

Repros Therapeutics (RPRX - \$ 8.79)

Management Discussions of Corporate Updates

After series of meetings we arranged between RPRX and investors last week, we concluded with renewed confidence in our positive outlook for Androxal potential approval. Major highlights from these meetings include:

- **Androxal NDA filing likely in 1Q15.** RPRX is completing the NDA filing process and we anticipate filing could occur in 1Q15. The potential FDA acceptance decision of the filed NDA (60 days post filing) could be reported in late 1Q14 or early 2Q14. NDA acceptance by the FDA, in our opinion, could be an important catalyst for RPRX shares. Environmental assessment studies are underway and the status of the study does not have an impact on the NDA filing. RPRX anticipate studies should be completed prior to the FDA's potential approval decision. We anticipate an FDA expert meeting to be held in late 2H15 to discuss Androxal approvability; and RPRX expects to bring major KOLs to stipulate the value of Androxal. There is increasing acknowledgement by the medical community and the regulatory agency for the distinctions between TRT and alternative approaches to restore testosterone. This further enhances the outlook for the potential approval of Androxal, in our opinion.
- **Majority of investor interest focuses on knowing more details of the exchanges between the FDA and RPRX during the pre-NDA meeting.** In addition to RPRX lengthy prior conference call regarding the pre-NDA meeting, a majority of investors have requested more details of the exchanges between the agency and RPRX management, especially the six major questions by the agency (see our 11-11-2014 note).
- **Proellex Phase II studies.** RPRX is scheduled to advance Proellex in uterine fibroids (UF) and endometriosis with two Phase II studies (low dose oral and vaginally-delivered) in UF to start in 4Q14. The study design is identical for both studies (n=45) with either two doses (6mg and 12mg) or a placebo. Patients will be treated for two cycles, followed by a six month follow-up. The study will use the alkaline-hematin method to measure the menstrual blood losses. RPRX plans to report interim results after the completion of the first treatment cycle (possibly in 4Q15) and schedule a meeting with the FDA for discussion to gain further guidance.
- **Action.** We are reiterating our Buy rating, and \$28 target price to reflect our positive outlook for Androxal. Our valuation is based on our P/E, NPV-driven-and-probability adjusted sum-of-the-parts analyses.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.37A	-0.38A	-0.32A	-0.26	-1.33	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

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (11/21/2014)	\$ 8.79
52-Week High (1/23/2014)	\$ 22.57
52-Week Low (10/21/2014)	\$ 5.92
Market Cap. (MM)	\$ 213
Shares Out. (MM)	24

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Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	Potential NDA filing	1Q15	****
		Potential FDA decision on acceptance of filed NDA	2Q15	****
		FDA expert panel meeting	2H15	*****
		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	4Q14	***
		Potentially to commence low dose vaginally-delivered Proellex Phase II study	4Q14	***
		Potentially to report top-line results from low dose oral Proellex Phase II study	4Q15	***
		Potentially to determine low dose oral vs. vaginal Proellex as final format for Phase III trial	2H15	****
		Potentially to start a Phase III study	2016	*****
	Endometriosis	Possible to complete patient enrollment for Phase II study	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	3Q14	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	-	-	-	-	-	-	-	-	-
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	6.1	4.9	25.8	16.0	16.5	18.1	19.8
General and administrative	3.8	4.8	4.8	1.2	1.3	1.3	1.3	5.0	7.6	11.4	12.5	12.6
Sales and marketing	-	-	-	-	-	-	-	0.0	0.0	14.0	16.1	18.5
Interest expense and amortization of intangibles	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	\$12.5	\$18.2	\$27.7	\$8.6	\$8.7	\$7.4	\$6.2	\$30.9	\$23.6	\$41.9	\$30.6	\$32.4
Operating Income (loss)	(\$12.5)	(\$18.2)	(\$27.7)	(\$8.5)	(\$8.7)	(\$7.4)	(\$6.2)	(\$30.9)	(\$23.6)	(\$31.9)	\$38.5	\$81.9
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)	(7.4)	(6.2)	(30.9)	(23.6)	(31.9)	38.5	81.9
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(27.7)	(8.5)	(8.7)	(7.4)	(6.2)	(30.9)	(23.6)	(31.9)	38.5	81.9
Income tax expense	-	-	-	-	-	-	-	-	-	0.0	13.1	27.9
Net Incomes (Losses)	(\$12.5)	(\$18.2)	(\$27.7)	(\$8.5)	(\$8.7)	(\$7.4)	(\$6.2)	(\$30.9)	(\$23.6)	(\$31.9)	\$25.4	\$54.1
Net Earnings (Losses) Per Share—Basic	(\$1.04)	(\$1.18)	(\$1.33)	(\$0.37)	(\$0.38)	(\$0.32)	(\$0.26)	(\$1.33)	(\$1.00)	(\$1.32)	\$1.04	\$2.18
Net Earnings (Losses) Per Share—Diluted	(\$1.04)	(\$1.18)	(\$1.33)	(\$0.37)	(\$0.38)	(\$0.32)	(\$0.26)	(\$1.33)	(\$1.00)	(\$1.32)	\$1.04	\$2.18
Shares outstanding—basic	12.0	15.3	20.8	23.0	23.1	23.3	23.5	23.3	23.7	24.1	24.5	24.9
Shares outstanding—diluted	12.0	15.3	20.8	23.0	23.1	23.3	23.5	23.3	23.7	24.1	24.5	24.9
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%	N.A.	N.A.	N.A.	N.A.	N.A.	165%	24%	16%
SG&A	190550%	160900%	53533%	61300%	N.A.	N.A.	N.A.	N.A.	N.A.	114%	17%	10%
Operating Income (loss)	-624550%	-605567%	-308011%	-427450%	N.A.	N.A.	N.A.	N.A.	N.A.	-319%	51%	65%
Pretax	0%	0%	0%	-427450%	N.A.	N.A.	N.A.	N.A.	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%	N.A.	N.A.	N.A.	N.A.	N.A.	-319%	34%	43%
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%	-100%	0%	0%	0%	0%
Total Revenue	-100%	50%	200%	100%	-100%	-100%	-100%	-100%	N.A.	N.A.	657%	66%
Research and development	199%	54%	72%	16%	23%	28%	-14%	13%	-38%	3%	10%	9%
General and administrative	67%	27%	0%	15%	7%	5%	-6%	5%	50%	50%	10%	1%
Sales and marketing								N.A.	0%	393%	15%	15%
Operating incomes	162%	45%	53%	16%	21%	23%	-13%	11%	-24%	35%	-221%	113%
Total Other Income, net	162%	45%	53%	16%	21%	23%	-13%	11%	-24%	35%	-221%	113%
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%	23%	-13%	11%	-24%	35%	-180%	113%
EPS - Basic	76%	13%	13%	-8%	-1%	21%	-15%	0%	-25%	33%	-178%	109%
EPS - Diluted	76%	13%	13%	-8%	-1%	21%	-15%	0%	-25%	33%	-178%	109%
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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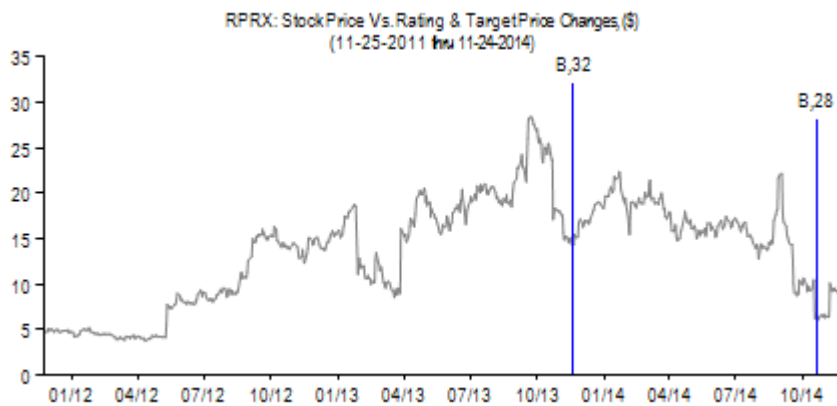
Rating and Price Target Change History

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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Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
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