Zacks Small-Cap Research

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ADMA Biologics, Inc. (ADMA - NASDAQ)

BTBU Closed; The Adventure Begins

Based on our DCF model and a 20% 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 (8/21/2017)	$2.76
Valuation	**$9.00**

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	**$7.70**
52-Week Low	**$2.76**
One-Year Return (%)	**-51.4**
Beta	**2.55**
Average Daily Volume (sh)	**62,750**
Shares Outstanding (mil)	**25.8**
Market Capitalization ($mil)	**71.2**
Short Interest Ratio (days)	**0.47**
Institutional Ownership (%)	**66**
Insider Ownership (%)	**38**
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)
2016	$2.1 A	$2.3 A	$2.9 A	$3.3 A	$10.7 A
2017	$2.6 A	$3.4 A	$7.1 E	$7.2 E	$20.3 E
2018					$49.1 E
2019					$118.6 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.43 A	-$0.50 A	-$0.34 A	-$0.35 A	-$1.61 A
2017	-$0.51 A	-$0.55 A	-$0.64 E	-$0.63 E	-$2.33 E
2018					-$2.06 E
2019					-$0.05 E

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WHAT'S NEW

Second Quarter 2017 Financial Results and Corporate Update

ADMA Biologics, Inc. (NASDAQ: ADMA) closed the Biotest Therapy Business Unit (BTBU) transaction on June 6, 2017 and began the process of remedying the outstanding discrepancies at the facilities in order to resume production of several immunoglobulin products and resubmit the BLA for RI-002. Shortly following the transaction, ADMA sent in a team of subject matter experts in plasma products and biologics to identify factors related to remediating compliance and inspection discrepancies. Efforts to resume production at the facility are also on track and the company expects to continue production of Nabi-HB this month. There is a long list of milestones related to preparing the facilities for re-inspection prior to resuming production of Bivigam and re-submitting the BLA for RI-002 which are included in our report. Achieving these milestones are key markers for supporting our valuation target and we expect that ADMA will continue to achieve them according to our timeline. Efforts at the new plasma facility are on track and we expect the first blood draw to take place before the end of the year.

On August 11, ADMA filed its second quarter 10-Q and provided additional details regarding achievements during the period in a press release. Second quarter revenues were $3.4 million, ahead of our $3.1 million estimate representing a 50% increase over the prior year. The growth in revenues was attributable to a 26% rise in plasma sales and the recognition of new revenues from the BTBU assets. Net loss of ($9.0) million was below our estimates of ($8.8) million due to higher transaction-related expenses. We note that many of these expenses are one-time in nature related to the acquisition of the Biotest facilities.

2Q:17 blood plasma sales of $2.8 million comprise 83% of total revenues and compare to $2.3 million in the second quarter of 2016 and $3.3 million in the prior quarter. Gross margin on plasma center sales fell to 35.5%, which compares to 37.7% last quarter and 39.9% last year due to contractual pricing that is not rising as fast as costs. Sales for ADMA Biomanufacturing were $0.5 million[1] ($7.7 million on a *pro forma*, full quarter basis). Cost of goods sold in the BTBU segment was $2.5 million, which included expenditures related to the hiring of the subject matter experts, resulting in negative gross margin.[2] License revenues were again $36,000, consistent with prior periods, and related to services and financial payments provided by Biotest.

R&D declined by 60% to $1.4 million vs. 2Q:16 due to lower validation, testing and production costs for RI-002 partially offset by the addition of R&D related to the BTBU acquisition. Plasma center expenses rose 24% to $1.6 million on hiring of additional staff and increasing center operating hours, just below the pace of plasma revenue growth. G&A moved up sharply, in excess of 150% to $4.4 million as expenses related to the Biotest acquisition were recognized and as a partial month of BTBU operations were expensed. Acquisition related amounts for legal, accounting, financial advisory and due diligence were the major expenses incurred.

Operations and capital expenditures (cash burn) consumed approximately ($8.9) million in the quarter, up from ($4.8) million in the same period last year. ADMA also paid down $1.7 million in principal related to its loan with Oxford Finance and received $15.0 million from Biotest as part of the acquisition agreement. The net of these movements increased cash balance over 1Q:17 by $16.8 million to a balance of $25.6 million as of June 30, 2017.

Our forecasts present the anticipated gross margin for both the plasma centers and the immunoglobulin products, contract manufacturing and intermediates sold (previously transferred internally) to Biotest. For the remainder of 2017, cost of goods sold includes expenses related to the remediation of the warning letter, which will result in negative gross margins. These costs will go away following the withdrawal of the warning letter by the FDA. We note that the core cash margins will be close to 100% for Nabi-HB, as material costs will be zero due to inventories of the product. However, GAAP core gross margins will be close to zero percent, as inventory ready for sale was written up to market price, as per acquisition accounting rules.

We anticipate revenues of $7.1 million in 3Q:17 and $7.2 million in 4Q:17. Loss per share is forecast to be ($0.64) and ($0.63) for the third and fourth quarters respectively. We note that ADMA may not sell all the plasma generated from the facilities and may retain some for higher margin sales when it relaunches Bivigam, which may result in actual revenues coming in below our estimates. We note that cash gross margins for sales of Nabi-HB will be essentially 100% as there is $8.2 million in Nabi-HB inventory included in the transaction. This Nabi-HB inventory

[1] Sales for ADMA Biomanufacturing represent the abbreviated period of June 6 to June 30, 2017.
[2] Based on accounting rules, when a product is approved (but production halted due to a warning letter), costs related to preparing the product for manufacturing are considered as part of cost of goods sold. If a product is not yet approved, these costs are allocated to R&D.

was marked up to market as part of the transaction and will result in significantly lower GAAP margins than what was historically reported by Biotest due to this accounting treatment.

Achievements

- On May 30, 2017, shareholders voted to approve BTBU acquisition
- Completed BTBU acquisition on June 6, 2017
- Company received $12.5 million in cash and $15 million in loan proceeds in conjunction with acquisition
- Achieved BTBU/ADMA synergies with accounting and operational practices
- Received US patent for methods to provide immunotherapy to patients using immune globulin compositions proprietary to ADMA

Upcoming Milestones

Based on ADMA's updated timeline, we forecast a resumption of Nabi-HB production, contract manufacturing and intermediates during 3Q:17. We note that the FDA's inspection schedule is unpredictable; however, the filing of a BLA or other change submission may precipitate a visit by FDA inspectors. At the latest, we see the FDA inspection occurring in 1Q:18. Bivigam should begin production following this event and with a mid-2018 resubmission of the BLA for RI-002, we anticipate first production of the high titer IG in 1Q:18. Below, we outline our expected timeline for ADMA's milestones:

- Resume production of Nabi-HB at BTBU 3Q:17
- Completion of build out of new plasma draw facility in Marietta, Georgia
    - Submit BLA for center 4Q:17
    - First draw expected before end of year
- Address issues in warning letter and complete response letter (CRL) – 3Q:17 to 4Q:17
- Re-inspection by FDA – 4Q:17 to 1Q:18
- Submit BLA for 3rd Plasma Collection Center 4Q:17
- Favorable response from the FDA regarding warning letter and CRL – 4Q:17
- Refinancing and capital raise – 3Q:17 to 1Q:18
- Resume production of Bivigam – 1Q:18
- Resubmit BLA for RI-002 – Mid-2018
- Favorable response from FDA regarding RI-002 – year-end 2018
- Begin production of RI-002 – 2019

While there are execution risks related to management solving the outstanding issues raised by the FDA, we believe they have sufficient incentive and ability to fix the problems. Prior to achieving the milestones listed above, there may be an attractive buying opportunity for investors that have confidence in ADMA's plan and the fortitude to withstand share price volatility. Our analysis has risk-adjusted our DCF valuation and we have also performed an asset valuation in a previous report which estimated a liquidation value above current levels. Based on our analysis, we see an attractive opportunity for investors who can withstand the risk and have the patience required to see ADMA through the FDA review process.

Our Forecasts

ADMA achieved a June 6th close to the BTBU acquisition. We anticipate an immediate effort to bring in the necessary experts to address the issues outlined in the warning letter and CRL. This is expected to be followed by an FDA re-inspection and lifting of the warning letter. So far, ADMA has hired subject matter experts to address the compliance and inspection matters at the BTBU facilities. Following a positive nod by the FDA, ADMA will resubmit its BLA for RI-002 and resume production of Bivigam. It remains unclear whether or not the resubmission of the BLA will require a two or six month review, and our conservative estimates assume the six month period suggesting a response by the agency before year-end 2018 and ultimate production shortly after.

Sales of RI-002 are forecast to be near $50 million in 2019 and reach over $100 million by 2020. Previous sales levels achieved under Biotest management for Bivigam were approximately $50 million, and we anticipate a slow

ramp up back to this level beginning in 2018. Nabi-HB sales were just under $8 million in 2015 and 2016 and we anticipate similar levels of sales in 2017, rising at modest rates in future years. Contract manufacturing was just under $8 million in 2016, and we anticipate a reset slightly lower at $7.0 million in 2017, increasing modestly over the next several years.

Intermediates/Biotest Revenues are byproducts of immunoglobulin fractionation. Based on historical relationships, from 15% to 20% of specialty plasmas yield Intermediates revenues, therefore we maintain this proportion in our forecast model. Both plasma centers should be fully mature by 2018 and generate revenues between $6 and $7 million per year. We take a conservative view and forecast at the low end of this range for the company's two existing plasma centers. As part of the agreement to acquire BTBU, the two currently operational plasma centers will be transferred to Biotest in 2019. In early 2017, ADMA announced a lease to begin improvements on a space in Marietta, Georgia for a third plasma center which we anticipate will be online by the end of 2017 and begin to generate revenues by late 2018. ADMA took control of the facility as of July 1st and is currently doing the buildout. We anticipate a slow ramp-up over the next few years to annual revenue of between $6 and $7 million.

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 quarterly estimates based on the closing date. Despite the share price volatility, we remain positive regarding the company's prospects. Even 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 rapidly address them followed by a timely review. We maintain our target price at $9 per share.

PROJECTED FINANCIALS

ADMA Biologics, Inc. - Income Statement

ADMA Biologics, Inc.	2016 A	Q1 A	Q2 A	Q3 E	Q4 E	2017 E	2018 E	2019 E
Total Revenues	**$10.7**	**$2.6**	**$3.4**	**$7.1**	**$7.2**	**$20.3**	**$49.1**	**$118.6**
YOY Growth	*49%*	*24%*	*50%*	*142%*	*116%*	*91%*	*142%*	*141%*
Cost of Product Revenue	$6.4	$1.6	$4.3	$4.8	$4.8	$15.6	$25.0	$44.9
Product Gross Margin	*39.5%*	*37.7%*	*-28.8%*	*32.0%*	*33.0%*	*23.0%*	*50.8%*	*37.9%*
Research and development	$7.7	$1.2	$1.4	$2.2	$2.2	$7.0	$6.0	$6.1
Plasma centers	$5.4	$1.5	$1.6	$1.4	$1.4	$5.9	$6.6	$0.8
Manufacturing costs	$0.0	$0.0	$0.0	$8.8	$8.8	$17.5	$35.4	$35.6
Selling Costs	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$5.0	$7.5
Amortization of Intangibles	$0.0	$0.0	$0.1	$0.0	$0.0	$0.1	$0.0	$0.0
General and administrative	$8.5	$4.3	$4.4	$5.6	$5.6	$20.0	$21.4	$21.6
Income from operations	($17.3)	($5.9)	($8.4)	($15.7)	($15.6)	($45.6)	($50.2)	$2.0
Operating Margin	*-163%*	*-226%*	*-247%*	*-221%*	*-216%*	*-224%*	*-102%*	*2%*
Other income (expense)	($2.2)	($0.6)	($0.6)	($0.8)	($0.8)	($2.8)	($3.4)	($3.4)
Pre-Tax Income	($19.5)	($6.5)	($9.0)	($16.5)	($16.4)	($48.4)	($53.6)	($1.4)
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%*
Net Income	**($19.5)**	**($6.5)**	**($9.0)**	**($16.5)**	**($16.4)**	**($48.4)**	**($53.6)**	**($1.4)**
Net Margin	*-183%*	*-249%*	*-266%*	*-232%*	*-227%*	*-238%*	*-109%*	*-1%*
Reported EPS	**($1.61)**	**($0.51)**	**($0.55)**	**($0.64)**	**($0.63)**	**($2.33)**	**($2.06)**	**($0.05)**
YOY Growth	*-11.3%*	*17.8%*	*10.9%*	*90.0%*	*79.3%*	*45.1%*	*-11%*	*-97%*
Basic Shares Outstanding	12.15	12.89	16.43	25.80	25.82	20.78	26.00	26.50

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

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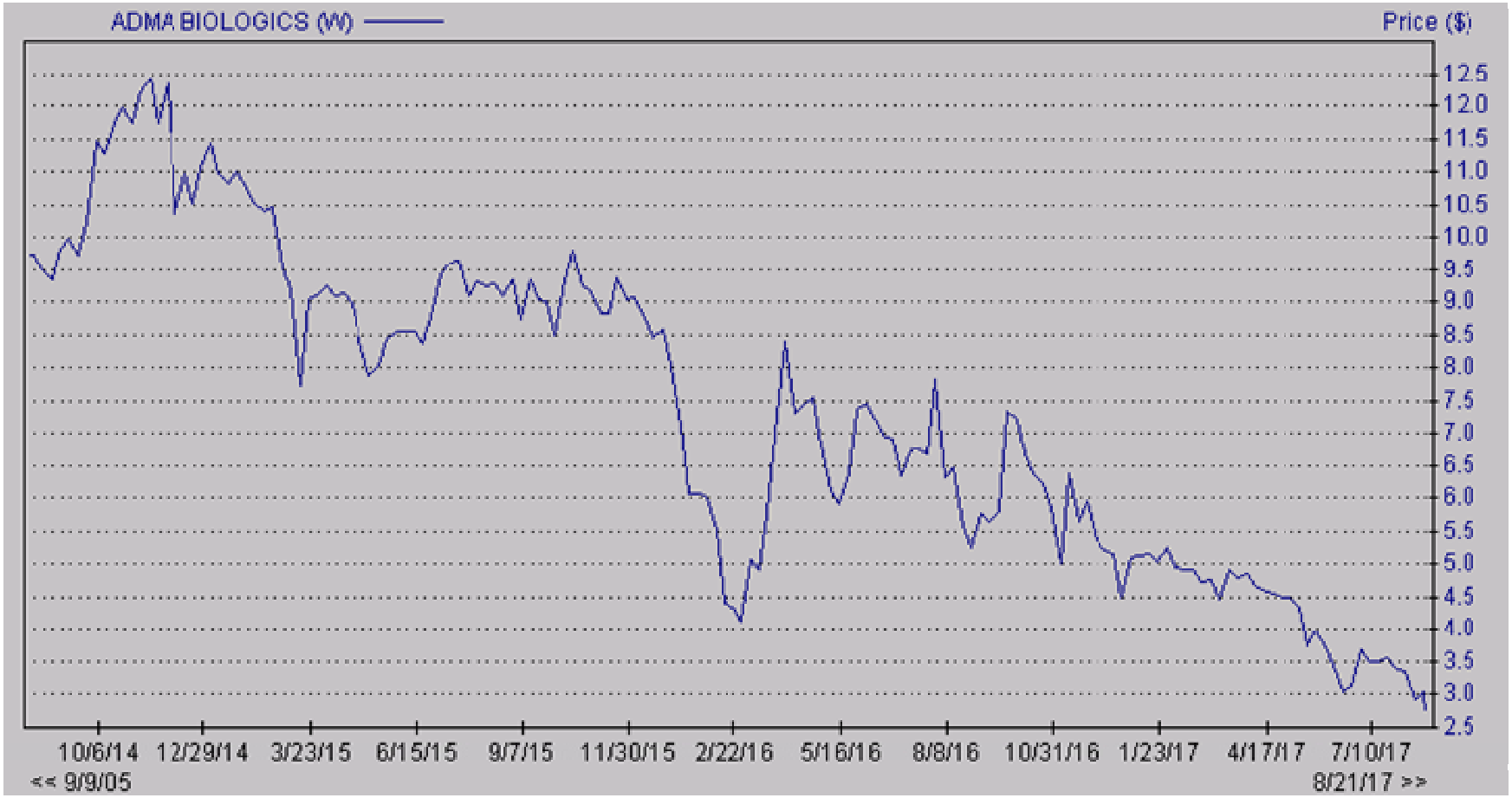

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