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Est. 1842
London
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San Francisco
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EQUITY RESEARCH
Company Report

November 11, 2016

ADMA Biologics (ADMA - $ 5.63)

Healthcare/Biotechnology

3Q16: Continuing the Progress Toward Potential Resolution of the CRL Identified Third-Party Manufacturer Issues

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

ADMA reported 3Q16 results yesterday after the market close with a net loss of ($4.3MM) vs. Laidlaw ($4.6MM) and the Street ($5.3MM) estimates. Net loss/share was ($0.34) vs. ($0.38) and ($0.42) for Laidlaw and the Street, respectively. ADMA ended 3Q16 with cash of ~$18.9MM, sufficient to support operations deep into 2H17, in our opinion.

- **Updates on addressing RI-002 as IVIG in PIDD BLA CRL issues.** ADMA indicated the efforts for resolving issues identified by the complete response letter (CRL) related to the RI-002 as intravenous immune globulin (IVIG) in PIDD BLA are ongoing. The issues are related to the three third-party manufactures and vendors: Biotest, Ajinomoto Althea, and an un-disclosed ex-U.S. testing laboratory. As a reminder, the FDA indicated they do not have safety and efficacy concerns about RI-002 and did not request additional clinical studies. The key issues relate to outstanding inspection issues and deficiencies at three third-party contract manufacturers. Among them, we believe at least some Biotest issues could relate to an FDA-issued warning letter dated 11/25/2014 (see our 2016-08-15 note). We believe all these companies should have a strong incentive to correct these problems given the potential damage to their current and future commercial outlook in and the possibility of operation shutdown by the FDA. Although we do not have any insights on the specific issues related to the CRL, we are cautiously optimistic that the problems can be resolved, possibly in 2017.
- **Plasma center revenue higher.** The 3Q16 plasma center revenue has grown substantially both Q/Q (29%) and Y/Y (59%). Management indicated the increase is due to the expansion of the first center and greater utilization of the second center. In addition, ADMA also gained a second customer for its plasma product, and the purchase from this customer accounts for greater than 10% of the production.
- **Action.** We are reiterating our Buy rating and $15 target price to reflect that ADMA should resolve issues of the CRL, resulting in 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.

Trading Data:

Last Price (11/10/2016)	$ 5.63
52–Week High (12/3/2015)	$ 9.65
52–Week Low (2/26/2016)	$ 4.15
Market Cap. (MM)	$ 73
Shares Out. (MM)	13

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.43A	-0.50A	-0.34A	-0.29	-1.53	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
FY-13A	-0.55	-0.83	-0.46	-0.55	-2.38	NM

Source: Laidlaw & Company estimates

Yale Jen, Ph.D.
Managing Director /
Senior Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

Anticipated milestones in 2016 and beyond

Program	Indication	Event	Timing	Importance
RI-002	RSV infection prevention in PIDD	Potential resubmit BLA	**2017**	*****
		Potential U.S. approval	**2017**	*****
		Potential U.S. product launch	**2017**	*****
VZIG (Varitect)	Vicella Zoster virus infection	Potential commence Phase II/III study	**2017**	***
BioCenters		FDA approval of 3rd BioCenter	**2017**	****

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

ADMA Biologics – Income Statement

($ '000)	2013	2014	2015	1Q16	2Q16	3Q16	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue												
Product revenue	3,024	5,840	7,050	2,088	2,236	2,902	3,131	10,358	12,844	13,871	14,565	15,395
RI-002 revenue	-	-	-					-	7,044	70,955	130,491	170,129
License revenue	44	76	127	36	36	36	36	143	143	143	143	143
Total Revenue	3,068	5,916	7,178	2,124	2,272	2,938	3,167	10,501	20,030	84,969	145,199	185,666
Cost of product revenue	2,023	3,742	4,311	1,266	1,344	1,736	1,879	6,225	7,706	8,323	8,739	9,237
Cost of RI-002				-	-	-	-	-	3,522	35,477	65,246	85,064
Gross revenue (RI-002)				-	-	-	-	-	3,522	35,477	65,246	85,064
Gross revenue (Biocenter)	1,000	2,076	2,739	822	892	1,166	1,253	4,133	5,137	5,548	5,826	6,158
Total gross revenue	1,000	2,076	2,739	822	892	1,166	1,253	4,133	8,659	41,026	71,071	91,222
Research and development	9,303	9,517	7,016	2,028	3,400	1,677	1,493	8,598	8,942	9,389	9,858	10,351
Plasma center operating expenses	2,418	3,851	4,618	1,280	1,294	1,483	1,379	5,436	5,817	6,049	6,231	6,355
General and administrative	4,365	4,824	6,746	1,708	1,724	1,779	1,655	6,866	7,448	7,850	8,164	8,491
Marketing and sales								-	7,398	7,842	8,265	8,679
Total Operating Expenses	16,087	18,192	18,380	5,016	6,418	4,939	4,526	20,899	29,604	31,130	32,518	33,876
Operating Income (loss)	(15,042)	(16,019)	(15,514)	(4,159)	(5,491)	(3,737)	(3,238)	(16,624)	(20,802)	10,039	38,696	57,490
Interest income	8	14	38	14	12	12	10	47	61	74	88	97
Interest expense	(618)	(1,286)	(1,843)	(467)	(538)	(606)	(483)	(2,094)	(2,094)	(2,094)	(2,094)	(2,094)
Change in fair value of stock warrants	43	(74)	68	-	-	-	-	-	-	-	-	-
Other income	82	-	(719)	-	4	-	-	4	4	4	4	4
Total other expenses	(485)	(1,346)	(2,456)	(454)	(521)	(594)	(473)	(2,043)	(2,029)	(2,016)	(2,002)	(1,993)
Income (loss) before tax expense	(15,527)	(17,365)	(17,975)	(4,612)	(6,012)	(4,331)	(3,711)	(18,667)	(22,830)	8,023	36,694	55,497
Income tax expense-State income tax benefit	-	552	-	-	-	-	-	-	-	(2,968)	(13,577)	(20,534)
Net Incomes (Losses)	(15,527)	(17,917)	(17,975)	(4,612)	(6,012)	(4,331)	(3,711)	(18,667)	(22,830)	5,054	23,117	34,963
Net Earnings (Losses) Per Share—Basic	($2.38)	($1.93)	($1.73)	($0.43)	($0.50)	($0.34)	($0.29)	($1.53)	($1.71)	$0.29	$1.30	$1.93
Net Earnings (Losses) Per Share—Diluted	($2.38)	($1.93)	($1.73)	($0.43)	($0.50)	($0.34)	($0.29)	($1.53)	($1.71)	$0.29	$1.30	$1.93
Shares outstanding—basic	6,531	9,292	10,412	10,711	12,122	12,887	12,937	12,164	13,337	17,337	17,737	18,137
Shares outstanding—diluted	6,531	9,292	10,412	10,711	12,122	12,887	12,937	12,164	13,337	17,337	17,737	18,137
Margin Analysis (% of Revenue)												
Gross (Biocenter)	33%	36%	39%	39%	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%	47%	82%	45%	11%	7%	6%
Plasma operation	80%	66%	66%	61%	58%	51%	44%	52%	45%	44%	43%	41%
G&A	142%	82%	94%	80%	76%	61%	52%	65%	37%	9%	6%	5%
M&S									37%	9%	6%	5%
Operating Income (loss)	-490%	-271%	-216%	-196%	-242%	-127%	-102%	-158%	-104%	12%	27%	31%
Net Income	-506%	-303%	-250%	-217%	-265%	-147%	-117%	-178%	-114%	6%	16%	19%
Financial Indicator Growth Analysis (Y/Y)												
Product (Biocenter) revenue	170%	93%	21%	41%	73%	59%	28%	47%	24%	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.	907%	84%	30%
Total Revenue	174%	93%	21%	41%	73%	59%	26%	46%	91%	324%	71%	28%
Research and development	168%	2%	-26%	45%	126%	-21%	-25%	23%	4%	5%	5%	5%
Plasma center operating expenses	38%	59%	20%	22%	18%	22%	10%	18%	7%	4%	3%	2%
General and administrative	39%	11%	40%	27%	20%	-14%	-12%	2%	-12%	5%	4%	4%
Marketing and sales										6%	5%	5%
Operating incomes	90%	6%	-3%	30%	56%	-20%	-22%	7%	25%	-148%	285%	49%
Pretax Income	96%	12%	4%	28%	28%	-15%	-19%	4%	22%	-135%	357%	51%
Net Income	113%	15%	0%	28%	28%	-15%	-19%	4%	22%	-122%	357%	51%
EPS - Basic	35%	-19%	-10%	18%	13%	-29%	-35%	-11%	12%	-117%	347%	48%
EPS - Diluted	35%	-19%	-10%	18%	13%	-29%	-35%	-11%	12%	-117%	347%	48%
Shares outstanding—basic	58%	42%	12%	9%	13%	20%	25%	17%	10%	30%	2%	2%
Shares outstanding—diluted	58%	42%	12%	9%	13%	20%	25%	17%	10%	30%	2%	2%

Yale Jen, Ph.D. 212-953-4978

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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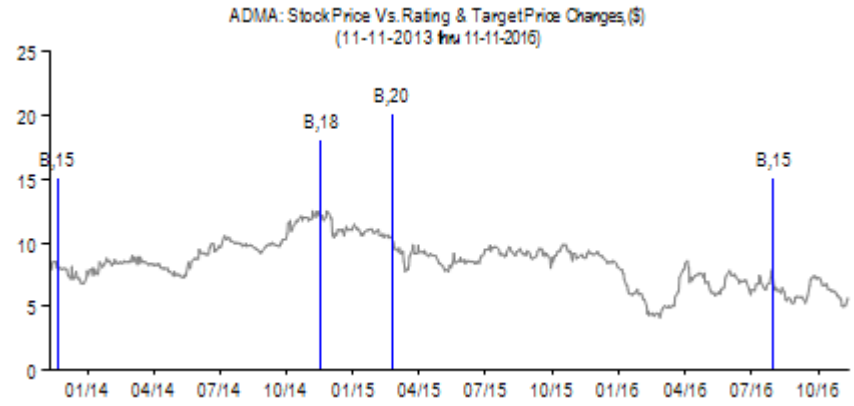
Rating and Price Target Change History



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
08/01/2016	15.00	6.49

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.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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Yale Jen, Ph.D.
yjen@laidlawltd.com

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Yale Jen, Ph.D.
yjen@laidlawltd.com

NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com