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ADMA Biologics, Inc. (ADMA - NASDAQ)

FDA Submissions are Next Milestones

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 (8/21/2018)	$5.65
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	**$6.86**
52-Week Low	**$2.01**
One-Year Return (%)	**95.5**
Beta	**3.22**
Average Daily Volume (sh)	**320,506**
Shares Outstanding (mil)	**47.0**
Market Capitalization ($mil)	**266**
Short Interest Ratio (days)	**4.78**
Institutional Ownership (%)	**56**
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 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	$4.7 A	$6.5 E	$6.5 E	$21.7 A
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	-$0.35 A	-$0.29 E	-$0.29 E	-$1.31 E
2019					$0.00 E
2020					$0.87 E

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WHAT'S NEW

Second Quarter 2018 Financial Results and Corporate Update

ADMA Biologics, Inc. (NASDAQ: ADMA) filed its 10-K and press release for its second quarter 2018 financial results on August 10, 2018. The highlights year to date have included the release of the first commercial batch of Nabi-HB to be manufactured under its ownership, the retirement of 8.6 million shares issued to Biotest and the grant of a patent for treating respiratory infections related to RI-002. The company's main focus over the last year has been to remedy the discrepancies at the former Biotest facilities related to the outstanding warning letter and CRL for RI-002. On June 12, ADMA closed $40 million in equity financing followed just over six weeks later by the successful close out of the FDA compliance inspection.

ADMA reported 2Q:18 revenues of $4.7 million which was a 37% increase over the prior year due to the addition of Nabi-HB sales offset by lower plasma collection facility revenue. Blood Plasma sales declined 12% for the quarter due to a decrease in donor collections. Cost of product revenue was $9.6 million in the quarter, up 120% due to $4.4 million of unabsorbed manufacturing costs at BTBU. Cost of product revenue also included $0.9 million additional expense related to Nabi-HB. Plasma centers saw a second quarter gross margin of 32.2% compared to 35.0% in 2Q:17.

Research and development expenses were $1.5 million an 8% increase over the same period in 2017. The increase is due to increased testing expense related to RI-002. Plasma center expenses rose 9% to $1.7 million from the opening of the third plasma center. Selling, general and administrative expenses were $5.0 million, expanding 13% compared to 2Q:17. The inflation was due to increased salaries, benefits and other employee related costs of approximately $1.5 million, increased headcount resulting from the BTBU acquisition, higher insurance expense of $0.4 million offset by $1.2 million in non-recurring BTBU transaction costs in 2017.

Interest expense rose to $1.4 million from $0.6 million in the prior year on higher debt levels.

Cash used in operations and capital expenditures totaled ($15.4) million in 2Q:18 compared to ($8.9) million in the prior year period. The increase was due to the addition of the BTBU. Proceeds from equity financing were $42.9 million yielding a cash balance of $55.2 million as of June 30, 2018. Total debt was $43.5 million.

FDA Compliance Inspection

On July 26, 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.

[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.

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. 9.62 million shares were sold at $4.78 apiece, which included 1.26 million (15%) optional shares which were exercised in full. The addition of these proceeds, less expenses, plus the cash on the balance sheet resulted in a cash balance of $55.2 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

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 receive a response to its PAS for Bivigam and submit its BLA for RI-002. 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. We maintain our target price of $9 per share.

PROJECTED FINANCIALS

ADMA Biologics, Inc. - Income Statement

ADMA Biologics, Inc.	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$22.8**	**$4.0**	**$4.7**	**$6.5**	**$6.5**	**$21.7**	**$111.1**	**$197.5**
YOY Growth	*113%*	*54%*	*37%*	*37%*	*-46%*	*-5%*	*412%*	*78%*
Cost of Product Revenue	$29.2	$12.2	$9.6	$11.2	$11.8	$44.9	$72.3	$111.3
Product Gross Margin	*-86.7%*	*-205.6%*	*-108.7%*	*42.0%*	*43.0%*	*-106.9%*	*35.0%*	*43.6%*
Research and development	$6.2	$1.3	$1.5	$1.5	$1.5	$5.8	$5.8	$6.1
Plasma centers	$6.5	$1.8	$1.7	$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	$5.0	$5.7	$5.4	$21.1	$28.8	$29.2
Income from operations	($39.3)	($16.5)	($13.4)	($13.9)	($14.2)	($58.0)	$3.4	$48.8
Operating Margin	*-173%*	*-409%*	*-288%*	*-214%*	*-218%*	*-267%*	*3%*	*25%*
Other income (expense)	($4.4)	($1.3)	($1.3)	($0.6)	($0.6)	($3.4)	($3.4)	($3.4)
Pre-Tax Income	($43.8)	($17.8)	($14.7)	($14.5)	($14.7)	($61.4)	$0.0	$45.4
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%*	*0%*
Net Income	**($43.8)**	**($17.8)**	**($14.7)**	**($14.5)**	**($14.7)**	**($61.4)**	**$0.0**	**$45.4**
Net Margin	*-192%*	*-441%*	*-317%*	*-222%*	*-227%*	*-283%*	*0%*	*23%*
Reported EPS	**($1.91)**	**($0.39)**	**($0.35)**	**($0.29)**	**($0.29)**	**($1.31)**	**$0.00**	**$0.87**
YOY Growth	*19.0%*	*-22.5%*	*-37.2%*	*-50.0%*	*11.5%*	*-31%*	*-100%*	*221671%*
Basic Shares Outstanding	22.90	45.32	42.71	49.00	50.00	46.76	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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