Zacks Small-Cap Research

December 7, 2015
Nisha Hirani, MD
312-265-9442 / nhirani@zacks.com
David Bautz, PhD
312-265-9471 / dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

ADMA Biologics, Inc. (ADMA - NASDAQ)

UPDATE

ADMA: The Year in Review & The Year Ahead…

Current Recommendation	**BUY**
Prior Recommendation	N/A
Date of Last Change	06/29/2015
Current Price (12/04/15)	$9.09
Target Price	**$22.00**

We have been proponents of ADMA (NASDAQ:ADMA) since we initiated on the company back in June 2015. Notable highlights from 2015 include the company receiving FDA acceptance of its Biologics License Application (BLA) for RI-002 and FDA approval of its second plasma collection center in addition to strengthening its intellectual property portfolio by receiving a 20-year "*Compositions and Methods for the Treatment of Immunodeficiency*" patent. In our opinion, ADMA remains on track for RI-002 approval to occur during the second half of 2016.

For the purpose of this update, we will offer a recap of 2015 with focus on major achievements of the company, as well as offering some insight regarding next steps for the company for the year ahead.

At the current price, we continue to view ADMA shares as meaningfully undervalued, and as providing significant long-term upside potential. We are increasing our price target to $22 per share, and continue to rate the stock a 'Buy'.

SUMMARY DATA

52-Week High	**$11.45**
52-Week Low	**$7.75**
One-Year Return (%)	**-12.60**
Beta	**0.21**
Average Daily Volume (sh)	**7,380**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$97**
Short Interest Ratio (days)	**10.95**
Institutional Ownership (%)	**66**
Insider Ownership (%)	**65**
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 2013 Estimate	**N/A**
P/E using 2014 Estimate	**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)
2014	1.6 A	1.5 A	1.4 A	1.5 A	5.9 A
2015	1.5 A	1.3 A	1.9 A	2.4 E	7.1 E
2016					19.2 E
2017					47.6 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.64 A	-$0.43 A	-$0.36 A	-$0.38 A	-$1.81 A
2015	-$0.34 A	-$0.44 A	-$0.48 A	-$0.48 E	-$1.73 E
2016					-$1.20 E
2017					$0.07 E

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

ADMA Biologics, Inc. (NASDAQ:ADMA) is a late-stage biopharmaceutical company that develops, manufactures and intends to commercialize specialty plasma-based biologics for the primary immunodeficiency (PIDD) population and the treatment and prevention of certain infectious diseases.

ADMA's lead candidate, RI-002, is a specialty intravenous immunoglobulin (IVIG) product that contains polyclonal antibodies against various infectious agents that are derived from human plasma. RI-002 contains standardized, high levels of antibodies to respiratory syncytial virus (RSV) in addition to naturally occurring polyclonal antibodies (such as *Streptococcus pneumoniae*, *Haemophilus influenzae* type B, Cytomegalovirus, measles, tetanus, etc.). RI-002 is intended to prevent infections in a subset of patients diagnosed with Primary Immunodeficiency Disease (PIDD), and in particular Primary Humoral Immunodeficiency. The polyclonal antibodies that are found in RI-002 are expected to prevent infections in this population group. ADMA plans to seek approval for RI-002 for a target population range of approximately 8,000 to 15,000 patients primarily suffering from PIDD presentations. Potential off-label follow-on indications include hematopoietic stem cell transplant (HSCT) patients, solid organ transplant (lung, heart, liver, and multi-organ) patients, and cancer patients receiving chemotherapy during the winter months.

Management believes that there is no other IVIG product currently on the market that contains standardized, high levels of RSV antibodies. Additionally, RI-002 is produced with reported consistent lot-to-lot potency. We believe that these features are what differentiate RI-002 from currently marketed IVIG products. More importantly, if approved, physicians and patients would have an additional selection for IVIG therapy, which in our opinion, could lead to enhanced quality of life for patients. The goal is for RI-002 to replace standard IVIG therapy during the winter months for the subset of patients with PIDD.

Class	Est. Incidence (US Population)	Comments	Target Population Numbers
Common Variable Immune Deficiency (CVID)	1 in 25,000 to 1 in 50,000 (7,000-14,000 patients)	30% to 50% of these patients have both T-Cell and B-cell deficiencies, some with CLD	2,000 to 5,000 patients
Severe Combined Immune Deficiency Syndrome (SCID)	New diagnoses of ~100 cases reported each year	SCID patients lack T and B -cell function, many receive bone marrow transplant upon diagnosis, many require IVIG treatments post transplant	500-1,000 patients on IVIG post transplant
Wiskott-Aldrich Syndrome (WAS)	4 in every 1 million males has the disorder - sometimes not diagnosed until adulthood	WAS patients lack T-cell function, many receive bone marrow transplant upon diagnosis, many require IVIG treatments post transplant	600 patients on IVIG therapy
DiGeorge Syndrome (DGS)	1 in 4,000 births suffers from DGS (700-800 patients)	70%+ of these patients have both T-Cell and B-cell deficiencies	1,000 patients receive IVIG therapy
Ataxia Telangiectasia (AT)	1 in 40,000 to 1 in 100,000	Patients typically have neuromuscular issues along with T-cell immunodeficiency; patients are more susceptible to infection and to cancer	3,000 to 8,000 patients
X-Linked Hyper IgM Deficiency (XHMD)	2 in every 1,000,000 males	Patients have low levels of three other classes of antibodies: immunoglobulin G (IgG), immunoglobulin A (IgA), and immunoglobulin E (IgE)	350 patients receive IVIG therapy
X-Linked Agammaglobulinanemia (XLA)	1 in 10,000 are diagnosed with XLA (35,000 patients)	The absence of functional BTK protein blocks B cell development, many patients require more frequent IVIG infusions (3 weeks v. 4 weeks)	3,500 patients are more susceptible to viral infections

ADMA BIOLOGICS

2015: The Year in Review…

We have remained proponents of ADMA since we initiated on the company back in June 2015. In our opinion, the company has achieved several significant, value-creating milestones during 2015. For the purpose of this update, we would like to offer a review of major milestones that the company has achieved during 2015 in addition to offering some insight into what 2016 holds for ADMA. We believe that the company remains laser focused on getting RI-002 approved in 2016 and continues to move in the right direction towards this goal.

- ***February 2015 – ADMA Announces Data from Phase 3 Trial of RI-002***

On February 23, 2015, ADMA announced positive results on the primary and secondary endpoints from its Phase 3 trial for RI-002 in Primary Immune Deficiency Disease (PIDD) at the American Academy of Allergy Asthma & Immunology Annual Meeting. Secondary endpoints included safety, pharmacokinetic (PK) data points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion, incidence of all

serious and non-serious infections, lost days of work or school, hospitalizations, emergency room visits, and antibiotic use among others.

As a reminder, on December 3, 2014, ADMA announced that RI-002 demonstrated positive Phase 3 results and achieved its primary endpoint of preventing serious bacterial infections (SBI) in immunocompromised patients with PIDD. As per the FDA, SBI are defined as bacteremia/sepsis, bacterial meningitis, osteomyelitis/septic arthritis, bacterial pneumonia, and/or visceral abscess. No SBI were reported in patients during the course of the study. These results more than meet the requirement specified by FDA guidance of ≤ 1 SBI per patient-year.

ADMA completed the Phase 3 clinical trial of RI-002 as a treatment for PIDD in accordance with the FDA "Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency." The Phase 3 trial was designed as a multi-site, single arm, open label study in which 59 patients diagnosed with PIDD were treated once every 21 to 28 days for 12 months across 9 treatment centers located throughout the United States. The patients were then followed for an additional 90 days for follow-up and safety monitoring (*below*). The average doses of RI-002 that were administered in the 3 and 4 week groups were 527.3mg/kg and 491.1mg/kg, respectively.

PATIENT POPULATION	PRIMARY IMMUNE DEFICIENCY DISEASE (PIDD)
PRIMARY ENDPOINT	*Serious infection rate per person-year of < 1
SECONDARY ENDPOINTS	Safety, incidence of all infections (serious & non-serious), lost days of work or school, any hospitalizations, ER visits, antibiotic use etc. PK profile of total IgG and specific antibody level testing for H. flu type B, CMV, measles, tetanus and RSV
# OF PATIENTS	59 (fully enrolled, enrollment closed)
# OF SITES	9 US sites
TREATMENT DURATION	12 months
PATIENT FOLLOW-UP	30 days beyond final dose for adverse events 90 days beyond final dose for viral testing
DOSING	300 mg/kg to 800 mg/kg, based on current IVIG dose 21 or 28 day dosing based on patients requirements

*A serious infection is defined by FDA to be: bacteremia / sepsis, bacterial meningitis, osteomyelitis / septic arthritis, bacterial pneumonia and visceral abscess.

Source: ADMA Biologics, Inc.

Twenty-one patients (35.6%) had at least 1 study drug related event within 72 hours after completion of RI-002 infusion. There were only 4 symptoms evaluated within this time period that were reported by 3 or more of the subjects (>5%). The four symptoms that were reported as drug related events included headache (8 patients), myalgia/muscle pain (3 patients), pruritus/itchy skin (3 patients), and adverse drug reaction without further specification (3 patients).

Number of Days Lost from Work/ School/ Day Care Due to Infections and their Treatment

Statistics	Total (Subjects=59)	3-Week Cycle (Subjects=19)	4-Week Cycle (Subjects= 40)
Total days missed in the study	93	27	66
No. of days missed per person per year	1.66	1.56	1.71
1-sided 95% Upper Bound	1.97	2.14	2.09

Hospitalizations Due to Infection

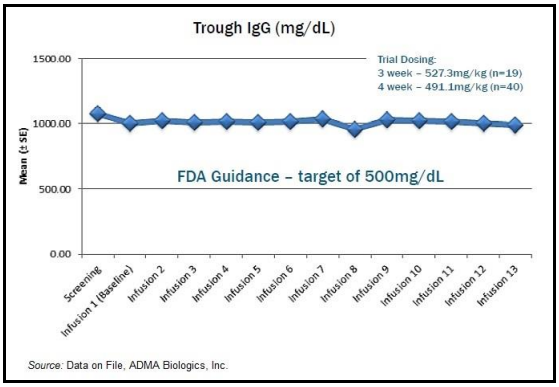
Summary Category	Total (Subjects=59)	3-Week Cycle (Subjects=19)	4-Week Cycle (Subjects=40)
Total Hospitalizations due to infection	1	0	1
Number of days of Hospitalization	5	0	5
Hospitalizations per subject per year	0.018	0.000	0.026

Unscheduled Medical Visits to ER or Physician's Office Due to Infection

Summary Category	Total (Subjects=59)	3-Week Cycle (Subjects=19)	4-Week Cycle (Subjects=40)
Unscheduled Medical Visits Due to Infection			
Total Visits in the study	54	18	36
Visits per person per year	0.966	1.041	0.933
1-Sided 95% Upper Bound	1.209	1.533	1.227

Source: Data on File, ADMA Biologics, Inc.

Scientific investigators reported on the secondary outcomes that included: a total of 93 days (or 1.66 days per patient per year) lost from work or school due to infection; 1 hospitalization due to an infection of 5 days duration in the entire study (*above*); and IgG trough levels above those required by the FDA for IVIG products (*below*).



Specific antibody levels were also measured for *H. influenzae*, CMV, measles, *S. pneumoniae* (12 serotypes), RSV, and tetanus. An increase in all of the measured specific anti-pathogen antibodies in PK subjects (n=31) was also observed. The mean of maximum fold increases in specific antibody levels after infusion of RI-002 ranged from 1.9 fold (*S. pneumoniae* type 19A) to 5.3 fold (RSV), which were statistically significant fold increases from the pathogen's specific measured baselines (*below*).

		Total (n=31)*
RSV	Mean Fold Increase (s.e)	5.3 (0.54)
	P value	.0001
H. Influenza	Mean Fold Increase (s.e)	3.2 (0.25)
	P value	.0001
S. Pneumoniae	Mean Fold Increase (s.e)	2.89 (0.30)
	P value	.006

*Data on PK Subjects

Source: Data on File, ADMA Biologics, Inc.

As per ADMA, the safety profile of RI-002 was comparable to that of other immunoglobulins. As per the company, over 790 infusions of RI-002 were administered to 59 patients, and were well tolerated with no reported serious adverse events attributable by investigators to the study drug.

Overall, we see these results as excellent news for ADMA, and they suggest that RI-002 is safe and effective, and could be an important new alternative therapy for a subset of individuals with PIDD. We think utilizing standardized high levels of anti-RSV neutralizing antibodies is a unique approach, and believe the data supports moving forward with the drug. We believe that the data compares favorably with historical clinical data for other marketed immunoglobulin products, and the results from the Phase 3 RI-002 trial may allow for the differentiation of the drug candidate from other immunoglobulins. For instance, with ADMA's RI-002 therapy, only 1.66 days per patient per year were lost from work or school due to infection as compared to 8.7 days missed with Gammaplex®, and 3 days missed with Flebogamma® (Schroeder *et al*., 2012).

- ***March 2015 – ADMA Closes Public Offering of Common Stock***

On March 18, 2015, ADMA announced the closing of a public offering of 1.225 million shares of common stock at a public offering price of $8.00 per share, as well as 183,750 additional shares of its common stock pursuant to the full exercise of the over-allotment option granted to the underwriters. ADMA walked away with net proceeds of approximately $10.3 million. The net proceeds of the offering are being used for pre-launch and commercialization activities, which include the procurement of commercial inventory and build out of a commercial organization and staffing infrastructure relating to the company's anticipated launch of RI-002 (if the FDA grants marketing approval for the product) in addition to general and corporate purposes.

- ***June 2015 – ADMA Biologics & Jeffrey Modell Foundation Initiate Strategic Patient Advocacy Alliance***

On June 11, 2005, ADMA announced a collaboration with the Jeffrey Modell Foundation (JMF), a global nonprofit organization dedicated to patients with PIDD. The Jeffrey Modell Foundation Centers network includes over 600 physicians at over 200 academic institutions in over 200 cities, approximately 80 countries in 6 continents. As part of this collaborative effort, ADMA will have access to the Jeffrey Modell Foundation's Global Databases of over 140,000 patients who have varying forms of PIDD. We believe this strategic alliance is crucial in order for ADMA to raise awareness among physicians and patients regarding RI-002. There are approximately 500 leading specialty

programs for treating PIDD patients in the U.S., and we believe ADMA continues to concentrate efforts on these areas as well.

- ***June 2015 – ADMA Secures Up to $21 Million Loan Commitment From Oxford Finance***

ADMA currently has total debt of approximately $16 million with Oxford Finance LLC that bears interest of 7.8%. On June 22, 2015, ADMA announced that it has entered into a loan and security agreement with Oxford for up to $21 million. ADMA received the first tranche of $16 million, which will be used to repay the existing Notes Payable with Hercules Technology Growth Capital, Inc. Beginning on February 1, 2017, the principal must be repaid in monthly installments over the following 36 months. The interest-only period may be extended until August 1, 2017, upon ADMA's receipt of approval for its BLA for RI-002 from the FDA on or before January 31, 2017. ADMA has the option to draw upon the remaining additional $5 million once the BLA is approved by the FDA. If drawn upon, it will be used towards ongoing commercialization activities, working capital and general corporate purposes.

- ***June 2015 – ADMA joins the Russell Microcap® Index***

ADMA joined the Russell Microcap® Index following market close on June 26, 2015. We believe that this step was important in increasing ADMA's visibility with institutional investors.

- ***July 2015 – ADMA Strengthens Commercial Team***

On July 6, 2015, ADMA announced multiple senior appointments to the company's commercial team as part of the ADMA's ongoing commercialization activities for lead product candidate, RI-002. The company announced the appointment of Mr. James Hauert (Senior Vice President of Commercialization & Strategy), Dr. Doris Connell, Pharm.D. (Vice President of Medical Affairs), and Ms. Theresa Gwaltney (Senior Director of Supply Chain Operations) to the team.

- ***July 2015 – ADMA Files RI-002 Biologics License Application***

As a reminder, on July 31, 2015, ADMA announced submission of its RI-002 Biologics License Application (BLA) to the FDA, seeking marketing authorization of its lead product candidate, and the FDA had 60 days to review the application to determine whether ADMA's BLA submission for RI-002 was complete and acceptable for filing. Under PDUFA V, the BLA filing fee is usually $2.3 million, but since ADMA submitted a small business waiver application that was approved the company did not have to pay this fee. We view this as meaningful, and continue to believe the company is on the right track towards approval and commercialization.

- ***August 2015 – ADMA Strengthens Intellectual Property Portfolio***

On August 31, 2015, ADMA announced that the U.S. Patent and Trademark Office (USPTO) issued United States Patent 9,107,906 entitled, "*Compositions and Methods for the Treatment of Immunodeficiency*." The patent relates to the use of human plasma immunoglobulin compositions containing select antibody titers that are specific for a plurality of respiratory pathogens; methods of identifying human donors and donor samples for use in the compositions; methods of manufacturing the compositions; and methods of utilizing the compositions by prophylactic and/or therapeutic treatments (such as passive immunization). The term of the newly issued patent extends to January 2035. As a reminder, on June 30, 2015, ADMA announced that the U.S. Patent and Trademark Office (USPTO) had issued a Notice of Allowance for U.S. patent application 14/592,721 entitled "*Compositions and Methods for the Treatment of Immunodeficiency*." We believe this is great news for ADMA as it not only strengthens the company's intellectual property portfolio, but also offer protection of RI-002 and is an important step towards commercialization of RI-002, if approved.

- ***September 2015 – FDA Approves Second Plasma Center***

On September 17, 2015, ADMA announced that its second plasma center received FDA approval to sell human source plasma within the U.S. The center is located in Marietta, GA, and is over 10,000 square feet with the potential to support over 50 donor beds. We were expecting the facility to receive approval in the fourth quarter of 2015 or the first quarter of 2016, and so we view this early news as great for the company. We still believe that ADMA continues to retain plasma in order to build up inventory in preparation for commercial manufacturing of RI-002 related to the anticipated product launch during the second half of 2016, and that any plasma that is not used to manufacture RI-002 will be released for sale. We are happy to report that ADMA began generating additional revenues from the newly approved second plasma center sooner than anticipated in the third quarter 2015.

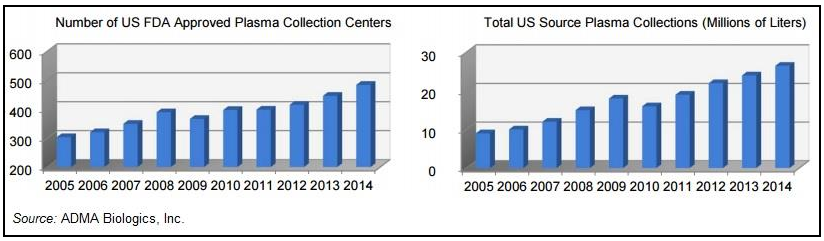
We like the concept of ADMA BioCenters Plasma Collections Centers because it is a revenue-generating and cost-lowering operation. Both of ADMA BioCenters are now FDA-licensed source plasma collection facilities that provide a portion of plasma for the manufacturing of lead product candidate, RI-002, in addition to a revenue stream. The Norcross, Georgia facility is also a member of the International Quality Plasma Program (IQPP) as certified by the Plasma Protein Therapeutics Association (PPT), is GHA (German Health Authority) certified, and MFDS (Korean Ministry of Food and Safety) certified.



Source: ADMA Biologics, Inc.

In April 2015, ADMA BioCenters received a two-year re-certification from the GHA, which allows plasma collected at the Norcross center to be imported into the EU, and to be purchased and processed by European Plasma Fractionators. Subsequently, in September 2014, the Norcross center received MFDS approval to sell source plasma into South Korea. During the third quarter of 2014, the ADMA BioCenters facility expanded by securing additional space to grow its donor and collection screening areas to meet the increase in market demand for source plasma. In November 2014, the opening of a second plasma collection center in Marietta, GA was announced, and prior to recent approval, the second center was collecting plasma. The company started generating accretive revenues from the sale of plasma that was not used to manufacture RI-002 starting in the third quarter 2015, shortly after receiving FDA approval. Management believes inventory of source plasma will continue to increase as ADMA ramps up for commercialization efforts.

We believe there may be future opportunity for the company to add additional centers, and in turn would result in additional source plasma necessary for RI-002 production as well as additional revenue for the company by selling unused amounts in the U.S. and abroad. There are hundreds of diseases that rely on products made from human plasma as treatment, and there we believe there continues to be a demand for plasma. The trends show that the number of U.S. FDA approved plasma collection centers as well as total U.S. source plasma collections continue to increase (below).



ADMA BioCenters Plasma Collections Centers, as well as other typical plasma collection centers, can usually collect between 30,000 to 50,000 liters of source plasma annually. The plasma can be sold for different prices depending upon the type of plasma, quantity of purchase, and market conditions at the time of sale. Plasma that is collected by the center that is not used for making RI-002 is sold to customers in the U.S. and where it is approved worldwide under existing supply agreements or in the open "spot" market generating revenues for the company. As per ADMA, a fully operational plasma center can generate more than $6 million/year.

- ***September 2015 – FDA Accepts BLA for RI-002***

On September 21, 2015, ADMA announced that the Biologics License Application (BLA) for RI-002 was accepted for review by the U.S. Food and Drug Administration (FDA). The PDUFA date for the FDA to complete the review is scheduled for the second half of 2016. If all goes well and the BLA is approved, we could see a potential approval of RI-002 during the second half of 2016. Management believes that first commercial sales could also occur as early as the second half of 2016. If approved, we believe the proposed dosage would be 300-800 mg/kg every 21 or 28 days during the winter months in the select PIDD population (or approximately 3-5 doses per year). Management believes based on guidance documented from the U.S. FDA that a successful single Phase 3 trial and complete BLA submission should lead to final approval of RI-002.

- ***November 2015 – ADMA Presents Additional Data at the PIDD Congress in Budapest***

ADMA presented a poster entitled "*Protection Against Palivizumab Resistant RSV with an IVIG Containing High Titer Anti RSV Neutralizing Antibodies*," at the 2nd International Primary Immunodeficiencies Congress held November 5-6, 2015 in Budapest, Hungary. The data compared the effectiveness of anti-RSV monoclonal antibody, palivizumab (Synagis®), to that of high titer anti-RSV RI-002 when administered prophylactically to RSV infected cotton rats. The data demonstrated the presence of higher anti-RSV neutralizing activity in RI-002 as compared to that which is present in palivizumab in the animal model ($p < 0.0039$; Student t test, 2-tailed), and that IVIG containing high titer neutralizing antibodies to RSV can prevent infection in cotton rats infected with a palivizumab resistant strain of RSV. We believe the 4 to 8 fold greater increase in the anti-RSV neutralizing antibody titers from the serum of cotton rats using RI-002 as compared to the rats injected with palivizumab further supports the unique antibody profile of RI-002.

Table 3. RSV/A serum neutralization titers with cotton rat serum taken immediately after infusion

Group	Treatment/Challenge Virus	RSV/A neutralization titer (log_2) in cotton rat						
		A	B	C	D	E	Mean*	SD
1	PBS/wt-RSV	2	2	2	2	2	**2**	0
2	RI-002/wt-RSV	9.0	9.0	9.5	9.0	8.0	**8.9**	0.5
3	Pmab/wt-RSV	7.0	7.0	7.5	7.5	7.5	**7.3**	0.3
4	PBS/PR-RSV	2	2	2	2	2	**2**	0
5	RI-002/PR-RSV	9.0	9.0	8.5	9.5	9.0	**9.0**	0.4
6	Pmab/PR-RSV	7.0	7.0	7.0	8.0	7.0	**7.2**	0.4

*P values (Student t test, two-tailed): Group 2 v 3 P=0.00066; Group 5 v 6, P=0.00011.

Table 4. RSV/A serum neutralization titers with cotton rat serum taken 4 days after infusion

Group	Treatment/Challenge Virus	RSV/A neutralization titer (log_2) in cotton rat						
		A	B	C	D	E	Mean*	SD
1	PBS/wt-RSV	2	2	2	2	2	**2**	0
2	RI-002/wt-RSV	9.0	8.5	8.5	8.5	8.0	**8.5**	0.4
3	Pmab/wt RSV	7.0	6.0	7.0	7.0	6.5	**6.7**	0.4
4	PBS/PR-RSV	2	2	2	2	2	**2**	0
5	RI-002/PR-RSV	8.8	7.5	8.5	7.5	7.5	**8.0**	0.6
6	Pmab/PR-RSV	5.5	6.0	6.5	7.0	5.5	**6.1**	0.7

* Student t test, two-tailed. Minimal detection = 2.5; for statistical analysis a value of <2.5 was counted as 2. Additional significant P values (Student t test, two-tailed): Group 2 v 3, 4, 6, P=0.00011; Group 3 v 4, 5, P = 0.007; Group 4 v 5, 6, P=0.00001; Group 5 v 6, P=0.0019.

Table 5. RSV/B/18537 serum neutralization titers with cotton rat serum taken immediately after infusion

Group	Treatment/Challenge Virus	RSV/B neutralization titer (log_2) in cotton rat						
		A	B	C	D	E	Mean*	SD
1	PBS/wt-RSV	2	2	2	2	2	**2**	0
2	RI-002/wt-RSV	9.0	9.0	9.5	9.0	ns	**9.1**	0.3
3	Pmab/wt-RSV	6.0	6.0	6.0	6.0	7.0	**6.2**	0.4
4	PBS/PR-RSV	2	2	2	2	2	**2**	0
5	RI-002/PR-RS	9.0	9.0	8.0	9.0	9.0	**8.8**	0.4
6	Pmab/PR-RSV	5.5	5.5	6.0	6.0	6.0	**5.8**	0.3

*P values (Student t test, two-tailed): Group 2 v 3, P<0.00001; Group 5 v 6, P<0.00001.

Fig. 1 Effect of IP RI-002 IVIG on RSV/A/Tracy Serum Neutralizing Antibody Titers

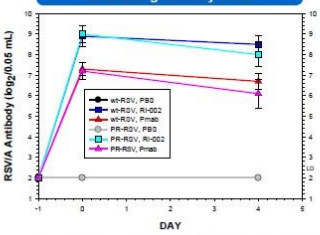
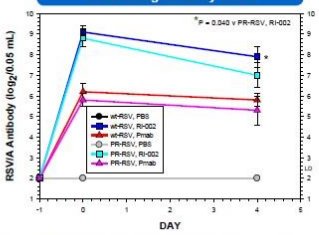


Fig. 2 Effect of IP RI-002 IVIG on RSV/B/18537 Serum Neutralizing Antibody Titers

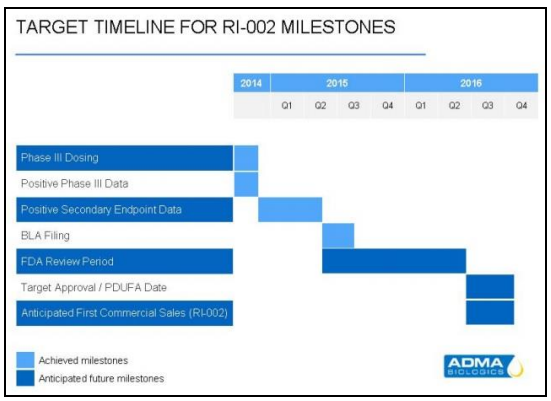


Source: Gilbert, 2015 - 2nd International Primary Immunodeficiencies Congress - Budapest, Hungary

2016: The Year Ahead…

As mentioned above, ADMA achieved several major milestones in 2015 including receiving the FDA's acceptance of the BLA submission for RI-002, and obtaining FDA approval of the second ADMA BioCenters plasma collection center in addition to strengthening its intellectual property portfolio. ADMA has several anticipated milestones on the horizon, and in our opinion, the potential approval of RI-002 for the indication of PIDD is of utmost importance. Remaining anticipated milestones that we would like to highlight include:

- Continuing commercialization and marketing preparation for RI-002
- Obtaining FDA approval to manufacture and market RI-002 for the treatment of PIDD patients
- First commercial sales of RI-002
- Continuing to expand intellectual property protection for RI-002 and related IVIG products
- Initiating new specialty plasma collection programs at ADMA BioCenters



We note that the current management team has met prior commitments and milestones in a timely fashion (for instance, most recently with the BLA filing, and FDA approval of the second plasma center), and we are hoping that the trend continues into 2016. ADMA's current strategy for moving RI-002 forward includes:

- Exploring other possible indications for RI-002
- Developing additional plasma-derived products for the treatment of infectious diseases in immunocompromised patient populations
- Expanding the network of ADMA BioCenters facilities, both to maintain control of a portion of the raw material supply and to generate additional revenue through the collection and sale of source plasma to third party customers

We expect ADMA will continue to build out its commercial infrastructure. In order to move forward with U.S. commercialization plans, ADMA plans to hire a small, specialized sales force to market RI-002 to physician offices/clinics, hospitals, as well as other specialty treatment organizations. We expect ADMA to hire between 25-30 sales reps initially. We believe that ADMA will focus on physicians that are concerned with the identification of infections in the immunocompromised patient population, which primary attention placed on immunologists, and infectious disease doctors. We also believe that other specialists such as pulmonologists, and hematologists may also be included.

We expect ADMA to hire between 25-30 sales reps initially. Additionally, the company has recently appointed some new hires to strengthen the commercial team. ADMA also expects to add additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources, and financial and operational management. In order to fulfill orders for RI-002, ADMA may also use a network of national distributors. We believe that the company will need to secure additional financing prior to launching RI-002 in order to support commercial efforts as well as launch expenses.

Conclusion

ADMA had a very busy 2015, and the company has achieved several significant, value-creating milestones during year. With the BLA for RI-002 in patients with PIDD accepted for review, FDA approval of the second plasma center in place (which is now generating revenue), and a key patent issued that further expands ADMA's RI-002 intellectual property portfolio, we see things as continuing to move in the right direction.

We continue to view the area of infection prevention (such as RSV) in immunocompromised patients (specifically PIDD, transplantation, and chemotherapy) to be one of significant unmet medical need. We believe that a polyclonal IVIG product that is specifically tailored to high-risk immunocompromised patients that could potentially protect against RSV infection (as well as other pathogens) would provide a unique, alternative treatment option for physicians and patients. We believe ADMA Biologics has a product with a unique antibody profile that sets itself apart from other IVIG products that are currently on the market. Due to the unique antibody profile of RI-002, we believe that ADMA has the opportunity to charge a premium over currently marketed standard IVIG products if approved.

There is a well-established FDA regulatory path to approval, and we see RI-002 gaining approval during the second half of 2016. Management anticipates product launch as early as the second half of 2016 if FDA approval is received in accordance with the standard review timeline. It may take some time for the product to gain momentum, but given management's experience of launching and commercializing plasma derived biological products and the sizeable market for RI-002, we believe this is a very attractive opportunity for investors. We believe ADMA is capable of commercializing and marketing RI-002 on its own if approved. We also believe that if RI-002 is approved, ADMA could potentially become a very attractive acquisition candidate for a big pharmaceutical or larger biotech company. For example, we see the possibility for a key player operating in the U.S. IVIG market such as Baxalta (BXLT; formerly known as Baxter International Inc.: BAX), Biotest AG (ETR:BIO), CSL Behring (CSL.AX), Octapharma AG, Kedrion SpA, and/or Grifols, S.A. (GRFS) becoming interested in the company and a differentiated IVIG product like RI-002.

As of September 30, 2015, ADMA had $20.9 million of total cash and short-term investments (consisting primarily of $9.2 million of cash and cash equivalents and $11.8 million of short-term investments) as compared to $23.8 million at June 30, 2015. Our model suggests current cash provides adequate funding into the second half of 2016.

Based on our assumptions and increasing the probability of success for RI-002 to 75% given the recent BLA acceptance of the IVIG candidate, we calculate a fair value for ADMA at approximately $270 million. With a market cap of approximately $112 million, we feel that the market does not yet fully appreciate ADMA's potential. Of note, in the fourth quarter, ADMA's senior management team purchased 16,711 shares, at an average price of $9.17, which in our opinion, shows that management not only believes that the shares are undervalued, but also that they doing something about it by investing their own capital in the company. Should RI-002 prove to be an effective treatment for additional indications, there is the possibility for significant upside to this valuation. In our opinion, with positive Phase 3 data in place and the company moving in the right direction towards RI-002 approval, we feel as though ADMA is a relatively low risk investment, especially at the current price. We continue to view ADMA as a compelling investment opportunity, and look forward to seeing management execute on its strategy. We are increasing our price target to $22 per share, and continue to rate the stock a 'Buy'.

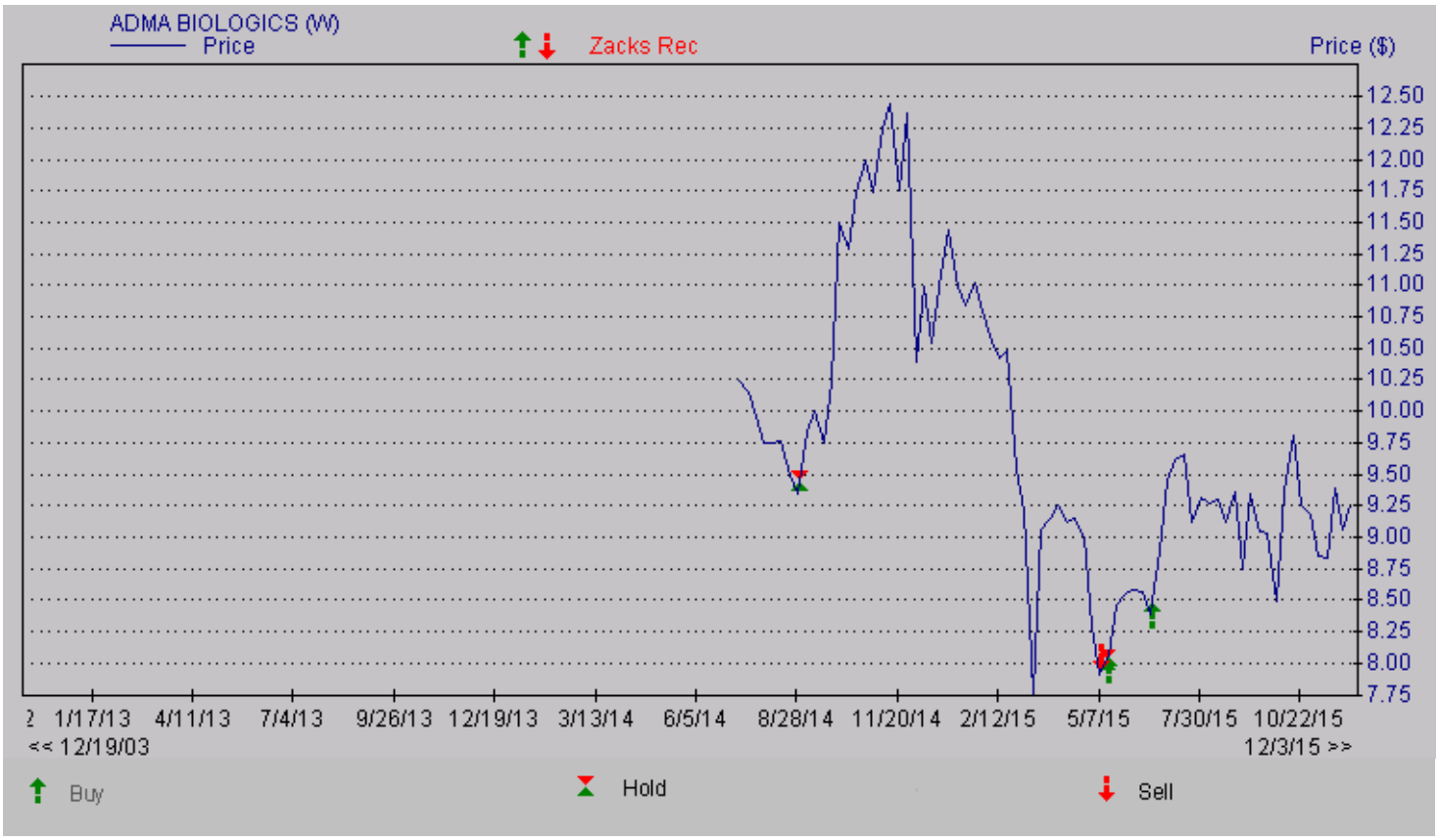
PROJECTED FINANCIALS

ADMA Biologics, Inc. - Income Statement

ADMA Biologics, Inc.	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E	2017 E
RI-002 Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$8.1	$35.5
YOY Growth								*336%*
Blood Plasma Sales	$5.8	$1.5	$1.3	$1.8	$2.4	$7.0	$10.9	$12.0
YOY Growth	*93%*	*-4%*	*-13%*	*35%*	*63%*	*20%*	*56%*	*10%*
License Revenue	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
YOY Growth	*71%*	*0%*	*0%*	*65%*	*65%*	*33%*	*3%*	*3%*
Total Revenues	**$5.9**	**$1.5**	**$1.3**	**$1.9**	**$2.4**	**$7.1**	**$19.2**	**$47.6**
YOY Growth	*93%*	*-4%*	*-13%*	*36%*	*63%*	*20%*	*170%*	*148%*
Cost of Product Revenue	$3.7	$0.9	$0.8	$1.1	$1.5	$4.3	$9.8	$21.1
Product Gross Margin	*37%*	*39%*	*40%*	*40%*	*39%*	*40%*	*49%*	*56%*
Research and development	$9.5	$1.4	$1.5	$2.1	$2.2	$7.2	$6.7	$7.1
Plasma centers	$3.9	$1.0	$1.1	$1.2	$1.3	$4.7	$6.9	$6.0
General and administrative	$4.8	$1.3	$1.4	$2.1	$2.2	$7.1	$8.6	$10.6
Income from operations	($16.0)	($3.2)	($3.5)	($4.7)	($4.8)	($16.1)	($12.8)	$2.8
Operating Margin	*-271%*	*-213%*	*-268%*	*-252%*	*-195%*	*-227%*	*-67%*	*6%*
Other income (expense)	($1.3)	($0.4)	($1.2)	($0.4)	($0.4)	($2.4)	($1.8)	($1.8)
Pre-Tax Income	($17.4)	($3.6)	($4.7)	($5.1)	($5.2)	($18.6)	($14.6)	$1.0
Income Taxes Paid	($0.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*3%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($16.8)**	**($3.6)**	**($4.7)**	**($5.1)**	**($5.2)**	**($18.6)**	**($14.6)**	**$1.0**
Net Margin	*-284%*	*-240%*	*-357%*	*-275%*	*-213%*	*-262%*	*-76%*	*2%*
Reported EPS	**($1.81)**	**($0.34)**	**($0.44)**	**($0.48)**	**($0.48)**	**($1.73)**	**($1.20)**	**$0.07**
YOY Growth	*($0.24)*	*($0.47)*	*$0.03*	*$0.31*	*$0.26*	*($0.04)*	*-33.5%*	*-106.0%*
Basic Shares Outstanding	9.29	10.71	10.71	10.71	10.71	10.71	12.10	14.10

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

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

We, Nisha Hirani, MD, and David Bautz, PhD, hereby certify that the views expressed in this research report accurately reflect our personal views about the subject securities and issuers. We also certify that no part of our compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. We believe the information used for the creation of this report has been obtained from sources we considered to be reliable, but we can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1214 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 25.0%, Hold/Neutral- 55.0%, Sell/Underperform – 16.1%. Data is as of midnight on the business day immediately prior to this publication.