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Est. 1842
London
New York
San Francisco
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Ft. Lauderdale

EQUITY RESEARCH
Company Report

October 20, 2014

Repros Therapeutics (RPRX - $ 6.31)

Healthcare/Biotechnology

Pre-NDA Meeting with FDA Scheduled in November 2014 Would be Type-C Instead of Type-B

Ticker:	**RPRX**
Rating:	**Buy**
Price Target: ↓ lower	**$ 28.00**

RPRX reported late last week that the pre-NDA meeting scheduled with the FDA in the first half of November, 2014 would be a Type C instead of a type-B meeting as announced on September 26.

- **Details.** RPRX reported late last week that the upcoming pre-NDA meeting in the first half of November will be categorized as Type C instead of Type B. The change was based on FDA's opinion after their preliminary review of the submitted briefing documents indicating insufficient clinical information. RPRX speculated the reason might be that the results of one year DEXA safety study and the drug-drug interaction study were not available at the time the briefing document was submitted. RPRX shares were down ~40% on Friday due to the news.
- **Implications.** Although the designation of the pre-NDA meeting has changed, we do not view that this event **alone** has increased the risk, given the company still can fully communicate their perspective with the agency for potential approval of Androxal. Further, the probability of whether the agency might request (or suggest) conducting an additional clinical benefit study for potential approval under either a Type B or C meeting setting remains unchanged, in our opinion. That said, although it is too early to determine whether a requirement for a clinical benefit study is imminent; in our view the probability will increase the development risk of Androxal from both a prolonged timeline and raised clinical risks. It is encouraging, however, that RPRX has already prepared for a potential clinical benefit study (either as Phase III or IV); while several peer-reviewed publications have pointed out the correlation between increased testosterone and weight loss and other relevant benefits. RPRX indicated that if they are satisfied with the agency's responses to the company's questions at the November meeting, they might not request an additional meeting near term. Management reiterated that RPRX will provide more visibility at the Analyst Day (Oct. 31st) to showcase their NDA filing plans.
- **Action.** We are reiterating our Buy rating, and reducing our target price to $28 from $32 to reflect our still positive outlook for Androxal with the increased risks of a possible delay in potential approval if additional Phase III study is required. Our valuation is based on our P/E, NPV-driven-and-probability adjusted sum-of-the-parts analyses.

Trading Data:

Last Price (10/17/2014)	$ 6.31
52–Week High (10/18/2013)	$ 26.14
52–Week Low (10/17/2014)	$ 6.01
Market Cap. (MM)	$ 146
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

Source: Laidlaw & Company estimates

Yale Jen, Ph.D.
Managing Director /
Senior Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	Potential pre-NDA meeting with the FDA	**4Q (Nov.) '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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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-

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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%

Yale Jen, Ph.D. 212-953-4978

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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Additional information available upon request.

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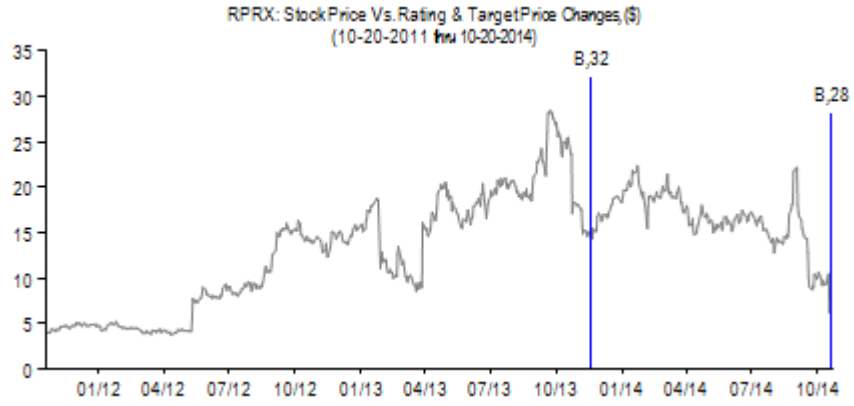
Rating and Price Target Change History



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	6.31*

** Previous Close10/17/2014*

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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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%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Yale Jen, Ph.D.
yjen@laidlawltd.com

NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com