Zacks Small-Cap Research

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ADMA Biologics, Inc. (ADMA - NASDAQ)

FDA's CRL Delays Approval of RI-002. No Issues with Clinical Safety or Efficacy Data.

Based on our DCF model and a 15% discount rate, ADMA is valued at approximately $14.00 per share. We apply a 60% probability of FDA approval for RI-002.

Current Price (7/29/2016)	$7.85
Valuation	**$14.00**

OUTLOOK

ADMA has developed an IVIG product, RI-002, with high levels of RSV antibodies that can treat immune compromised patients and address a host of other evidence-based uses. One year after its July 31, 2015 BLA submission, the FDA issued a CRL citing deficiencies at third party manufacturers. While no issues related to safety and efficacy were noted in the CRL, we expect an eight month delay in eventual marketing of the biologic compared to our previous estimates. We anticipate eventual approval by 2Q:17 and first sales of RI-002 by 3Q:17.

ADMA is currently operating two plasma collection centers. When up to full capacity, the two Atlanta-based centers are anticipated to produce up to 60k liters of plasma annually, providing the source material for RI-002 and generate diversifying income.

SUMMARY DATA

52-Week High	**$9.96**
52-Week Low	**$4.15**
One-Year Return (%)	**-13.7**
Beta	**2.48**
Average Daily Volume (sh)	**38,753**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$98.9**
Short Interest Ratio (days)	**3.93**
Institutional Ownership (%)	**66**
Insider Ownership (%)	**25**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Biologics**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	$1.5 A	$1.3 A	$1.9 A	$2.5 A	$7.2 A
2016	$2.1 A	$2.6 E	$3.0 E	$3.2 E	$10.9 E
2017					$22.3 E
2018					$77.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.34 A	-$0.44 A	-$0.48 A	-$0.48 A	-$1.73 A
2016	-$0.43 A	-$0.37 E	-$0.38 E	-$0.38 E	-$1.54 E
2017					-$1.16 E
2018					$1.08 E

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WHAT'S NEW

FDA Issues Complete Response Letter Regarding RI-002

The Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) to ADMA Biologics, Inc. (NASDAQ:ADMA) regarding its Biologics License Application (BLA) for RI-002. The company issued a press release on July 29, 2016 highlighting the details provided in the letter. We remind investors that a CRL is issued by the FDA in response to a sponsor's BLA notifying the sponsor that the biologic product submitted cannot be approved in its current form. The CRL outlines the deficiency, provides a complete review of the data submitted in support of the application, and recommends the actions necessary to support future approval.

According to ADMA's press release, the FDA identified inspection issues and deficiencies at ADMA's third party contract manufacturers. This includes the contract drug substance and product manufacturer and its contract fill and finisher. The FDA also found fault with compliance at a third party contract testing laboratory.

ADMA's contract manufacturer, Biotest, was found to have deficiencies in its manufacturing process during the current review, and while they may continue to fractionate currently approved products, they will not be allowed to manufacture new products. This issue is not a new one for Biotest as they were delivered a warning letter in 2014 related to current good manufacturing processes.

There were also deficiencies at the fill and finish partner, located on the West coast and the laboratory that performs the final inspection for release. The other two labs that are involved initial testing of RI-002 for antibody levels and for virus and disease did not have any deficiencies noted by the agency and were not identified in the CRL.

The FDA requires that the same manufacturing partners that are listed in the BLA be used for production following approval. If there is a change in the manufacturing supply chain, then the FDA requires the company to withdraw and start over again with another BLA. Therefore, ADMA will not be able to change its third party providers to resolve the issues and maintain a reasonable timeline.

ADMA's press release also highlighted that they are working with the FDA to develop the label for RI-002. Approximately a month before the approval date, the FDA began to discuss the label and package insert with ADMA. The discussion is centered on language that may be included regarding the manufacturing process and the ability to differentiate whether this is standard IVIG or IVIG with high levels of antibodies. Currently, no decision has been made.

Management's next steps are to consult with their partners and identify the remedies with them before meeting with the FDA to develop a plan of action. A sponsor is able to request a Type A meeting with the FDA to be scheduled within 30 days of the request following a CRL. This meeting is available to provide additional guidance on what needs to be accomplished before approval can be given.

Assuming that ADMA's partners are able to remedy the deficiencies within a reasonable amount of time, the next step is to resubmit the BLA. There are two pathways that can be pursued: either a Class 1 resubmission or a Class 2 resubmission. To resubmit under the Class 1 category, the deficiencies noted in the CRL must be related to labeling, discussions of post-marketing requirements, final release testing, and other minor clarifying information. If the resubmission does not fall under the Class 1 constraints, then it will be categorized under Class 2. Class 2 is required for a presentation to an advisory committee (which is not applicable) and also if a reinspection is required (which may be applicable). It is not clear at this point whether or not the resubmission will be a Class 1 or a Class 2, however, we take a conservative view and anticipate a Class 2 resubmission will be required as the facilities under question may require a reinspection. This assumption means that we forecast a six month response time for the FDA.

We adjust our estimates to reflect an overall eight month delay in RI-002 sales. Previously we had estimated first sales of RI-002 in late 2016 and have now shifted this to late 2Q:17. We anticipate two months to consult with third party partners, correct deficiencies, and resubmit to the FDA under a Class 2 resubmission standard, and six months for the FDA to provide a response. If the FDA considers the discrepancies to be relatively minor, it is possible that the resubmission could fall under Class 1 constraints, which would result in an overall four month delay relative to our original estimates.

We estimate that based on cash burn levels of approximately $5 million per quarter and the impacts of recent financing, that ADMA had approximately $23 million in cash on the balance sheet at the end of 2Q:16. Looking forward, and including the company's monthly cash burn guidance of $1.4 to $1.6 million per month, we anticipate sufficient cash on the balance sheet to support an additional four quarters of operations with a margin for error. We note that the increasing contributions from the maturing plasma centers should offset some of the cash burn as we move forward.

If the eventual launch takes longer than we forecast, then ADMA may require additional financing. If FDA approval for RI-002 is granted prior to January 31, 2017, ADMA may draw an additional $5 million from its Oxford loan and security agreement. If approval is granted after this date, the company may need to issue additional shares or may need to borrow under less favorable conditions.

We adjust revenues and cash flows in the DCF model to reflect our forecasted delay and reduce the probability of eventual approval to 60% to account for additional risk. The results of these estimate changes lower our price target from $19 per share to $14 per share. Much is not clear at this point with the two primary unknowns being the time it will take for the partners to correct the deficiencies, and whether the resubmission review time will be two months or six months. As management consults with its partners and the FDA, we will adjust our model and valuation accordingly.

Summary

The FDA's complete response letter was a surprise given the strong data supporting RI-002 and the fact that partners were already manufacturing, processing and testing FDA approved products. This issuance of the CRL will cause a several month delay in the eventual marketing of RI-002 as partners remedy discrepancies and an additional FDA review is conducted. On the positive side, none of the deficiencies were related to the lead product's clinical safety or efficacy. The main deficiencies were related to manufacturing and testing partners' good manufacturing practices. We are hopeful that the partners will be responsive and that the deficiencies will be rapidly remedied followed by a timely review by the FDA. However, we have taken a conservative stance and assumed an 8-month delay to our previous timeline which places eventual launch some time in 2Q:17. The result of this increase in timeline and a higher risk profile reduces our target price from $19 per share to $14 per share.

PROJECTED FINANCIALS

ADMA Biologics, Inc. - Income Statement

ADMA Biologics, Inc.	2015 A	Q1 A	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
Total Revenues	**$7.2**	**$2.1**	**$2.6**	**$3.0**	**$3.2**	**$10.9**	**$22.3**	**$77.0**
YOY Growth	*21%*	*41%*	*96%*	*62%*	*28%*	*52%*	*104%*	*246%*
Cost of Product Revenue	$4.3	$1.3	$1.5	$1.8	$1.9	$6.4	$11.0	$32.6
Product Gross Margin	*40%*	*40%*	*41%*	*41%*	*41%*	*41%*	*51%*	*58%*
Research and development	$7.0	$2.0	$1.7	$1.7	$1.7	$7.1	$7.1	$7.5
Plasma centers	$4.6	$1.3	$1.7	$1.7	$1.7	$6.4	$6.0	$6.4
General and administrative	$6.7	$1.7	$2.0	$2.3	$2.5	$8.5	$12.0	$13.0
Income from operations	($15.5)	($4.2)	($4.3)	($4.5)	($4.6)	($17.5)	($13.8)	$17.6
Operating Margin	*-216%*	*-196%*	*-168%*	*-149%*	*-141%*	*-160%*	*-62%*	*23%*
Other income (expense)	($2.5)	($0.5)	($0.5)	($0.5)	($0.5)	($1.8)	($1.8)	($1.8)
Pre-Tax Income	($18.0)	($4.6)	($4.8)	($4.9)	($5.0)	($19.3)	($15.6)	$15.8
Income Taxes Paid	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($18.0)**	**($4.6)**	**($4.8)**	**($4.9)**	**($5.0)**	**($19.3)**	**($15.6)**	**$15.8**
Net Margin	*-250%*	*-217%*	*-185%*	*-164%*	*-155%*	*-177%*	*-70%*	*20%*
Reported EPS	**($1.73)**	**($0.43)**	**($0.37)**	**($0.38)**	**($0.38)**	**($1.54)**	**($1.16)**	**$1.08**
YOY Growth	*-4.6%*	*27.9%*	*-16.3%*	*-21.1%*	*-20.2%*	*-14.7%*	*-25.1%*	*-194%*
Basic Shares Outstanding	10.41	10.71	13.00	13.10	13.20	12.50	13.50	14.60

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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