

Repros Therapeutics (RPRX - \$ 16.87)

Sperm Endpoint of the ZA-304 /305 Phase III Studies Modified.

Yesterday after the market close, RPRX reported the adjustments of the sperm endpoint as the co-primary endpoint of the ZA-304/305 study, which include better maintenance of normal sperm concentration; and a smaller decline in sperm concentration to fulfill FDA's recommendation. RPRX reiterated being on track for reporting top-line results and NDA filing in mid- (Oct.) and late 4Q14, respectively.

- Details.** The overall study design has not changed. The 305 study has completed and the 304 study is about to complete (before end of May, in our estimate) patient enrollment. The modified sperm co-primary endpoints are comparing Androxal vs. AndroGel on 1) the proportion of subjects whose semen concentrations are below normal after 16 weeks of treatment; and 2) the percentage change from baseline in semen concentration after 16 weeks of treatment. The definition of normal of the first co-primary endpoint is "95% confidence interval of 15 million/mL" – essentially identical to the prior co-primary sperm endpoint. The study is 80% powered for a $\alpha=0.05$ (vs. prior 90% powered for a $\alpha=0.05$). Additional secondary efficacy and safety comparison endpoints include excursions of testosterone outside of the normal range; impact on testosterone levels after treatment stoppage; and impact on hematocrit. The FDA's rationale on the sperm co-endpoint was based on the need for a comparison between two treatments to demonstrate that one is 1) significantly more likely to maintain normal sperm concentrations; and 2) to have a significantly smaller decline in total sperm concentrations.
- Implications.** We do not view the endpoint modifications have changed our positive outlook for successful 304/305 study outcomes since the changes were minimal, while prior clinical studies, such as 203 (median sperm count of 93.8M [Androxal] vs. 6.2M [Testim]) and 201 have consistently demonstrated the disparity of sperm impact between Androxal and TRTs. Further, from a commercial prospective, a positive co-primary endpoint outcome on sperm impact could further highlight front and center the major distinction between Androxal and all other TRTs.
- Action.** We are reiterating our Buy rating and our \$32 target price to reflect the continued improved outlook of Androxal and the maturation of Proellex development.

Healthcare/Biotechnology

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

Trading Data:

Last Price (04/30/2014)	\$ 16.87
52-Week High (9/24/2013)	\$ 29.79
52-Week Low (4/15/2014)	\$ 13.93
Market Cap. (MM)	\$ 390
Shares Out. (MM)	23

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.32	-0.33	-0.33	-0.28	-1.27	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
FY-11A	-0.20	-0.30	-0.32	-0.22	-1.04	NM

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Source: Laidlaw & Company estimates

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Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	Potential pre-NDA meeting with the FDA	June '14	****
		Potential report ZA-303 DEXA safety study data	4Q14	****
		Potential report ZA-300 12 months safety study data	3Q14	****
		Potential to release Phase III 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	Mid-14	***
		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	****

**** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative

Source: Laidlaw & Company estimates and company presentation

Major risks

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 despite 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	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E
	Revenue											
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	-	-	-	-	-	-	-	-	-
Gain on disposal of fixed assets	-	-	0.0	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$71.4	\$146.4	\$270.8
Costs of goods												
Gross revenue	-	-	-	-	-	-	-	-	0.0	65.2	132.8	244.7
Research and development	8.7	13.3	22.9	6.0	6.2	6.2	5.0	23.3	14.5	14.9	16.4	17.9
General and administrative	3.8	4.8	4.8	1.5	1.7	1.7	1.7	6.6	7.9	11.9	13.1	13.2
Sales and marketing	-	-	-	-	-	0.0	0.0	0.0	5.0	24.7	28.3	32.6
Interest expense and amortization of intangibles	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	\$12.5	\$18.2	\$27.7	\$7.5	\$7.8	\$7.9	\$6.7	\$29.9	\$27.4	\$51.4	\$29.5	\$31.1
Operating Income (loss)	(\$12.5)	(\$18.2)	(\$27.7)	(\$7.5)	(\$7.8)	(\$7.9)	(\$6.7)	(\$29.9)	(\$27.4)	\$13.8	\$103.3	\$213.7
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)	(7.5)	(7.8)	(7.9)	(6.7)	(29.9)	(27.4)	13.8	103.3	213.7
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(27.7)	(7.5)	(7.8)	(7.9)	(6.7)	(29.9)	(27.4)	13.8	103.3	213.7
Income tax expense	-	-	-	-	-	-	-	-	-	4.7	35.1	72.6
Net Incomes (Losses)	(\$12.5)	(\$18.2)	(\$27.7)	(\$7.5)	(\$7.8)	(\$7.9)	(\$6.7)	(\$29.9)	(\$27.4)	\$9.1	\$68.2	\$141.0
Net Earnings (Losses) Per Share—Basic	(\$1.04)	(\$1.18)	(\$1.33)	(\$0.32)	(\$0.33)	(\$0.33)	(\$0.28)	(\$1.27)	(\$1.15)	\$0.37	\$2.76	\$5.62
Net Earnings (Losses) Per Share—Diluted	(\$1.04)	(\$1.18)	(\$1.33)	(\$0.32)	(\$0.33)	(\$0.33)	(\$0.28)	(\$1.27)	(\$1.15)	\$0.37	\$2.76	\$5.62
Shares outstanding—basic	12.0	15.3	20.8	23.2	23.4	23.6	23.8	23.5	23.9	24.3	24.7	25.1
Shares outstanding—diluted	12.0	15.3	20.8	23.2	23.4	23.6	23.8	23.5	23.9	24.3	24.7	25.1
Margin Analysis (% of Revenue)												
COGS				N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%	10%
R&D	434100%	444767%	254578%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	21%	11%	7%
SG&A	190550%	160900%	53533%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	17%	9%	5%
Operating Income (loss)	-624550%	-605567%	-308011%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	19%	71%	79%
Pretax	0%	0%	0%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	0%	0%	0%
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	34%	34%	34%
Net Income	-624550%	-605567%	-308011%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	13%	47%	52%
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.	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%	-100%	0%	0%	0%	0%
Total Revenue	-100%	50%	200%	-100%	-100%	-100%	-100%	-100%	N.A.	N.A.	105%	85%
Research and development	199%	54%	72%	-4%	2%	29%	-14%	2%	-38%	3%	10%	9%
General and administrative	67%	27%	0%	41%	41%	41%	27%	37%	20%	50%	10%	1%
Sales and marketing								N.A.	0%	393%	15%	15%
Operating incomes	162%	45%	53%	2%	8%	31%	-6%	8%	-9%	-150%	650%	107%
Total Other Income, net	162%	45%	53%	2%	8%	31%	-6%	8%	-9%	-150%	650%	107%
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%	2%	8%	31%	-6%	8%	-9%	-133%	650%	107%
EPS - Basic	76%	13%	13%	-20%	-12%	28%	-9%	-5%	-10%	-133%	638%	104%
EPS - Diluted	76%	13%	13%	-20%	-12%	28%	-9%	-5%	-10%	-133%	638%	104%
Shares outstanding—basic	48%	28%	36%	28%	23%	3%	3%	13%	2%	2%	2%	2%
Shares outstanding—diluted	48%	28%	36%	28%	23%	3%	3%	13%	2%	2%	2%	2%

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

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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

Source: Laidlaw & Company

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			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.	81.25%	31.25%	12.50%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	6.25%	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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