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EQUITY RESEARCH
Company Report

December 20, 2018

ADMA Biologics (ADMA - $2.39)

Healthcare/Biotechnology

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

Bivigam CRL Pertaining Only to Drug Substance Prior Approval Supplement Submission

ADMA reported yesterday after the market close that the FDA has issued a CRL for Bivigam pertaining only to the drug substance Prior Approval Supplement (PAS) submission and previously approved the drug product PAS submission.

- **Details.** The FDA issued a CRL pertaining to the drug substance PAS submission, which relates to chemistry, manufacturing and controls information. The FDA did approve product PAS submission comprised of fill, finish and final release information of the drug product. The agency did not request information regarding compliance status, clinical study safety, efficacy and third-party contract manufacturers and vendors; and did not ask for more manufacturing runs. During the conference call this morning, ADMA suggested that the drug substance PAS submission issues mainly related to documentation and are likely resolvable. ADMA will start to address the CRL issues shortly and if they can respond to the agency by late 1Q19, we estimate the next FDA decision could slate to mid-2019 (type I review) or 2H19 (type II review). ADMA indicated that issues raised by the CRL are mainly only associated with Bivigam, while issues related to the RI-002 CRL mainly compliance of third parties. ADMA also indicated that issues related to the RI-002 CRL have already being addressed. So far, ADMA shares this morning were down 40+%.
- **Implications** Although in-theory the risks of RI-002 BLA filing seem could have been increased, we may argue that the regulatory trajectory of RI-002 would be rather independent to that of Bivigam. Given the mostly different nature of issues related to the CRL between Bivigam and RI-002, we do not believe Bivigam's drug substance PAS submission issues should automatically become a concern of RI-002 BLA refiling. From valuation perspective, in our assessment, the sales potential of RI-002 would be significantly greater than (~5x) that of Bivigam and, we believe, the outlook of RI-002 has not been impaired. Further, based on the characterization by ADMA on the Bivigam CRL issues, we believe there is a good probability that the drug would ultimately be approved if the company resolves those issues.
- **Action.** We reiterate our Buy rating, $15 target price and view the current valuation a buying opportunity. Our view reflects ADMA's successful transition into a fully integrated company with potential RI-002 launch near term. Our target price is supported by P/E, peer comparable and risk-adjusted cash flow sum-of-the-parts analyses.

Trading Data:

Last Price (12/20/2018)	$2.39
52–Week High (9/6/2018)	$6.96
52–Week Low (12/21/2017)	$2.49
Market Cap. (MM)	$107.8
Shares Out. (MM)	46.32

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.39A	-0.35A	-0.33A	-0.39	-1.45	NM
FY-17A	-0.51	-0.55	-0.59	-0.36	-1.91	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

Source: Laidlaw & Company estimates

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

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Anticipated milestones in 2018 and beyond

Program	Indication	Event	Timing	Importance
RI-002	RSV infection prevention in PIDD	PDUFA date for potential approval	**4/2/2019**	*****
		Potential U.S. product launch	**2H19**	*****
Bivigam	IVIG	Potentially reponding to the CRL issues to the FDA	**1H19**	***
		Potential FDA decision	**2H19/2020**	***
VZIG (Varitect)	Vicella Zoster virus infection	Potential commence Phase II/III study	**2019**	***

***** / ***** 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 ended 3Q18 with $43MM cash, ADMA could potentially need more financial resources going forward if they want to expand and further develop its pipeline.

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

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

Income Statement

ADMA Biologics – Income Statement

($ '000)	2016	2017	1Q18	2Q18	3Q18	4Q18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenue														
Plasma center revenue	10,518	11,637	2,340	2,476	2,209	2,584	9,610	2,573	3,010	5,719	6,291	6,921	7,592	8,313
RI-002 revenue	-	-	-			-	-	10,133	69,845	125,083	172,867	215,397	236,447	252,209
Legacy products		10,981	1,666	2,145	1,986	2,502	8,298	18,121	24,826	32,274	40,019	48,423	58,108	65,081
License revenue	143	143	36	36	36	36	143	144	144	144	144	144	144	144
Total Revenue	10,661	22,761	4,042	4,657	4,230	5,122	18,051	30,971	97,825	163,220	219,322	270,884	302,290	325,746
Total cost of revenue	6,361	29,164	12,243	9,646	9,164	12,990	44,043	36,813	35,353	57,436	81,134	100,755	115,045	125,592
Total gross revenue	4,157	(6,404)	(8,201)	(4,989)	(8,389)	(7,868)	(29,590)	(5,842)	62,328	105,639	138,044	169,986	187,101	200,010
Research and development	7,688	6,230	1,282	1,472	1,317	1,304	5,375	6,134	6,441	6,698	6,966	7,245	7,535	7,836
Plasma center operating expenses	5,448	6,504	1,834	1,738	1,973	1,914	7,459	1,328	1,886	2,489	3,137	3,199	3,263	3,329
Asset impairment charge		845												
Selling, general and administrative	8,495	18,093	5,005	5,007	5,356	5,383	20,750	31,781	33,053	34,375	35,750	37,180	38,667	40,214
Amortization of intangibles		1,235	211	211	211	211	845	845	845	845	845	845	845	845
Total Operating Expenses	21,631	32,906	20,575	18,074	18,022	21,802	78,472	76,902	77,577	101,844	127,831	149,224	165,355	177,815
Operating Income (loss)	(17,330)	(39,310)	(16,533)	(13,417)	(13,791)	(16,680)	(60,421)	(45,930)	(15,106)	3,939	10,357	20,906	21,890	22,339
Interest income	50	57	27	33	76	65	200	134	147	162	178	196	216	237
Interest expense	(2,240)	(3,286)	(1,323)	(1,359)	(1,402)	(1,325)	(5,410)	(3,602)	(3,602)	(3,602)	(3,602)	(3,602)	(3,602)	(3,602)
Loss on extinguishment of debt		(1,210)												
Change in fair value of stock warrants	-	-					-	-	-	-	-	-	-	-
Other income	4	(10)	7	(4)	(17)	(5)	(20)	17	9	9	9	9	9	9
Total other expenses	(2,185)	(4,449)	(1,290)	(1,330)	(1,344)	(1,265)	(5,229)	(3,451)	(3,446)	(3,431)	(3,415)	(3,397)	(3,378)	(3,356)
Income (loss) before tax expense	(19,515)	(43,759)	(17,822)	(14,748)	(15,135)	(17,945)	(65,650)	(49,381)	(18,552)	508	6,942	17,509	18,512	18,983
Income tax expense-State income tax benefit	-	-					-	-	-	(127)	(1,735)	(4,377)	(4,628)	(4,746)
Net Incomes (Losses)	(19,515)	(43,759)	(17,822)	(14,748)	(15,135)	(17,945)	(65,650)	(49,381)	(18,552)	381	5,206	13,132	13,884	14,237
Net Earnings (Losses) Per Share—Basic	($1.61)	($1.91)	($0.39)	($0.35)	($0.33)	($0.39)	($1.45)	($1.00)	($0.35)	$0.01	$0.10	$0.24	$0.25	$0.25
Net Earnings (Losses) Per Share—Diluted	($1.61)	($1.91)	($0.39)	($0.35)	($0.33)	($0.39)	($1.45)	($1.00)	($0.35)	$0.01	$0.10	$0.24	$0.25	$0.25
Shares outstanding—basic	12,153	22,896	45,317	42,712	46,350	46,450	45,207	49,400	53,750	54,250	54,750	55,250	55,750	56,250
Shares outstanding—diluted	12,153	22,896	45,317	42,712	46,350	46,450	45,207	49,400	53,750	54,250	54,750	55,250	55,750	56,250
Margin Analysis (% of Revenue)														
Gross (Biocenter)	40%	38%	34%	32%	33%	33%	33%	34%	34%	34%	34%	34%	34%	34%
Cost of legacy products			642%	371%	561%	450%		65%	50%	50%	63%	65%	67%	68%
Cost of RI-002	0%							50%	30%	30%	30%	30%	30%	30%
R&D	72%	27%	32%	32%	31%	25%	30%	20%	7%	4%	3%	3%	2%	2%
Plasma operation	52%	56%	78%	70%	89%	74%	78%	52%	63%	44%	50%	46%	43%	40%
M&S&G&A	80%	79%	124%	108%	127%	105%	115%	103%	34%	21%	16%	14%	13%	12%
M&S		#REF!				#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Operating Income (loss)	-163%	-173%	-409%	-288%	-326%	-326%	-335%	-148%	-15%	2%	5%	8%	7%	7%
Net Income	-183%	-192%	-441%	-317%	-358%	-350%	-364%	-159%	-19%	0%	2%	5%	5%	4%
Financial Indicator Growth Analysis (Y/Y)														
Product (Biocenter) revenue	49%	11%	-10%	-12%	-21%	-24%	-17%	-73%	17%	90%	10%	10%	10%	10%
RI-002 revenue (projected)	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	589%	79%	38%	25%	10%	7%
Legacy products			N.A.	298%	6%	-71%	-24%	118%	37%	30%	24%	21%	20%	12%
Total Revenue	49%	113%	54%	37%	-11%	-57%	-21%	72%	216%	67%	34%	24%	12%	8%
Research and development	10%	-19%	7%	8%	-27%	-30%	-14%	14%	5%	4%	4%	4%	4%	4%
Plasma center operating expenses	18%	19%	24%	9%	25%	4%	15%	-82%	42%	32%	26%	2%	2%	2%
Marketing and sales and general and administrative	26%	113%	17%	13%	28%	4%	15%	53%	4%	4%	4%	4%	4%	4%
Marketing and sales							26%	26%	5%					
Operating incomes	12%	127%	178%	60%	-4%	58%	54%	-24%	-67%	-126%	163%	102%	5%	2%
Pretax Income	9%	124%	173%	63%	0%	38%	50%	-25%	-62%	-103%	1266%	152%	6%	3%
Net Income	9%	124%	173%	63%	0%	38%	50%	-25%	-62%	-102%	1266%	152%	6%	3%
EPS - Basic	-7%	19%	-22%	-37%	-45%	9%	-24%	-31%	-65%	-102%	1254%	150%	5%	2%
EPS - Diluted	-7%	19%	-22%	-37%	-45%	9%	-24%	-31%	-65%	-102%	1254%	150%	5%	2%
Shares outstanding—basic	17%	88%	252%	160%	80%	27%	97%	9%	9%	1%	1%	1%	1%	1%
Shares outstanding—diluted	17%	88%	252%	160%	80%	27%	97%	9%	9%	1%	1%	1%	1%	1%

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

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

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3 Year Rating Change History

Date	Rating	Closing Price ($)
08/01/2016	Buy (B)	6.49

3 Year Price Change History

Date	Target Price ($)	Closing Price ($)
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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	61.67%	25.00%	3.33%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	6.67%	1.67%	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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NOTES:

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