

## Repros Therapeutics (RPRX - \$ 20.40)

### 2014 Top-Pick Based on Favorable Risk/Reward Profile

We are recommending RPRX as one of our 2014 top pick stocks based on its favorable risk/reward profile. Supported by a clinically well de-risked Androxal in secondary hypogonadism development with NDA filing expected in 4Q14; and potentially three Proellex in uterine fibroid (UF) and endometriosis Phase II studies underway in 2014, we believe RPRX share value could substantially advance going forward comparing to current valuation.

- Androxal in secondary hypogonadism development is on-track with NDA submission expected in 4Q14.** RPRX already started comparative (vs. AndroGel 1.62%) studies (ZA-304 & 305) in 1Q14 and is scheduled to discuss with the FDA in Feb. 14 for clarifying the validity of the completed pivotal studies (ZA-301 & 302). Together, we anticipate the company to report the 304/305 study top-line results in 4Q14 (possibly in Oct.) and potentially to submit clinical package which includes four clinical and other safety (300 and 303 or DEXA) studies for NDA filing in 4Q14.
- Proellex clinical advancement expected in 2014 with possible Phase III studies to start in 2015.** RPRX commenced a low dose oral Proellex in endometriosis Phase II study with patient enrollment completion expected in 2H14 (we est. top-line results in 2015). Two Proellex in UF Phase II studies, one of low dose oral and the second of vaginally administrated, could start in 2Q14 with results possibly in late 14 or 1H15. Together, Proellex potentially could enter Phase III studies in one or both indications in 2015.
- Billion dollar market potential assets with encouraging partnership outlook.** We believe market potential for RPRX's assets could exceed a billion dollars with Androxal having shorter development time and more mitigated clinical risks. Combining Androxal's potential positive 304 / 305 studies results and NDA submission in 4Q14 and further maturation of Proellex development, the outlook of partnership for both assets, in our opinion, is further enhanced with a possible partnering decision in 2014/2015.
- Action.** We are reiterating our Buy rating and our \$32 target price to reflect the continued improved outlook of Androxal and maturation of Proellex development. Valuation is based on our P/E, and NPV-driven-and-probability adjusted sum-of-the-parts analyses

### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-14E</b>	-0.28	-0.28	-0.28	-0.24	-1.08	NM
<b>FY-13E</b>	-0.41A	-0.38A	-0.26A	-0.26	-1.28	NM
<b>FY-12A</b>	-0.17	-0.21	-0.30	-0.47	-1.18	NM
<b>FY-11A</b>	-0.20	-0.30	-0.32	-0.22	-1.04	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **RPRX**  
 Rating: **Buy**  
 Price Target: **\$ 32.00**

### Trading Data:

Last Price (01/24/2014)	\$ 20.40
52-Week High (9/24/2013)	\$ 29.79
52-Week Low (3/20/2013)	\$ 8.42
Market Cap. (MM)	\$ 469
Shares Out. (MM)	23

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## Highlights

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- **The meeting with the FDA in Feb. '14 could clarify the validity of study 301 and 302.** We recently had a discussion with RPRX management for a corporate update. The company is scheduled to conduct a face-to-face meeting with the FDA in February to discuss issues of the completed 301 and 302 studies. RPRX expects to demonstrate that some patients (from Site 9 of which mostly referred from infertility clinics) enrolled in the 301 study did meet the inclusion and exclusion criteria of the study despite they have lower baseline sperm counts vs. other sites of the same study (17.6MM vs. 86.2MM). If the Site 9 data is not excluded, study 301 did meet the endpoint of sperm count preservation. Drs. Edward Kim (University of Tennessee) and Wayne Hellstrom (Tulane University) will participate in the meeting as expert to discuss the need for additional treatment option in secondary hypogonadism; and validity of the 301 and 302 clinical data. Albeit it is difficult to gauge the FDA decision, we believe the clinical results from the two studies have clearly demonstrated that Androxal is efficacious in restoring testosterone and without negative impact on spermatogenesis. With study 304 and 305 underway (see our prior RPRX note published on 2014-01-08 for more detail), we view the total clinical package to be submitted for NDA would likely be very comprehensive; and the potential FDA comments in Feb., in our opinion, should have limited impact on the overall outlook of Androxal development.
- **Proellex development details.** The company expects to have three Phase II studies on progress in 2014 to evaluate Proellex in uterine fibroid (UF) and endometriosis. A 60-patient study that evaluates low dose oral Proellex in endometriosis is underway and the company expects to add additional clinical sites ex-U.S. and complete patient enrollment in 2H14. We estimate top-line results could potentially be available in 2015. RPRX plans to commence a 90-patient Phase II study evaluating low dose oral Proellex in uterine fibroid (UF) possibly in 2Q14 after the company submitted a request to the FDA for the agency to lift the current full clinical hold in 1Q14. The company is also planning to commence a Phase IIb trial that evaluate vaginally delivered Proellex in 90 UF patients in 2Q14. We estimate top-line results from both studies could be available in late 2014 or 1H15. The outcome could potentially help the company to determine the format of Proellex to be used for potential Phase III studies in UF. Further, the study outcome from the two indications could potentially position the company to start Phase III study(ies) in one or both indications in 2015.

### Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing	Importance
		Potential pre-NDA meeting with the FDA	Feb. '14	*****
		Potential report ZA-303 DEXA safety study data	4Q14	***
		Potential report ZA-300 12 months safety study data	3Q14	***
		Potential to release Phase III comparative studies results	4Q (Oct.) '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 Phase II study vs. vaginal Proellex as final format for Phase III trial	2Q14	***
		Potentially to commence vaginal Proellex Phase IIb trial	2Q14	***
		Potentially to determine low dose oral vs. vaginal Proellex as final format for Phase III trial	1H15	****
		Potentially to start a Phase III study	2015	*****
	Endometriosis	Possible to complete patient enrollment for Phase II study	2H14	***
		Possible to report Phase II study top-line results	2015	****

\*\*\*\* / \*\*\*\*\* 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 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 majority of RPRX share valuation (both assessed by us and the Street) resided on 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 task; could significantly reduce RPRX share value. As such, we view the outcome from the FDA discussion and report 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 coupling with 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 well-entrenched TRT treatment paradigm, substantial and effective education effects, in our opinion, are necessary to change physician's 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 dynamic 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 despite Proellex only accounts for a minor portion of the RPRX valuation.

**Potential financing could dilute shareholders.** Despite the company's cash position could support operation, including R&D and M&S expenses, into 2016; the possibility exists as additional cash could be needed for other un-expected 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	1Q13	2Q13	3Q13	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E
<b>Revenue</b>																
Licensing fees	-	-	-	-	-	-	-	-	-	-	-	-	-	10.0	10.0	10.0
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	61.4	136.4	260.8
Research and development grants	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest income	0.0	0.0	-	0.0	0.0	-	0.0	-	-	-	-	-	-	-	-	-
Gain on disposal of fixed assets	-	-	0.0	-	-	-	0.0	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$71.4</b>	<b>\$146.4</b>	<b>\$270.8</b>
<b>Costs of goods</b>																
Gross revenue	-	-	-	-	-	-	-	-	-	-	-	-	0.0	6.1	13.6	26.1
Research and development	8.7	13.3	6.3	6.0	4.8	4.9	22.0	5.1	5.2	5.2	4.2	19.6	12.2	12.5	13.8	15.0
General and administrative	3.8	4.8	1.1	1.2	1.2	1.2	4.7	1.4	1.5	1.6	1.6	6.0	7.2	10.8	11.9	12.0
Sales and marketing	-	-	-	-	-	-	-	-	-	0.0	0.0	0.0	5.0	24.7	28.3	32.6
Interest expense and amortization of intangibles	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Operating Expenses</b>	<b>\$12.5</b>	<b>\$18.2</b>	<b>\$7.4</b>	<b>\$7.2</b>	<b>\$6.0</b>	<b>\$6.1</b>	<b>\$26.7</b>	<b>\$6.4</b>	<b>\$6.7</b>	<b>\$6.7</b>	<b>\$5.8</b>	<b>\$25.6</b>	<b>\$24.4</b>	<b>\$48.0</b>	<b>\$25.7</b>	<b>\$27.0</b>
<b>Operating Income (loss)</b>	<b>(\$12.5)</b>	<b>(\$18.2)</b>	<b>(\$7.4)</b>	<b>(\$7.2)</b>	<b>(\$6.0)</b>	<b>(\$6.1)</b>	<b>(\$26.7)</b>	<b>(\$6.4)</b>	<b>(\$6.7)</b>	<b>(\$6.7)</b>	<b>(\$5.8)</b>	<b>(\$25.6)</b>	<b>(\$24.4)</b>	<b>\$17.2</b>	<b>\$107.1</b>	<b>\$217.7</b>
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(12.5)	(18.2)	(7.4)	(7.2)	(6.0)	(6.1)	(26.7)	(6.4)	(6.7)	(6.7)	(5.8)	(25.6)	(24.4)	17.2	107.1	217.7
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(12.5)	(18.2)	(7.4)	(7.2)	(6.0)	(6.1)	(26.7)	(6.4)	(6.7)	(6.7)	(5.8)	(25.6)	(24.4)	17.2	107.1	217.7
Income tax expense	-	-	-	-	-	-	-	-	-	-	-	-	-	5.9	36.4	74.0
<b>Net Incomes (Losses)</b>	<b>(\$12.5)</b>	<b>(\$18.2)</b>	<b>(\$7.4)</b>	<b>(\$7.2)</b>	<b>(\$6.0)</b>	<b>(\$6.1)</b>	<b>(\$26.7)</b>	<b>(\$6.4)</b>	<b>(\$6.7)</b>	<b>(\$6.7)</b>	<b>(\$5.8)</b>	<b>(\$25.6)</b>	<b>(\$24.4)</b>	<b>\$11.4</b>	<b>\$70.7</b>	<b>\$143.7</b>
Net Earnings (Losses) Per Share—Basic	(\$1.04)	(\$1.18)	(\$0.41)	(\$0.38)	(\$0.26)	(\$0.26)	(\$1.28)	(\$0.28)	(\$0.28)	(\$0.28)	(\$0.24)	(\$1.08)	(\$1.01)	\$0.46	\$2.84	\$5.68
Net Earnings (Losses) Per Share—Diluted	(\$1.04)	(\$1.18)	(\$0.41)	(\$0.38)	(\$0.26)	(\$0.26)	(\$1.28)	(\$0.28)	(\$0.28)	(\$0.28)	(\$0.24)	(\$1.08)	(\$1.01)	\$0.46	\$2.84	\$5.68
Shares outstanding—basic	12.0	15.3	18.2	19.0	23.0	23.2	20.8	23.4	23.6	23.8	24.0	23.7	24.1	24.5	24.9	25.3
Shares outstanding—diluted	12.0	15.3	18.2	19.0	23.0	23.2	20.8	23.4	23.6	23.8	24.0	23.7	24.1	24.5	24.9	25.3
<b>Margin Analysis (% of Revenue)</b>																
COGS								N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%	10%
R&D	434100%	444767%	630800%	603700%	159533%	N.A.	440254%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	18%	9%	6%
SG&A	190550%	160900%	106700%	117100%	40500%	N.A.	93846%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	15%	8%	4%
Operating Income (loss)	-624550%	-605567%	-737400%	-720700%	-199933%	N.A.	-534000%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	24%	73%	80%
Pretax	0%	0%	-737400%	-720700%	-199933%	N.A.	0%	N.A.	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%	0%	0%	0%	34%	34%	34%
Net Income	-624550%	-605567%	-737400%	-720700%	-199933%	N.A.	-534000%	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	16%	48%	53%
<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.	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.	N.A.	N.A.	N.A.	122%	91%
Research and development grants	N.A.	N.A.	N.A.	N.A.	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%	N.A.	N.A.	200%	-100%	33%	N.A.	-100%	-100%	N.A.	-100%	0%	0%	0%	0%
Total Revenue	-100%	50%	N.A.	N.A.	200%	-100%	67%	-100%	-100%	-100%	N.A.	-100%	N.A.	N.A.	105%	85%
Research and development	199%	54%	330%	177%	53%	-26%	65%	-20%	-14%	8%	-14%	-11%	-38%	3%	10%	9%
General and administrative	67%	27%	10%	27%	-16%	-16%	-3%	28%	28%	28%	27%	28%	20%	50%	10%	1%
Sales and marketing												N.A.	0%	393%	15%	15%
Operating incomes	162%	45%	202%	132%	31%	-24%	47%	-13%	-7%	13%	-6%	-4%	-5%	-171%	522%	103%
Total Other Income, net	162%	45%	202%	132%	31%	-24%	47%	-13%	-7%	13%	-6%	-4%	-5%	-171%	522%	103%
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.	N.A.	N.A.	N.A.	N.A.
Net Income	162%	45%	202%	132%	31%	-24%	47%	-13%	-7%	13%	-6%	-4%	-5%	-147%	522%	103%
EPS - Basic	76%	13%	133%	82%	-12%	-44%	8%	-32%	-26%	9%	-9%	-16%	-7%	-146%	512%	100%
EPS - Diluted	76%	13%	133%	82%	-12%	-44%	8%	-32%	-26%	9%	-9%	-16%	-7%	-146%	512%	100%
Shares outstanding—basic	48%	28%	30%	28%	49%	35%	36%	29%	25%	3%	3%	14%	2%	2%	2%	2%
Shares outstanding—diluted	48%	28%	30%	28%	49%	35%	36%	29%	25%	3%	3%	14%	2%	2%	2%	2%

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

## DISCLOSURES:

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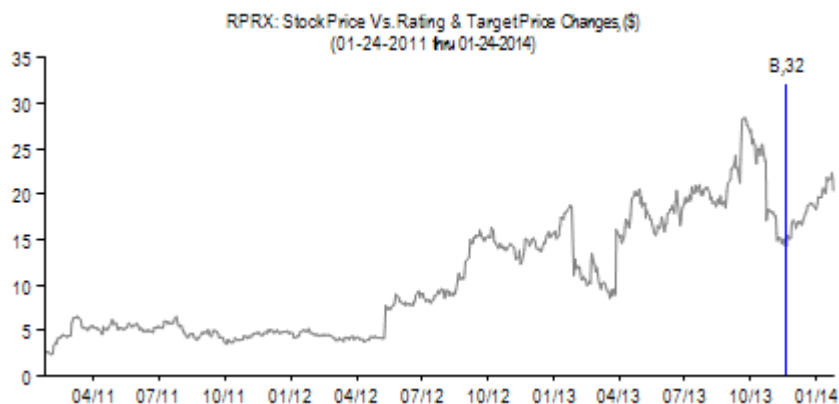
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*Additional information available upon request.*

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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

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
<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.	83.33%	33.33%	16.67%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	16.67%	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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