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ADMA Biologics, Inc. (ADMA - NASDAQ)

Bivigam Delay But Will Recoup Sales Later

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 (10/12/2018)	$5.23
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 a December PDUFA date. Additionally, the favorable inspection results allowed ADMA to resubmit the BLA for RI-002 on October 1st, 2018. 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. ADMA received approval for a third collection center in October 2018 which is expected to begin generating revenues in 4Q:18.

SUMMARY DATA

52-Week High	**$6.96**
52-Week Low	**$2.01**
One-Year Return (%)	**79.7**
Beta	**3.81**
Average Daily Volume (sh)	**261,798**
Shares Outstanding (mil)	**47.0**
Market Capitalization ($mil)	**246**
Short Interest Ratio (days)	**9.92**
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 2018 Estimate	**N/A**
P/E using 2019 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	$6.0 E	$6.3 E	$21.0 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	-$0.31 E	-$0.30 E	-$1.33 E
2019					$0.00 E
2020					$0.87 E

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WHAT'S NEW

PDUFA Delay

On October 11th, ADMA Biologics, Inc. (NASDAQ: ADMA) announced that the FDA considered the recently submitted Prior Approval Supplement (PAS) submission for Bivigam to be a major amendment and will require an additional two months for review. This change advances the target action date to December 18, 2018.

In July 2018 ADMA indicated that the FDA had received their PAS filing for Bivigam and anticipated an October 25 PDUFA date. Changes to a product, production process, quality controls, facilities and other factors require the submission of a PAS, and the FDA can consider the application to either be a major or minor amendment. Since the original indication, the FDA has determined that the PAS represents a major amendment and has decided to extend the period of review. The agency has discretion to decide whether supplementary submissions are major or minor[1] and determined that ADMA's PAS falls into the "major" category. As a result, the PDUFA date was extended by two months.

ADMA is able to produce and inventory production of plasma products while they are being considered by the FDA. Therefore, we do not see this change as ultimately impacting total sales of Bivigam; however, it will push back the availability of first sales. We reduce our 2018 estimate of Bivigam sales to reflect the delay and continue to expect to see regulatory approval of the immune globulin on the target action date.

Third Plasma Center FDA Approval

On October 3rd, 2018 ADMA reported that the FDA had granted approval for their Marietta, Georgia plasma collection center. The facility began collections in December 2017, and following the FDA-required observational period, approval was given to collect and enter into interstate commerce to sell and use the human source plasma for further manufacturing in the U.S. Further approval was given to collect whole blood from donors with rare blood types to produce specialty plasma with high levels of certain antibodies that yield higher market prices compared to normal source plasma. The timing of approval was expected and will allow the company to originate a portion of its own source plasma for eventual processing at the BioManufacturing facility in Boca Raton, Florida. We anticipate that after two to three years of operations, the 30,000 to 50,000 liter capacity facility can generate approximately $6.0 million per year in source plasma. ADMA will transfer its other two facilities to Biotest in 2019 and will lose the approximately $12 million in annual sales from them. However, the company has developed a competency in plasma center development and we anticipate the company will break ground on additional locations when funds are available. ADMA BioCenters hold licenses for plasma sales in the US, Germany and Korea.

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. The favorable outcome from the FDA inspection has been eagerly awaited as it is necessary for the company to refile the BLA for its lead candidate RI-002. ADMA announced the resubmission of RI-002 on September 28th and within 60 days should receive a target action (PDUFA) date. The PDUFA date assigned will depend on whether or not the resubmission is considered Class 1 or Class 2. 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 is applicable). Based on this understanding, we take a conservative view and anticipate a Class 2 resubmission will be required and forecast a six month response time from the FDA.

ADMA has run three conformance lots for Bivigam using its improved manufacturing process and has employed 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] Some examples of major and minor amendments can be found here: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm077097.pdf

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 for 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 – October 2018
- FDA approval for 3rd plasma collection center – October 2018
- Resume production of Bivigam – Following PDUFA date of December 18, 2018
- FDA assignment of PDUFA date for RI-002 – 4Q:18
- Begin production of RI-002 and first sales – 1H:19
- Expand pipeline with additional plasma-derived therapeutics – 1H:19

Valuation

We adjust our revenue estimates to reflect lower sales from the delay in Bivigam partially offset by slightly higher sales from the third plasma center. The impact on our valuation is minimal and we maintain our target price of $9 per share.

Summary

While disappointing to see a delay in the Bivigam approval date, in the medium term it should not impact total revenues as ADMA is able to inventory production until regulatory approval is granted. We think the negative perception about the delay should be offset by the RI-002 resubmission and FDA approval for the new plasma center, two important milestones fundamental to our thesis. ADMA has spared no effort or expense to ensure that the BioManufacturing facility is compliant with FDA requirements. We have a high degree of confidence that this will be reflected in a favorable decision regarding Bivigam and RI-002 when their target action dates arrive.

We reduce our estimates for 2H:18 to reflect the anticipated delay in Bivigam sales, partially offset by increased sales from the new plasma collection center. We see a number of catalysts in the near future that if achieved should continue to drive the share price towards our target price. 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'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**	**$6.0**	**$6.3**	**$21.0**	**$111.1**	**$197.5**
YOY Growth	*113%*	*54%*	*37%*	*27%*	*-48%*	*-8%*	*429%*	*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%*	*-113.8%*	*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)	($14.4)	($14.4)	($58.7)	$3.4	$48.8
Operating Margin	*-173%*	*-409%*	*-288%*	*-240%*	*-228%*	*-280%*	*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)	($15.0)	($14.9)	($62.1)	$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)**	**($15.0)**	**($14.9)**	**($62.1)**	**$0.0**	**$45.4**
Net Margin	*-192%*	*-441%*	*-317%*	*-249%*	*-237%*	*-296%*	*0%*	*23%*
Reported EPS	**($1.91)**	**($0.39)**	**($0.35)**	**($0.31)**	**($0.30)**	**($1.33)**	**$0.00**	**$0.87**
YOY Growth	*19.0%*	*-22.5%*	*-37.2%*	*-48.2%*	*13.0%*	*-30%*	*-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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