

Repros Therapeutics (RPRX - \$ 6.45)

Pre-NDA Meeting Update: No Additional Clinical Studies Are Required for Androxal NDA Filing

Yesterday after the market close, RPRX reported the discussion with the FDA from a pre-NDA meeting held the day before.

- Details.** RPRX reported the results from a pre-NDA meeting with the FDA. Highlights included: 1) No new clinical studies were requested by the agency before filing for NDA. The agency indicated that based on discussions from the recent AdCom meeting regarding TRT, they paid particular interest to cardiovascular risk and that additional safety studies could be required in the future; 2) The FDA advised that an environmental assessment of Androxal as part of NDA filling should be discussed with appropriate agency prior to NDA submission; and 3) RPRX has scheduled a conference call on Friday morning at 9:00am EST to discuss the path forward. The dial-in number is **877-407-8629**.
- Implications.** Based on information available, we view the development is very positive for the clinical advancement of Androxal. It appears to us that the demands by the agency are overall rather benign. We believe Androxal clinical results have suggested that the drug is safe overall. In addition, given Androxal is a Selective Estrogen Receptor Modulator (SERM), we anticipate the environmental assessment could evaluate Androxal as another SERM product, as drugs of this class have already been in the market for decades. As such, we believe RPRX might file for NDA in late 4Q14 or 1Q15 after the company addresses issues by the FDA. We view today's news could alleviate some of the investor concerns of a potential requirement for an additional clinical benefit trial before the NDA filing. We anticipate investors might address these questions, such as additional clinical benefit trials, during the conference call. RPRX shares rose 19% after the market close yesterday.
- Action.** We are reiterating our Buy rating, and our target price of \$28 to reflect our still positive outlook for Androxal; acknowledging the increased risks of a possible delay in potential approval if an additional Phase III study is required. Our valuation is based on our P/E, NPV-driven-and-probability adjusted sum-of-the-parts analyses.

Healthcare/Biotechnology

Ticker: **RPRX**
Rating: **Buy**
Price Target: **\$ 28.00**

Trading Data:

Last Price (11/06/2014)	\$ 6.45
52-Week High (1/23/2014)	\$ 22.57
52-Week Low (10/21/2014)	\$ 5.92
Market Cap. (MM)	\$ 149
Shares Out. (MM)	23

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.37A	-0.38A	-0.35	-0.29	-1.40	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 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	****

**** / ***** 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 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 lower probability of clinical failure, in our opinion, 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. 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
Revenue												
Licensing fees	-	-	-	-	-	-	-	-	-	10.0	10.0	10.0
Product revenue	-	-	-	-	-	-	-	-	-	0.0	65.7	115.9
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	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$10.0	\$75.7	\$125.9
Costs of goods									0.0	0.0	6.6	11.6
Gross revenue									0.0	10.0	69.2	114.3
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	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	\$12.5	\$18.2	\$27.7	\$8.6	\$8.7	\$8.2	\$6.9	\$32.4	\$28.1	\$51.3	\$29.3	\$31.1
Operating Income (loss)	(\$12.5)	(\$18.2)	(\$27.7)	(\$8.5)	(\$8.7)	(\$8.2)	(\$6.9)	(\$32.4)	(\$28.1)	(\$41.3)	\$39.9	\$83.2
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)	(41.3)	39.9	83.2
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)	(41.3)	39.9	83.2
Income tax expense	-	-	-	-	-	-	-	-	-	0.0	13.5	28.3
Net Incomes (Losses)	(\$12.5)	(\$18.2)	(\$27.7)	(\$8.5)	(\$8.7)	(\$8.2)	(\$6.9)	(\$32.4)	(\$28.1)	(\$41.3)	\$26.3	\$54.9
Net Earnings (Losses) Per Share—Basic	(\$1.04)	(\$1.18)	(\$1.33)	(\$0.37)	(\$0.38)	(\$0.35)	(\$0.29)	(\$1.40)	(\$1.19)	(\$1.72)	\$1.08	\$2.21
Net Earnings (Losses) Per Share—Diluted	(\$1.04)	(\$1.18)	(\$1.33)	(\$0.37)	(\$0.38)	(\$0.35)	(\$0.29)	(\$1.40)	(\$1.19)	(\$1.72)	\$1.08	\$2.21
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
Margin Analysis (% of Revenue)												
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.	174%	25%	17%
SG&A	190550%	160900%	53533%	61300%	62800%	N.A.	N.A.	255377%	N.A.	92%	13%	8%
Operating Income (loss)	-624550%	-605567%	-308011%	-427450%	-435200%	N.A.	N.A.	-1621056%	N.A.	-413%	53%	66%
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%	0%	34%	34%
Net Income	-624550%	-605567%	-308011%	-427450%	-435200%	N.A.	N.A.	-1621056%	N.A.	-413%	35%	44%
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.	N.A.	76%
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.	657%	66%
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%	47%	-197%	109%
Total Other Income, net	162%	45%	53%	16%	21%	37%	-3%	17%	-13%	47%	-197%	109%
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%	47%	-164%	109%
EPS - Basic	76%	13%	13%	-8%	-1%	36%	-5%	5%	-15%	45%	-163%	105%
EPS - Diluted	76%	13%	13%	-8%	-1%	36%	-5%	5%	-15%	45%	-163%	105%
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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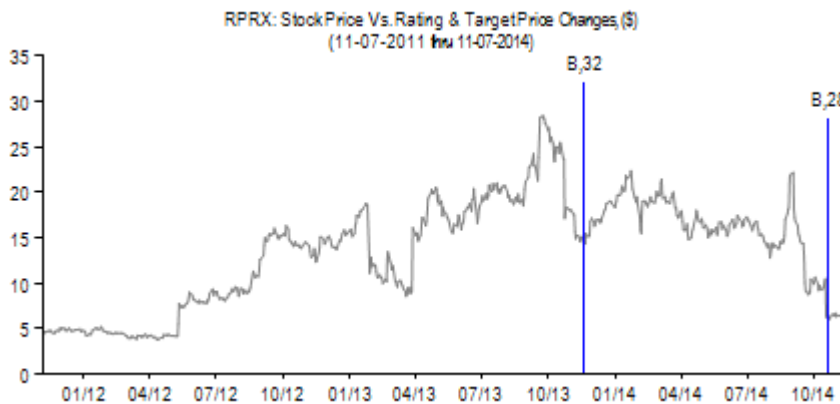
Rating and Price Target Change History

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



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.	95.24%	33.33%	14.29%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.76%	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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