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May 25, 2018
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ADMA Biologics, Inc. (ADMA - NASDAQ)

Biotest Share Retirement Good for Shareholders

Based on our DCF model and a 20% discount rate, ADMA is valued at approximately $8.00 per share. We apply an 80% blended probability of FDA approval for ADMA's suite of immunoglobulin products.

Current Price (5/24/2018)	$5.28
Valuation	**$8.00**

In June 2017, ADMA closed its transformational Biotest acquisition and is currently addressing issues raised in the FDA-issued warning letter for the facility so it may resume processing of plasma. The facility is approved to produce several IG products and is expected to resume production of Bivigam following the resolution of issues highlighted in the warning letter. Addressing these issues will also allow ADMA to resubmit the BLA for RI-002. Eventually, other IG products may be manufactured.

The success of the transaction will hinge on ADMAs ability to address the problems at the facility 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 developing a third collection center which is expected to begin generating revenues in 2018.

OUTLOOK

SUMMARY DATA

52-Week High	**$5.70**
52-Week Low	**$2.01**
One-Year Return (%)	**49.6**
Beta	**2.70**
Average Daily Volume (sh)	**130,735**
Shares Outstanding (mil)	**45.3**
Market Capitalization ($mil)	**193.9**
Short Interest Ratio (days)	**0.69**
Institutional Ownership (%)	**47**
Insider Ownership (%)	**54**
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)
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	-$0.39 E	-$0.39 E	-$0.32 E	-$1.50 E
2019					$0.00 E
2020					$0.94 E

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WHAT'S NEW

First Quarter 2018 Financial Results and Corporate Update

ADMA Biologics, Inc. (NASDAQ: ADMA) filed its 10-K and press release for its first quarter 2018 financial results on May 14, 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. The facility has been inspection-ready by the turn of the year and we await the arrival of the FDA inspection team. ADMA has also opened their third plasma collection center and filed a BLA with the FDA, which could mean first revenues before year end 2018. Below we discuss the company's 2018 financial performance.

ADMA reported 1Q:18 revenues of $4.0 million which was a 54% increase over the prior year due to the addition of Nabi-HB sales offset by lower plasma collection facility revenue. Blood Plasma sales declined 10% for the quarter due to timing of sales. Total operating expenses for the year were $20.6 million, up 140% from the $8.6 million in the prior year due to the addition of the BTBU assets. The largest item by far was the cost of product revenue, which includes amounts both for the plasma centers and for BTBU, as well as one-time costs for remediation and third party consultant fees. Gross margin was ($8.2) million comprised of BTBU margins of ($9.0) million and plasma center margins of $0.8 million. We remind investors that due to the write up of inventory and one-time expenses, gross margins for ADMA BioManufacturing are not representative of long-term levels. Amounts included in cost of goods sold were $5.2 million of unabsorbed manufacturing costs related to the BTBU, $2.5 million of costs related to the production of RI-002, $1.1 million of costs related to the production of Bivigam, $0.7 million of third-party consultant fees pertaining to the remediation efforts in response to the Warning Letter, cost of product revenue related to Nabi-HB in the amount of $0.7 million and $0.4 million of costs related to the production of intermediates. We expect margins for the BTBU to fall between 50% and 60% after one-time costs and acquired inventories have been exhausted. Plasma centers saw a first quarter gross margin of 34.0% compared to 37.7% in 1Q:17.

Research and development expenses were $1.3 million a 7.5% increase over the same period in 2017. The increase is due to the opening of the third plasma collection center. Plasma center expenses rose 24% to $1.8 million on new staff hires and increase hours of operation for the centers. Selling, general and administrative expenses were $5.0 million, expanding 17% compared to 1Q:17 due to increased salaries, benefits and other employee related costs of approximately $1.6 million, primarily due increased headcount resulting from the BTBU acquisition, other expenses associated with the BTBU of $0.7 million, increased legal and professional fees of $0.6 million, increased marketing expenses of $0.2 million and greater insurance expense of approximately $0.2 million, partially offset by $2.6 million in costs associated with the BTBU acquisition that were recognized in the prior year.

Interest expense rose to $1.3 million from $0.6 million in the prior year on higher debt levels.

Cash used in operations and capital expenditures totaled ($17.0) million in 1Q:18 compared to ($5.4) million in the prior year period. The increase was due to the addition of the BTBU. Proceeds from financing were essentially zero yielding a cash balance of $26.1 million as of March 31, 2018. Total debt was $43.2 million.

Biotest Share Transfer

In 2017, Creat Group Corporation announced its acquisition of Biotest AG, who transferred the Biotest Therapy Business Unit (BTBU) to ADMA in June 2017. As a condition of US approval of the merger, Biotest's US assets are required to be divested. In order to expedite regulatory approval, Biotest has transferred to ADMA 8,591,160 shares of its nonvoting stock, which were subsequently retired. Additionally, Biotest waived and terminated its rights to a director and observer to the ADMA Board. In return for this consideration, ADMA has relinquished its rights to repurchase its two FDA-approved plasma collection centers scheduled to be transferred to Biotest on January 1, 2019 and provided a release to all indemnity claims arising from the sale of the BTBU to ADMA. The shares retired represent 19% of shares outstanding at the time of the agreement.

FDA Inspection Ready

ADMA was able to bring the BTBU to inspection-ready status by year-end 2017. They hired more than 25 subject matter experts and implemented many new quality policies as well as putting in place a new information management system. While the FDA is unpredictable in its inspection timing, they generally follow a two year cycle, which suggests they could provide an inspection in the second quarter 2018.

The company identified three main problems that were resolved. These included filter clogging with Bivigam, non-regulated manufacturing process times and quality systems documentation. These issues have been addressed, and we await the FDA visit to clear this critical hurdle.

ADMA is not disclosing whether or not the FDA has yet inspected the facility. They have provided guidance in their May investor presentation that the inspection and the compliance determination are anticipated to be complete in the first half of 2018. It is our understanding that ADMA will only provide an update as to the status of the inspection when they receive a response. The maintenance of this guidance suggests that the FDA has visited the BTBU and their response could come at any time.

Milestones

ADMA production for Bivigam and other products will be on hold until the FDA provides a favorable inspection result. The company has highlighted that they will inform the investment community when the FDA provides a response. We note that the FDA's inspection schedule is unpredictable. Following a successful FDA inspection, Bivigam should begin production and then a resubmission of the BLA for RI-002. Below, we highlight ADMA's important milestones:

- First commercial batch of ADMA-manufactured Nabi-HB released – April 2018
- Issue of patent: RI-002: methods of treating respiratory infections – May 2018
- Receipt of favorable response from the FDA regarding warning letter and CRL - 2018
- Increase Nabi-HB marketing – 2018
- Resume production of Bivigam – After FDA approval
- Submit PAS for optimized Bivigam/IVIG manufacturing process
- Resubmit BLA for RI-002 as treatment for PIDD – After FDA approval
- BLA filed for 3rd plasma collection center – 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

Valuation

Our target price moves to $8 per share due to the net change in capital raised over the prior six months and a reduction in revenue forecasts, based on later production and sale of Bivigam and RI-002. We note that ADMA has stated that it will only report the results of the FDA inspection and not the agency's visit. It is possible that the FDA has already conducted their on-site and a result they response could be available any day now. Our confidence in the value of the BTBU asset is strengthened by transactions that have taken place. In June 2017, CSL Limited acquired[1] an 80% stake in plasma-derived therapies manufacturer Wuhan Zhong Yuan Rui De Biological Products Co. Ltd. ("Ruide") from Humanwell Healthcare Group for $352 million, valuing the entire asset at $440 million. The purchase includes four plasma collection centers. The processing capacity of the facility is approximately 400 tonnes per annum, which when converted to liters[2] is essentially equivalent to ADMA's manufacturing asset. We compare this to our value for ADMA, which is approximately $330 million. This transactional support gives us confidence in our valuation despite a slower response from the FDA than we were originally anticipating.

[1] https://wcsecure.weblink.com.au/pdf/CSL/01864869.pdf
[2] There are 1025 grams per liter of blood plasma. A 400 tonne plant is equivalent to a 390,000 liter capacity plant. ADMA management has stated that BTBU is approximately 400,000 liters capacity.

Summary

The close of the BTBU deal is an important milestone which we anticipate will be rapidly followed by integration with ADMA operations and close work with the FDA to resolve the outstanding warning letter and CRL issues. We update our model to reflect the current status of the remediation. Despite the share price volatility, we remain positive regarding the company's prospects and see transactions in the space supportive of our valuation. On a liquidation basis, we see valuation above current levels and we believe that investors who have a two to three year time 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 address the deficiencies at the facility and obtain FDA approval to launch new products, we believe they will be able to address them and the FDA will lift the warning letter. To reflect the higher share balance and our revenue adjustments, we adjust our target price to $8 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)**	**($0.39)**	**($0.39)**	**($0.32)**	**($1.50)**	**($0.00)**	**$0.94**
YOY Growth	*19.0%*	*-22.5%*	*-29.1%*	*-33.7%*	*21.2%*	*-22%*	*-100%*	*-21406%*
Basic Shares Outstanding	22.90	45.32	36.80	37.00	46.00	41.28	46.00	48.00

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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