

## Repros Therapeutics (RPRX - \$ 8.49)

### FDA Accepted Androxal in Secondary Hypogonadism NDA Filing.

Yesterday after market close, RPRX reported that the FDA has accepted the Androxal (enclomiphene citrate) in secondary hypogonadism NDA filing.

- Details.** RPRX reported yesterday after market close that the FDA has accepted the NDA filing of Androxal (enclomiphene citrate) as a potential treatment in secondary hypogonadism for overweight men wishing to restore normal testicular function. The agency indicated that the application is sufficiently complete to permit a substantive review. As a reminder, RPRX submitted the NDA on February 2<sup>nd</sup> and the FDA is required to make a decision whether to accept the filing within 60 days.
- Implications.** While we believe the risk that the FDA would not accept the NDA filing was low, bearish investors had different opinion, which put pressure on RPRX shares and valuation. With the NDA filing accepted, we believe this overhang affecting the shares has been removed. Now, we anticipate the major catalyst for RPRX shares in 2015 will be the outcome of discussions and voting decisions at the FDA expert panel meeting; which is likely to be held in early 4Q15. A possible PDUFA date is likely to slate to 1Q16. Given the robust results of multiple Phase III studies, we remain bullish on a positive outlook from the expert panel meeting and likely approval by the FDA for Androxal. In addition, the company will present more clinical data at this year's American Urological Association (AUA) annual meeting (May 15 -19), including a late breaker presentation by Dr. Edward Kim of University of Tennessee. In addition, there are two Proellex in uterine fibroids (UF) Phase IIb studies (with two different delivery methods: oral and vaginal) underway; with interim results potentially available in late 4Q15 if patient recruitment proceeds as expected.
- Action.** We are reiterating our Buy rating, and our target price of \$28 to reflect our positive outlook for Androxal and clinical advancement of Proellex. 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 (04/01/2015)	\$ 8.49
52-Week High (9/2/2014)	\$ 22.55
52-Week Low (10/21/2014)	\$ 5.92
Market Cap. (MM)	\$ 206
Shares Out. (MM)	24

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-15E</b>	-0.23	-0.20	-0.20	-0.21	-0.84	NM
<b>FY-14A</b>	-0.37	-0.38	-0.32	-0.31	-1.37	NM
<b>FY-13A</b>	-0.41	-0.38	-0.26	-0.31	-1.33	NM
<b>FY-12A</b>	-0.17	-0.21	-0.30	-0.47	-1.18	NM

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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	2H15	*****
		Clinical data presentation at AUA	May 15 -19, 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	4Q15	***

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

Source: Laidlaw & Company estimates and company presentation.

## Major risks

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**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	2014					2015E	2016E	2017E	2018E
					1Q15E	2Q15E	3Q15E	4Q15E				
<b>Revenue</b>												
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	-	-	-	-	-	-	-	-
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
<b>Costs of goods</b>												
Gross revenue										0.0	6.6	11.6
Research and development	8.7	13.3	22.9	26.7	4.3	3.5	3.6	3.7	15.2	15.6	17.2	18.7
General and administrative	3.8	4.8	4.8	5.4	1.4	1.4	1.4	1.4	5.6	8.4	9.2	9.3
Sales and marketing	-	-	-	0.0	-	-	-	-	0.0	14.0	16.1	18.5
Interest expense and amortization of intangibles	-	-	-	-	-	-	-	-	0.0	-	-	-
<b>Total Operating Expenses</b>	\$12.5	\$18.2	\$27.7	\$32.1	\$5.7	\$4.9	\$5.0	\$5.1	\$20.8	\$38.0	\$26.4	\$28.0
<b>Operating Income (loss)</b>	(\$12.5)	(\$18.2)	(\$27.7)	(\$32.1)	(\$5.7)	(\$4.9)	(\$5.0)	(\$5.1)	(\$20.8)	(\$28.0)	\$42.8	\$86.3
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)	(32.1)	(5.7)	(4.9)	(5.0)	(5.1)	(20.8)	(28.0)	42.8	86.3
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(27.7)	(32.1)	(5.7)	(4.9)	(5.0)	(5.1)	(20.8)	(28.0)	42.8	86.3
Income tax expense	-	-	-	-	-	-	-	-	0.0	14.5	29.3	-
<b>Net Incomes (Losses)</b>	(\$12.5)	(\$18.2)	(\$27.7)	(\$32.1)	(\$5.7)	(\$4.9)	(\$5.0)	(\$5.1)	(\$20.8)	(\$28.0)	\$28.2	\$57.0
Net Earnings (Losses) Per Share—Basic	(\$1.04)	(\$1.18)	(\$1.33)	(\$1.37)	(\$0.23)	(\$0.20)	(\$0.20)	(\$0.21)	(\$0.84)	(\$1.11)	\$1.11	\$2.20
Net Earnings (Losses) Per Share—Diluted	(\$1.04)	(\$1.18)	(\$1.33)	(\$1.37)	(\$0.23)	(\$0.20)	(\$0.20)	(\$0.21)	(\$0.84)	(\$1.11)	\$1.11	\$2.20
Shares outstanding—basic	12.0	15.3	20.8	23.4	24.4	24.6	24.8	25.0	24.7	25.1	25.5	25.9
Shares outstanding—diluted	12.0	15.3	20.8	23.4	24.4	24.6	24.8	25.0	24.7	25.1	25.5	25.9
<b>Margin Analysis (% of Revenue)</b>												
COGS				N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%
R&D	434100%	444767%	254578%	888433%	216413%	175294%	180553%	185970%	N.A.	156%	23%	15%
SG&A	190550%	160900%	53533%	181233%	68798%	69486%	70181%	70883%	N.A.	84%	12%	7%
Operating Income (loss)	-624550%	-605567%	-308011%	-1069567%	-285111%	-244680%	-250634%	-256752%	N.A.	-280%	56%	69%
Pretax	0%	0%	0%	-1069567%	-285111%	-244680%	-250634%	-256752%	N.A.	0%	0%	0%
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	34%	34%
Net Income	-624550%	-605567%	-308011%	-1069567%	-285111%	-244680%	-250634%	-256752%	N.A.	-280%	37%	45%
<b>Financial Indicator Growth Analysis (Y/Y)</b>												
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.	N.A.	0%	0%	0%
Interest income	N.A.	50%	167%	-63%	N.A.	N.A.	N.A.	-100%	-100%	0%	0%	0%
Total Revenue	-100%	50%	200%	-67%	0%	N.A.	N.A.	-33%	-100%	N.A.	657%	66%
Research and development	199%	54%	72%	16%	-41%	-53%	-41%	-36%	-43%	3%	10%	9%
General and administrative	67%	27%	0%	13%	12%	11%	10%	-16%	3%	50%	10%	1%
Sales and marketing				N.A.					N.A.	393%	15%	15%
Operating incomes	162%	45%	53%	16%	-33%	-44%	-32%	-31%	-35%	35%	-253%	102%
Total Other Income, net	162%	45%	53%	16%	-33%	-44%	-32%	-31%	-35%	35%	-253%	102%
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%	-33%	-44%	-32%	-31%	-35%	35%	-201%	102%
EPS - Basic	76%	13%	13%	3%	-37%	-47%	-36%	-33%	-39%	33%	-199%	99%
EPS - Diluted	76%	13%	13%	3%	-37%	-47%	-36%	-33%	-39%	33%	-199%	99%
Shares outstanding—basic	48%	28%	36%	13%	6%	7%	6%	3%	6%	2%	2%	2%
Shares outstanding—diluted	48%	28%	36%	13%	6%	7%	6%	3%	6%	2%	2%	2%

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

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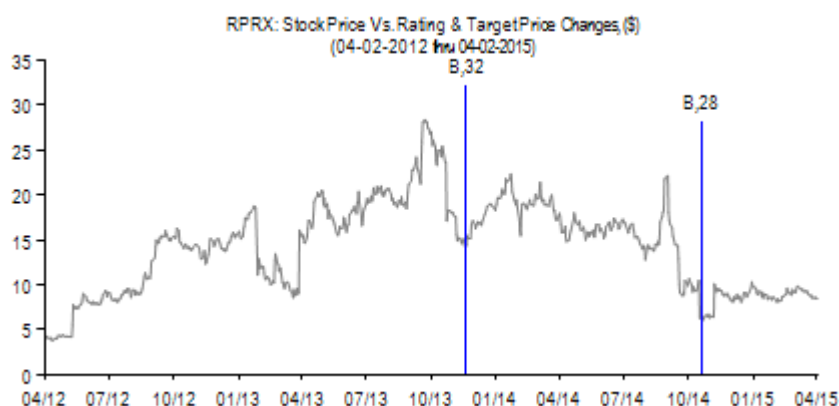
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#### Rating and Price Target Change History



#### 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

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<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	68.18%	31.82%	9.09%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.55%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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