

ADMA Biologics (ADMA – 9.30)

RI-002 BLA Filed and Investor Focus Might Shift to Product Commercialization

This morning, ADMA announced that the company has filed a BLA for RI-002 as an IVIG in patients suffering from primary immune deficiency disease (PIDD). It is noted that the product contains a higher titer of anti-respiratory syncytial virus (RSV) antibodies.

- Details.** This morning, ADMA announced that it has filed a BLA for RI-002 as an IVIG in patients suffering from PIDD. RI-002 contains a higher titer of anti- RSV polyclonal antibodies – the feature that well differentiates RI-002 from all other commercially available IVIG, in our opinion. The FDA can accept the application if the agency does not have any objection within 60 days after the submission (late Sep./early Oct.). If so, we anticipate the potential PDUFA date could slate to August 2016. As such, in our opinion, it would allow ADMA to have a brief but sufficient time to commercialize RI-002 for the 2016/2017 winter season. ADMA benefited from a small business status as the FDA waived the \$2.3MM fee typically required for BLA filing.
- Implications.** We view the BLA filing as an important milestone and a positive to ADMA shareholders. We anticipate the FDA will accept the application. Afterward, we believe investors' focus would likely shift to the commercialization preparation, since the RI-002 approval as an IVIG in PIDD patients is very likely. Given ADMA recently already started RI-002 pre-launch efforts with several key senior management hires (medical affairs, supply chain operations and commercialization & strategy) already in place, we believe the company should have sufficient time to prepare for launching the product shortly after the approval. The use of IVIG in PIDD is seasonal (from October to March of subsequent year), so a potential approval in August could afford ADMA a small window to prepare the product launch. In addition to building up the senior management team, the company is also preparing its inventory to ensure sufficient supply to fulfill patient demands once RI-002 is approved. The IVIG use in transplant patients is not seasonal.
- Action.** We are reiterating our Buy rating and \$20 target price to reflect the company's transition to a commercial-stage company. Our target price is supported by P/E, peer comparable and risk-adjusted cash flow sum-of-the-parts analyses.

Healthcare/Biotechnology

Ticker: **ADMA**
Rating: **Buy**
Price Target: **\$ 20.00**

Trading Data:

Last Price (07/31/2015)	\$ 9.30
52-Week High (12/3/2014)	\$ 14.0000
52-Week Low (5/8/2015)	\$ 7.517.51
Market Cap. (MM)	\$ 10099.6
Shares Out. (MM)	11.7

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.37A	-0.40	-0.54	-0.62	-1.93	NM
FY-14A	-0.64	-0.43	-0.36	-0.38	-1.93	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

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Source: Laidlaw & Company estimates

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Anticipated milestones in 2015 and beyond

Program	Indication	Event	Timing	Importance
RI-002	RSV infection prevention in PIDD	Potentially build commercialization structure	2H15	****
		FDA accept BLA filed	Early Oct. 2015	***
		Potential U.S. approval	3Q16	*****
		Potential U.S. product launch	4Q16	*****
VZIG (Varitect)	Vicella Zoster virus infection	Potential commence Phase II/III study	2015	***
BioCenters		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

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. Instead it may be based 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. There is also risk that more rapid sales expansion might only occur after the company conducts more clinical studies and demonstrates positive clinical outcomes.

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 a business with relatively sustainable positive cash flows, and ADMA management appears to have substantial experience; risks of mismanagement or other factors could result in sub-par business performance. Less successful performance in this area could negatively impact 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, which raised \$26.5MM of 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	2014	1Q15	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
Product revenue	1,118	3,024	5,840	1,484	1,455	1,556	1,603	6,098	9,391	12,772	13,411	14,081	14,884
RI-002 revenue	-	-	-	-	-	-	-	-	17,318	52,409	90,303	143,560	185,046
License revenue	-	44	76	19	19	19	19	76	300	300	300	300	300
Total Revenue	1,118	3,068	5,916	1,503	1,473	1,575	1,622	6,174	27,009	65,481	104,013	157,941	200,229
Cost of product revenue	669	2,023	3,742	910	1,025	1,097	1,130	4,162	6,386	8,685	9,119	9,575	10,121
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	2,076	575	429	459	473	1,936	3,005	4,087	4,291	4,506	4,763
Total gross revenue	449	1,000	2,076	575	429	459	473	1,936	11,664	30,292	49,443	76,286	97,286
Research and development	3,469	9,303	9,517	1,402	981	1,756	1,774	5,913	6,150	6,396	6,716	7,051	7,404
Plasma center operating expenses	1,747	2,418	3,851	1,048	1,052	1,063	1,084	4,247	4,417	4,726	4,915	5,063	5,164
General and administrative	3,142	4,365	4,824	1,346	1,979	2,711	3,497	9,532	9,913	10,310	10,660	11,023	11,398
Marketing and sales	-	-	-	-	-	-	-	-	8,400	8,904	9,438	9,948	10,445
Total Operating Expenses	8,358	16,087	18,192	3,796	4,012	5,530	6,355	19,693	28,880	30,336	31,730	33,085	34,411
Operating Income (loss)	(7,909)	(15,042)	(16,019)	(3,202)	(3,564)	(5,052)	(5,863)	(17,681)	(1,871)	35,145	72,284	124,856	165,818
Interest income	21	8	14	5	6	6	6	23	37	59	71	85	93
Interest expense	(31)	(618)	(1,286)	(476)	(322)	(322)	(322)	(1,442)	(1,442)	(1,442)	(1,442)	(1,442)	(1,442)
Change in fair value of stock warrants	-	43	(74)	68	(40)	(40)	(40)	(52)	(100)	(100)	(100)	(100)	(100)
Other income	-	82	-	-	-	-	1	1	1	1	1	1	1
Total other expenses	(10)	(485)	(1,346)	(403)	(356)	(356)	(355)	(1,470)	(1,504)	(1,482)	(1,470)	(1,456)	(1,448)
Income (loss) before tax expense	(7,919)	(15,527)	(17,365)	(3,606)	(3,920)	(5,408)	(6,218)	(19,152)	(3,376)	33,663	70,813	123,400	164,370
Income tax expense-State income tax benefit	618	-	552	-	-	-	-	-	-	12,455	26,201	45,658	60,817
Net Incomes (Losses)	(7,301)	(15,527)	(17,917)	(3,606)	(3,920)	(5,408)	(6,218)	(19,152)	(3,376)	21,208	44,612	77,742	103,553
Net Earnings (Losses) Per Share—Basic	(\$1.76)	(\$2.38)	(\$1.93)	(\$0.37)	(\$0.40)	(\$0.54)	(\$0.62)	(\$1.93)	(\$0.27)	\$1.65	\$3.37	\$5.70	\$7.38
Net Earnings (Losses) Per Share—Diluted	(\$1.76)	(\$2.38)	(\$1.93)	(\$0.37)	(\$0.40)	(\$0.54)	(\$0.62)	(\$1.93)	(\$0.27)	\$1.65	\$3.37	\$5.70	\$7.38
Shares outstanding—basic	4,146	6,531	9,292	9,855	9,905	9,955	10,005	9,930	12,430	12,830	13,230	13,630	14,030
Shares outstanding—diluted	4,146	6,531	9,292	9,855	9,905	9,955	10,005	9,930	12,430	12,830	13,230	13,630	14,030
Margin Analysis (% of Revenue)													
Gross	40%	33%	36%	39%	30%	30%	30%	32%	32%	32%	32%	32%	32%
Cost of RI-002	-	-	-	-	-	-	-	-	50%	50%	50%	50%	50%
R&D	310%	303%	161%	93%	67%	111%	109%	96%	23%	10%	6%	4%	4%
Plasma operation	156%	80%	66%	71%	72%	68%	68%	70%	47%	37%	37%	36%	35%
G&A	281%	142%	82%	90%	134%	172%	216%	154%	37%	16%	10%	7%	6%
M&S	-	-	-	-	-	-	-	-	31%	14%	9%	6%	5%
Operating Income (loss)	-707%	-490%	-271%	-213%	-242%	-321%	-361%	-286%	-7%	54%	69%	79%	83%
Net Income	-653%	-506%	-303%	-240%	-266%	-343%	-383%	-310%	-12%	32%	43%	49%	52%
Financial Indicator Growth Analysis (Y/Y)													
Product (Biocenter) revenue	47%	170%	93%	-4%	-2%	16%	9%	4%	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%	93%	-4%	-2%	15%	9%	4%	337%	142%	59%	52%	27%
Research and development	436%	168%	2%	-68%	-45%	18%	-8%	-38%	4%	4%	5%	5%	5%
Plasma center operating expenses	50%	38%	59%	31%	28%	4%	-10%	10%	4%	7%	4%	3%	2%
General and administrative	119%	39%	11%	19%	28%	162%	214%	98%	4%	4%	3%	3%	3%
Marketing and sales	-	-	-	-	-	-	-	-	4%	6%	6%	5%	5%
Operating incomes	71%	90%	6%	-44%	-1%	66%	58%	10%	-89%	-1978%	106%	73%	33%
Pretax Income	27%	96%	12%	-39%	-1%	60%	51%	10%	-82%	-1097%	110%	74%	33%
Net Income	24%	113%	15%	-39%	-1%	60%	74%	7%	-82%	-728%	110%	74%	33%
EPS - Basic	-89%	35%	-19%	-42%	-7%	49%	62%	0%	-86%	-709%	104%	69%	29%
EPS - Diluted	-89%	35%	-19%	-42%	-7%	49%	62%	0%	-86%	-709%	104%	69%	29%
Shares outstanding—basic	1074%	58%	42%	6%	7%	7%	8%	7%	25%	3%	3%	3%	3%
Shares outstanding—diluted	1074%	58%	42%	6%	7%	7%	8%	7%	25%	3%	3%	3%	3%

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

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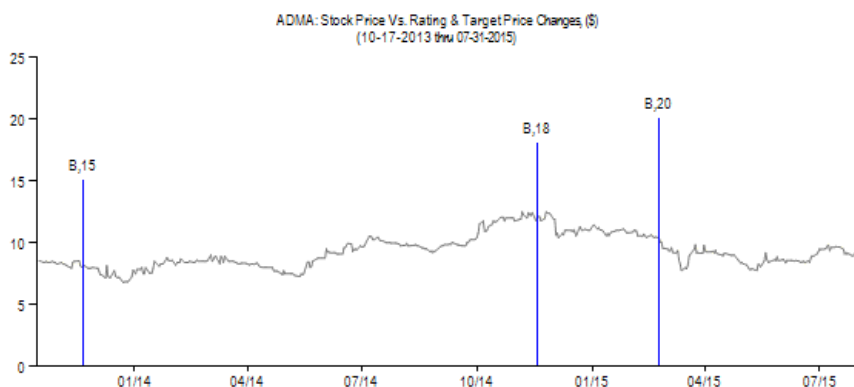
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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
11/21/2013	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
02/23/2015	20.00	10.40

Source: Laidlaw & Company

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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%

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