Zacks Small-Cap Research

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ADMA Biologics, Inc. (ADMA - NASDAQ)

2016 Results; Plasma Centers Strong; Need Clarity on Biotest.

Based on our DCF model and a 15% discount rate, ADMA is valued at approximately $13.00 per share. We apply a 60% probability of FDA approval for RI-002.

Current Price (3/2/2017)	$4.54
Valuation	**$13.00**

OUTLOOK

ADMA has developed an IVIG product, RI-002, with high levels of RSV antibodies that can treat immune compromised patients and address a host of other evidence-based uses. Currently ADMA is addressing deficiencies cited in a CRL issued in July 2016 for RI-002. In January 2017, ADMA announced its intent to acquire Biotest's out-of-compliance manufacturing facility in return for a 50% interest in ADMA and their two plasma collection facilities.

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.

SUMMARY DATA

52-Week High	**$8.85**
52-Week Low	**$4.24**
One-Year Return (%)	**-8.1**
Beta	**2.70**
Average Daily Volume (sh)	**30,785**
Shares Outstanding (mil)	**12.9**
Market Capitalization ($mil)	**$58.5**
Short Interest Ratio (days)	**2.25**
Institutional Ownership (%)	**66**
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 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)
2015	$1.5 A	$1.3 A	$1.9 A	$2.5 A	$7.2 A
2016	$2.1 A	$2.3 A	$2.9 A	$3.3 A	$10.7 A
2017					$12.5 E
2018					$25.1 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.34 A	-$0.44 A	-$0.48 A	-$0.48 A	-$1.73 A
2016	-$0.43 A	-$0.50 A	-$0.34 A	-$0.35 A	-$1.61 A
2017					-$1.24 E
2018					-$0.74 E

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WHAT'S NEW

Fourth Quarter and Full Year 2016 Financial Results

ADMA Biologics, Inc. (NASDAQ:ADMA) recently filed its 2016 10-K and provided a press release highlighting 2016 financial and operational results. The income statement indicated full year revenues of $10.7 million, exceeding our estimate of $10.0 million and representing a 49% increase over the prior year. The growth in revenues was attributable to increased sales of plasma from the new plasma facility in Marietta, Georgia and better spot-market pricing. Net loss of ($19.5) million matched our estimates. Higher expenses of $28.0 (vs. our $27.4) million arising from higher G&A expenses were partially offset by lower R&D costs. On a per share basis, the loss of ($1.61) was essentially in-line with our ($1.60) estimate.

Full-year cost of plasma product was $6.4 million, and gross margin was 40%, matching the rate from 2015.

On a quarterly basis, revenues of $3.3 million rose 32% relative to the prior year and were ahead of our $2.6 million estimate. R&D costs declined substantially to $0.6 million as attention shifted to addressing the CRL. Plasma center expenses rose slightly to $1.4 million due to higher collection levels and matched our estimates. G&A expenses were sharply higher in the quarter rising to $3.3 million, vs. $1.9 million in the prior year's fourth quarter and vs. $1.8 million in 3Q:16. The increase came from legal, accounting and due diligence costs related to the Biotest acquisition. Plasma center cost was $1.4 million.

Operations and capital expenditures consumed approximately $18.3 million for the year and $3.6 million in the fourth quarter, which is an increase from $15.4 for the full year of 2015. Total cash and equivalents levels fell to $15.3 million at year-end 2016 compared to $16.8 million one year earlier with an $18 million stock and debt capital raise in the second quarter offsetting use of cash.

Due to limited progress by partner Biotest in resolving manufacturing issues related to a 2014 warning letter and the issues as outlined in RI-002's CRL, in January ADMA came to an agreement to acquire Biotest's Florida manufacturing facility to directly resolve the deficiencies. We are awaiting clarity from the company and its partners regarding the steps that need to be taken before the facility will be ready for re-inspection.

Assuming that the discrepancies can be remedied in the third quarter of 2017 and the FDA can provide a clean inspection in the following quarter, we anticipate an early 2018 resubmission of the Biologics License Application. If the FDA requires a longer review under a Class 2 resubmission, we might see a response by 2H:18 and sales shortly thereafter. However, the wait for approval could vary widely depending on the FDA's schedule to inspect and review.

Biotest Therapy Business Unit (BTBU) Transaction Review

ADMA announced the acquisition of certain Biotest assets related to the manufacture of RI-002 and other plasma and immunoglobulin products on January 23, 2017. The deal also includes additional financing for ADMA from Biotest in return for a 50% stake in the company and an eventual transfer of ADMA's two plasma facilities in Atlanta, Georgia. Key details of the transaction include:

ADMA Receives:

- Boca Raton Manufacturing Facility, including two buildings with plasma fractionation and purification plant
- FDA licensed products including Nabi-HB
- Cash consideration of $40 million
    - $12.5 million in cash
    - $15 million unsecured term interest-only term loan
    - $12.5 million future equity commitment

Biotest Receives:

- 50% of ADMA capital stock, less one share
- Voting common stock equal to 25% of issued and outstanding stock
- Appointment of director and observer to ADMA board
- Transfer of both plasma centers to Biotest January 1, 2019
- Right to market new, plasma-based products in Biotest territories

The Boca Raton facilities were recently manufacturing three products: BIVIGAM, an immune globulin indicated for the treatment of primary humoral immunodeficiency, Nabi-HB, a hyperimmune globulin that is rich in antibodies to the hepatitis B virus and plasma for further manufacturing. In conjunction with the announcement of the BTBU deal, Biotest and Kedrion decided to halt production of BIVIGAM until the issues at the facility can be remedied.

ADMA plans to release additional information in an upcoming proxy filing that will provide revenue and cost information to guide an updated discounted cash flow model. Based on available historical transaction information, we perform an asset value review to gauge the attractiveness of the deal based on known details. We will defer the results of our DCF model until additional information is available.

Biotest originally bought the biologic manufacturing facilities from Nabi Pharmaceuticals in 2007 for $185 million in cash. The deal included the plasma protein production plant, the Boca Raton headquarters, and nine plasma collection centers. Based on management commentary, from $50 to $80 million was invested in the plant to upgrade the facilities and another $70 to $80 million was invested to build a monoclonal antibody production facilities. Below, we outline our rough estimates for the components that drive our post deal asset value.

Exhibit I – Asset Valuation

Asset Valuation	Value	Note
Biotest Facilities (2007 Purchase)	$185,000	Including 9 Collection Facilities
Less: 9 Collection Facilities	$81,000	Using low end of Grifols valuation in 2016 deal
Boca Raton Assets to ADMA	$104,000	
Depreciation on Plant over 9 years:	-20%	Net of inflation 2% depreciation rate
Depreciation	($20,290)	
Plus: Upgrades	$50,000	Low end according to ADMA mgmt
Plus: Monoclonal plant	$70,000	Low end according to ADMA mgmt
Less: Valuation Adj for Monoclonal Plant	($60,000)	Not currently being used
Value Estimate	**$143,710**	
Biotest Inventory	$5,000	Outlined in 8K
ADMA Plasma Inventory	$5,000	Detailed in Zack's 3Q:16 report
Plus: Cash from Biotest	$12,500	As listed in deal terms
4Q:16 Cash & Equivalents	$15,305	End of year cash levels
4Q:16 Debt	($20,223)	End of year debt levels
Equity Value	$161,293	Excludes nominal amount of net debt on ADMA BS
Shares Outstanding	26,000	Assumes current 12.9 MM shares x 2
Price Per share	**$6.20**	**Asset Value**

Biotest originally purchased the facilities for $185 million in a deal that included nine plasma collection centers, which will not be transferred to ADMA. We subtract $81 million from this amount to reflect these nine centers based on last year's transaction between Grifols SA (NASDAQ: GRFS) and Interstate Blood Bank where plasma collections centers were valued between $8 and $9 million.[1] While asset values have increased over the last decade, we do not inflate the Biotest purchase price, but do use a recent value for the collection centers in order to maintain a conservative approach. We reduce the value of the assets by 2% per annum to reflect our estimate of the net depreciation partially offset by asset and land appreciation.

Biotest made substantial investments of $70 to $80 million in a monoclonal plant. Continuing our conservative approach, we use the low end of these ranges to estimate the value of the upgrades undertaken since the asset was purchased by Biotest. Currently, the monoclonal plant is not operational, and we apply a severe discount that yields a net value of $10 million. To this subtotal, we add $10 million in inventories, half of which are included as part of the asset acquisition and the other half related to plasma that ADMA is currently carrying on the books as well as the $12.5 million in cash that Biotest will contribute to ADMA. Net debt on the balance sheet as of December 31, 2016, was approximately $5 million, which is subtracted from the total. We divide the sum of the figures by the estimated 26 million shares that will be outstanding following the consummation of the deal.

[1] Grifols acquired a 49% stake in Interstate Blood Bank, a US based plasma and blood center operator in early 2016. Grifols paid $100 million for the interest, which consisted of 23 plasma collection centers, equating to an average center value between $8 and $9 million. The deal also included an option to purchase a full interest at a later date.

This yields an asset value of just over $6 per share. While we recognize that the adjustments for depreciation of fixed life assets, appreciation of the manufacturing facilities as a whole, appreciation of the land value, and the value of the collection facilities at the time of the deal *et alia* are not precise, our approach in each case was conservative. Asset valuations are frequently used to generate a floor value for a business, and we believe that our result satisfies this goal.

Furthermore, we do not include any value for the two collection centers that will continue to be owned until January 2019, as per the purchase agreement. Currently, these assets are generating a slight positive cash flow, but more importantly are generating plasma inventories that will eventually be used in the production of RI-002. These plasma inventories yet to be produced are excluded from the sum of the parts analysis.

Addressing the Discrepancies; The Key to Value

In discussions with management and review of available materials, we believe that Biotest's reluctance to change ineffective management at the facility and include outside experts to assist in the correction of deficiencies contributed to their inability to address the warning letter issued in November 2014. Biotest's physically distant German management is also less experienced in US regulatory procedures, further contributing to the failure.

The issues that require attention are not infrastructure related, as the facilities have received substantial upgrades over the last nine years, reducing the risk of required capital investments. The issues are related to management providing clear operating procedures and proper training of staff to follow these operating procedures. Based on ADMA's assessment, successful management will need to be very critical of operational and manufacturing processes that are out of specification and develop procedures that are less cumbersome and easier to follow. Streamlining of document flow is also necessary as is involving experts with FDA experience to critically assess the existing problems and develop approaches to address them. Since the issuance of the CRL in July 2016, ADMA management has been working closely with Biotest to address the problems and has developed a thorough understanding of them over this period. This understanding led to the development of the purchase agreement as ADMA was more motivated and more experienced in addressing the problems than Biotest.

Based on updated commentary by ADMA's management, we believe that the issues at the facilities can be resolved before year-end by installing experienced and motivated management, implementing new standard operating procedures, conducting training for management and employees and obtaining FDA approval to use the facility to develop biologic products.

The success of the asset deal and the likelihood it will add incremental value to our target price are directly dependent on ADMA management's ability to address the problems at the manufacturing plant. Up to the announcement of the deal, ADMA management had taken the lead in addressing many of the problems at the facility from Biotest which puts them in a strong position to understand the current situation and rapidly implement the necessary changes when they have control. Management understands and has outlined many of the areas where Biotest failed to make progress in addressing the problems and has a high-level plan to provide a remedy. Based on our asset valuation, the transaction appears to be a favorable one, with our conservative approach providing a value over 30% above the company's current equity valuation. Of course, the true value in any asset is its ability to generate long term revenues and cash flows. As more information becomes available through the upcoming proxy filing and continued interaction with management, we will update our DCF model to reflect this.

We have adjusted our income statement forecasts to reflect a later resubmission of the biologic license application to the beginning of 2018, which lowers our DCF based target price slightly based solely on RI-002 revenues. However, the transaction is a transformative event which has the potential to add substantial revenues through leveraging the plasma currently generated by the company and the monoclonal plant that is included in the facilities. However, it is too soon to forecast revenues from the plant prior to the close of the deal and additional guidance from management.

RI-002 Complete Response Letter Details

On July 29, 2016, the Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) to ADMA regarding its BLA for RI-002. The company issued a press release on the same day highlighting the details provided therein. ADMA's contract manufacturer, Biotest, was found to have deficiencies in its manufacturing process during the current review, and while they may continue to fractionate currently approved products, they will not be allowed to manufacture new products. This issue is not a new one for Biotest as they were delivered a warning letter in 2014 related to current good manufacturing processes.

There were also deficiencies at the fill and finish partner and the laboratory that performs the final inspection for release. The other two labs that are involved with initial testing of RI-002 for antibody levels and for virus and disease did not have any deficiencies noted by the agency and were not identified in the CRL.

Our Forecasts

Our expense estimates reflect the delay in approval of RI-002 and a delay in hiring of personnel to support the marketing of the biologic. No additional expenses, such as re-filing costs or consultant fees are anticipated as a result of the CRL or resubmission activities

Following an anticipated FDA approval of RI-002, we expect ADMA to hire between 25-30 sales representatives. Personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources, and financial and operational management are also expected to be hired. In order to fulfill orders for RI-002, ADMA may also use a network of national distributors. If the product launch occurs in 2H:18, we do not anticipate an overall profit for ADMA until 2019. Revenues from plasma sales are expected to expand to $12.5 million in 2017 as both centers move to near full capacity of between $6 and $7 million per year. ADMA has also announced that they have signed a lease for space that will be built out over the next several quarters for a third plasma collection center.

Given the deal announcement regarding Biotest, it is possible that ADMA will not require outside funding before the launch of RI-002, assuming the FDA grants approval in-line with our expectations. We will update our cash flow analysis following additional detail regarding the operational profile of the Biotest facilities.

Cash burn for 2017 is expected to decline as R&D and sales expenses will be at minimal levels until there is more clarity on RI-002's progress. Absent the BTBU deal, ADMA would have sufficient cash to make it through the year. However, we have a high degree of confidence that the BTBU deal will close, at which time we will update our forecasts. Additionally, the increasing contributions from the maturing plasma centers should provide a tailwind to cash flow.

We adjust revenues and cash flows in the DCF model to reflect the anticipated delay and apply a 60% probability of approval to account for additional risk. Much is not clear at this point regarding the close of the BTBU transaction, the resolution of the CRL and the sales and profitability of the BTBU itself. As management works through the details of the transaction and resubmission, we will adjust our model and valuation accordingly. Due to the anticipated launch of RI-002 in 2H:17, our price target moves to $13 per share.

2017 Milestones

- Close Biotest Therapy Business Unit (BTBU) transaction
- Integrate BTBU into existing operations
- Maximize revenues from BTBU
- Address issues in warning letter and CRL
- Establish timeline with FDA for reinspection, resubmission and approval
- Launch new plasma collection center[2]

[2] ADMA signed a lease for space to build a new plasma collection center in February 2017.

Summary

ADMA reported a quarter that reflected continued growth of plasma center sales, and a decline in R&D costs offset by increases in G&A expenses reflecting the costs related to the BTBU deal. Several weeks prior, ADMA announced a transformative transaction to buy Biotest's plasma manufacturing facilities which have suffered from FDA violations and a warning letter in recent years. As part of the deal, the company will transfer their two currently owned plasma collection facilities to Biotest in 2019 and also receive financing of up to $40 million as part of the deal. While our estimates for eventual approval and launch of RI-002 are delayed as ADMA begins to address the deficiencies that exist at the facility, the deal provides substantial value in assets that will transform ADMA into a vertically integrated plasma products company. Our conservative asset approach generates a number that is above the current trading value of the company, lending credence to the merits of the deal. 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 by the FDA. We maintain our methodology of determining target price using our forecasts for RI-002 yielding an updated target of $13 per share.

PROJECTED FINANCIALS

ADMA Biologics, Inc. - Income Statement

ADMA Biologics, Inc.	2015 A	Q1 A	Q2 A	Q3 A	Q4 A	2016 A	2017 E	2018 E
Total Revenues	**$7.2**	**$2.1**	**$2.3**	**$2.9**	**$3.3**	**$10.7**	**$12.5**	**$25.1**
YOY Growth	*21%*	*41%*	*73%*	*59%*	*32%*	*49%*	*18%*	*100%*
Cost of Product Revenue	$4.3	$1.3	$1.3	$1.7	$2.0	$6.4	$7.2	$11.9
Product Gross Margin	*40%*	*40%*	*41%*	*41%*	*39%*	*40%*	*43%*	*53%*
Research and development	$7.0	$2.0	$3.4	$1.7	$0.6	$7.7	$2.3	$2.4
Plasma centers	$4.6	$1.3	$1.3	$1.5	$1.4	$5.4	$5.6	$6.4
General and administrative	$6.7	$1.7	$1.7	$1.8	$3.3	$8.5	$12.0	$13.0
Income from operations	($15.5)	($4.2)	($5.5)	($3.7)	($3.9)	($17.3)	($14.5)	($8.6)
Operating Margin	*-216%*	*-196%*	*-242%*	*-127%*	*-119%*	*-163%*	*-116%*	*-34%*
Other income (expense)	($2.5)	($0.5)	($0.5)	($0.6)	($0.6)	($2.2)	($2.2)	($2.2)
Pre-Tax Income	($18.0)	($4.6)	($6.0)	($4.3)	($4.6)	($19.5)	($16.7)	($10.8)
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	**($18.0)**	**($4.6)**	**($6.0)**	**($4.3)**	**($4.6)**	**($19.5)**	**($16.7)**	**($10.8)**
Net Margin	*-250%*	*-217%*	*-265%*	*-147%*	*-137%*	*-183%*	*-134%*	*-43%*
Reported EPS	**($1.73)**	**($0.43)**	**($0.50)**	**($0.34)**	**($0.35)**	**($1.61)**	**($1.24)**	**($0.74)**
YOY Growth	*-4.6%*	*27.9%*	*13.5%*	*-29.5%*	*-25.6%*	*-11.3%*	*-22.7%*	*-40%*
Basic Shares Outstanding	10.41	10.71	12.12	12.89	12.90	12.15	13.50	14.60

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

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