Zacks Small-Cap Research

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ADMA Biologics, Inc. (ADMA - NASDAQ)

ADMA: Files BLA for RI-002 with FDA Approval on Track for Second Half of 2016

Current Recommendation	**BUY**
Prior Recommendation	N/A
Date of Last Change	06/29/2015
Current Price (08/12/15)	$9.01
Target Price	**$20.00**

UPDATE

On August 11, 2015, ADMA Biologics, Inc. reported financial results for the second quarter 2015. The company reported $1.3 million in revenues, and had a net loss of $4.7 million, or $0.44 per share.

As a reminder to investors, ADMA has positive Phase 3 data for lead product candidate 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). We believe the unique antibody profile of RI-002 could result in significant revenue for ADMA once commercialized, and could be a better option for a subset of patients at high-risk for infections.

Since initiating on ADMA, the company has filed its BLA for RI-002, and has also received a notice of a patent allowance. In our opinion, these are signs that show that ADMA remains on track, and at the current price, we continue to view ADMA shares as meaningfully undervalued, and as providing significant long-term upside potential.

SUMMARY DATA

52-Week High	**$12.50**
52-Week Low	**$7.75**
One-Year Return (%)	**-7.14**
Beta	**N/A**
Average Daily Volume (sh)	**7,056**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$97**
Short Interest Ratio (days)	**5.60**
Institutional Ownership (%)	**65**
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	1.4 E	1.5 E	5.8 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	-$0.39 E	-$0.40 E	-$1.57 E
2016					-$1.41 E
2017					$0.08 E

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WHAT'S NEW

Financial Review & Business Update

On August 11, 2015, ADMA Biologics, Inc. (ADMA) reported financial results for the second quarter ending June 30, 2015. ADMA reported revenues of $1.3 million for the second quarter 2015 vs. revenues of $1.5 million for the second quarter 2014. The product revenues quarter-over-quarter decreased by 13% and were slightly below our expectations due to ADMA's decision 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.

ADMA reported a net loss of $4.7 million, or $0.44 per share, for the second quarter 2015, as compared to a net loss of $4.0 million, or $0.43 per share, for the second quarter 2014. The increased quarter-over-quarter net loss was primarily due to loss on extinguishment of debt of $0.7 million related to paying off a prior $15 million loan, and increased plasma center costs of $0.3 million primarily related to the opening of ADMA's second plasma center during the fourth quarter of 2014. Excluding the one-time loss from the extinguishment of debt, EPS would have been a loss of $0.37 per share. The increased costs associated with the second plasma center were comprised of increases in wages, rent, maintenance, and plasma collection supplies during the second quarter 2015 as compared to the second quarter 2014. ADMA's second plasma center is currently collecting plasma in order to build up inventory, and any plasma that is not used to manufacture RI-002 will be released for sale upon approval of the facility by the FDA.

Research and development expenses were $1.5 million for the second quarter of 2015, compared with $1.8 million for the second quarter of 2014. This decrease in research and development expenses was primarily due to the closing and completion of the Phase 3 clinical study during the fourth quarter 2014. For the second quarter of 2015, general and administrative expenses were $1.4 million, compared to $1.5 million for the same period in 2014. Although R&D as well as G&A expenses were below our expectations for the quarter, we anticipate increases in G&A expenses in the second half of 2015 as ADMA continues to prepare for a 2016 commercial launch of RI-002. We expect to see G&A expenses increase 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 a reminder, ADMA was uplisted to the NASDAQ in November 2014, and was added to the Russell Microcap® Index at the end of June 2015. On March 18, 2015, ADMA announced the closing of a public follow-on offering, raising net proceeds of approximately $10.3 million from the sale of 1.4 million shares of common stock at an $8.00 per share offering price. This total includes the full exercise of the underwriters' over-allotment option to purchase an additional 183,750 shares. As of May 12, 2015, the number of shares outstanding was 10.7 million.

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.

We view the second quarter financial results as secondary to the focus on the much more relevant clinical/regulatory developments, such as the BLA filing for RI-002 which was announced on July 31, 2015. As of June 30, 2015, ADMA had $23.9 million of total cash and short term investments (consisting primarily of $7.8 million of cash and cash equivalents and $15.9 million of short-term investments) as compared to $21.9 million at December 31, 2014. Our model suggests current cash provides adequate funding into 2016.

…Intellectual Property Protection in Place…

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 offers protection of RI-002 and is an important step towards commercialization of RI-002, if approved.

…ADMA Files BLA for RI-002…

On July 31, 2015, ADMA Biologics, Inc. (ADMA) announced submission of its RI-002 Biologics License Application (BLA) to the FDA, seeking marketing authorization of its lead product candidate. The FDA will have 60 days to review the application to determine whether ADMA's BLA submission for RI-002 is complete and acceptable for filing, and so we should know more by the end of September or early October. If all goes well and the BLA is approved, we could see a potential approval of RI-002 and the first commercial sales during the second half of 2016, approximately 10 months from the expected BLA approval date). 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.

A Brief 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

Source: ADMA Biologics, Inc.

Overview of PIDD & RSV

IVIG is used to treat a variety of conditions, including Primary Immunodeficiency Disease, commonly referred to as PIDD, which is a group of disorders caused by hereditary or genetic defects that lead to an individual having an absent or deficient immune system as a result of either a shortage of essential antibodies or a failure of these antibodies to function appropriately. In certain cases, this leads to the immune system not being able to protect against infection and pathogens. Individuals with PIDD are more susceptible to infections, and furthermore, are at a greater risk of suffering from complications related to these infections and oftentimes, repeated infections. According to the Immune Deficiency Foundation, these infections may occur in different areas of the body such as the skin, sinuses, throat, ears, lungs, brain, spinal cord, urinary tract, and gastrointestinal tract.

According to the World Health Organization, there are over 200 different types or presentations of PIDD. The Expert Committee of the International Union of Immunological Societies (IUIS) updated the classification of primary immunodeficiencies in April 2014, and includes more than 30 new gene defects in comparison to the previous version. This classification system serves as the most current source of all known primary immunodeficiencies, and is a crucial reference tool for the diagnosis of many of these rare diseases.

Although the clinical presentation of PIDD diseases may differ, they all share the common feature of resulting from a defect in one of the functions of the body's normal immune system. Patients with PIDD typically present with infections, which are often chronic, and may result in end organ damage such as bronchiectasis (*below*). Bronchiectasis is typically caused by an infection or another condition that results in airway wall injury. As a consequence, the airway passages are widened, scarred and eventually lose the ability to clear out mucous. The mucous build up results in repeated, serious lung infections, which in turn further damages the airways. Eventually, air is unable to move in and out of the lungs, and organs may not receive proper oxygen as a result. Bronchiectasis can lead to respiratory and heart failure as well as atelectasis (collapse of the lung) (NIH, 2014).

Since PIDD patients often do not respond to antimicrobial therapy, they tend to suffer from repeated infection with the same pathogen. Some of the typical presentation features of PIDD patients can include:

- Antibody deficiency and recurrent bacterial infections
- T-lymphocyte deficiency and opportunistic infections
- Other lymphocyte defects causing opportunistic infections
- Neutrophil defects causing immunodeficiency
- Complement deficiencies

Since patients with PIDD lack a properly functioning immune system, the standard of care is usually outpatient infusions of immunoglobulin (IVIG) therapy, as mentioned above. Currently, there are several FDA approved immunoglobulin products on the market. Administration of exogenous antibody treatment is crucial for patients with PIDD, because without it, they would be at a heightened risk for infectious diseases. Oftentimes, IVIG treatment is necessary for survival in certain PIDD patients, and benefits include a reduction of the severity and frequency of infections, as well as prevention of certain diseases such as chronic lung disease.

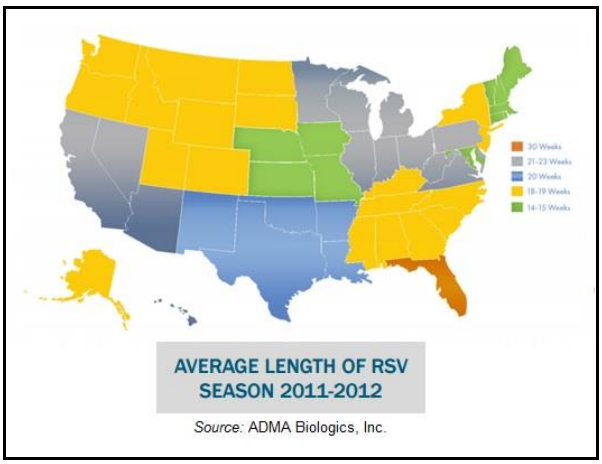
In the United States, PIDD has an estimated prevalence of 1:1,200 or about 250,000 individuals, with about 50% of them receiving IVIG treatment on a monthly basis. The National Institutes of Health (NIH) estimates there may up to approximately 500,000 Americans with PIDD, many of whom are undiagnosed. Some PIDD disorders are present at birth or early childhood, while others present at adulthood, thus the diagnosis is often difficult for physicians. The diagnosis of PIDD can often be a challenging and lengthy process.

…Why RSV is a Problem in Immunocompromised Patients…

Respiratory syncytial virus, or RSV, is a common respiratory virus that presents as mild, cold symptoms in healthy individuals, but can present with significant morbidity and mortality in high risk groups such as infants, the elderly, and immunocompromised individuals, such as those with PIDD or who have undergone transplantation and may be on immunosuppressive drugs or chemotherapeutic agents. Infection with RSV is highly contagious, and as mentioned above, usually self-limited, with symptoms typically resolving after one or two weeks in the healthy population. In order to help diagnose RSV, nonspecific lab tests such as complete blood count (CBC), oxygen saturation and urinalysis, as well as chest x-ray may be ordered. Specific tests to confirm RSV infection include nasopharynx secretion analysis via polymerase chain reaction (PCR) (Krilov *et al.*, 2014). In the United States, RSV is the most common cause of pneumonia and bronchiolitis (inflammation of the small airways of the lung) in children

under 1 year of age, and is often a major cause of respiratory illness in the elderly population. Historically, immunocompromised patients have 5-15% RSV infection rate, and if untreated, lower respiratory tract infections due to RSV can result in a mortality rate of up to 40% in infected patients.

Hematopoietic stem cell transplant (HSCT) patients are a specific subset of the immunocompromised population, and if infected with RSV, also have a poor prognosis. Patients that have undergone transplantation are given immunosuppressive therapy to ensure the body accepts the new organs and/or stem cells, and are therefore rendered immunocompromised, and resemble patients with PIDD. Approximately 25,000 HSCT transplants are performed each year in the United States, and 25% of these patients treated with the current standard of care (aerosolized ribavirin) will progress to lower respiratory tract infection while another 41% of untreated patients will also progress to lower respiratory tract infection. It's important to note that lower respiratory tract disease has up to a 40% mortality rate in these patients.



In the United States, RSV commonly presents during the winter months, but often appears seasonally in the late fall and early spring, with the majority of children having been infected with the virus by age two (*above*). RSV is the leading cause of infant hospitalization in the U.S., with over 125,000 infants hospitalized annually. According to the Centers for Disease Control Prevention, on average, in the United States, RSV leads to over 57,000 hospitalizations among children less than 5 years of age, 2.1 million outpatient visits among children less than 5 years old, as well as approximately 177,000 hospitalizations, and 14,000 deaths among adults over 65 years of age annually.

…Treatment for RSV in High Risk Population…

Supportive therapy remains the standard of care for those infected with RSV. If a patient is hospitalized with RSV, therapy should include supplemental oxygen, fluid replacement as well as mechanical ventilation if necessary. Bronchodilation via beta agonists (such as albuterol) is sometimes but not always administered. Ribavirin (Virazole) is an aerosolized broad-spectrum antiviral agent reserved for high-risk patients, especially children, with severe RSV disease (such as transplant recipients). It is an analogue of the nucleic acid guanosine, and inhibits viral replication. The use of ribavirin has been limited over the years due to costs and lack of benefit in decreasing mortality and hospitalization (Krilov *et al.*, 2014, Ohmit *et al.*, 1996).

AstraZeneca's specialty care division, MedImmune, manufactures Synagis® (palivizumab), which is a humanized monoclonal antibody (as opposed to IVIG that contains many or polyclonal antibodies) that is approved in over 80 countries. AbbVie holds rights to Synagis® outside of the U.S. The U.S. FDA approved Synagis® in 1998 for the reduction of serious lower respiratory tract infection caused by RSV in children that were at increased risk of severe disease. The American Academy of Pediatrics (AAP) originally recommended that prophylactic treatment with palivizumab be administered to high-risk infants and children that might be susceptible for serious RSV infection, such as those that are premature, immunocompromised and/or suffering with congenital heart disease or neuromuscular disorders that affect the airways. However, in July 2014, the American Academy of Pediatrics Committee on Infectious Disease revised the guidelines, restricting some patients in certain situations that may have been previously eligible for prophylactic treatment. The guidelines were updated to reflect "new information regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effect of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, the effect of prophylaxis on wheezing, and palivizumab-resistant RSV isolates." For instance, the committee now states that monthly prophylaxis should be discontinued in any infant or

child that experiences a breakthrough RSV hospitalization because there is a low likelihood (<0.5%) of a second RSV hospitalization in the same season. Additionally, palivizumab prophylaxis is no longer recommended for primary asthma prevention; for the reduction of subsequent episodes of wheezing; for otherwise healthy infants born at or after 29 weeks, 0 days' gestation; for the prevention of health care-associated RSV disease; and in the second year of life except for children who required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (AAP Guidelines).

According to the University of Illinois at Chicago College of Pharmacy, the AAP has historically recommended decreased usage of palivizumab with each new guidance document, which has led to a significant drop in palivizumab sales. In response to the updated guidelines, AstraZeneca began a newspaper advertising campaign stating that the new AAP recommendations "will leave approximately 140,000 babies unprotected" from RSV, and a website that provides a review of palivizumab data, costs associated with RSV disease, and also issues the company has with the updated guidelines.

Synagis® is administered as monthly intramuscular injections, typically in the thigh, during the RSV season, which generally occurs during fall, winter and spring in most areas in the United States. For optimal efficacy, it is recommended that the first injection of palivizumab be given before the onset of the RSV season in order to provide protection before the virus becomes active. According to AstraZeneca, since its approval in 1998, Synagis® has helped protect over 2.8 billion babies worldwide against RSV. According to the company, RSV affects approximately half of all infants globally within the first year of life, and is also the leading cause of hospitalizations and admissions to pediatric intensive care units. Synagis® had over $1 billion in global sales in 2012 and 2013, but with patent expiration coming up in October 2015 and more restrictive guidelines now set forth by the AAP, sales have declined over the last two years. In 2014, sales dropped to approximately $900 million, a decrease of about 15%. Sales in the U.S. were down 19% to $499 million in 2014 from $617 million in 2013. We do believe that the decline in sales was largely due to new guidelines that were issued by the AAP which restricts prophylactic treatment with Synagis® in certain patient groups, which are no longer consistent with the approved label.

We believe that palivizumab is representative of the market opportunity for a product like RI-002. MedImmune developed Synagis® for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease. It's important to mention that the drug has also been used off-label, such as to prevent RSV in cystic fibrosis and Down syndrome patients, and in some cases, to even fight active RSV infection. Despite the declining sales of Synagis® and the looming patent expiration, this remains a key area of interest for AstraZeneca. The company recently received fast track designation by the FDA for the development of MEDI8897, a high-potency extended half-life monoclonal antibody for the prevention of lower respiratory tract illness caused by RSV in infants and young children. AstraZeneca has initiated a Phase 1 study to assess the safety, tolerability, and pharmacokinetics of MEDI8897 in healthy adults as well as a separate Phase 1b/2a study of the drug in healthy, preterm infants.

As a side note, AstraZeneca was previously investigating motavizumab, a humanized monoclonal antibody for the prevention of RSV infection in high-risk infants. In June 2010, the U.S FDA Antiviral Drugs Advisory Committee declined to endorse licensure of motavizumab in a 14 to 3 decision due to safety and efficacy concerns in addition to hypersensitivity side effects. It followed that in December 2010, the company announced discontinuation of motavizumab development. Nevertheless, despite motavizumab's failure, we believe that AstraZeneca continues to be keenly interested in being part of the RSV prevention space with candidates like MEDI8897.

…More Attention Surrounding the RSV Space…

In addition to AstraZeneca's interest in RSV, we would like to mention that Novavax, Inc. (Nasdaq: NVAX), a clinical-stage vaccine company, announced positive data on August 11, 2015 from its Phase 2 study of its RSV F vaccine for the prevention of RSV infection in healthy adults over the age of 60. Currently, there is no approved RSV vaccine on the market, and the NVAX data showed that the vaccine was 46% effective in preventing RSV disease with symptoms related to lower respiratory tract infection, and was 44% effective in preventing all symptomatic RSV disease, with a four-fold increase in titer levels.

For comparison, in ADMA's Phase 3 clinical trial of RI-002 as a treatment for PIDD, 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. In particular, after infusion, RI-002 showed a 5.3 fold increase in RSV neutralizing antibodies, which was statistically significant 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

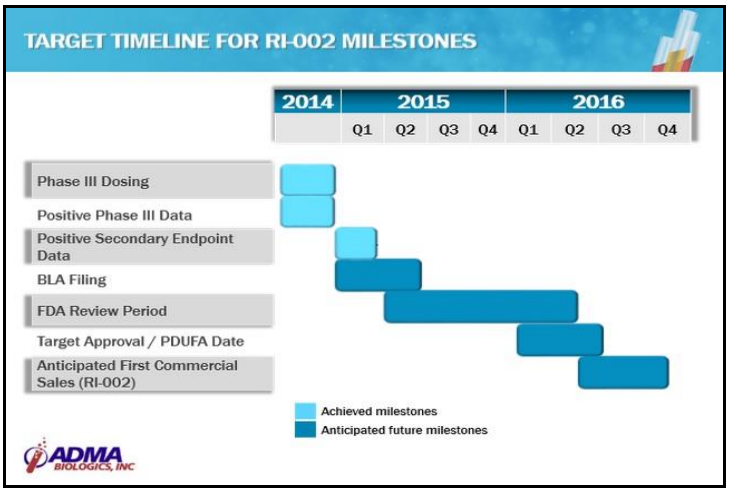
*Data on PK Subjects

Source: Data on File, ADMA Biologics, Inc.

Although we need to be cautious when comparing data across studies, especially since ADMA's RI-002 and Novavax's RSV F vaccine target completely different patient populations, we believe it is worthwhile to mention that the Novavax data supports the claim that a 4x to 5x increase in RSV titer levels may be clinically meaningful and may confer clinical protection against infection. We are interested in reviewing Phase 3 Novavax data when it becomes available, and if it the findings are confirmed in a Phase 3 trial, we believe that this could further support the claim. We also wanted to mention Novavax, as we believe there appears to be increasingly more interest in the RSV space, and we continue to believe that ADMA has a strong presence with RI-002 for a subset of patients with PIDD, and potential follow-on indications. As more players enter the RSV space, there is always the potential for future M&A and partnership activity.

All-in-all, this combined information strengthens our belief 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.

ADMA is Moving Along with RI-002



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
- Receiving FDA's decision regarding acceptance of the BLA submission for RI-002
- Obtaining FDA's decision regarding approval of second ADMA BioCenters plasma collection center in Marietta, Georgia
- 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 we are hoping that the trend continues. ADMA's current strategy for moving RI-002 forward includes:

- Obtaining FDA approval to manufacture and market RI-002 for the treatment of PIDD patients
- 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 to continue to build out its commercial infrastructure once the BLA has been accepted. 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 & Valuation

We 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 there are multiple high-value milestones on the horizon for ADMA. The company recently submitted its Biologics License Application (BLA) to the U.S. FDA. 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 in the second half of 2016 if FDA approval is received in accordance with the standard review timeline.

Based on our assumptions, we calculate a fair value for ADMA at approximately $250 million. With a market cap of $110 million, we feel that the market does not yet fully appreciate ADMA’s potential. With a fully diluted share count of 12.2 million as of June 30, 2015, this equates to a fair value target price of approximately $20 per share. Should RI-002 prove to be an effective treatment for additional indications, there is the possibility for significant upside to this valuation. We view ADMA as a compelling investment opportunity, and look forward to seeing management execute on its strategy.

PROJECTED FINANCIALS

ADMA Biologics, Inc.
Income Statement

ADMA Biologics, Inc.	2014 A	Q1 A	Q2 A	Q3 E	Q4 E	2015 E	2016 E	2017 E	2018 E
RI-002 Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$2.7	$35.5	$82.6
YOY Growth								*1208%*	*133%*
Blood Plasma Sales	$5.8	$1.5	$1.3	$1.4	$1.5	$5.7	$12.5	$13.0	$13.5
YOY Growth	*93%*	*-4%*	*-13%*	*4%*	*2%*	*-3%*	*120%*	*4%*	*4%*
License Revenue	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1	$0.1
YOY Growth	*71%*	*0%*	*0%*	*0%*	*0%*	*0%*	*3%*	*3%*	*3%*
Total Revenues	**$5.9**	**$1.5**	**$1.3**	**$1.4**	**$1.5**	**$5.8**	**$15.3**	**$48.6**	**$96.2**
YOY Growth	*93%*	*-4%*	*-13%*	*4%*	*2%*	*-3%*	*166%*	*218%*	*98%*
Cost of Product Revenue	$3.7	$0.9	$0.8	$0.9	$0.9	$3.5	$8.6	$21.7	$40.5
Product Gross Margin	*37%*	*39%*	*40%*	*39%*	*39%*	*39%*	*44%*	*55%*	*58%*
Research and development	$9.5	$1.4	$1.5	$1.6	$1.6	$6.1	$6.7	$7.1	$7.4
Plasma centers	$3.9	$1.0	$1.1	$1.0	$1.0	$4.1	$6.9	$6.5	$6.7
General and administrative	$4.8	$1.3	$1.4	$1.8	$2.0	$6.6	$8.6	$10.6	$11.1
Income from operations	($16.0)	($3.2)	($3.5)	($3.8)	($4.0)	($14.6)	($15.5)	$2.7	$30.5
Operating Margin	*-271%*	*-213%*	*-268%*	*-271%*	*-264%*	*-253%*	*-101%*	*6%*	*32%*
Other income (expense)	($1.3)	($0.4)	($1.2)	($0.4)	($0.4)	($2.4)	($1.6)	($1.6)	($1.6)
Pre-Tax Income	($17.4)	($3.6)	($4.7)	($4.2)	($4.4)	($16.9)	($17.1)	$1.1	$28.9
Income Taxes Paid	($0.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*3%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($16.8)**	**($3.6)**	**($4.7)**	**($4.2)**	**($4.4)**	**($16.9)**	**($17.1)**	**$1.1**	**$28.9**
Net Margin	*-284%*	*-240%*	*-357%*	*-300%*	*-290%*	*-295%*	*-112%*	*2%*	*30%*
Reported EPS	**($1.81)**	**($0.34)**	**($0.44)**	**($0.39)**	**($0.40)**	**($1.57)**	**($1.41)**	**$0.08**	**$1.80**
YOY Growth	*($0.24)*	*($0.47)*	*$0.03*	*$0.08*	*$0.04*	*($0.14)*	*-22.0%*	*-105.5%*	*2232.0%*
Basic Shares Outstanding	9.29	10.71	10.71	10.80	11.10	10.83	12.10	14.10	16.00

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

HISTORICAL ZACKS RECOMMENDATIONS



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