

May 13, 2016



# ADMA Biologics Reports First Quarter 2016 Results

## Company Announces Recent Accomplishments and Upcoming Milestones

RAMSEY, N.J., May 13, 2016 (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, today announced its financial results for the quarter ended March 31, 2016, and recent accomplishments and anticipated milestones for 2016.

“We are very pleased with our continued progress and quarter-over-quarter revenue growth. We have continued to generate important laboratory and animal testing data for our lead product candidate, RI-002, which was presented at various medical conferences during the first quarter,” stated Adam Grossman, President and CEO of ADMA Biologics. “Most recently, we completed a follow-on public offering in May 2016 through which we raised gross proceeds of approximately \$14.1 million, and secured an additional \$4.0 million of capital from our venture debt partner. ADMA is now in an improved financial position as we approach the anticipated commercial launch of RI-002, which we expect during the second half of 2016, pending U.S. Food and Drug Administration approval.”

### **First Quarter 2016 and Recent Accomplishments**

- Presented various pre-clinical and animal study data demonstrating activity of RI-002’s elevated levels of neutralizing antibodies to RSV at multiple medical conferences
- Completed a follow-on public offering of common stock, with full exercise of the underwriters’ over-allotment option
- Obtained additional venture debt funding

### **2016 Anticipated Milestones**

- Obtain U.S. Food and Drug Administration (FDA) approval for RI-002
- Secure first commercial sales of RI-002
- Initiate new specialty plasma collection programs at ADMA BioCenters

### **Financial Results for the First Quarter Ended 2016**

The consolidated net loss for the first quarter ended March 31, 2016 was \$4.6 million, or \$(0.43) per share, as compared to a consolidated net loss of \$3.6 million, or \$(0.37) per share for the first quarter ended March 31, 2015. We had revenues of \$2.1 million for the

first quarter ended March 31, 2016 compared to \$1.5 million for the first quarter ended March 31, 2015, which represents approximately 40% growth quarter-over-quarter. This growth was primarily driven by revenues generated by our second plasma center, which received FDA approval in the third quarter of 2015. The increased quarter-over-quarter net loss was a result of higher research and development costs due to increased testing and validation for RI-002, along with increased headcount and increased plasma center operating expenses, as we continued to scale up operations of our second plasma collection center; increased general and administrative costs associated with the pre-launch, commercial planning activities, including various market research and analysis costs, and commercial new hires, in anticipation of the RI-002 product candidate launch. Included in the net loss for the quarter ended March 31, 2016, were non-cash expenses of stock based compensation of \$0.4 million and depreciation and amortization of \$0.3 million. At March 31, 2016, the Company had cash, cash equivalents and short-term investments of \$11.6 million, as compared to \$16.8 million at December 31, 2015. Pro-forma cash, cash equivalents and short-term investments as of March 31, 2016, including approximately \$13.0 million of net proceeds from the May 2016 public offering and an additional \$4.0 million of funding received in May 2016 from its venture debt partner was approximately \$28.6 million.

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

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, and a Biologics License Application (BLA) for RI-002 was accepted by the FDA on September 18, 2015. The company has received U.S. Patent 9,107,906 relating to certain aspects of its product candidate. For more information, please visit [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 (IVIG) 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 levels of antibodies to respiratory syncytial virus (RSV). ADMA is pursuing an indication for the use of this specialty IVIG product for treatment of patients diagnosed with PIDD. Polyclonal antibodies are the primary active component of IVIG 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.

## **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 IVIG 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 timing and ability to conduct further testing of RI-002 in humans, the expected timing of and our ability to obtain and maintain regulatory approvals for RI-002 or any other product candidates, the timeframe within which we may receive approval from the FDA, if at all, of 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 or the enforceability of our patent or its effectiveness in providing protection for any of our product candidates. 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 future 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 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 second plasma collection 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 Months Ended March 31, 2016 and 2015**  
**(Unaudited)**

	<u>Three Months Ended March 31,</u>	
	<u>2016</u>	<u>2015</u>
<b>REVENUES:</b>		
Product revenue	\$ 2,088,178	\$ 1,484,217
License and other revenue	35,708	18,889
<b>Total Revenues</b>	<u>2,123,886</u>	<u>1,503,106</u>
<b>OPERATING EXPENSES:</b>		
Cost of product revenue	1,266,421	909,629
Research and development	2,027,712	1,401,723
Plasma centers	1,280,419	1,048,094
General and administrative	1,707,870	1,345,997
<b>TOTAL OPERATING EXPENSES</b>	<u>6,282,422</u>	<u>4,705,443</u>
<b>LOSS FROM OPERATIONS</b>	<u>(4,158,536 )</u>	<u>(3,202,337 )</u>
<b>OTHER INCOME (EXPENSE):</b>		
Interest income	13,508	4,982
Interest expense	(467,441 )	(476,040 )
Change in fair value of stock warrants	-	67,860
<b>OTHER EXPENSE, NET</b>	<u>(453,933 )</u>	<u>(403,198 )</u>
<b>NET LOSS</b>	<u>\$ (4,612,469 )</u>	<u>\$ (3,605,535 )</u>

**NET LOSS PER COMMON SHARE,**

Basic and Diluted	<u>\$ (0.43 )</u>	<u>\$ (0.37 )</u>
-------------------	-------------------	-------------------

**WEIGHTED AVERAGE SHARES**

OUTSTANDING, Basic and Diluted	<u>10,710,587</u>	<u>9,855,323</u>
--------------------------------	-------------------	------------------

**CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION:**

	<u>*March 31, 2016</u> <u>(Unaudited)</u>	<u>*December 31, 2015</u>
Assets		
Cash, cash equivalents and short-term investments	\$ 11,620,110	\$ 16,809,136
Total Assets	\$ 19,684,920	\$ 23,714,517
Accumulated deficit	\$ (92,032,136 )	\$ (87,419,667 )
Total Stockholders' (Deficiency) Equity	\$ (3,369,315 )	\$ 820,974

**\*Condensed from audited financial statements**

CONTACT: Brian Lenz

Vice President and Chief Financial Officer | 201-478-5552 | [www.admabiologics.com](http://www.admabiologics.com)



Source: ADMA Biologics, Inc.