Zacks Small-Cap Research

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ADMA Biologics, Inc. (ADMA - NASDAQ)

3Q:16 Results. Incremental Progress on CMC Issue Resolution.

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 (11/11/2016)	$6.38
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 eleven month delay in eventual marketing of the biologic compared to our original estimates. We anticipate eventual approval by 3Q:17 and first sales of RI-002 shortly thereafter.

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 generating diversifying income.

SUMMARY DATA

52-Week High	**$9.65**
52-Week Low	**$4.15**
One-Year Return (%)	**-36.1**
Beta	**2.45**
Average Daily Volume (sh)	**41,264**
Shares Outstanding (mil)	**12.9**
Market Capitalization ($mil)	**$82.2**
Short Interest Ratio (days)	**2.58**
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	$2.9 A	$2.6 E	$10.0 E
2017					$18.8 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	-$0.34 A	-$0.35 E	-$1.60 E
2017					-$1.42 E
2018					$0.92 E

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WHAT'S NEW

Third Quarter 2016 Financial Results

ADMA Biologics, Inc. (NASDAQ:ADMA) reported 3Q:16 results after the close on November 10, 2016. The income statement indicated revenues of $2.9 million, exceeding our estimate of $2.4 million, which was 59% higher than year ago levels. The growth in revenues was attributable to increased sales of plasma from the new plasma facility in Marietta, Georgia and better spot-market pricing. Net loss of ($4.3) million compared to our estimates of a ($5.0) million loss with the difference attributable to higher revenues and lower R&D expenditures. On a per share basis, the loss of ($0.34) was better than our ($0.39) estimate.

Cost of plasma product was $1.7 million, and gross margin was 41%, up from 40% in the same period in 2015.

Research and development costs fell to $1.7 million in 3Q:16 from $2.1 million in 3Q:15 and $3.4 million in the prior quarter. Expenses decreased as the company actively reduced testing and validation spend following the issuance of the CRL regarding RI-002. Plasma center cost was $1.5 million, slightly ahead of prior periods and our estimate of $1.4 million with the increase attributable to variable costs tied to plasma volumes, especially labor. General and administrative expenses matched our estimate and were down compared to 3Q:15 on greater cost control focus and lower pre-launch commercialization expenditures.

Operations consumed approximately $4.7 million in cash in 3Q:16, which compares to the $14.7 consumed year to date and the $11.4 million used for the first 9 months of 2015. Total cash and equivalent levels declined to $18.9 million from $23.8 million in 2Q:16.

ADMA's continues 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. The FDA had identified three areas in third party partners where there were discrepancies: the drug manufacturer, the fill and finisher, and the testing laboratory.

Progress is still being made at Biotest (the drug manufacturer) and next steps include the partner addressing the issues that were listed in a previously issued warning letter by the FDA, then a reinspection which, if passed will resolve this issue. The fill and finish partner discrepancy is related to a request the FDA made for compliance documentation, however, the request was made for the incorrect location. This alternate location had a warning letter issued against it. The actual location where the fill and finish takes place for ADMA was in compliance with all regulations and this should be resolved when the correct information is presented to the regulators. The testing laboratory continues to work with ADMA and the FDA to address the issues listed in the CRL.

At this point it is unclear when the issues at the drug manufacturer and the testing laboratory will be resolved. Assuming that the discrepancies can be remedied by year end, the Biologics License Application (BLA) may be resubmitted by January. If the FDA requires a longer review under a Class 2 resubmission, we might see a response by 3Q:17 and sales shortly thereafter. However, the actual time to potential approval could vary in a range of 3 months from current to late next year depending upon the success of ADMA's partners in addressing the issues raised in the CRL and the length of time needed by the FDA to inspect and review.

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 BLA for RI-002. The company issued a press release on the same day highlighting the details provided therein. 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 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 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 issues 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 following the resolution of the identified issues 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

Our expense estimates reflect the delay in approval of RI-002 and reduced R&D and G&A expenses in 4Q: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 2H: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 forecast first sales of RI-002 beginning in 3Q:17. We anticipate five 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 seven month delay relative to our original estimates.

Based on cash burn levels of approximately $5 million per quarter and 3Q:16 cash levels of approximately $19 million, we anticipate sufficient cash on the balance sheet to support an additional three 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; however, given the current timeline we believe it is unlikely approval will be granted prior to this date. We believe that if progress towards remedying the discrepancies with partners is made, that the close relationship that ADMA has with Oxford could allow for flexibility in loan arrangements.

Assuming a second half 2017 launch, ADMA may need to raise additional capital to build up its sales force and contribute to working capital by mid-year 2017. The company does have assets that can either be used to borrow against or liquidate in addition to an equity issuance. Based on a recent transaction between Grifols SA (NASDAQ: GRFS) and Interstate Blood Bank, the plasma collections centers were valued between $8 and $9 million[1] suggesting that ADMA's two assets could be valued from $16 to $18 million. Additionally, the company holds plasma inventory at ADMA is valued at $5 million. We are optimistic that these assets will provide flexibility for ADMA to raise additional capital when needed.

We adjust revenues and cash flows in the DCF model to reflect the anticipated delay and apply a 60% probability of approval 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 third quarter posted higher revenues and lower expenses compared to our expectations, however, due to slow progress with partners we anticipate first sales of RI-002 by in 3Q:17. We are hopeful that the partners will be responsive to the deficiencies cited in the CRL and will rapidly address them followed by a timely review by the FDA. We maintain our target price of $14 per share to reflect the projected timeline.

[1] Grifols acquired a 49% stake in Interstate Blood Bank, a US based plasma and blood center operator. Grifols paid $100 million for the interest, which consists of 23 plasma collection centers, which equates to an average center value between $8 and $9 million. The deal also included an option to purchase a full interest at a later date.

PROJECTED FINANCIALS

ADMA Biologics, Inc. - Income Statement

ADMA Biologics, Inc.	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 E
Total Revenues	**$7.2**	**$2.1**	**$2.3**	**$2.9**	**$2.6**	**$10.0**	**$18.8**	**$77.0**
YOY Growth	*21%*	*41%*	*73%*	*59%*	*5%*	*39%*	*89%*	*309%*
Cost of Product Revenue	$4.3	$1.3	$1.3	$1.7	$1.6	$5.9	$9.6	$32.6
Product Gross Margin	*40%*	*40%*	*41%*	*41%*	*41%*	*41%*	*49%*	*58%*
Research and development	$7.0	$2.0	$3.4	$1.7	$2.0	$9.1	$9.0	$9.5
Plasma centers	$4.6	$1.3	$1.3	$1.5	$1.4	$5.4	$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)	($3.7)	($4.1)	($17.4)	($17.1)	$15.5
Operating Margin	*-216%*	*-196%*	*-242%*	*-127%*	*-155%*	*-175%*	*-91%*	*20%*
Other income (expense)	($2.5)	($0.5)	($0.5)	($0.6)	($0.5)	($2.0)	($2.0)	($2.0)
Pre-Tax Income	($18.0)	($4.6)	($6.0)	($4.3)	($4.5)	($19.5)	($19.1)	$13.5
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)**	**($4.3)**	**($4.5)**	**($19.5)**	**($19.1)**	**$13.5**
Net Margin	*-250%*	*-217%*	*-265%*	*-147%*	*-172%*	*-195%*	*-101%*	*18%*
Reported EPS	**($1.73)**	**($0.43)**	**($0.50)**	**($0.34)**	**($0.35)**	**($1.60)**	**($1.42)**	**$0.92**
YOY Growth	*-4.6%*	*27.9%*	*13.5%*	*-29.5%*	*-26.8%*	*-11.7%*	*-11.4%*	*-165%*
Basic Shares Outstanding	10.41	10.71	12.12	12.89	13.00	12.18	13.50	14.60

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

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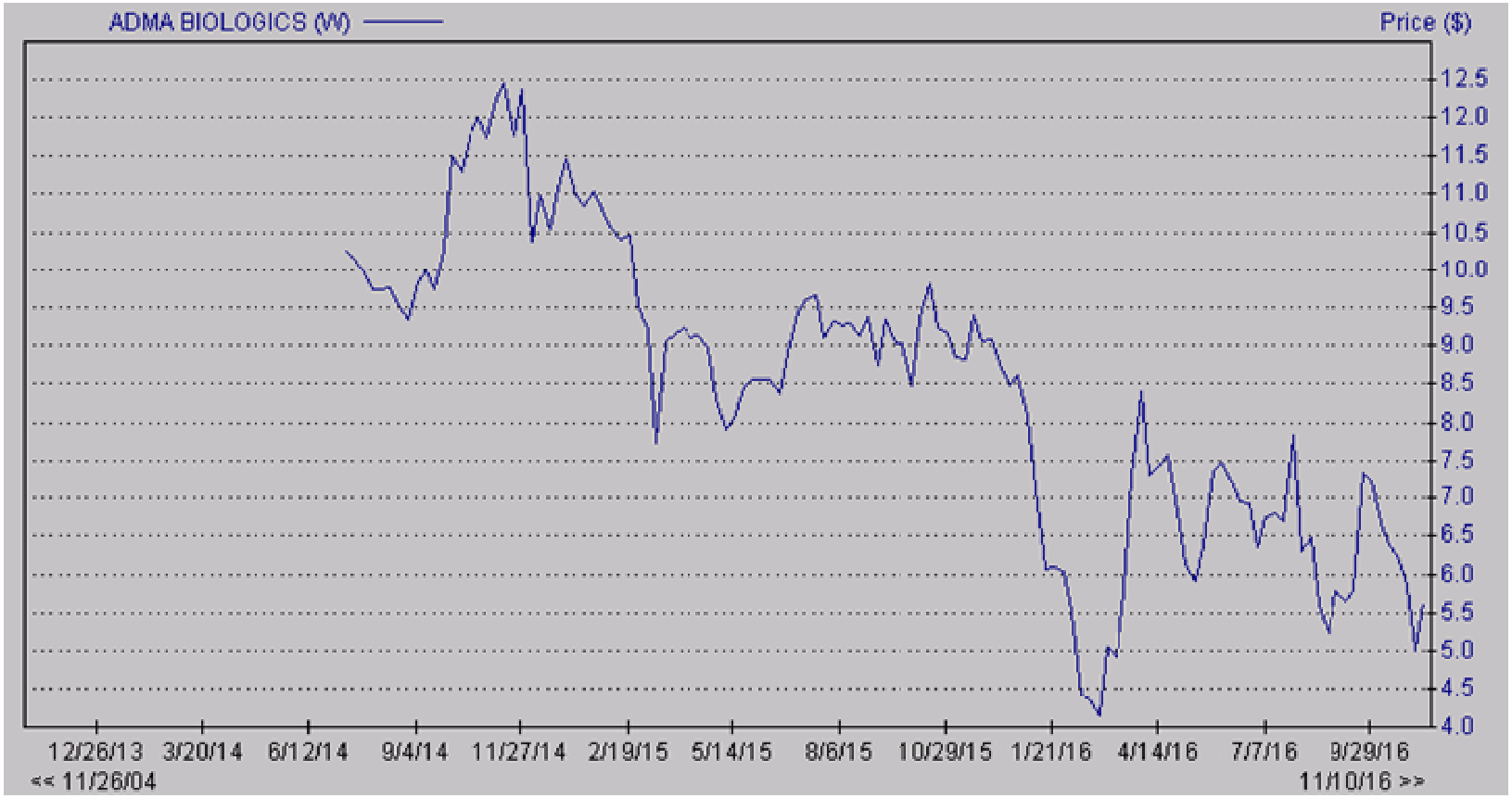

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