Zacks Small-Cap Research

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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)

Inspection Concluded; Product Filings Can Begin

Based on our DCF model and a 15% discount rate, ADMA is valued at approximately $9.00 per share. We apply an 80% blended probability of FDA approval for ADMA's suite of immunoglobulin products.

Current Price (7/26/2018)	$6.00
Valuation	**$9.00**

OUTLOOK

In June 2017, ADMA closed its transformational Biotest acquisition and in July 2018 received notice of VAI status from the FDA related to its compliance inspection, allowing for new product filings. The company's BioManufacturing facility is expected to resume production of Bivigam following a PAS approval with an October PDUFA date. Additionally, the favorable inspection results allow ADMA to resubmit the BLA for RI-002. We anticipate additional new product filings in 2019 and beyond.

The success of the BioManufacturing facility will hinge on ADMAs ability to address the discrepancies cited and obtain FDA approval to manufacture and commercialize additional Ig products.

ADMA's two plasma collection centers will continue to generate cash flow and plasma inventories until transferred to Biotest. 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 other Ig products. Currently ADMA is seeking approval a third collection center which is expected to begin generating revenues in 2H:18.

SUMMARY DATA

52-Week High	**$6.29**
52-Week Low	**$2.01**
One-Year Return (%)	**63.0**
Beta	**2.89**
Average Daily Volume (sh)	**285,884**
Shares Outstanding (mil)	**47.0**
Market Capitalization ($mil)	**282**
Short Interest Ratio (days)	**0.83**
Institutional Ownership (%)	**43**
Insider Ownership (%)	**26**
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 2017 Estimate	**N/A**
P/E using 2018 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)
2017	$2.6 A	$3.4 A	$4.7 A	$12.0 A	$22.8 A
2018	$4.0 A	$6.0 E	$6.5 E	$6.5 E	$23.0 E
2019					$111.1 E
2020					$197.5 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.51 A	-$0.55 A	-$0.59 A	-$0.50 A	-$1.91 A
2018	-$0.39 A	-$0.31 E	-$0.29 E	-$0.29 E	-$1.29 E
2019					$0.00 E
2020					$0.87 E

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WHAT'S NEW

FDA Compliance Inspection

ADMA Biologics, Inc. (NASDAQ: ADMA) posted a press release announcing that the FDA had successfully closed out its April inspection of the Boca Raton BioManufacturing facility and announced the target action date for Bivigam's prior approval supplement (PAS). The favorable outcome from the FDA inspection has been eagerly awaited as it is necessary for the company to resume production of Bivigam and refile the BLA for RI-002.

The FDA communicated to management that the facility received "Voluntary Action Indicated" (VAI) status as a result of the inspection. Public confirmation of VAI[1] status is forthcoming. This status indicates some objectionable conditions exist; however, no regulatory action needs to be taken. The Agency requested clarifications regarding these "objectionable conditions" related to previous deficiencies which are expected to be addressed during a pre-approval inspection for Bivigam. Management believes that the desired "No Action Indicated" (NAI) status was withheld as the facility was not able to do sample production runs of Bivigam during the inspection. Therefore, it is likely that NAI status will be granted in conjunction with the PAS review and pre-approval inspection when these production runs can take place. If the results of this review and inspection are favorable, NAI status should be awarded on or before the announced PDUFA date of October 25, 2018. Importantly, the current VAI status allows ADMA to resubmit the BLA for their lead development candidate RI-002 which is expected to occur in 2H:18.

ADMA has run three conformance lots for Bivigam using its improved manufacturing process and has used this data to support the June PAS submission. Additional conformance lots are expected to be produced for the duration of the year to satisfy pre-approval inspection requirements. All of these lots will be available for sale following a favorable FDA review and approval of the PAS.

Public Offering of Shares

In June, ADMA announced a public offering of shares and was successful in raising $46.0 million gross in an offering led by Raymond James and Oppenheimer. 9.26 million shares were sold at $4.78 apiece, which included 1.26 million (15%) optional shares which were exercised in full. We anticipate that this funding along with the March 31, 2018 cash balance of $26 million will provide sufficient capital to support operations until well into 2019.

Milestones

With the receipt of the Establishment Inspection Report (EIR), upgrade to VAI status and sufficient capital to carry through with the PAS and resubmission of the BLA, ADMA is in a strong position to achieve the potential of the BioManufacturing facility they acquired from Biotest in 2017. We anticipate an aggressive pursuit of the milestones below and strong revenue growth in 2019 as Bivigam and RI-002 begin to contribute to the topline if approved.

- First commercial batch of ADMA-manufactured Nabi-HB released – April 2018
- Issue of patent: RI-002: methods of treating respiratory infections – May 2018
- Submit PAS for optimized Bivigam/IVIg manufacturing process – June 2018
- Issuance of EIR and grant of VAI status – July 2018
- BLA filed for 3rd plasma collection center – 2018
- Increase Nabi-HB marketing – 2018
- Resubmit BLA for RI-002 as treatment for PIDD – 2H:18
- Resume production of Bivigam – Following PDUFA date of October 25, 2018
- FDA response regarding BLA for RI-002 – 2H:18
- Begin production of RI-002 and first sales – 1H:19
- Expand pipeline with additional plasma-derived therapeutics – 1H:19

[1] VAI = Voluntary Action Indicated, meaning objectionable conditions were found and documented but the agency is not prepared to take or recommend regulatory action. Any corrective action is left to the investigator to take voluntarily.

Valuation

Our target price increases to $9 per share due to the application of a lower discount rate of 15%. This rate reflects the lower risk following the grant of VAI status for the BioManufacturing facility. We also reflect the increased share count related to the capital raise in early June. The result of these adjustments increase the value of ADMA to $9 per share. The increased share count changes our per share estimates, however, our net income and revenue projections do not change.

Summary

The close-out of the April 2018 compliance inspection was the key event we were anticipating this year. With the grant of VAI status, ADMA is now able to submit its PAS for Bivigam and BLA for RI-002. All of the discrepancies raised by the FDA for these two products can be addressed in-house at this point and we have a high degree of confidence in the ability and commitment of management to do so. We update our model to reflect the favorable inspection results, yielding an increase in our target price. We see valuation above current levels and we believe that investors who have a long term investment horizon will be rewarded for their patience. The BTBU deal provides substantial value in assets that will transform ADMA into a vertically integrated plasma products company. While the ultimate value of the transaction will depend on ADMA management's ability to obtain approval for plasma derived products at the facility, we believe management is up to the task and capacity utilization will increase markedly over the next few years. To reflect the favorable response from the FDA regarding the inspection and to reflect the resulting lower risk profile, we adjust our target price to $9 per share.

PROJECTED FINANCIALS

ADMA Biologics, Inc. - Income Statement

ADMA Biologics, Inc.	2017 A	Q1 A	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$22.8**	**$4.0**	**$6.0**	**$6.5**	**$6.5**	**$23.0**	**$111.1**	**$197.5**
YOY Growth	*113%*	*54%*	*77%*	*37%*	*-46%*	*1%*	*382%*	*78%*
Cost of Product Revenue	$29.2	$12.2	$11.1	$11.2	$11.8	$46.3	$72.3	$111.3
Product Gross Margin	*-86.7%*	*-423.2%*	*42.0%*	*42.0%*	*43.0%*	*-101.1%*	*35.0%*	*43.6%*
Research and development	$6.2	$1.3	$1.4	$1.5	$1.5	$5.7	$5.7	$6.0
Plasma centers	$6.5	$1.8	$1.8	$1.8	$1.8	$7.2	$0.8	$2.0
Asset Impairment	$0.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Amortization of Intangibles	$1.2	$0.2	$0.2	$0.2	$0.2	$0.8	$0.0	$0.0
Selling, general & administrative	$18.1	$5.0	$5.3	$5.7	$5.4	$21.4	$29.1	$29.5
Income from operations	($39.3)	($16.5)	($13.8)	($13.9)	($14.2)	($58.4)	$3.2	$48.6
Operating Margin	*-173%*	*-409%*	*-230%*	*-214%*	*-218%*	*-254%*	*3%*	*25%*
Other income (expense)	($4.4)	($1.3)	($0.6)	($0.6)	($0.6)	($3.4)	($3.4)	($3.4)
Pre-Tax Income	($43.8)	($17.8)	($14.4)	($14.5)	($14.7)	($61.8)	($0.2)	$45.2
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	**($43.8)**	**($17.8)**	**($14.4)**	**($14.5)**	**($14.7)**	**($61.8)**	**($0.2)**	**$45.2**
Net Margin	*-192%*	*-441%*	*-239%*	*-222%*	*-227%*	*-268%*	*0%*	*23%*
Reported EPS	**($1.91)**	**($0.39)**	**($0.31)**	**($0.29)**	**($0.29)**	**($1.29)**	**($0.00)**	**$0.87**
YOY Growth	*19.0%*	*-22.5%*	*-44.5%*	*-50.0%*	*11.5%*	*-32%*	*-100%*	*-21905%*
Basic Shares Outstanding	22.90	45.32	47.00	49.00	50.00	47.83	51.00	52.00

Source: Company Filing // Zacks Investment R

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HISTORICAL STOCK PRICE

ADMA Biologics, Inc. – 3-Year Stock Price Chart



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