

ADMA Biologics (ADMA - \$4.78)

4Q16: Biotest Transaction and Efforts for Resolving CMC Issues Relating to CRL are All Underway

ADMA reported 4Q16 results last Friday after the market close with a net loss of (\$3.3MM) vs. Laidlaw (\$3.2MM) and the Street (\$2.9MM) estimates. Net loss/share was (\$0.36) vs. (\$0.29) and (\$0.32) for Laidlaw and the Street, respectively. ADMA ended 4Q16 with cash of ~\$15.3MM and plus recent financial transactions could support operations into 2018, in our opinion.

- Biotest transaction expected to close in 1H17.** ADMA recently signed a definitive agreement to acquire the U.S. immune globulin manufacturing facility (which processes RI-002), two marketed products (BIVIGAM and Nabi-HB), contract manufacturing revenue, and ~\$40MM financing from Biotest Pharmaceuticals in exchange for ~50% of ADMA shares and two plasma collection centers (starting 1/1/2019). The transaction activities are underway and we believe the deal could close in 2Q17. We anticipate ADMA will continue the integration of the two organizations and also resolve certain existing CMC issues related to the CRL for RI-002 in PIDD and to other Biotest legacy products. Going forward, we believe ADMA is becoming a vertically integrated plasma producer pure play with multiple marketed products. In addition, we view the Biotest deal as favorable for ADMA as the latter gains the control of a manufacturing facility and other assets that could worth >\$70MM, in our estimate. For 4Q16, plasma center revenue has continued to grow 34% Y/Y. We believe 2017 revenue growth could be modest as more collected plasma might be used as raw material source for RI-002.
- Possible RI-002 BLA resubmission in 2017 with potential approval and launch in 2018.** We estimate ADMA could resolve CMC issues later in 2017 and potentially resubmit RI-002 BLA shortly thereafter, with possible product launch in 2018. The timeline might be difficult to pinpoint precisely: the FDA has the two regulatory options (Class I resubmission of two months and Class II resubmission of six months), depending on whether plant inspection is needed.
- Action.** We reiterate our Buy rating and \$15 target price, reflecting that ADMA should resolve issues of the CRL, 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
FY-17E	-0.30	-0.16	-0.27	-0.24	-0.93	NM
FY-16A	-0.43	-0.50	-0.34	-0.35	-1.61	NM
FY-15A	-0.37	-0.44	-0.48	-0.44	-1.73	NM
FY-14A	-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 (2/24/2017)	\$4.78
52-Week High (4/4/2016)	\$8.85
52-Week Low (2/26/2016)	\$4.15
Market Cap. (MM)	\$61
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	2017	*****
		Potential U.S. approval	2017/18	*****
		Potential U.S. product launch	2018	*****
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

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	1Q16	2Q16	3Q16	4Q16	2016	1Q17E	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E	2020E
Revenue																
Product revenue	3,024	5,840	7,050	2,088	2,236	2,902	3,292	10,518	2,930	2,695	2,614	2,641	10,880	11,751	12,338	13,041
RI-002 revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	20,218	61,829	96,269
Legacy products	-	-	-	-	-	-	-	-	-	-	1,900	2,500	4,400	10,000	11,000	12,000
License revenue	44	76	127	36	36	36	36	143	36	36	36	36	144	144	144	144
Total Revenue	3,068	5,916	7,178	2,124	2,272	2,938	3,328	10,661	2,966	2,731	4,550	5,177	15,424	32,112	74,312	109,455
Cost of product revenue	2,023	3,742	4,311	1,266	1,344	1,736	2,014	6,361	1,758	1,617	1,569	1,584	6,528	7,050	7,403	7,825
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	822	892	1,166	1,278	4,157	1,172	1,078	1,046	1,056	4,352	4,700	4,935	5,217
Total gross revenue	1,000	2,076	2,739	822	892	1,166	1,278	4,157	1,172	1,078	2,946	3,556	8,752	24,809	46,850	65,351
Research and development	9,303	9,517	7,016	2,028	3,400	1,677	583	7,688	1,400	1,680	2,999	3,059	9,139	9,596	10,076	10,579
Plasma center operating expenses	2,418	3,851	4,618	1,280	1,294	1,483	1,390	5,448	1,494	1,348	1,307	1,320	5,469	5,688	5,859	5,976
General and administrative	4,365	4,824	6,746	1,708	1,724	1,779	3,284	8,495	1,642	1,658	2,975	2,999	9,273	9,774	10,165	10,572
Marketing and sales	-	-	-	-	-	-	-	-	-	-	-	-	-	9,321	9,825	10,316
Total Operating Expenses	16,087	18,192	18,380	5,016	6,418	4,939	5,257	21,631	4,536	4,686	7,281	7,378	23,882	34,380	35,924	37,443
Operating Income (loss)	(15,042)	(16,019)	(15,514)	(4,159)	(5,491)	(3,737)	(3,944)	(17,330)	(3,328)	(3,572)	(4,300)	(3,786)	(14,986)	(9,427)	11,070	28,052
Interest income	8	14	38	14	12	12	13	50	12	12	12	12	48	58	69	76
Interest expense	(618)	(1,286)	(1,843)	(467)	(538)	(606)	(628)	(2,240)	(510)	(520)	(746)	(750)	(2,526)	(2,526)	(2,526)	(2,526)
Change in fair value of stock warrants	43	(74)	68	-	-	-	-	-	-	-	-	-	-	-	-	-
Other income	82	-	(719)	-	4	-	-	4	-	-	(1,900)	(1,900)	(3,800)	(7,600)	(7,600)	(3,800)
Total other expenses	(485)	(1,346)	(2,456)	(454)	(521)	(594)	(615)	(2,185)	(498)	(508)	(2,634)	(2,638)	(6,278)	(10,068)	(10,057)	(6,250)
Income (loss) before tax expense	(15,527)	(17,365)	(17,975)	(4,612)	(6,012)	(4,331)	(4,559)	(19,515)	(3,826)	(4,080)	(6,934)	(6,424)	(21,264)	(19,495)	1,013	21,802
Income tax expense-State income tax benefit	-	552	-	-	-	-	-	-	-	-	-	-	-	-	(375)	(8,067)
Net Incomes (Losses)	(15,527)	(17,917)	(17,975)	(4,612)	(6,012)	(4,331)	(4,559)	(19,515)	(3,826)	(4,080)	(6,934)	(6,424)	(21,264)	(19,495)	638	13,735
Net Earnings (Losses) Per Share—Basic	(\$2.38)	(\$1.93)	(\$1.73)	(\$0.43)	(\$0.50)	(\$0.34)	(\$0.35)	(\$1.61)	(\$0.30)	(\$0.16)	(\$0.27)	(\$0.24)	(\$0.93)	(\$0.79)	\$0.03	\$0.54
Net Earnings (Losses) Per Share—Diluted	(\$2.38)	(\$1.93)	(\$1.73)	(\$0.43)	(\$0.50)	(\$0.34)	(\$0.35)	(\$1.61)	(\$0.30)	(\$0.16)	(\$0.27)	(\$0.24)	(\$0.93)	(\$0.79)	\$0.03	\$0.54
Shares outstanding—basic	6,531	9,292	10,412	10,711	12,122	12,887	12,895	12,153	12,915	25,830	26,030	26,230	22,751	24,751	25,151	25,551
Shares outstanding—diluted	6,531	9,292	10,412	10,711	12,122	12,887	12,895	12,153	12,915	25,830	26,030	26,230	22,751	24,751	25,151	25,551
Margin Analysis (% of Revenue)																
Gross (Biocenter)	33%	36%	39%	39%	40%	40%	39%	40%	40%	40%	40%	40%	40%	40%	40%	40%
Cost of RI-002	-	-	-	-	-	-	-	0%	0%	-	-	-	50%	50%	50%	50%
R&D	303%	161%	98%	95%	150%	57%	18%	72%	47%	62%	66%	59%	59%	30%	14%	10%
Plasma operation	80%	66%	66%	61%	58%	51%	42%	52%	51%	50%	50%	50%	50%	48%	47%	46%
G&A	142%	82%	94%	80%	76%	61%	99%	80%	55%	61%	65%	58%	60%	30%	14%	10%
M&S	-	-	-	-	-	-	-	-	-	-	-	-	0%	29%	13%	9%
Operating Income (loss)	-490%	-271%	-216%	-196%	-242%	-127%	-119%	-163%	-112%	-131%	-94%	-73%	-97%	-29%	15%	26%
Net Income	-506%	-303%	-250%	-217%	-265%	-147%	-137%	-183%	-129%	-149%	-152%	-124%	-138%	-61%	1%	13%
Financial Indicator Growth Analysis (Y/Y)																
Product (Biocenter) revenue	170%	93%	21%	41%	73%	59%	34%	49%	40%	21%	-10%	-20%	3%	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.	N.A.	N.A.	N.A.	N.A.	206%	56%
Total Revenue	174%	93%	21%	41%	73%	59%	32%	49%	40%	20%	55%	56%	45%	108%	131%	47%
Research and development	168%	2%	-26%	45%	126%	-21%	-71%	10%	-31%	-51%	79%	424%	19%	5%	5%	5%
Plasma center operating expenses	38%	59%	20%	22%	18%	22%	10%	18%	17%	4%	-12%	-5%	0%	4%	3%	2%
General and administrative	39%	11%	40%	27%	20%	-14%	74%	26%	-4%	-4%	67%	-9%	9%	5%	4%	4%
Marketing and sales	-	-	-	-	-	-	-	-	-	-	-	-	-	26%	5%	5%
Operating incomes	90%	6%	-3%	30%	56%	-20%	-5%	12%	-20%	-35%	15%	-4%	-14%	-37%	-217%	153%
Pretax Income	96%	12%	4%	28%	28%	-15%	-1%	9%	-17%	-32%	60%	41%	9%	-8%	-105%	2053%
Net Income	113%	15%	0%	28%	28%	-15%	-1%	9%	-17%	-32%	60%	41%	9%	-8%	-103%	2053%
EPS - Basic	35%	-19%	-10%	18%	13%	-29%	-20%	-7%	-31%	-68%	-21%	-31%	-42%	-16%	-103%	2019%
EPS - Diluted	35%	-19%	-10%	18%	13%	-29%	-20%	-7%	-31%	-68%	-21%	-31%	-42%	-16%	-103%	2019%
Shares outstanding—basic	58%	42%	12%	9%	13%	20%	24%	17%	21%	113%	102%	103%	87%	9%	2%	2%
Shares outstanding—diluted	58%	42%	12%	9%	13%	20%	24%	17%	21%	113%	102%	103%	87%	9%	2%	2%

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

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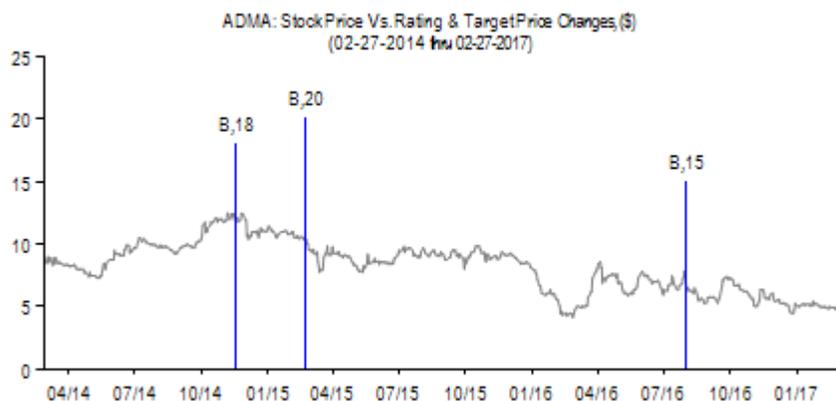
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3 Year Rating Change History

Date	Rating	Closing Price (\$)
11/18/2014	Buy (B)	12.05

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
11/18/2014	18.00	12.05
02/23/2015	20.00	10.40
08/01/2016	15.00	6.49

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.44%	2.44%	0.00%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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