November 10, 2015

ADMA Biologics Reports Third Quarter 2015 Results

RAMSEY, N.J., Nov. 10, 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 third quarter ended September 30, 2015 and provided a corporate update and anticipated upcoming milestones.

“ADMA achieved a number of significant, value-creating milestones, during the third quarter. We submitted our Biologics License Application (BLA) seeking marketing approval for RI-002 to the U.S. Food and Drug Administration (FDA), which the FDA subsequently accepted for review. In addition, we were issued by the U.S. Patent and Trademark Office a key patent for RI-002, ‘Compositions and Methods for the Treatment of Immunodeficiency,’ which extends through January 2035. ADMA also received FDA approval of our second plasma collection center, which enabled the Company to begin generating additional revenues sooner than anticipated,” stated Adam Grossman, President and CEO of ADMA Biologics. “As we begin the fourth quarter, we are very pleased to report that our pre-launch commercialization activities are progressing as planned. We continue to build our commercial infrastructure, develop and increase volumes of high titer respiratory syncytial virus (RSV) plasma raw material inventory in preparation for commercial manufacturing and conduct stakeholder market research, market access and reimbursement analysis, in preparation for RI-002’s anticipated commercialization during the second half 2016.”

Recent Accomplishments

- FDA accepted BLA for RI-002 in patients with Primary Immune Deficiency Disease (PIDD)
- Received FDA approval for second plasma collection center
- Announced data demonstrating the ability of RI-002 to prevent infection in the cotton rat with a palivizumab resistant strain of RSV. Data was also reported demonstrating that serum obtained from cotton rats injected with RI-002 had higher anti-RSV neutralizing activity as compared to serum taken from cotton rats injected with palivizumab.
- Appointed senior team members with a focus on commercialization and supply-chain management
- Key patent issued that further expands ADMA’s RI-002 intellectual property portfolio
- Received success-based milestone payment
- Initiated patient advocacy alliance with Jeffrey Modell Foundation
- Added to Russell Microcap® Index
- Secured financing agreement for up to $21 million from Oxford Finance, LLC
- Recognized as one of the 50 fastest growing companies in New Jersey

Anticipated Milestones

- Initiate new specialty plasma collection programs at ADMA BioCenters
- Obtain FDA approval for RI-002
- First commercial sales of RI-002
- Continue to expand intellectual property protection for RI-002 and related IVIG products

Financial Results for the Third Quarter Ended September 30, 2015

At September 30, 2015, the Company had cash, cash equivalents and short-term investments of $20.9 million, as compared to $21.9 million at December 31, 2014.

ADMA had total revenues of $1.9 million for the third quarter ended September 30, 2015, compared to $1.4 million for the third quarter ended September 30, 2014. The increase in product revenues was primarily attributable to sales of normal source plasma collected at the Company’s recently FDA approved second plasma center.

The consolidated net loss for the third quarter ended September 30, 2015 was $5.1 million, or $(0.48) per share, as compared to a consolidated net loss of $3.4 million, or ($0.36) per share, for the third quarter ended September 30, 2014. The increased net loss was primarily attributable to higher general and administrative costs, primarily related to consulting expenses associated with pre-launch, commercial planning activities, market research costs and analysis in preparation for an anticipated RI-002 product launch during the second half of 2016. The increased net loss was also attributable to higher research and development costs of $0.6 million, primarily related to regulatory

consulting and third party costs supporting the filing of our BLA for RI-002, which was accepted by the FDA during the third quarter of 2015.

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 accepted by the FDA on September 18, 2015. The company has received U.S. Patent 9,107,906. For more information, please visit the company's website at 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. *influenza* 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 ≤ 1 SBI per patient-year. A BLA was accepted by FDA on September 18, 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 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 Nine Months Ended September 30, 2015 and 2014

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
REVENUES:				
Product revenue	$ 1,821,229	$ 1,347,041	$ 4,596,490	$ 4,370,141
License revenue	31,184	18,889	68,962	56,667
Total Revenues	1,852,413	1,365,930	4,665,452	4,426,808
OPERATING EXPENSES:				
Cost of product revenue	1,112,782	867,681	2,808,726	2,785,526
Research and development	2,111,505	1,482,929	5,019,138	7,597,295
Plasma centers	1,214,158	1,018,382	3,359,130	2,641,700
General and administrative	2,078,166	1,035,220	4,861,598	3,711,875
TOTAL OPERATING EXPENSES	6,516,611	4,404,212	16,048,592	16,736,396
LOSS FROM OPERATIONS	(4,664,198)	(3,038,282)	(11,383,140)	(12,309,588)
OTHER INCOME (EXPENSE):				
Interest income	11,102	3,508	25,878	8,912
Interest expense	(449,328)	(335,299)	(1,378,778)	(904,934)
Change in fair value of stock warrants	-	(14,616)	67,860	(44,196)
Loss on extinguishment of debt	-	-	(719,097)	-
OTHER EXPENSE, NET	(438,226)	(346,407)	(2,004,137)	(940,218)
NET LOSS	$ (5,102,424)	$ (3,384,689)	$ (13,387,277)	$ (13,249,806)
NET LOSS PER COMMON SHARE, Basic and Diluted	$ (0.48)	$ (0.36)	$ (1.28)	$ (1.43)
WEIGHTED AVERAGE SHARES OUTSTANDING, Basic and Diluted	10,707,728	9,291,823	10,425,310	9,291,823

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	*December 31, 2014
Assets		
Cash, cash equivalents and short-term investments	$ 20,942,128	$ 21,851,705
Total Assets	$ 27,824,030	$ 27,023,516
Accumulated deficit	$ (82,837,014)	$ (69,449,737)
Total Stockholders' Equity	$ 4,914,242	$ 6,008,650

***Condensed from audited financial statements**

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Source: ADMA Biologics, Inc.