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EQUITY RESEARCH
Company Report

September 21, 2015

ADMA Biologics (ADMA - $ 9.05)

Healthcare/Biotechnology

FDA Accepted Review of BLA for RI-002 in Primary Immune Deficiency Disease (PIDD) Ahead of the 60 Day Projections

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

This morning, ADMA reported that the FDA has accepted the review for the BLA of RI-002 as an IVIG for the prevention of infection in primary immune deficiency disease (PIDD) patients.

- **Details.** As anticipated, the FDA accepted the review of RI-002 BLA as an IVIG for the prevention of infection in PIDD. As such, the company indicated that the PDUFA date is scheduled for 2H16. ADMA filed RI-002 BLA on July 31st, 2015 and the FDA typically has 60 days (projected to be the end of September or early October) to decide whether accepting the application. The agency's decision is almost two to three weeks ahead of the estimated 60 day deadline.
- **Implication.** We view the earlier FDA decision as positive for ADMA shareholders as it not only lifts a minor overhang for the shares, but also suggests that the BLA package submitted by the company is comprehensive enough without the need for a longer examination. The company did not provide a more precise time for the PDUFA date; our estimate is August 2016. Along with the high likelihood of approval, this timeline could afford ADMA a brief but sufficient time post approval to commercialize RI-002 for the 2016/2017 winter season. As a reminder, our bullish view of likely RI-002 approval is based on the well-established path for IVIG approval. Specifically, the trial design and primary endpoint of the RI-002 Phase III (ADMA-003) study are based on the requirement and FDA guidance for approving a typical IVIG. The study met the primary endpoint of preventing serious bacterial infections (SBI) with <1 SBI per patient-year. RI-002 also exhibited consistently high anti-RSV antibody and antibodies against other respiratory infectious pathogens – a unique attribute among all IVIGs. Supported by recently granted patents for RI-002 and the company's initial commercialization efforts, ADMA, in our opinion, could be an interesting prospect as a potential acquisition target.
- **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.

Trading Data:

Last Price (09/18/2015)	$ 9.05
52–Week High (12/3/2014)	$ 14.00
52–Week Low (5/8/2015)	$ 7.51
Market Cap. (MM)	$ 97
Shares Out. (MM)	11

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.37A	-0.44A	-0.46	-0.52	-1.78	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

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	**2015**	****
		Potential U.S. approval	**2H16**	*****
		Potential U.S. product launch	**2H16**	*****
VZIG (Varitect)	Vicella Zoster virus infection	Potential commence Phase II/III study	**2015**	***
BioCenters		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.

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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 immunoglobin, 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

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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.

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ADMA Biologics – Income Statement

($ '000)	2012	2013	2014	1Q15	2Q15	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
Product revenue	1,118	3,024	5,840	1,484	1,291	1,511	1,556	5,842	8,996	12,235	12,846	13,489	14,258
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	1,310	1,529	1,575	5,917	26,614	64,944	103,449	157,349	199,603
Cost of product revenue	669	2,023	3,742	910	786	1,065	1,097	3,858	6,117	8,320	8,736	9,172	9,695
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	505	446	459	1,984	2,879	3,915	4,111	4,316	4,562
Total gross revenue	449	1,000	2,076	575	505	446	459	1,984	11,538	30,120	49,262	76,097	97,085
Research and development	3,469	9,303	9,517	1,402	1,506	2,018	2,038	6,964	7,242	7,532	7,908	8,304	8,719
Plasma center operating expenses	1,747	2,418	3,851	1,048	1,097	1,108	1,130	4,383	4,558	4,877	5,072	5,224	5,329
General and administrative	3,142	4,365	4,824	1,346	1,437	1,969	2,540	7,293	7,585	7,888	8,156	8,434	8,720
Marketing and sales									8,400	8,904	9,438	9,948	10,445
Total Operating Expenses	8,358	16,087	18,192	3,796	4,040	5,095	5,708	18,640	27,785	29,201	30,575	31,910	33,214
Operating Income (loss)	(7,909)	(15,042)	(16,019)	(3,202)	(3,517)	(4,631)	(5,231)	(16,580)	(1,171)	35,743	72,874	125,439	166,389
Interest income	21	8	14	5	10	6	6	27	43	69	82	99	109
Interest expense	(31)	(618)	(1,286)	(476)	(453)	(322)	(322)	(1,573)	(1,573)	(1,573)	(1,573)	(1,573)	(1,573)
Change in fair value of stock warrants	-	43	(74)	68	-	(40)	(40)	(12)	(100)	(100)	(100)	(100)	(100)
Other income	-	82	-	-	(719)	-	1	(718)	(718)	(718)	(718)	(718)	(718)
Total other expenses	(10)	(485)	(1,346)	(403)	(1,163)	(356)	(355)	(2,277)	(2,349)	(2,323)	(2,309)	(2,293)	(2,283)
Income (loss) before tax expense	(7,919)	(15,527)	(17,365)	(3,606)	(4,679)	(4,987)	(5,586)	(18,857)	(3,520)	33,420	70,565	123,146	164,106
Income tax expense-State income tax benefit	618	-	552	-	-	-		-	-	12,365	26,109	45,564	60,719
Net Incomes (Losses)	(7,301)	(15,527)	(17,917)	(3,606)	(4,679)	(4,987)	(5,586)	(18,857)	(3,520)	21,055	44,456	77,582	103,387
Net Earnings (Losses) Per Share—Basic	($1.76)	($2.38)	($1.93)	($0.37)	($0.44)	($0.46)	($0.52)	($1.78)	($0.27)	$1.57	$3.21	$5.45	$7.07
Net Earnings (Losses) Per Share—Diluted	($1.76)	($2.38)	($1.93)	($0.37)	($0.44)	($0.46)	($0.52)	($1.78)	($0.27)	$1.57	$3.21	$5.45	$7.07
Shares outstanding—basic	4,146	6,531	9,292	9,855	10,706	10,756	10,806	10,531	13,031	13,431	13,831	14,231	14,631
Shares outstanding—diluted	4,146	6,531	9,292	9,855	10,706	10,756	10,806	10,531	13,031	13,431	13,831	14,231	14,631
Margin Analysis (% of Revenue)													
Gross	40%	33%	36%	39%	30%	30%	30%	34%	32%	32%	32%	32%	32%
Cost of RI-002									50%	50%	50%	50%	50%
R&D	310%	303%	161%	93%	115%	132%	129%	118%	27%	12%	8%	5%	4%
Plasma operation	156%	80%	66%	71%	85%	73%	73%	75%	51%	40%	39%	39%	37%
G&A	281%	142%	82%	90%	110%	129%	161%	123%	28%	12%	8%	5%	4%
M&S									32%	14%	9%	6%	5%
Operating Income (loss)	-707%	-490%	-271%	-213%	-268%	-303%	-332%	-280%	-4%	55%	70%	80%	83%
Net Income	-653%	-506%	-303%	-240%	-357%	-326%	-355%	-319%	-13%	32%	43%	49%	52%
Financial Indicator Growth Analysis (Y/Y)													
Product (Biocenter) revenue	47%	170%	93%	-4%	-13%	12%	6%	0%	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%	-13%	12%	6%	0%	350%	144%	59%	52%	27%
Research and development	436%	168%	2%	-68%	-16%	36%	6%	-27%	4%	4%	5%	5%	5%
Plasma center operating expenses	50%	38%	59%	31%	34%	9%	-7%	14%	4%	7%	4%	3%	2%
General and administrative	119%	39%	11%	19%	-7%	90%	128%	51%	4%	4%	3%	3%	3%
Marketing and sales										6%	6%	5%	5%
Operating incomes	71%	90%	6%	-44%	-2%	52%	41%	4%	-93%	-3152%	104%	72%	33%
Pretax Income	27%	96%	12%	-39%	18%	47%	36%	9%	-81%	-1049%	111%	75%	33%
Net Income	24%	113%	15%	-39%	18%	47%	57%	5%	-81%	-698%	111%	75%	33%
EPS - Basic	-89%	35%	-19%	-42%	3%	27%	35%	-8%	-85%	-680%	105%	70%	30%
EPS - Diluted	-89%	35%	-19%	-42%	3%	27%	35%	-8%	-85%	-680%	105%	70%	30%
Shares outstanding—basic	1074%	58%	42%	6%	15%	16%	16%	13%	24%	3%	3%	3%	3%
Shares outstanding—diluted	1074%	58%	42%	6%	15%	16%	16%	13%	24%	3%	3%	3%	3%

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

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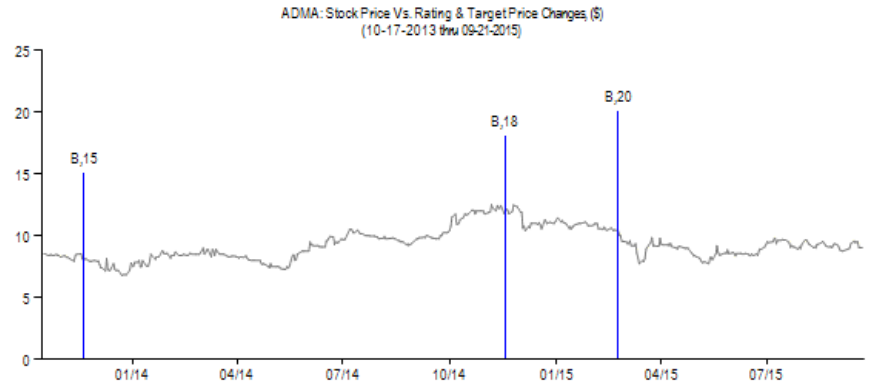
Additional information available upon request.

‡ Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

RATINGS INFORMATION

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 **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
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.	74.19%	25.81%	6.45%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.23%	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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