

ADMA Biologics (ADMA - \$ 12.23)

3Q14: All Eyes Are On RI-002 in Primary Immune Deficiency Disease (PIDD) Phase III Results in 4Q14.

This morning, ADMA reported 3Q14 financial results with net loss of (\$3.4MM), vs. estimate for Laidlaw (\$3.0MM) and the Street (\$3.5MM). Net loss per share equated (\$0.36) vs. (\$0.32) and (\$0.40) for Laidlaw and the Street, respectively. With cash of ~\$20.3MM by the end of 3Q14, we believe it is sufficient to support operations entering 2016.

- Major investors focus is on the RI-002 Phase III study top-line results expected in 4Q14.** As a reminder, RI-002 is under a Phase III trial in primary immune deficiency disease (PIDD) patients for a potential approval as an intravenous immunoglobulin (IVIG). The primary endpoint is to achieve < 1 serious infection/person/year; while secondary endpoints include: safety; lost days of work/school due to hospitalizations, ER visits, or antibiotic use; PK profile of total IgG; and several specific antibody levels testing, especially RSV. We believe the company will report top-line results in 4Q14 with additional detailed clinical data to be reported later. Should the outcome be positive, we anticipate the company will file for BLA in 1H15 with possible approval in 1H16.
- Positive RI-002 pre-clinical results presented at 9th International Respiratory Syncytial Virus (RSV) Symposium are encouraging.** The study demonstrated a 99.9% (3 log₁₀) reduction in viral load in both the lung and nasal tissue in a cotton rat animal model with RI-002 treatment after responses to RSV infection. The study also demonstrated that by comparison to other standardized IVIG, RI-002 not only contains high levels of neutralizing RSV antibody titers but also elevated levels of antibodies against other respiratory viruses.
- Plasma center updates.** ADMA is constructing the 2nd center and management indicated that completion and PLA filing are expected in 4Q14; with potential approval in 2015. As such, we anticipate healthy revenue growth in 2015 supported by expanded capacities.
- Action.** We are reiterating our Buy rating and our \$15 target price to reflect the completion of the RI-002 Phase III study and expansion of additional plasma collection centers. Our \$15 target price is supported by P/E, peer comparable and risk-adjusted cash flow sum-of-the-parts analyses.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.64A	-0.43A	-0.36A	-0.30	-1.33	NM
FY-13A	-0.55	-0.83	-0.46	-0.55	-2.38	NM
FY-12A	-0.18	-0.20	-0.70	-0.68	-1.76	NM
FY-11A	-4.50	-6.79	-2.79	-2.64	-16.72	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **ADMA**
Rating: **Buy**
Price Target: **\$ 15.00**

Trading Data:

Last Price (11/10/2014)	\$ 12.23
52-Week High (11/10/2014)	\$ 13.53
52-Week Low (12/26/2013)	\$ 6.52
Market Cap. (MM)	\$ 113
Shares Out. (MM)	9

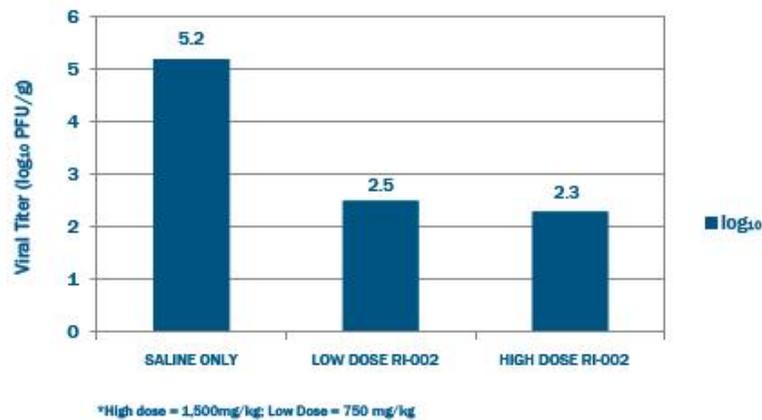
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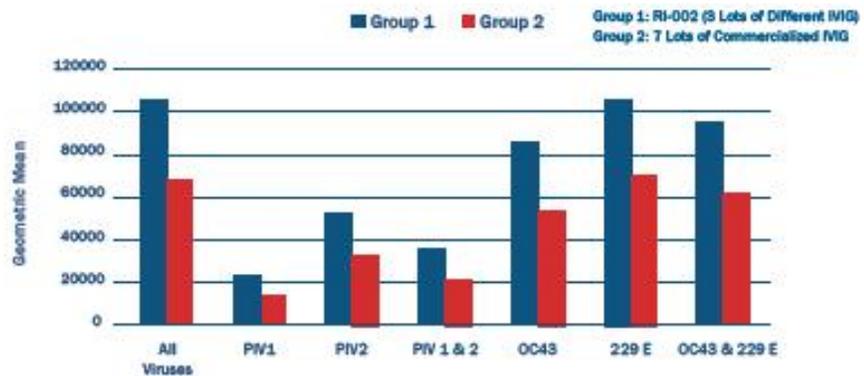
- RI-002 pre-clinical results presented at the 9th International Respiratory Syncytial Virus (RSV) Symposium demonstrated a 99.9% (3 log₁₀) reduction in viral load in both the lung and nasal tissue in a cotton rat animal model with RI-002 treatment after responses to RSV infection (Figure 1). In addition, the study also demonstrated that by comparison to other standardized IVIG, RI-002 not only contains high levels of neutralizing RSV antibody titers but also elevated levels of antibodies against other respiratory viruses (Figure 2).

Figure 1: Reduction of Viral Load in the Lungs of Normal cotton rats treated with RI-002



Source: Mond, J.J., et al., 2014, 9th International RSV Symposium

Figure 2: Comparison of anti-body titers between RI-002 and standardized IVIG



Analysis	Ratio of Geometric Means (95% CI) (Group 1 ÷ Group 2)	P-Value*
All Viruses	1.529 (1.227, 1.907)	0.0002
PIV1	1.792 (1.282, 2.505)	0.0010
PIV2	1.601 (1.160, 2.210)	0.0050
PIV 1 & 2	1.694 (1.250, 2.296)	0.0009
OC43	1.610 (1.127, 2.301)	0.0099
229E	1.494 (1.144, 1.950)	0.0039
OC43 & 229E	1.551 (1.237, 1.945)	0.0002

* 2-group t-test for null hypothesis of no difference between the groups in geometric means (ie, ratio of geometric means =1).

PIV1 & 2: Parainfluenza
OC43 & 229E: Coronavirus

Source: Mond, J.J., et al., 2014, 9th International RSV Symposium

Table 1 Estimated and reported 3Q14 results

3Q14 Estimates and Reported Results			
(\$ MM)	Laidlaw Estimate	Actual	Consensus
Total revenue	\$1,457	\$1,366	\$1,453
Total op. profit (loss)	(\$3,005)	(\$3,038)	(\$3,280)
R&D	\$1,035	\$1,483	
SG&A	\$829	\$1,018	
EPS	(\$0.32)	(\$0.36)	(\$0.40)
Net income (loss)	(\$3,005)	(\$3,384)	(\$3,477)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing	Importance
RI-002	RSV infection prevention in PIDD	Potential report top-line Phase III trial results	4Q14	*****
		Potential BLA filing	1H15	*****
		Potential U.S. approval	4Q15 / 1Q16	*****
		Potential U.S. product launch	1H16	*****
VZIG (Varitect)	Vicella Zoster virus infection	Potential commence Phase II/III study	2H14	***
		Potential report top-line Phase II/III trial results	2015	****
BioCenters		Possibly to start 3rd center build-out & FDA review process	1H15	****
		FDA approval of 2nd BioCenter	2015	****
		FDA approval of 3rd BioCenter	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

Risks of clinical study failure could have a major impact on ADMA share value. Despite a well-established path for IVIG approval, risks still exist as RI-002 might not be approved by the FDA if the pivotal study does not meet its endpoints. Given that the majority of upside for ADMA shares is currently based on the assumption that the product can be approved before its commercial potential can be realized, an unsuccessful approval application would have a significant negative impact on ADMA share value.

Commercial success of the RI-002 in PIDD and potentially in transplantation is less predictable. We believe that the potential product label for RI-002, if approved, would likely to indicate as a regular IVIG; and higher titer of anti-RSV antibodies could appear on the label if the pivotal study met the relevant secondary endpoint. As such, the company may not promote the product directly for the prevention or treatment of RSV infection, but instead, it will base on the understanding that receiving high titer RSV antibodies should reduce probability of RSV infection. With more limited sales and marketing tactics available, the sales ramp up could be slower than projected. The risk could also exist as more rapid sales expansion might only occur after the company conducting more clinical studies and demonstrating positive clinical outcome.

Developments by competitors may render RI-002 or relevant technologies obsolete or un-competitive. Although the manufacturing processes of RI-002 are protected by proprietary technology, trade secrets and know-how, it is possible that other competitors develop similar processes to produce similar or even better anti-RSV IVIG. As such, the company might not enjoy the competitive edge and potentially damage RI-002's commercial outlook

Plasma collection center operations might not perform as expected. The company currently operates one and expects to expand into three plasma collection centers over the next 12 months. Although the plasma collection operation is business with relatively sustainable positive cash inflow and ADMA management appears to have substantial experience, risks of mismanagement as well as internal and external factors could change, resulting in sub-par business performance. Although the plasma collection operation might not be the main reason for investing in ADMA shares, a less successful performance could negatively impact on the expected cash flow and strategic objective of diversifying plasma sources for RI-002 production.

Limited product diversity could increase overall risk. Given the nascent stage of the corporate development, the majority of the product pipeline value mainly resides on RI-002. The second potential pipeline product, an anti-Vicella Zoster virus immunoglobulin, is in very early development stage with

market potential possibly much smaller. As such, we believe the company at the current stage has very limited diversification potential in its product pipeline.

Lack of cash could impede corporate development. Despite the company's recent successful IPO to raise \$26.5MM cash, ADMA could potentially need more financial resources going forward if they want to expand and further develop its pipeline. Should the product not receive FDA approval or product revenue does not reach expectations, the company might have to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

Limited trading liquidity limits shareholder options. Given that ADMA shares only entered the public market recently; daily trading volume and name recognition are relatively low. With relatively illiquid trading volume, shareholders wanting to increase or reduce their positions in a volatile stock market may face constraints.

Income Statement

ADMA Biologics – Income Statement

(\$ '000)	2012	2013	1Q14	2Q14	3Q14	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
Product revenue	1,118	3,024	1,542	1,481	1,347	1,320	5,690	7,682	11,830	16,089	16,893	17,738	18,749
RI-002 revenue	-	-	-	-	-	-	-	-	17,318	52,409	90,303	143,560	185,046
License revenue	-	44	19	19	19	19	76	200	300	300	300	300	300
Total Revenue	1,118	3,068	1,561	1,500	1,366	1,339	5,766	7,882	29,448	68,798	107,496	161,598	204,095
Cost of product revenue	669	2,023	977	941	868	871	3,678	5,224	8,044	10,940	11,487	12,062	12,749
Cost of RI-002	-	-	-	-	-	-	-	-	8,659	26,205	45,151	71,780	92,523
Gross revenue (RI-002)	-	-	-	-	-	-	-	-	8,659	26,205	45,151	71,780	92,523
Gross revenue (Biocenter)	449	1,000	565	541	458	449	2,012	2,458	3,786	5,148	5,406	5,676	6,000
Total gross revenue	449	1,000	565	541	458	449	2,012	2,458	12,445	31,353	50,557	77,456	98,522
Research and development	3,469	9,303	4,330	1,784	1,483	1,083	8,680	8,506	8,846	9,200	9,660	10,143	10,651
Plasma center operating expenses	1,747	2,418	802	821	1,018	1,059	3,701	3,886	4,041	4,324	4,497	4,632	4,725
General and administrative	3,142	4,365	1,135	1,542	1,035	1,077	4,789	4,980	5,179	5,386	5,570	5,759	5,955
Marketing and sales	-	-	-	-	-	-	-	1,000	8,400	8,904	9,438	9,948	10,445
Total Operating Expenses	8,358	16,087	6,268	4,147	3,537	3,218	17,169	18,372	26,467	27,815	29,165	30,482	31,775
Operating Income (loss)	(7,909)	(15,042)	(5,684)	(3,587)	(3,038)	(2,750)	(11,403)	(10,490)	2,981	40,983	78,331	131,116	172,319
Interest income	21	8	2	4	4	10	19	30	48	77	93	112	123
Interest expense	(31)	(618)	(227)	(343)	(335)	(162)	(1,067)	(1,067)	(1,067)	(1,067)	(1,067)	(1,067)	(1,067)
Change in fair value of stock warrants	-	43	5	(35)	(15)	(40)	(84)	(700)	(100)	(100)	(100)	(100)	(100)
Other income	-	82	-	-	-	2	2	2	2	2	2	2	2
Total other expenses	(10)	(485)	(220)	(374)	(346)	(190)	(1,130)	(1,735)	(1,117)	(1,087)	(1,072)	(1,053)	(1,042)
Income (loss) before tax expense	(7,919)	(15,527)	(5,904)	(3,961)	(3,384)	(2,940)	(12,533)	(12,225)	1,864	39,896	77,259	130,063	171,277
Income tax expense-State income tax benefit	618	-	-	-	-	-	-	-	690	14,761	28,586	48,123	63,373
Net Incomes (Losses)	(7,301)	(15,527)	(5,904)	(3,961)	(3,384)	(2,940)	(12,533)	(12,225)	1,175	25,134	48,673	81,939	107,905
Net Earnings (Losses) Per Share—Basic	(\$1.76)	(\$2.38)	(\$0.64)	(\$0.43)	(\$0.36)	(\$0.30)	(\$1.33)	(\$1.07)	\$0.08	\$1.76	\$3.31	\$5.42	\$6.95
Net Earnings (Losses) Per Share—Diluted	(\$1.76)	(\$2.38)	(\$0.64)	(\$0.43)	(\$0.36)	(\$0.30)	(\$1.33)	(\$1.07)	\$0.08	\$1.76	\$3.31	\$5.42	\$6.95
Shares outstanding—basic	4,146	6,531	9,292	9,292	9,292	9,792	9,417	11,417	13,917	14,317	14,717	15,117	15,517
Shares outstanding—diluted	4,146	6,531	9,292	9,292	9,292	9,792	9,417	11,417	13,917	14,317	14,717	15,117	15,517
Margin Analysis (% of Revenue)													
Gross	40%	33%	37%	36%	34%	34%	35%	32%	32%	32%	32%	32%	32%
Cost of RI-002	-	-	-	-	-	-	-	-	50%	50%	50%	50%	50%
R&D	310%	303%	277%	119%	109%	81%	151%	108%	30%	13%	9%	6%	5%
Plasma operation	156%	80%	52%	55%	76%	80%	65%	51%	34%	27%	27%	26%	25%
G&A	281%	142%	73%	103%	76%	80%	83%	63%	18%	8%	5%	4%	3%
M&S	-	-	-	-	-	-	-	-	29%	13%	9%	6%	5%
Operating Income (loss)	-707%	-490%	-364%	-239%	-222%	-205%	-198%	-133%	10%	60%	73%	81%	84%
Net Income	-653%	-506%	-378%	-264%	-248%	-220%	-217%	-155%	4%	37%	45%	51%	53%
Financial Indicator Growth Analysis (Y/Y)													
Product (Biocenter) revenue	47%	170%	94%	101%	24%	226%	88%	35%	54%	36%	5%	5%	6%
RI-002 revenue (projected)	N.A.	N.A.	203%	72%	59%	29%							
Total Revenue	47%	174%	97%	102%	23%	216%	88%	37%	274%	134%	56%	50%	26%
Research and development	436%	168%	195%	-49%	5%	-63%	-7%	-2%	4%	4%	5%	5%	5%
Plasma center operating expenses	50%	38%	56%	52%	55%	50%	53%	5%	4%	7%	4%	3%	2%
General and administrative	119%	39%	-21%	41%	22%	8%	10%	4%	4%	4%	3%	3%	3%
Marketing and sales	-	-	-	-	-	-	-	-	6%	6%	5%	5%	5%
Operating incomes	71%	90%	80%	-26%	20%	-39%	-24%	-8%	-128%	1275%	91%	67%	31%
Pretax Income	27%	96%	82%	-19%	26%	-37%	-19%	-2%	-115%	2040%	94%	68%	32%
Net Income	24%	113%	82%	-19%	26%	-37%	-19%	-2%	-110%	2040%	94%	68%	32%
EPS - Basic	-89%	35%	15%	-49%	-20%	-46%	-44%	-20%	-108%	1980%	88%	64%	28%
EPS - Diluted	-89%	35%	15%	-49%	-20%	-46%	-44%	-20%	-108%	1980%	88%	64%	28%
Shares outstanding—basic	1074%	58%	58%	58%	58%	15%	44%	21%	22%	3%	3%	3%	3%
Shares outstanding—diluted	1074%	58%	58%	58%	58%	15%	44%	21%	22%	3%	3%	3%	3%

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

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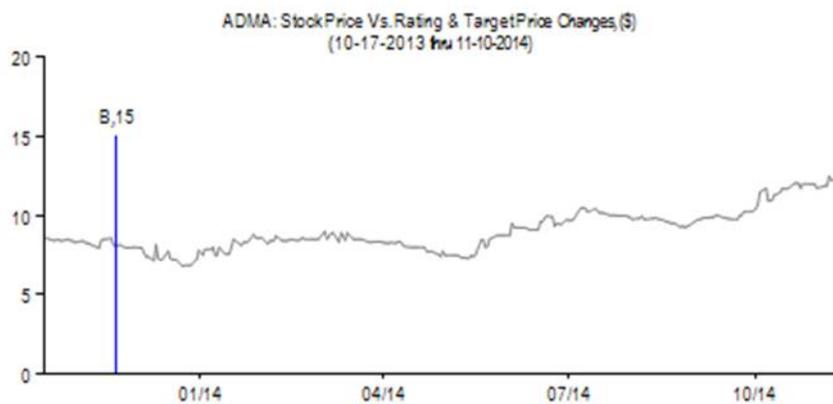
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Source: Laidlaw & Company

Created by: Blue-Compass.net

3 Year Rating Change History

Date	Rating	Closing Price (\$)
11/21/2013	Buy (B)	8.10

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
11/21/2013	15.00	8.10

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.	95.24%	33.33%	14.29%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.76%	0.00%	0.00%
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