

## ADMA Biologics (ADMA - \$3.60)

### Significant Visibility Regarding ADMA Developments Going Forward with Biotest Facilities Acquisition Completed

This morning, ADMA provided an update following its completion of Biotest U.S. manufacturing facility acquisition. As such, ADMA is becoming a vertically integrated plasma producer, including fractionation operations and commercial products. ADMA highlighted near-term efforts, including remediating production issues related to the FDA warning letter, relaunch of Bivigam, and RI-002 BLA refiling.

- Resolving Biotest plant issues remains main focus.** ADMA pointed out that together with consultants, they are working on remediation of the manufacturing issues cited by the FDA warning letter of the prior Biotest plant. The objective is to bring the facility into cGMP compliant standards so it would be inspection-ready potentially by YE17/1Q18 for a subsequent reinspection and lifting of the outstanding FDA warning letter. In addition, ADMA has worked on the production issues associated with Bivigam that led to previously halting its marketing. The problem, clogging during production, is mainly caused by protein aggregations. To ameliorate this, a gentler mixing process was implemented by changing the rotary pump to a diaphragm pump. ADMA guided to resume manufacturing in 8 weeks—a first step before refiling for Bivigam relaunch in the U.S. ADMA could refile for Bivigam relaunch in 1H18 and a BLA for RI-002 in mid-2018. We estimate RI-002 could potentially gain approval in 4Q18/1Q19 and Bivigam could be relaunched in 3Q18. In addition, ADMA will further expand its operation by building more plasma collection centers with the third one on track to open possibly in 2018.
- Implications.** We view today's update very positively given it provides greater visibility on the anticipated milestones and development timeline. Together, we anticipate the company is quickly morphing into a well vertically integrated plasma product company. Overall, we are impressed by the current management's ability to identify multiple issues and develop solutions even before the closing of the Biotest transaction. We look forward for ADMA to potentially resolve the production issues pass the FDA plant reinspections, and gain approval of RI-002 and launch Bivigam in 2018. As such, we believe some of these inflection points could potentially increase ADMA share valuation.
- Action.** We reiterate our Buy rating and \$15 target price, reflecting ADMA's resolution of the CRL issues, resulting in a potential RI-002 approval and launch. 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-17E</b>	-0.51A	-0.17	-0.27	-0.20	-1.02	NM
<b>FY-16A</b>	-0.43	-0.50	-0.34	-0.35	-1.61	NM
<b>FY-15A</b>	-0.37	-0.44	-0.48	-0.44	-1.73	NM
<b>FY-14A</b>	-0.64	-0.43	-0.36	-0.38	-1.93	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

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

#### Trading Data:

Last Price (6/26/2017)	\$3.60
52-Week High (7/29/2016)	\$8.00
52-Week Low (6/23/2017)	\$2.93
Market Cap. (MM)	\$106
Shares Out. (MM)	12.153

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## Anticipated milestones in 2017 and beyond

Program	Indication	Event	Timing	Importance
RI-002	RSV infection prevention in PIDD	Potential resubmit BLA	Mid-18	*****
		Potential U.S. approval	4Q18/early 2019	*****
		Potential U.S. product launch	2018/2019	*****
Issues related to manufacturing facility cited on the FDA Warning Letter		Completion of the remediation work	YE2017	*****
Bivigam	IVIG	Manufacture-ready	3Q17	
		File for potential re-launch	1Q18	
		Potentially launch	3Q18	
VZIG (Varitect)	Vicella Zoster virus infection	Potential commence Phase II/III study	2017	***
BioCenters		FDA approval of 3rd BioCenter	2018	***

\*\*\*\* / \*\*\*\*\* 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. 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)	2013	2014	2015	2016	1Q17	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E	2020E
<b>Revenue</b>												
Product revenue	3,024	5,840	7,050	10,518	2,593	2,386	2,314	2,337	9,630	10,401	10,921	11,543
RI-002 revenue	-	-	-	-	-	-	-	-	-	20,218	61,829	96,269
Legacy products	-	-	-	-	-	-	1,900	3,500	5,400	15,000	16,500	17,490
License revenue	44	76	127	143	36	36	36	36	144	144	144	144
<b>Total Revenue</b>	<b>3,068</b>	<b>5,916</b>	<b>7,178</b>	<b>10,661</b>	<b>2,629</b>	<b>2,422</b>	<b>4,250</b>	<b>5,873</b>	<b>15,174</b>	<b>30,762</b>	<b>72,894</b>	<b>107,956</b>
Cost of product revenue	2,023	3,742	4,311	6,361	1,616	1,431	1,388	1,402	5,839	6,240	6,552	6,926
Cost of RI-002	-	-	-	-	-	-	-	-	-	10,109	30,915	48,135
Gross revenue (RI-002)	-	-	-	-	-	-	-	-	-	10,109	30,915	48,135
Gross revenue (Biocenter)	1,000	2,076	2,739	4,157	977	954	926	935	3,792	4,160	4,368	4,617
<b>Total gross revenue</b>	<b>1,000</b>	<b>2,076</b>	<b>2,739</b>	<b>4,157</b>	<b>977</b>	<b>954</b>	<b>2,826</b>	<b>4,435</b>	<b>9,192</b>	<b>29,269</b>	<b>51,783</b>	<b>70,242</b>
Research and development	9,303	9,517	7,016	7,688	1,193	1,252	2,490	2,540	7,476	7,849	8,242	8,654
Plasma center operating expenses	2,418	3,851	4,618	5,448	1,479	1,193	1,157	1,169	4,998	5,198	5,354	5,461
General and administrative	4,365	4,824	6,746	8,495	4,277	2,353	3,676	3,705	14,012	14,768	15,359	15,973
Marketing and sales	-	-	-	-	-	-	-	-	-	9,321	9,825	10,316
<b>Total Operating Expenses</b>	<b>16,087</b>	<b>18,192</b>	<b>18,380</b>	<b>21,631</b>	<b>6,950</b>	<b>4,798</b>	<b>7,323</b>	<b>7,414</b>	<b>26,485</b>	<b>37,137</b>	<b>38,779</b>	<b>40,404</b>
<b>Operating Income (loss)</b>	<b>(15,042)</b>	<b>(16,019)</b>	<b>(15,514)</b>	<b>(17,330)</b>	<b>(5,937)</b>	<b>(3,807)</b>	<b>(4,462)</b>	<b>(2,943)</b>	<b>(17,150)</b>	<b>(7,724)</b>	<b>13,147</b>	<b>29,982</b>
Interest income	8	14	38	50	19	12	12	12	55	65	79	86
Interest expense	(618)	(1,286)	(1,843)	(2,240)	(619)	(520)	(746)	(750)	(2,635)	(2,635)	(2,635)	(2,635)
Change in fair value of stock warrants	43	(74)	68	-	-	-	-	-	-	-	-	-
Other income	82	-	(719)	4	-	-	(1,900)	(1,900)	(3,800)	(7,600)	(7,600)	(3,800)
Total other expenses	(485)	(1,346)	(2,456)	(2,185)	(600)	(508)	(2,634)	(2,638)	(6,380)	(10,169)	(10,156)	(6,348)
Income (loss) before tax expense	(15,527)	(17,365)	(17,975)	(19,515)	(6,537)	(4,315)	(7,096)	(5,581)	(23,530)	(17,893)	2,991	23,633
Income tax expense-State income tax benefit	-	552	-	-	-	-	-	-	-	-	(1,107)	(8,744)
<b>Net Incomes (Losses)</b>	<b>(15,527)</b>	<b>(17,917)</b>	<b>(17,975)</b>	<b>(19,515)</b>	<b>(6,537)</b>	<b>(4,315)</b>	<b>(7,096)</b>	<b>(5,581)</b>	<b>(23,530)</b>	<b>(17,893)</b>	<b>1,885</b>	<b>14,889</b>
Net Earnings (Losses) Per Share—Basic	(\$2.38)	(\$1.93)	(\$1.73)	(\$1.61)	(\$0.51)	(\$0.17)	(\$0.27)	(\$0.20)	(\$1.02)	(\$0.60)	\$0.06	\$0.48
Net Earnings (Losses) Per Share—Diluted	(\$2.38)	(\$1.93)	(\$1.73)	(\$1.61)	(\$0.51)	(\$0.17)	(\$0.27)	(\$0.20)	(\$1.02)	(\$0.60)	\$0.06	\$0.48
Shares outstanding—basic	6,531	9,292	10,412	12,153	12,887	25,773	25,973	27,973	23,152	29,973	30,373	30,773
Shares outstanding—diluted	6,531	9,292	10,412	12,153	12,887	25,773	25,973	27,973	23,152	29,973	30,373	30,773
<b>Margin Analysis (% of Revenue)</b>												
Gross (Biocenter)	33%	36%	39%	40%	40%	40%	40%	40%	40%	40%	40%	40%
Cost of RI-002	-	-	-	0%	-	-	-	50%	50%	50%	50%	50%
R&D	303%	161%	98%	72%	45%	52%	59%	43%	49%	26%	11%	8%
Plasma operation	80%	66%	66%	52%	51%	50%	50%	50%	52%	50%	49%	47%
G&A	142%	82%	94%	80%	163%	97%	86%	63%	92%	48%	21%	15%
M&S	-	-	-	-	-	-	-	-	0%	30%	13%	10%
Operating Income (loss)	-490%	-271%	-216%	-163%	-226%	-157%	-105%	-50%	-113%	-25%	18%	28%
Net Income	-506%	-303%	-250%	-183%	-249%	-178%	-167%	-95%	-155%	-58%	3%	14%
<b>Financial Indicator Growth Analysis (Y/Y)</b>												
Product (Biocenter) revenue	170%	93%	21%	49%	24%	7%	-20%	-29%	-8%	8%	5%	6%
RI-002 revenue (projected)	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	206%	56%
Total Revenue	174%	93%	21%	49%	24%	7%	45%	77%	42%	103%	137%	48%
Research and development	168%	2%	-26%	10%	-41%	-63%	48%	335%	-3%	5%	5%	5%
Plasma center operating expenses	38%	59%	20%	18%	16%	-8%	-22%	-16%	-8%	4%	3%	2%
General and administrative	39%	11%	40%	26%	150%	36%	107%	13%	65%	5%	4%	4%
Marketing and sales	-	-	-	-	-	-	-	-	-	26%	5%	5%
Operating incomes	90%	6%	-3%	12%	43%	-31%	19%	-25%	-1%	-55%	-270%	128%
Pretax Income	96%	12%	4%	9%	42%	-28%	64%	22%	21%	-24%	-117%	690%
Net Income	113%	15%	0%	9%	42%	-28%	64%	22%	21%	-24%	-111%	690%
EPS - Basic	35%	-19%	-10%	-7%	18%	-66%	-19%	-44%	-37%	-41%	-110%	680%
EPS - Diluted	35%	-19%	-10%	-7%	18%	-66%	-19%	-44%	-37%	-41%	-110%	680%
Shares outstanding—basic	58%	42%	12%	17%	20%	113%	102%	117%	90%	29%	1%	1%
Shares outstanding—diluted	58%	42%	12%	17%	20%	113%	102%	117%	90%	29%	1%	1%

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

June 27, 2017

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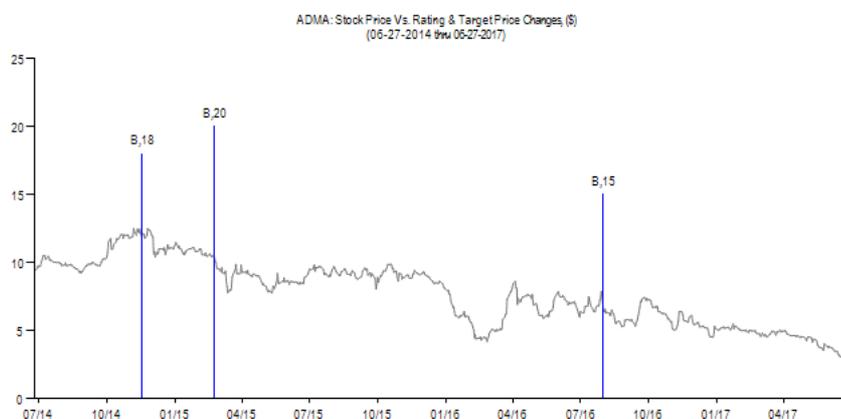
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#### Rating and Price Target Change History



#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
11/18/2...	Buy (B)	12.05

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
11/18/2...	18.00	12.05
02/23/2...	20.00	10.40
08/01/2...	15.00	6.49

Source: Laidlaw & Company

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			Investment Banking	Brokerage
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<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	64.44%	31.11%	2.22%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	2.22%	0.00%	0.00%
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