	****
		FDA expert panel meeting	3Q15	*****
		Potential partnership or other business development activities	2014 / 2015	*****
		Potential approval for 2nd hypogonadism	4Q15 / 1Q16	*****
Proellex	Uterine Fibroids	Potentially to commence low dose oral Proellex Phase II study	3Q14	***
		Potentially to report top-line results from low dose oral Proellex Phase II study	2H15	***
		Potentially to determine low dose oral vs. vaginal Proellex as final format for Phase III trial	2H15	****
		Potentially to start a Phase III study	2015	*****
	Endometriosis	Possible to complete patient enrollment for Phase II study	Late 14 / 2015	***
		Possible to report Phase II study top-line results	2H15	****
		Analyst Day	Oct. 31, 2014	***

\*\*\*\* / \*\*\*\*\* 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 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 valuation (both assessed by us and the Street) resides in the potential clinical and regulatory success of this program. Despite a lower probability of clinical failure, in our opinion, a scenario that if the FDA requests significantly more difficult Phase III studies at the upcoming meeting and the company cannot accomplish such a task; could significantly reduce RPRX share value. As such, we view the outcome from the FDA discussion and report of the top-line results from the pivotal comparative trials (possibly in 4Q14) could be important binary events for RPRX shares.

**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

Repros Therapeutics – Income Statement												
(\$ MM)	2011	2012	2013	1Q14	2Q14	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E
<b>Revenue</b>												
Licensing fees	-	-	-	-	-	-	-	-	-	10.0	10.0	10.0
Product revenue	-	-	-	-	-	-	-	-	-	61.4	136.4	260.8
Research and development grants	-	-	-	-	-	-	-	-	-	-	-	-
Interest income	0.0	0.0	0.0	-	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>\$0.0</b>	<b>\$0.0</b>	<b>\$71.4</b>	<b>\$146.4</b>	<b>\$270.8</b>
<b>Costs of goods</b>												
Gross revenue	-	-	-	-	-	-	-	-	0.0	6.1	13.6	26.1
Research and development	8.7	13.3	22.9	7.3	7.5	6.9	5.6	27.3	16.9	17.4	19.2	20.9
General and administrative	3.8	4.8	4.8	1.2	1.3	1.3	1.3	5.1	6.1	9.2	10.1	10.2
Sales and marketing	-	-	-	-	-	0.0	0.0	0.0	5.0	24.7	28.3	32.6
Interest expense and amortization of intangibles	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Operating Expenses</b>	<b>\$12.5</b>	<b>\$18.2</b>	<b>\$27.7</b>	<b>\$8.6</b>	<b>\$8.7</b>	<b>\$8.2</b>	<b>\$6.9</b>	<b>\$32.4</b>	<b>\$28.1</b>	<b>\$51.3</b>	<b>\$29.3</b>	<b>\$31.1</b>
<b>Operating Income (loss)</b>	<b>(\$12.5)</b>	<b>(\$18.2)</b>	<b>(\$27.7)</b>	<b>(\$8.5)</b>	<b>(\$8.7)</b>	<b>(\$8.2)</b>	<b>(\$6.9)</b>	<b>(\$32.4)</b>	<b>(\$28.1)</b>	<b>\$13.9</b>	<b>\$103.5</b>	<b>\$213.6</b>
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(12.5)	(18.2)	(27.7)	(8.5)	(8.7)	(8.2)	(6.9)	(32.4)	(28.1)	13.9	103.5	213.6
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(27.7)	(8.5)	(8.7)	(8.2)	(6.9)	(32.4)	(28.1)	13.9	103.5	213.6
Income tax expense	-	-	-	-	-	-	-	-	-	4.7	35.2	72.6
<b>Net Incomes (Losses)</b>	<b>(\$12.5)</b>	<b>(\$18.2)</b>	<b>(\$27.7)</b>	<b>(\$8.5)</b>	<b>(\$8.7)</b>	<b>(\$8.2)</b>	<b>(\$6.9)</b>	<b>(\$32.4)</b>	<b>(\$28.1)</b>	<b>\$9.2</b>	<b>\$68.3</b>	<b>\$141.0</b>
Net Earnings (Losses) Per Share—Basic	(\$1.04)	(\$1.18)	(\$1.33)	(\$0.37)	(\$0.38)	(\$0.35)	(\$0.29)	(\$1.40)	(\$1.19)	\$0.38	\$2.79	\$5.68
Net Earnings (Losses) Per Share—Diluted	(\$1.04)	(\$1.18)	(\$1.33)	(\$0.37)	(\$0.38)	(\$0.35)	(\$0.29)	(\$1.40)	(\$1.19)	\$0.38	\$2.79	\$5.68
Shares outstanding—basic	12.0	15.3	20.8	23.0	23.1	23.3	23.5	23.2	23.6	24.0	24.4	24.8
Shares outstanding—diluted	12.0	15.3	20.8	23.0	23.1	23.3	23.5	23.2	23.6	24.0	24.4	24.8
<b>Margin Analysis (% of Revenue)</b>												
COGS				N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%	10%
R&D	434100%	444767%	254578%	366250%	372500%	N.A.	N.A.	1365779%	N.A.	24%	13%	8%
SG&A	190550%	160900%	53533%	61300%	62800%	N.A.	N.A.	255377%	N.A.	13%	7%	4%
Operating Income (loss)	-624550%	-605567%	-308011%	-427450%	-435200%	N.A.	N.A.	-1621056%	N.A.	20%	71%	79%
Pretax	0%	0%	0%	-427450%	-435200%	N.A.	N.A.	-1621056%	N.A.	0%	0%	0%
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	34%	34%	34%
Net Income	-624550%	-605567%	-308011%	-427450%	-435200%	N.A.	N.A.	-1621056%	N.A.	13%	47%	52%
<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.	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.	122%	91%
Research and development grants	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	0%	0%	0%	0%
Interest income	N.A.	50%	167%	N.A.	100%	-100%	-100%	-75%	0%	0%	0%	0%
Total Revenue	-100%	50%	200%	100%	100%	-100%	-100%	-78%	-100%	N.A.	105%	85%
Research and development	199%	54%	72%	16%	23%	45%	-3%	19%	-38%	3%	10%	9%
General and administrative	67%	27%	0%	15%	7%	8%	-3%	6%	20%	50%	10%	1%
Sales and marketing								N.A.	0%	393%	15%	15%
Operating incomes	162%	45%	53%	16%	21%	37%	-3%	17%	-13%	-150%	643%	106%
Total Other Income, net	162%	45%	53%	16%	21%	37%	-3%	17%	-13%	-150%	643%	106%
Pretax Income	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	162%	45%	53%	16%	21%	37%	-3%	17%	-13%	-133%	643%	106%
EPS - Basic	76%	13%	13%	-8%	-1%	36%	-5%	5%	-15%	-132%	630%	103%
EPS - Diluted	76%	13%	13%	-8%	-1%	36%	-5%	5%	-15%	-132%	630%	103%
Shares outstanding—basic	48%	28%	36%	27%	22%	1%	2%	12%	2%	2%	2%	2%
Shares outstanding—diluted	48%	28%	36%	27%	22%	1%	2%	12%	2%	2%	2%	2%

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

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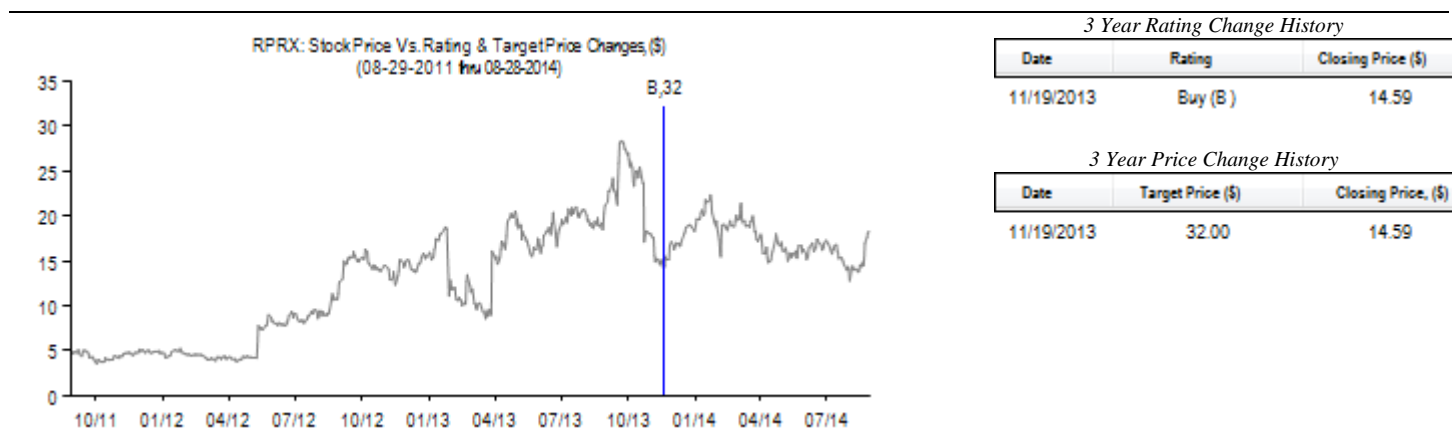
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