Zacks Small-Cap Research

August 15, 2016
John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

ADMA Biologics, Inc. (ADMA - NASDAQ)

2Q:16 Results. Waiting for Clarity on Resubmission Timeline.

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 (8/15/2016)	$6.15
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	**$4.15**
One-Year Return (%)	**-31.3**
Beta	**2.48**
Average Daily Volume (sh)	**57,230**
Shares Outstanding (mil)	**12.9**
Market Capitalization ($mil)	**$77.5**
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	$2.3 A	$2.4 E	$2.6 E	$9.5 E
2017					$22.2 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	-$0.50 A	-$0.39 E	-$0.39 E	-$1.69 E
2017					-$1.26 E
2018					$0.93 E

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Second Quarter 2016 Financial Results

ADMA Biologics, Inc. (NASDAQ:ADMA) reported 2Q:16 results after the close on August 12, 2016, two weeks after the company received a complete response letter (CRL) for its biological license application (BLA) for RI-002.

The income statement indicated revenues of $2.3 million, falling behind our estimate of $2.5 million, but 73% higher than year ago levels. The growth in revenues was attributable to increased sales of plasma from the new plasma facility in Marietta, Georgia. Net loss of ($6.0) million compared to our estimates of a ($4.8) million loss with the difference attributable to higher R&D expenditures. On a per share basis, the loss of ($0.50) was less than our ($0.37) estimate.

Cost of plasma product was $1.3 million, and gross margin was fractionally higher than in previous quarters, rounding up to 41%.

Research and development costs rose to $3.4 million from $1.5 million in 2Q:15 and $2.0 million in the prior quarter. Expenses increased due to higher validation, testing and production costs related to RI-002 along with increased regulatory consulting services related to ADMA's BLA. Plasma center cost was $1.3 million, even with the prior quarter, but up $0.2 million over the prior year due to the opening of the new facility in the second half last year. General and administrative expenses were also flat with 1Q:16, but up compared to 2Q:15.

Operations consumed approximately $4.8 million in cash in 2Q:16, which was offset by additional loan proceeds from Oxford Finance LLC, and issuance of stock which contributed to the $17.0 million in cash from financing. Total cash and equivalent levels rose from $11.6 million to $23.8 million.

ADMA's current focus is to work with its manufacturing partners to resolve the deficiencies cited in the CRL. We are awaiting clarity from the company and its partners regarding the steps that need to be taken and whether the resubmission will fall into the Class 1 or Class 2 category.

FDA Issues Complete Response Letter Regarding RI-002

On July 29, 2016, the Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) to ADMA regarding its Biologics License Application (BLA) for RI-002. The company issued a press release on the same day 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 with 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.

We remind investors that 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.

Following the issuance of the CRL, ADMA consulted with the three partners to work on resolving the items listed in the FDA's response letter. The partners have been both responsive and cooperative according to ADMA and are additionally highly incentivized to address the discrepancies as it is likely that none of them will be able to take on any new business that requires FDA approval until the problems are resolved. As of the date of this report, all of the management teams are currently developing an action plan and will request a Type A meeting with the FDA in the as yet undetermined future. The meeting with the FDA will be granted 30 days of the request following a CRL and 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.

ADMA will provide additional guidance when a timeline for resolution and resubmission are available.

Our Forecasts

We have adjusted our expense estimates to reflect the delay in approval of RI-002 and reduced R&D and G&A expenses in 2H:16. The lower expenses come from a delay in hiring of personnel to support the marketing of the biologic. No additional expenses, such as re-filing costs or consultant fees are anticipated as a result of the CRL or resubmission activities. Currently, it is unclear whether the resubmission will fall under Class 1 or Class 2 constraints. In the former, we expect a 2 month response time from the FDA following resolution of the issues at the third party manufacturers. In the latter, we anticipate a 6 month length of review from the agency.

Following FDA approval of RI-002, we continue to expect ADMA to hire between 25-30 sales representatives. ADMA also expects to add personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources, and financial and operational management. In order to fulfill orders for RI-002, ADMA may also use a network of national distributors. If the product launch progresses as expected, we anticipate first sales in 2Q:17, but we do not anticipate an overall profit for ADMA until 2018. Revenues from plasma sales are expected to expand to $9.3 million in 2016 as the new center matures. By 2017, we anticipate that the Marietta facility will be running at near full capacity of between $6 and $7 million per year.

Given current cash balances, we believe that ADMA will require additional funding and will access the debt or equity markets sometime in the third quarter 2017 following what we hope will be a positive announcement by the FDA regarding RI-002. Note that in March 2015, ADMA raised approximately $10 million in a public stock offering. In 2H:17, we anticipate that ADMA will be cash flow neutral and will be both self-sustaining and able to generate profits and cash in 2018.

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.

Based on cash burn levels of approximately $5 million per quarter and 2Q:16 cash levels of approximately $24 million, 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. ADMA has indicated a positive relationship with Oxford and is in frequent contact with them. If positive progress is being made, Oxford could allow for an extension of interest only payments and an extension of the cutoff date for FDA approval.

We adjust revenues and cash flows in the DCF model to reflect our forecasted delay and use a probability of eventual approval to 60% to account for additional risk. 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. We maintain our price target of $14 per share.

Summary

ADMA's second quarter had higher R&D expenses than expected, but we reduce 2H:16 expenses to reflect the anticipated delay in the hiring of a sales team. Overshadowing the quarterly results, 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 generates a price target of $14 per share.

PROJECTED FINANCIALS

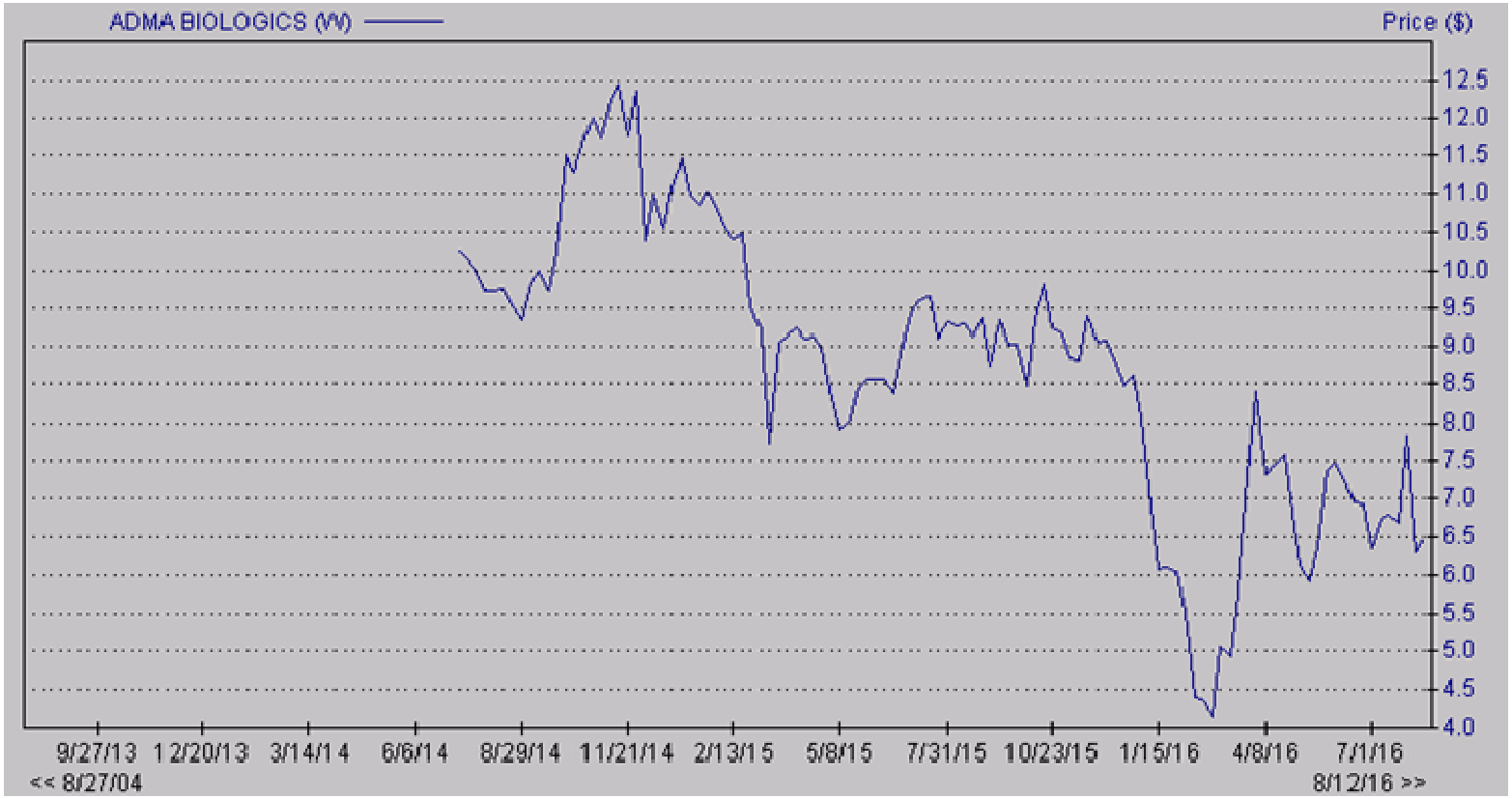
ADMA Biologics, Inc. - Income Statement

ADMA Biologics, Inc.	2015 A	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	2017 E	2018 E
Total Revenues	**$7.2**	**$2.1**	**$2.3**	**$2.4**	**$2.6**	**$9.5**	**$22.2**	**$77.0**
YOY Growth	*21%*	*41%*	*73%*	*32%*	*5%*	*32%*	*134%*	*247%*
Cost of Product Revenue	$4.3	$1.3	$1.3	$1.4	$1.6	$5.6	$11.0	$32.6
Product Gross Margin	*40%*	*40%*	*41%*	*41%*	*41%*	*41%*	*51%*	*58%*
Research and development	$7.0	$2.0	$3.4	$2.4	$2.5	$10.3	$9.0	$9.5
Plasma centers	$4.6	$1.3	$1.3	$1.4	$1.4	$5.3	$5.3	$6.4
General and administrative	$6.7	$1.7	$1.7	$1.8	$1.8	$7.0	$12.0	$13.0
Income from operations	($15.5)	($4.2)	($5.5)	($4.6)	($4.6)	($18.8)	($15.1)	$15.5
Operating Margin	*-216%*	*-196%*	*-242%*	*-187%*	*-174%*	*-198%*	*-68%*	*20%*
Other income (expense)	($2.5)	($0.5)	($0.5)	($0.5)	($0.5)	($1.9)	($1.9)	($1.9)
Pre-Tax Income	($18.0)	($4.6)	($6.0)	($5.0)	($5.0)	($20.6)	($17.0)	$13.6
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)**	**($6.0)**	**($5.0)**	**($5.0)**	**($20.6)**	**($17.0)**	**$13.6**
Net Margin	*-250%*	*-217%*	*-265%*	*-205%*	*-191%*	*-218%*	*-76%*	*18%*
Reported EPS	**($1.73)**	**($0.43)**	**($0.50)**	**($0.39)**	**($0.39)**	**($1.69)**	**($1.26)**	**$0.93**
YOY Growth	*-4.6%*	*27.9%*	*13.5%*	*-18.6%*	*-18.7%*	*-6.4%*	*-25.9%*	*-174%*
Basic Shares Outstanding	10.41	10.71	12.12	12.90	13.00	12.18	13.50	14.60

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

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

© Copyright 2016, Zacks Investment Research. All Rights Reserved.