



# ADMA Biologics Reports Second Quarter 2015 Results

## Provides Corporate Update and Anticipated Upcoming Milestones

RAMSEY, N.J., Aug. 11, 2015 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (Nasdaq:ADMA), a late-stage biopharmaceutical company that develops, manufactures, and intends to commercialize specialty plasma-based biologics for the treatment and prevention of certain infectious diseases, announced its financial results for the second quarter ended June 30, 2015, in addition to providing a corporate update and anticipated milestones for 2015.

"The last several months have been a transformational period for ADMA and its stakeholders. During this time, we submitted our Biologics License Application (BLA) seeking marketing approval for RI-002 to the U.S. Food and Drug Administration (FDA) and also received notice of a patent allowance entitled, 'Compositions and Methods for the Treatment of Immunodeficiency.' These important milestones support our efforts to create long-term shareholder value. Also during this period, we continued our commercialization activities through the appointments of multiple key senior commercial team members, while also initiating a patient advocacy alliance with the Jeffrey Modell Foundation," stated Adam Grossman, President and CEO of ADMA Biologics. "Looking ahead to the remainder of 2015, we look forward to a response from the FDA regarding the potential acceptance of our BLA submission for RI-002 and the BLA approval of our second plasma center."

## Recent Accomplishments

- Submitted BLA to the FDA for RI-002 in patients with Primary Immune Deficiency Disease (PIDD)
- Appointed new commercialization and supply-chain-focused senior team members
- Received notice of key patent allowance pertaining to RI-002
- Joined Russell Microcap® Index
- Secured up to \$21 million financing agreement from Oxford Finance, LLC
- Initiated patient advocacy alliance with Jeffrey Modell Foundation

## Anticipated Milestones

- Continue commercialization and marketing preparation for RI-002
- Receive FDA's decision regarding acceptance of our BLA submission for RI-002
- Obtain FDA's decision regarding approval of our second ADMA BioCenters plasma collection facility in Marietta, Georgia
- Initiate new specialty plasma collection programs at ADMA BioCenters

## **Financial Results for the Second Quarter Ended June 30, 2015**

At June 30, 2015, the Company had cash, cash equivalents and short-term investments of \$23.8 million, as compared to \$21.9 million at December 31, 2014. The consolidated net loss for the second quarter ended June 30, 2015 was \$4.7 million, or \$(0.44) per share, as compared to a consolidated net loss of \$4.0 million, or \$(0.43) per share for the second quarter ended June 30, 2014. We had total revenues of \$1.3 million for the second quarter ended June 30, 2015, compared to \$1.5 million for the second quarter ended June 30, 2014. The decreased product revenues quarter-over-quarter is attributed to the Company electing to retain plasma in inventory in preparation for commercial manufacturing of RI-002 related to the expected launch of the product, which is anticipated to occur in the second half of 2016. The increased quarter-over-quarter net loss was primarily attributed to loss on extinguishment of debt of \$0.7 million related to paying off our prior \$15 million loan with a new debt lender with improved financial terms for the Company. The increased net loss was also attributed to higher quarter-over-quarter plasma center costs of \$0.3 million, primarily related to the opening of our second plasma center during the fourth quarter of 2014. Some of these costs were comprised of increases in wages, rent, maintenance and plasma collection supplies during the second quarter of 2015 compared to the second quarter of 2014. ADMA's second plasma center is currently collecting plasma which is being allocated to inventory and can be sold upon BLA approval of the facility by the FDA. The increased net loss was offset by lower research and development expenses of \$1.5 million during the second quarter ended June 30, 2015, compared to \$1.8 million during the second quarter ended June 30, 2014, as a result of the Phase III clinical study which was closed and completed during the fourth quarter of 2014, along with lower general and administrative costs as a result of pre-launch, market research activities undertaken during the second quarter of 2014. However, we expect that our G&A expenses will increase throughout the remainder of 2015 as a result of pre-launch, commercial planning, market research costs, and the hiring of additional staff as part of the commercial development of RI-002.

### **About ADMA Biologics, Inc.**

ADMA is a late-stage biopharmaceutical company that develops, manufactures and intends to commercialize specialty plasma-based biologics for the treatment and prevention of Primary Immune Deficiency Disease (PIDD) and certain infectious diseases. ADMA's mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease, or who may be immune-compromised for medical reasons. ADMA's lead product candidate, RI-002, has completed a Phase III clinical trial in patients with PIDD and has met the primary endpoint. A BLA for RI-002 was submitted to the FDA on July 31, 2015. For more information, please visit the company's website at [www.admabiologics.com](http://www.admabiologics.com).

### **About RI-002**

ADMA's lead product candidate, RI-002, is a specialty plasma-derived, polyclonal, intravenous immune globulin (IGIV) derived from human plasma containing naturally

occurring polyclonal antibodies (e.g., *Streptococcus pneumoniae*, *H. influenzae* type B, cytomegalovirus (CMV), measles, tetanus, etc.) as well as standardized, high levels of antibodies to respiratory syncytial virus (RSV). ADMA is pursuing an indication for the use of this specialty intravenous immune globulin (IGIV) product for treatment of patients diagnosed with PIDD. Polyclonal antibodies are the primary active component of IGIV products. Polyclonal antibodies are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses. Data review indicates that the polyclonal antibodies present in RI-002 support its ability to prevent infections in immune-compromised patients. ADMA's analysis demonstrated that the Phase III trial met the primary endpoint with no serious bacterial infections (SBI) reported. These results more than meet the requirement specified by the FDA guidance of  $\leq 1$  SBI per patient-year. A BLA was submitted to the FDA on July 31, 2015.

### **About Primary Immune Deficiency Disease (PIDD)**

PIDD is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system due to either a lack of necessary antibodies or a failure of these antibodies to function properly. PIDD patients are more vulnerable to infections and more likely to suffer complications from these infections. According to the World Health Organization, there are over 150 different presentations of PIDD. As patients suffering from PIDD lack a properly functioning immune system, they typically receive monthly, outpatient infusions of IGIV therapy. Without this exogenous antibody immune support, these patients would be susceptible to a wide variety of infectious diseases. PIDD has an estimated prevalence of 1:1,200 in the United States, or approximately 250,000 people.

### **Forward-Looking Statements**

*This press release contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "expect," "believe," "will," "will likely," "is likely", "should," "could," "would," "may" or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements include, but are not limited to, statements concerning our plans and timing to develop, market and commercialize RI-002 and the success of such efforts, the expected timing of and our ability to obtain and maintain regulatory approvals for our product candidates, the timeframe within which we may receive approval from the FDA, if at all, of our BLA for RI-002, our ability to generate revenue, if any, from the potential commercialization of RI-002, if approved by the FDA, the timing, progress and results of the clinical development, our plans to increase our supplies of plasma, regulatory processes, interpretations of final data, possible characteristics of RI-002, acceptability of RI-002 for any purpose by physicians patients or payers, concurrence by FDA with our conclusions and the satisfaction by us of its guidance, the likelihood and timing of FDA action with respect to any further filings by the Company, results of the clinical development, continuing demonstrations of safety, comparability of results of RI-002 to other comparably run IVIG trials, improvements in clinical outcomes, potential of RI-002 to provide meaningful clinical improvement for patients living with PIDD, as well as to offer*

clinicians with an option for their immune compromised patients, market data and incidence of infection, potential clinical trial initiations, potential investigational new product applications, biologics license applications, expansion plans, the achievement of clinical and regulatory milestones, commercialization efforts of the Company's product candidate(s) and trends relating to demand for source plasma. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results and the timing of certain events to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, risks as to whether final and secondary data will be accepted as encouraging, positive or will otherwise lead to an effective or approved product, whether we will be able to demonstrate efficacy or gain necessary approvals to market and commercialize any product, whether the FDA will accept our data, accept our submission of BLAs, continue to recognize its previously reported guidance, grant a license, or approve RI-002 for marketing, whether we will meet or achieve any of our clinical, regulatory or other milestones, whether we will develop any new products or expand existing ones, whether we will receive FDA approval of our new plasma collection facility, whether there may be changes in regional and worldwide supply and demand for source plasma, whether we will be able to attract sufficient donors and operate our new facility effectively or profitably, whether we can sell our plasma in the marketplace at prices that will lead to adequate amounts of revenue, whether we will be able to sustain the listing of our common stock on the NASDAQ Capital Market, whether we will meet any timing targets expressed by the Company, and other risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Therefore, current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. Except to the extent required by applicable laws or rules, ADMA does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements.

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**Three and Six Months Ended June 30, 2015 and 2014**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
<b>REVENUES:</b>				
Product revenue	\$1,291,044	\$1,481,430	\$2,775,261	\$3,023,100
License revenue	18,889	18,889	37,778	37,778
<b>Total Revenues</b>	<u>1,309,933</u>	<u>1,500,319</u>	<u>2,813,039</u>	<u>3,060,878</u>
<b>OPERATING EXPENSES:</b>				
Cost of product revenue	786,315	940,815	1,695,944	1,917,845

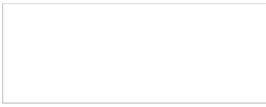
Research and development	1,505,909	1,783,909	2,907,633	6,114,366
Plasma centers	1,096,878	820,849	2,144,972	1,623,318
General and administrative	<u>1,437,436</u>	<u>1,542,066</u>	<u>2,783,432</u>	<u>2,676,655</u>
<b>TOTAL OPERATING EXPENSES</b>	<u>4,826,538</u>	<u>5,087,639</u>	<u>9,531,981</u>	<u>12,332,184</u>
<b>LOSS FROM OPERATIONS</b>	<u>(3,516,605)</u>	<u>(3,587,320)</u>	<u>(6,718,942)</u>	<u>(9,271,306)</u>
<b>OTHER INCOME (EXPENSE):</b>				
Interest income	9,795	3,625	14,776	5,404
Interest expense	(453,411)	(342,750)	(929,450)	(569,635)
Change in fair value of stock warrants	--	(34,800)	67,860	(29,580)
Loss on extinguishment of debt	<u>(719,097)</u>	<u>--</u>	<u>(719,097)</u>	<u>--</u>
<b>TOTAL OTHER EXPENSE</b>	<u>(1,162,713)</u>	<u>(373,925)</u>	<u>(1,565,911)</u>	<u>(593,811)</u>
<b>NET LOSS</b>	<u>\$ (4,679,318)</u>	<u>\$ (3,961,245)</u>	<u>\$ (8,284,853)</u>	<u>\$ (9,865,117)</u>
<b>NET LOSS PER COMMON SHARE,</b>				
<b>Basic and Diluted</b>	<u>\$ (0.44)</u>	<u>\$ (0.43)</u>	<u>\$ (0.81)</u>	<u>\$ (1.06)</u>
<b>WEIGHTED AVERAGE SHARES</b>				
<b>OUTSTANDING, Basic and Diluted</b>	<u>10,705,573</u>	<u>9,291,823</u>	<u>10,283,239</u>	<u>9,291,823</u>

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<u>June 30, 2015</u>	<u>*December 31,</u>
	<u>(Unaudited)</u>	<u>2014</u>
Assets		
Cash, cash equivalents and short-term investments	\$23,752,194	\$21,851,705
Total Assets	\$29,799,772	\$27,023,516
Accumulated deficit	\$ (77,734,590)	\$ (69,449,737)
Total Stockholders' Equity	\$9,519,508	\$6,008,650

**\*Condensed from audited financial statements**

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Source: ADMA Biologics, Inc.