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ADMA Biologics Reports Year End 2015 Financial Results, Accomplishments and Upcoming Milestones

RAMSEY, N.J., March 23, 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 year ended December 31, 2015, and outlined the company's 2015 accomplishments and anticipated milestones for 2016.

"During 2015 we achieved several meaningful milestones, including the filing and acceptance of a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for our lead product candidate, RI-002, received patent protection for RI-002 and received FDA approval for our second plasma collection center, which resulted in accretive revenues during the second half of 2015," stated Adam Grossman, President and CEO of ADMA Biologics. "As we continue to transition into a commercial company, with anticipated FDA approval of RI-002 during the second half of 2016, we hired key commercial staff members, procured additional raw material inventory for the future commercial production of RI-002 and continued marketing and reimbursement pre-launch activities."

2015 Accomplishments

- Filed and received acceptance of BLA by the FDA for RI-002
- Received patent protection for RI-002 for the treatment of patients with immunodeficiencies
- Received FDA approval for second plasma collection center and recognized accretive revenues in 2015
- Presented positive human clinical data from pivotal Phase III trial of RI-002, as well as presented various pre-clinical and animal studies at various medical conferences
- Announced strategic patients advocacy alliance with Jeffrey Modell Foundation
- Completed a secondary offering of common stock and refinanced loan commitment
- Added to the Russell Microcap® Index
- Hired key commercial staff in preparation for anticipated FDA approval and launch of RI-002
- Received a contractual milestone payment from Biotest AG for achieving a certain regulatory milestone for RI-002

2016 Anticipated Milestones

- Obtain 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 Year Ended 2015

The consolidated net loss for the year ended December 31, 2015 was \$18.0 million, or \$(1.73) per share, as compared to a consolidated net loss of \$16.8 million, or \$(1.81) per share for the year ended December 31, 2014. We had revenues of \$7.2 million for the year ended December 31, 2015 compared to \$5.9 million for the year ended December 31, 2014, which represents approximately 22% growth year-over-year, which was driven by our second plasma center receiving FDA approval in the third quarter of 2015. The increased year-over-year net loss was primarily attributed to higher 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 launch late in the second half of 2016. The increased net loss was also attributed to increased plasma center operating expenses as we continued to scale up our operations of the second plasma collection center which received FDA approval during the third quarter of 2015. The increased net loss was offset by lower research and development expenses of \$7.0 million during the year ended December 31, 2015, compared to \$9.5 million during the year ended December 31, 2014, as a result of completing our Phase III clinical study of RI-002 during the fourth quarter of 2014. Total other expense, increased to \$2.5 million for the year ended December 31, 2015 compared to \$1.3 million for the year ended December 31, 2014. The increase in other expense was primarily attributable to a loss on extinguishment of debt of \$0.7 million, which related to the refinancing of our venture debt loan to another lender and an increase in interest expense of \$0.5 million as a result of having a higher debt balance throughout 2015 as compared to 2014. Included in the net loss for the year ended December 31, 2015 were non-cash expenses of stock based compensation of \$1.7 million and depreciation and amortization of \$0.8 million. At December 31, 2015, the Company had cash, cash equivalents and short-term investments of \$16.8 million, as compared to \$21.9 million at December 31, 2014.

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 U.S. Food and Drug Administration (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.

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, high 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 ≤ 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 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 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 our 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 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
Years Ended December 31, 2015 and 2014

	2015	2014
REVENUES:		
Product revenue	\$ 7,050,283	\$ 5,839,989
License and other revenue	127,350	75,556
Total Revenues	7,177,633	5,915,545
OPERATING EXPENSES:		
Cost of product revenue	4,311,461	3,742,367
Research and development	7,015,946	9,517,014
Plasma centers	4,618,065	3,850,828
General and administrative	6,745,968	4,823,869
TOTAL OPERATING EXPENSES	22,691,440	21,934,078
LOSS FROM OPERATIONS	(15,513,807)	(16,018,533)

OTHER INCOME (EXPENSE):		
Interest income	37,830	14,217
Interest expense	(1,842,716)	(1,286,215)
Change in fair value of stock warrants	67,860	(74,356)
Loss on extinguishment of debt	(719,097)	-
OTHER EXPENSE, NET	<u>(2,456,123)</u>	<u>(1,346,354)</u>
LOSS BEFORE INCOME TAXES	(17,969,930)	(17,364,887)
State income tax benefit	-	551,724
NET LOSS	<u>\$ (17,969,930)</u>	<u>\$ (16,813,163)</u>
NET LOSS PER COMMON SHARE,		
Basic and Diluted	<u>\$ (1.73)</u>	<u>\$ (1.81)</u>
WEIGHTED AVERAGE SHARES OUTSTANDING, Basic and Diluted	<u>10,412,305</u>	<u>9,291,823</u>

CONDENSED CONSOLIDATED Balance Sheet INFORMATION:

	<u>*December 31, 2015</u>	<u>*December 31, 2014</u>
Assets		
Cash, cash equivalents and short-term investments	\$ 16,809,136	\$ 21,851,705
Total Assets	\$ 23,714,517	\$ 27,023,516
Accumulated deficit	\$ (87,419,667)	\$ (69,449,737)
Total Stockholders' Equity	\$ 820,974	\$ 6,008,650

*Condensed from audited financial statements

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Source: ADMA Biologics, Inc.