

## ADMA Biologics (ADMA - \$ 11.92)

### Positive RI-002 Phase III Study Results is a Major Upbeat Catalyst for ADMA Shares

This morning, ADMA reported its lead product, RI-002 in its primary immune deficiency disease (PIDD) Phase III study met the primary endpoint of preventing serious bacterial infections (SBI) with  $\leq 1$  SBI per patient-year.

- Details.** ADMA announced this morning that the RI-002 in PIDD Phase III (ADMA-003) study met primary endpoint of  $\leq 1$  SBI per patient-year. The company plans to report final data, including results of secondary endpoints, in 1Q15 and file a BLA in mid-2015 with possible approval, in our estimate, in 2H16. On the safety side, RI-002 is well tolerated and without drug related serious adverse events reported. As a reminder, ADMA-003 is a multicenter, open-label and 59-patient study. Patients received a dose between 300-800 mg/kg according to their current IVIG dose. Each patient was dosed every 21 or 28 days (a total of >750 infusions have been administered) for a total of 12 months based on the patient's requirement. Secondary endpoints include incidence of all infections (serious & non-serious), lost days of work or school, hospitalizations, emergency room visits, antibiotic use, PK profile of total IgG and specific antibody level testing for H. flu type B, CMV, measles, tetanus and RSV among others.
- Implications.** We have been optimistic on a positive outlook of the Phase III outcome all along, but today's news is a major positive catalyst for ADMA shares in our view; as it could have mitigated most of the clinical risks. Given the IVIG approval process is a well determined path and today's results met the approval requirement guidance established by the FDA, we believe the approvability of RI-002 has been significantly enhanced. Further, we remain bullish on the outlook that RI-002 could have a higher neutralizing antibody titer against RSV – a scenario that could be important for positive commercial potential. Our confidence is supported by encouraging pre-clinical study results reported earlier at the 9<sup>th</sup> International RSV Symposium illustrating that RI-002 contains high levels of neutralizing RSV antibody as well as antibodies against other respiratory viruses comparing to other standardized IVIG.
- Action.** We are reiterating our Buy rating and \$18 target price to reflect today's news and other accumulated positive developments. Our 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
<b>FY-14E</b>	-0.64A	-0.43A	-0.36A	-0.30	-1.33	NM
<b>FY-13A</b>	-0.55	-0.83	-0.46	-0.55	-2.38	NM
<b>FY-12A</b>	-0.18	-0.20	-0.70	-0.68	-1.76	NM
<b>FY-11A</b>	-4.50	-6.79	-2.79	-2.64	-16.72	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **ADMA**  
Rating: **Buy**  
Price Target: **\$ 18.00**

#### Trading Data:

Last Price (12/01/2014)	\$ 11.92
52-Week High (11/10/2014)	\$ 13.53
52-Week Low (12/26/2013)	\$ 6.52
Market Cap. (MM)	\$ 111
Shares Out. (MM)	9

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## Anticipated milestones in 2014 and beyond

Program	Indication	Event	Timing	Importance
RI-002	RSV infection prevention in PIDD	Potential report complete Phase III trial results	1Q15	****
		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	2H15	****
		FDA approval of 3rd BioCenter	2016	****

\*\*\*\* / \*\*\*\*\* 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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**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
<b>Revenue</b>													
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
<b>Total Revenue</b>	<b>1,118</b>	<b>3,068</b>	<b>1,561</b>	<b>1,500</b>	<b>1,366</b>	<b>1,339</b>	<b>5,766</b>	<b>7,882</b>	<b>29,448</b>	<b>68,798</b>	<b>107,496</b>	<b>161,598</b>	<b>204,095</b>
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
<b>Total gross revenue</b>	<b>449</b>	<b>1,000</b>	<b>565</b>	<b>541</b>	<b>458</b>	<b>449</b>	<b>2,012</b>	<b>2,458</b>	<b>12,445</b>	<b>31,353</b>	<b>50,557</b>	<b>77,456</b>	<b>98,522</b>
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
<b>Total Operating Expenses</b>	<b>8,358</b>	<b>16,087</b>	<b>6,268</b>	<b>4,147</b>	<b>3,537</b>	<b>3,218</b>	<b>17,169</b>	<b>18,372</b>	<b>26,467</b>	<b>27,815</b>	<b>29,165</b>	<b>30,482</b>	<b>31,775</b>
<b>Operating Income (loss)</b>	<b>(7,909)</b>	<b>(15,042)</b>	<b>(5,684)</b>	<b>(3,587)</b>	<b>(3,038)</b>	<b>(2,750)</b>	<b>(11,403)</b>	<b>(10,490)</b>	<b>2,981</b>	<b>40,983</b>	<b>78,331</b>	<b>131,116</b>	<b>172,319</b>
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
<b>Net Incomes (Losses)</b>	<b>(7,301)</b>	<b>(15,527)</b>	<b>(5,904)</b>	<b>(3,961)</b>	<b>(3,384)</b>	<b>(2,940)</b>	<b>(12,533)</b>	<b>(12,225)</b>	<b>1,175</b>	<b>25,134</b>	<b>48,673</b>	<b>81,939</b>	<b>107,905</b>
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
<b>Margin Analysis (% of Revenue)</b>													
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%
<b>Financial Indicator Growth Analysis (Y/Y)</b>													
Product (Biocenter) revenue	47%	170%	94%	101%	24%	226%	88%	35%	54%	36%	5%	5%	6%
RI-002 revenue (projected)	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	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.

## DISCLOSURES:

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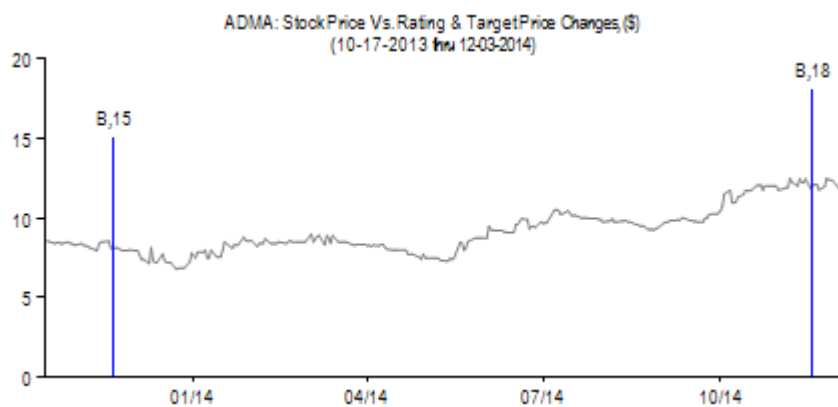
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#### Rating and Price Target Change History



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#### 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
11/18/2014	18.00	12.05

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