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EQUITY RESEARCH
Company Report

July 16, 2015

Repros Therapeutics (RPRX - $ 7.78)

Healthcare/Biotechnology

Management Update

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

After recent meeting with RPRX management and investors, we remain confident that outcome of AdCom meeting would be positive and Enclomiphene (formerly Androxal) could be approved by the FDA. Highlights include:

- **Outcome from the AdCom meeting should be positive**. We believe there is a high likelihood that the outcome from the Nov. 3rd AdCom meeting could be positive. Our bullish thesis is based on: 1) consistently robust clinical data; 2) increased awareness and off-label use of clomiphene for patients who want to preserve fertility; 3) Enclomiphene is the only near-term viable alternative therapy in front of the FDA; and 4) substantial unmet needs exist for large number (>80%) of hypogonadism (HG) patients. We also believe it would be important to have favorable decisions with substantially large margin by panel votes to demonstrate support from medical communities to the FDA.
- **Seeking more restricted label.** RPRX recently has changed the proposed product label to a more restricted one. It changed from all 2nd HG to 2nd HG with BMI>21 and <60 year old who exhibits endocrine society defined 2nd HG signs and intends to preserve fertility. We believe this could create some good will on the part of the FDA given the objective of agency's Sep. 2014 AdCom meeting was to curtail very broad use (possibly abuse) of TRT.
- **Mainly targeting urologists/endocrinologists and without DTC.** If approved, RPRX plans to target urologists/endocrinologists and would not employ direct-to-consumer (DTC) to avoid attracting patients that might not suitable for taking a 2nd HG therapy
- **Uncertainty of FDA decision could be an overhang.** Even assuming a positive outcome from the AdCom meeting, a potential wildcard or overhang for RPRX shares is whether the FDA would approve Enclomiphene based on recommendations or the agency might require additional clinical benefit results. Although we do not have any insight on FDA's decision process, we remain optimistic that Enclomiphene could be approved especially if AdCom votes are strongly favorable. Given the shortcoming of TRT and the lack of approved alternative in the market, it could be beneficial to patients as well as to the agency that Enclomiphene would be available. Further, Enclomiphene is safer and more potent than clomiphene.
- **Action**. We are reiterating our Buy rating, and our target price of $28 based on our P/E, NPV-driven-and-probability adjusted sum-of-the-parts analyses.

Trading Data:

Last Price (07/16/2015)	$ 7.78
52–Week High (9/2/2014)	$ 22.55
52–Week Low (10/21/2014)	$ 5.92
Market Cap. (MM)	$ 189
Shares Out. (MM)	24

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.35A	-0.20	-0.20	-0.20	-0.96	NM
FY-14A	-0.37	-0.38	-0.32	-0.31	-1.37	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

Source: Laidlaw & Company estimates

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Anticipated milestones in 2015 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	FDA expert panel meeting	**Nov. 3, 2015**	*****
		Expected PDUFA date	**Nov. 30, 2015**	*****
		Potential partnership or other business development activities	**2015 / 2016**	*****
		Potential approval for 2nd hypogonadism	**4Q15 / 1Q16**	*****
Proellex	Uterine Fibroids	Potentially to report top-line results after one cycle treatment from low dose Proellex Phase II study	**4Q15**	****
		Potentially to schedule a type C meeting with the FDA to discuss Proellex Phase III study	**Late 15 / early 16**	****
		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	**1Q16**	***

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

Source: Laidlaw & Company estimates and company presentation.

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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

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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.

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Figure 1: Income Statement

Repros Therapeutics – Income Statement

($ MM)	2013	2014	1Q15	2Q15E	3Q15E	4Q15E	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	-	-	-	-	-	-	-	-
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	$10.0	$75.7	$125.9
Costs of goods								0.0	6.6	11.6
Gross revenue								10.0	69.2	114.3
Research and development	22.9	26.7	7.3	3.7	3.8	3.9	18.8	19.3	21.3	23.2
General and administrative	4.8	5.4	1.2	1.2	1.2	1.2	4.8	7.2	8.0	8.0
Sales and marketing		0.0	-	-	-	-	0.0	14.0	16.1	18.5
Interest expense and amortization of intangibles	-	-	-	-	-	-	0.0	-	-	-
Total Operating Expenses	$27.7	$32.1	$8.5	$4.9	$5.1	$5.1	$23.6	$40.6	$29.2	$31.2
Operating Income (loss)	($27.7)	($32.1)	($8.5)	($4.9)	($5.0)	($5.1)	($23.6)	($30.6)	$39.9	$83.1
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(27.7)	(32.1)	(8.5)	(4.9)	(5.0)	(5.1)	(23.6)	(30.6)	39.9	83.1
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(8.5)	(4.9)	(5.0)	(5.1)	(23.6)	(30.6)	39.9	83.1
Income tax expense	-	-	-	-	-	-	-	0.0	13.6	28.3
Net Incomes (Losses)	($27.7)	($32.1)	($8.5)	($4.9)	($5.0)	($5.1)	($23.6)	($30.6)	$26.3	$54.8
Net Earnings (Losses) Per Share—Basic	($1.33)	($1.37)	($0.35)	($0.20)	($0.20)	($0.20)	($0.96)	($1.22)	$1.04	$2.13
Net Earnings (Losses) Per Share—Diluted	($1.33)	($1.37)	($0.35)	($0.20)	($0.20)	($0.20)	($0.96)	($1.22)	$1.04	$2.13
Shares outstanding—basic	20.8	23.4	24.3	24.5	24.7	24.9	24.6	25.0	25.4	25.8
Shares outstanding—diluted	20.8	23.4	24.3	24.5	24.7	24.9	24.6	25.0	25.4	25.8
Margin Analysis (% of Revenue)										
COGS		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%
R&D	254578%	888433%	732100%	186686%	192286%	194209%	N.A.	193%	28%	18%
SG&A	53533%	181233%	120500%	59648%	60244%	60846%	N.A.	72%	11%	6%
Operating Income (loss)	-308011%	-1069567%	-852500%	-246233%	-252430%	-254955%	N.A.	-306%	53%	66%
Pretax	0%	-1069567%	-852500%	-246233%	-252430%	-254955%	N.A.	0%	0%	0%
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	34%	34%
Net Income	-308011%	-1069567%	-852500%	-246233%	-252430%	-254955%	N.A.	-306%	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.	0%	0%
Product royalties	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.	0%	0%	0%
Interest income	167%	-63%	N.A.	N.A.	N.A.	-100%	-100%	0%	0%	0%
Total Revenue	200%	-67%	-50%	N.A.	N.A.	-33%	-100%	N.A.	657%	66%
Research and development	72%	16%	0%	-50%	-37%	-33%	-30%	3%	10%	9%
General and administrative	0%	13%	-2%	-5%	-6%	-27%	-11%	50%	10%	1%
Sales and marketing		N.A.					N.A.	393%	15%	15%
Operating incomes	53%	16%	0%	-43%	-32%	-32%	-26%	30%	-231%	108%
Total Other Income, net	53%	16%	0%	-43%	-32%	-32%	-26%	30%	-231%	108%
Pretax Income	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	53%	16%	0%	-43%	-32%	-32%	-26%	30%	-186%	108%
EPS - Basic	13%	3%	-5%	-47%	-35%	-33%	-30%	27%	-185%	105%
EPS - Diluted	13%	3%	-5%	-47%	-35%	-33%	-30%	27%	-185%	105%
Shares outstanding—basic	36%	13%	5%	6%	6%	3%	5%	2%	2%	2%
Shares outstanding—diluted	36%	13%	5%	6%	6%	3%	5%	2%	2%	2%

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

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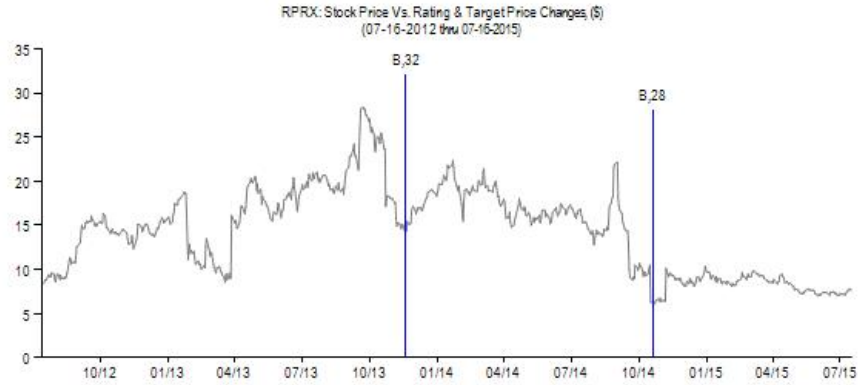
Rating and Price Target Change History



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 **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			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.	75.00%	32.14%	7.14%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%999

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