Zacks Small-Cap Research

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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)

ADMA: Moving Forward with RI-002; On Track for Second Half 2016 Approval

Current Recommendation	**BUY**
Prior Recommendation	N/A
Date of Last Change	06/29/2015
Current Price (11/11/15)	$9.07
Target Price	**$20.00**

UPDATE

On November 10, 2015, ADMA Biologics, Inc. (NASDAQ: ADMA) reported financial results for the third quarter 2015. The company reported $1.9 million in revenues, and had a net loss of $5.1 million, or $0.48 per share.

In the third quarter 2015, ADMA received FDA acceptance of its BLA for RI-002 as well as FDA approval of its second plasma center. As a reminder, RI-002, a plasma-derived intravenous immunoglobulin (IVIG) with high levels of standardized RSV antibody for the treatment and prevention of certain infectious diseases in patients with Primary Immunodeficiency Disease (PIDD), has a unique antibody profile that could result in significant revenue for ADMA once commercialized. The company recently reported additional data in cotton rats that we believe further supports the unique antibody profile of RI-002.

In our opinion, ADMA remains on track for RI-002 approval to occur during the second half of 2016. At the current price, we continue to view ADMA shares as meaningfully undervalued, and as providing significant long-term upside potential. We are maintaining our price target of $20 per share, and continue to rate the stock a 'Buy'.

SUMMARY DATA

52-Week High	**$12.49**
52-Week Low	**$7.75**
One-Year Return (%)	**-27.15**
Beta	**0.21**
Average Daily Volume (sh)	**11,553**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$97**
Short Interest Ratio (days)	**5.39**
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	2.5 E	7.2 E
2016					15.3 E
2017					48.6 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					-$1.42 E
2017					$0.07 E

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WHAT'S NEW

Financial Update

On November 10, 2015, ADMA Biologics, Inc. (ADMA) reported financial results for the third quarter ended September 30, 2015. ADMA reported revenues of $1.9 million for the third quarter 2015 vs. revenues of $1.4 million for the third quarter 2014. Product revenues were above our expectations, and the increase in quarter-over-quarter product revenues was primarily attributable to sales of normal source plasma collected at the ADMA's recently FDA approved second plasma center. Revenues also included a milestone payment from Biotest AG as a result of the filing of the BLA for RI-002 with the FDA, which is in accordance with the license agreement entered into on December 31, 2012.

ADMA reported a net loss of $5.1 million, or $0.48 per share, for the third quarter 2015, as compared to a net loss of $3.4 million, or $0.36 per share, for the third quarter 2014. The increased net loss was primarily attributable to higher research and development as well as general and administrative costs, and was above our expectations. R&D expenses were $2.1 million for the third quarter 2015, compared with $1.5 million for the third quarter of 2014. This increase in R&D expenses was primarily due to regulatory and third-party consulting fees and other costs incurred from the filing of the BLA for RI-002 with the FDA. We believe that R&D expenses will be lower throughout 2015 vs. 2014 as a result of the BLA filing and acceptance by the FDA for RI-002 during the third quarter 2015 and the completion of the Phase 3 clinical study of RI-002 during the fourth quarter 2014. For the third quarter 2015, G&A expenses were $2.1 million, compared to $1.0 million for the same period in 2014. The increased G&A expenses for the third quarter 2015 are primarily attributable to consulting expenses associated with pre-commercialization activities. R&D as well as G&A expenses were above our expectations for the quarter. We continue to anticipate increases in G&A expenses in the fourth quarter 2015 as a result of heightened pre-launch, commercial planning, and market research efforts, in addition to the hiring of additional staff as part of the commercial development plan for RI-002 as ADMA continues to prepare for a second half 2016 commercial launch of RI-002.

As a reminder, ADMA raised a new debt financing 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.

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.

Business Update

ADMA has had a very busy third quarter, and in our opinion, the company has achieved several significant, value-creating milestones during the quarter. Below, we will offer an update on the ADMA story and milestones that the company recently achieved. We believe that the company remains laser focused on getting RI-002 approved and continues to move in the right direction towards this goal.

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. As a reminder, on July 31, 2015, ADMA announced submission of its RI-002 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 will not have to pay this fee. We view this as meaningful, and believe the company is on the right track towards approval and commercialization. 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 even believes that first commercial sales could also occur in the second half of 2016.

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 because it is a revenue-generating and cost-lowering operation. ADMA BioCenters are 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.

More on ADMA BioCenters…

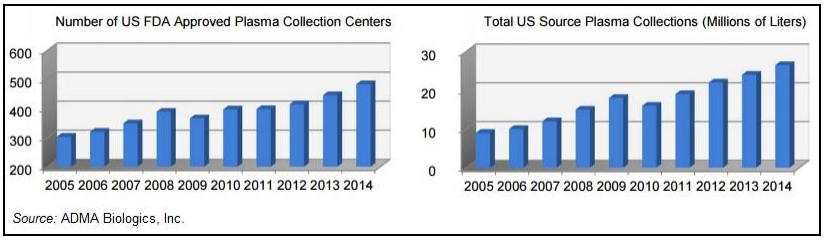
ADMA works closely with Biotest Pharmaceuticals for the manufacturing of RI-002. In addition to purchasing plasma from Biotest, ADMA operates ADMA BioCenters Plasma Collections Centers in Norcross, GA and Marietta, GA. Both of ADMA BioCenters are now FDA licensed facilities. The Norcross, Georgia facility 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.

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.

An Overview of RI-002

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): Approximately 25,000 HSCT procedures are performed annually in the U.S.
- ✓ Solid organ transplant (lung, heart, liver, and multi-organ): Approximately 11,000 solid organ transplants are performed annually in the U.S. (excluding kidney transplants)
- ✓ Cancer patients receiving chemotherapy: Approximately 375,000 patients receive chemotherapy in the U.S. 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 differentiates 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

Additional Pre-Clinical Data that Supports RI-002

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

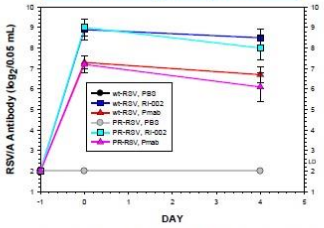
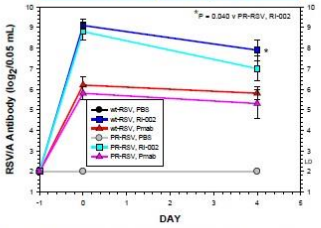


Fig. 2 Effect of IP RI-002 IVIG on RSV/B/18537 Serum Neutralizing Antibody Titers

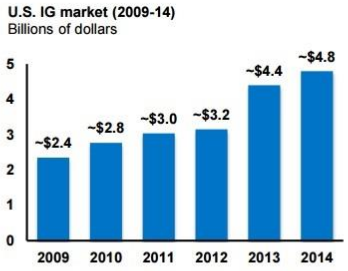


Source: Gilbert, 2015 - 2nd International Primary Immunodeficiencies Congress - Budapest, Hungary

The IVIG Market Opportunity

As a reminder, IVIG products are widely used and reimbursed for a variety of on-label and evidence-based disorders (*below*). In 2014, sales of IVIG products for all uses were reported to be approximately $4.8 billion in the U.S. alone (*below*). North America is the largest IVIG market followed by Europe and Asia. There are several approved IVIG products that are commercially available on the market. Key players operating in the U.S. IVIG market are Baxter International Inc. (soon to be Baxalta), Biotest AG, CSL Behring, Octapharma AG, Kedrion SpA,

and Grifols, S.A. Current standard IVIG is sold from anywhere between approximately $70-$100/gram by the companies mentioned above. According to the American Academy of Allergy, Asthma & Immunology guidelines, IVIG is indicated for patients with PIDD at a starting dose of 400-600 mg/kg every 3 to 4 weeks. Based on these guidelines, we estimate that the annual cost per PIDD patient on standard IVIG treatment ranges between $20,000 and $30,000 per year. It is important to remember that standard IVIG treatment dosage is weight dependent, and that is why there is a range for cost of treatment.



Uses of IG Products

FDA-Approved Uses	Additional Reimbursed Evidence-Based Uses		
Primary immunodeficiency (PIDD)	Acquired red cell aplasia	Multiple myeloma	Rasmussen's syndrome
Multifocal motor neuropathy	Bone marrow transplantation	Myasthenia gravis	Renal transplant from live donor
B-cell chronic lymphocytic leukemia	Dermatomyositis	Neonatal hemochromatosis	Solid organ transplantation
Immune thrombocytopenic purpura	Enteroviral meningoencephalitis	Parvovirus B19	Staphylococcal toxic shock
Kawasaki syndrome	Established bacterial sepsis	Pediatric HIV	Systemic lupus erythematosus
Chronic inflammatory demyelinating polyneuropathy	Multiple sclerosis	Post transfusion purpura	Toxic epidermal necrolysis

Source: ADMA information, on file, AAAAI, FDA, Product prescribing information, United Healthcare, Aetna, L.E.K. Consulting research and analysis
Any market information for IVIG is not necessarily indicative of the market for RI-002

We believe that the IVIG market is experiencing strong growth due to the rise in patients with immunodeficiencies, autoimmune disorders, bleeding disorders, chronic neuropathic conditions, other pathological diseases, and the overall geriatric population. However, it is important to note that we view the strict guidelines for the proper usage of IVIG set forth by various agencies (like the FDA), in addition to high treatment costs and side effect profile, as potentially hindering the growth of the IVIG market. There are strict U.S. FDA guidelines regarding IVIG products. As a reference, in June 2008, the FDA published "Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency" which outlines the regulatory pathway for IVIG approval for the treatment of PIDD.

In addition to standard immunoglobulins, we believe it is also important to highlight hyperimmune globulins, which are made from the plasma of individuals with elevated amounts (high-titers) of antibodies against a specific antigen or microorganism. For instance, there are hyperimmune products available for Cytomegalovirus, hepatitis B, rabies, tetanus, infant botulism, and varicella-zoster (Surkis *et al.*, 2014), which may be used to treat and prevent diseases caused by specific microbial organisms that are reactive with the high-titer antibodies contained in polyclonal IGIV products. We believe that hyperimmune products on the market sell anywhere between $300 to over $800/gram. For example, CSL Behring's Cytogam® is a human CMV-IVIG which contains a standardized amount of antibody to CMV for the prophylaxis of CMV disease associated with kidney, lung, liver, pancreas and heart transplantation, and sells for upwards of $430/gram as compared to $70-$100/gram for standard IVIG therapy (Ramirez-Avila *et al.*, 2014). We highlight some hyperimmune products below.

Company	Product Name	Indication
Grifols (GRFS)	HyperTET® S/D	Tetanus
Grifols (GRFS)	HyperRAB® S/D	Rabies
Sanofi (SNY)	IMOGAM® Rabies-HT	Rabies
Grifols (GRFS)	HyperHEP B® S/D	Hepatitis B
Emergent BioSolutions (EBS)	HepaGam B®	Hepatitis B
Biotest (BIO.DE)	Nabi-HB®	Hepatitis B
CSL Behring (CSL.AX)	Cytogam®	Cytomegalovirus

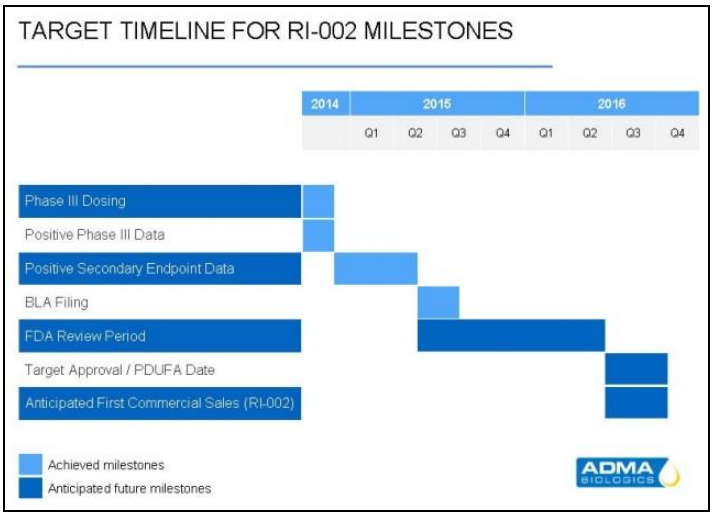
Source: Zacks SCR

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.

Moving Forward with RI-002

As mentioned above, ADMA recently achieved several milestones 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 Marietta, Georgia. 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. 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.

There are approximately 500 leading specialty programs for treating PIDD patients in the U.S., and we believe ADMA will concentrate efforts on these areas. For example, on June 11, 2015, a collaboration between ADMA and

the Jeffrey Modell Foundation (JMF), a global nonprofit organization dedicated to patients with PIDD was announced. 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.

Conclusion

ADMA had a very busy third quarter, and the company has achieved several significant, value-creating milestones during the quarter. 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 also see the new data demonstrating the ability of RI-002 to prevent infection in the cotton rat with a palivizumab resistant strain of RSV as additional support for the unique antibody profile of RI-002. 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. 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.

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. Although it may take some time for the product to gain momentum, 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. As mentioned above, historical sale prices for hyperimmune products have sold from $300 to over $800/gram, while standard IVIG therapies cost between $70-$100/gram. Although we believe that RI-002 will have comparable monthly dosage requirements for PIDD patients as standard IVIG therapies (~400-600 mg/kg every 3 to 4 weeks) during the winter months, we are estimating that RI-002 will cost closer to some of the hyperimmune products that are currently on the market, such as CSL Behring's Cytogam® which is a high titer CMV immunoglobulin for the prevention of CMV in transplant patients that sells for over $430/gram.

Based on our assumptions, we calculate a fair value for ADMA at approximately $250 million. With a market cap of approximately $110 million, we feel that the market does not yet fully appreciate ADMA's potential. Should RI-002 prove to be an effective treatment for additional indications, there is the possibility for significant upside to this valuation. We continue to view ADMA as a compelling investment opportunity, and look forward to seeing management execute on its strategy. We are maintaining our price target of $20 per share, and continue to rate the stock a 'Buy'.

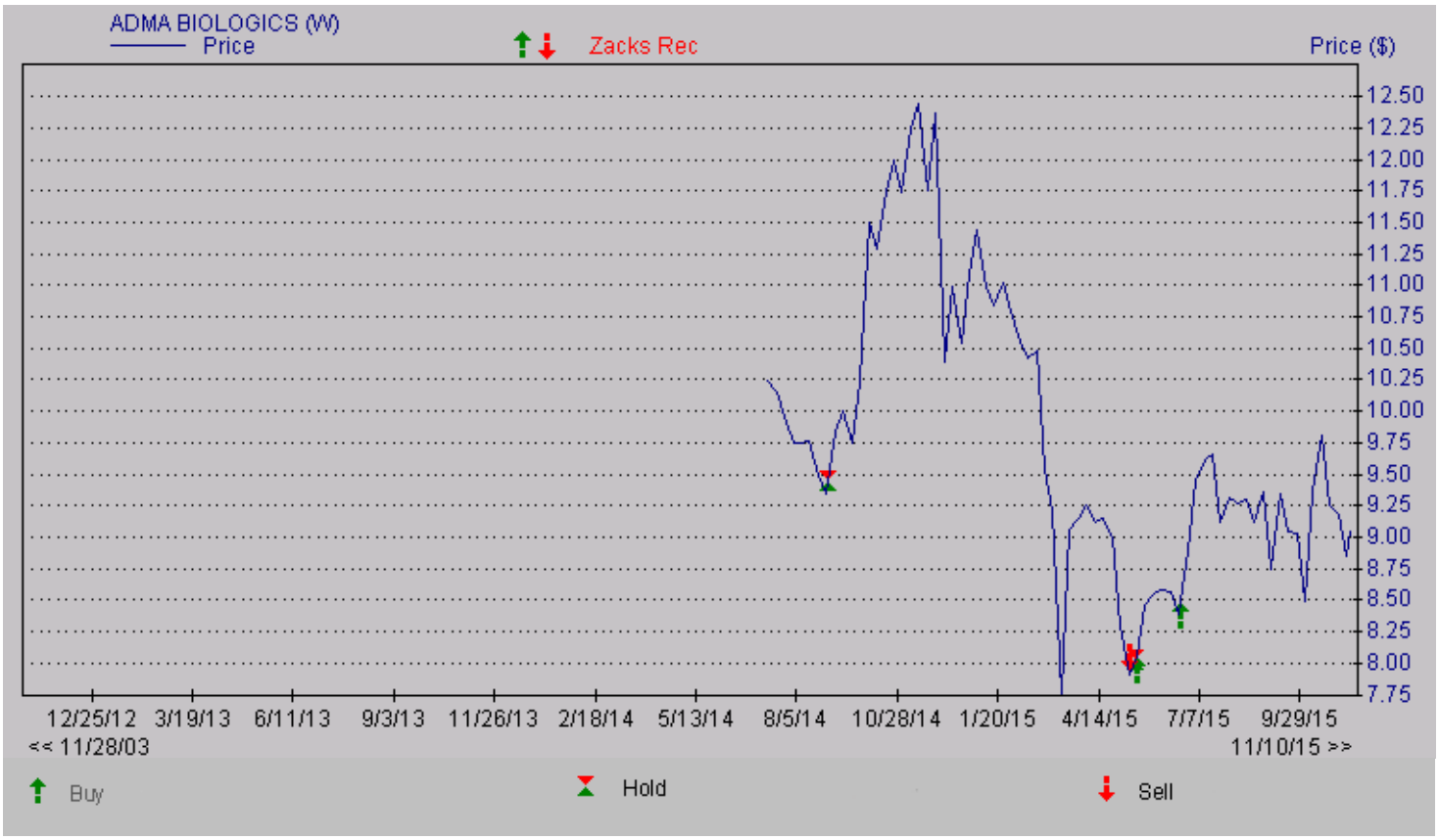
PROJECTED FINANCIALS

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	$2.7	$35.5
YOY Growth								*1208%*
Blood Plasma Sales	$5.8	$1.5	$1.3	$1.8	$2.5	$7.1	$12.5	$13.0
YOY Growth	*93%*	*-4%*	*-13%*	*35%*	*70%*	*22%*	*76%*	*4%*
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**	**$2.5**	**$7.2**	**$15.3**	**$48.6**
YOY Growth	*93%*	*-4%*	*-13%*	*36%*	*70%*	*22%*	*113%*	*218%*
Cost of Product Revenue	$3.7	$0.9	$0.8	$1.1	$1.5	$4.4	$8.6	$21.7
Product Gross Margin	*37%*	*39%*	*40%*	*40%*	*39%*	*40%*	*44%*	*55%*
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	$6.5
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)	($4.7)	($16.1)	($15.4)	$2.7
Operating Margin	*-271%*	*-213%*	*-268%*	*-252%*	*-186%*	*-224%*	*-101%*	*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)	($18.5)	($17.2)	$0.9
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)**	**($18.5)**	**($17.2)**	**$0.9**
Net Margin	*-284%*	*-240%*	*-357%*	*-275%*	*-204%*	*-258%*	*-112%*	*2%*
Reported EPS	**($1.81)**	**($0.34)**	**($0.44)**	**($0.48)**	**($0.48)**	**($1.73)**	**($1.42)**	**$0.07**
YOY Growth	*($0.24)*	*($0.47)*	*$0.03*	*$0.31*	*$0.25*	*($0.04)*	*-21.5%*	*-104.6%*
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



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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- 25.7%, Hold/Neutral- 53.7%, Sell/Underperform – 17.0%. Data is as of midnight on the business day immediately prior to this publication.