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ADMA Biologics Reports Year End 2016 Financial Results, Accomplishments and Upcoming Milestones

RAMSEY, N.J., Feb. 24, 2017 (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 proposed treatment of immune deficiencies and prevention of certain infectious diseases, today announced its financial results for the year ended December 31, 2016.

“During the recently completed fiscal year and into 2017, we have achieved significant progress towards transforming ADMA Biologics into a fully vertically integrated manufacturer and provider of commercial hyperimmune globulins and other plasma derived biological products,” stated Adam Grossman, President and Chief Executive Officer. “Since signing the definitive purchase agreement with Biotest to acquire certain manufacturing and therapy-related business unit assets in January 2017, we have been working aggressively on integration efforts and advancing toward the closing of this transformational transaction, which is anticipated to occur during the first half of 2017.”

Mr. Grossman continued, “We are also pleased with our continued year-over-year revenue growth from our plasma collection business segment. We believe this segment will serve as a strong foundation and supply resource for a portion of the raw material normal source plasma and specialty hyperimmune plasma used for our anticipated, near-term commercial production in our vertically integrated platform post-closing.

“Additionally, we continue to work on parallel paths collaborating with Biotest on remediation efforts to address the Complete Response Letter (“CRL”) for our lead product candidate RI-002, Biotest’s outstanding inspection issues and the Warning Letter, while we work on transition services arrangements and the total integration of the to-be acquired assets on a post-closing basis,” Mr. Grossman concluded.

2016 Accomplishments

- The U.S. Food and Drug Administration (the “FDA”) Indicated that no Additional Clinical Trials were Required in Order to Seek Approval of RI-002 for its Intended Indication in Patients with Primary Immune Deficiency Disease (“PIDD”)
- Achieved Approximately 50% Year-Over-Year Revenue Growth From Plasma Centers
- Presented Positive Data on Lead Product Candidate RI-002 at Multiple Medical Conferences
- Completed an Equity and Debt Financing to Enhance and Strengthen the Cash Position

2017 Anticipated Goals and Milestones

- Consummate and Close Biotest Therapy Business Unit (“BTBU”) Acquisition
- Successfully Integrate BTBU Operations into ADMA Biologics
- Generate Accretive Revenues From FDA-Approved BTBU Acquired Assets
- Progress Warning Letter and Inspection Issues Remediation Efforts and Work to Establish a Timeline with the FDA for Such Remediation
- Progress Resubmission of Biologics License Application for RI-002
- Initiate Buildout of Additional ADMA BioCenters Plasma Collection Operations
- Initiate New Specialty Plasma Collection Programs at ADMA BioCenters

Financial Results for the Year Ended 2016

At December 31, 2016, ADMA had cash, cash equivalents and short-term investments of \$15.3 million, as compared to \$16.8 million at December 31, 2015. The consolidated net loss for the year ended December 31, 2016 was \$19.5 million, or \$(1.61) per share, as compared to a consolidated net loss of \$18.0 million, or \$(1.73) per share, for the year ended December 31, 2015. ADMA reported revenues of \$10.7 million for the year ended December 31, 2016 compared to \$7.2 million for the year ended December 31, 2015, which represents 49% growth year-over-year. This growth was primarily driven by revenues generated from increased donor plasma collections from our plasma centers, in particular from our recently approved Marietta, Georgia, plasma center, which received FDA approval in the third quarter of 2015, as well as stronger “spot-market” pricing. The year-over-year increase in net loss of \$1.5 million is primarily attributable to increased cost of product revenue directly related to increased sales of normal source plasma, increased general and administrative expenses of \$1.7 million associated with fees incurred for the proposed acquisition of the BTBU consisting of fees paid for legal, accounting and due diligence advisors. Also contributing to the increase in net loss were costs associated with consulting services provided to us related to pre-launch, commercial planning, and market research, as well as increased plasma centers expenses of \$0.8 million which were primarily a result of increased plasma collections at our Marietta, Georgia plasma center, and increased research and development expenses of \$0.7 million attributable to increased validation, testing and production costs for RI-002 and an increase in regulatory consulting and legal fees. Total other expense decreased approximately \$0.3 million, to \$2.2 million for the year ended December 31, 2016, compared to \$2.5 million for the year ended December 31, 2015. The decrease in other expense is primarily attributable to a loss on extinguishment of debt of \$0.7 million, which was recorded in the second quarter of 2015 for the refinancing of an existing loan with our new lender, Oxford Finance LLC., offset by increased interest expense of \$0.4 million as a result of increased debt in 2016 as compared to 2015. Included in the net loss for the year ended December 31, 2016, were non-cash expenses of \$1.3 million for stock-based compensation and \$0.5 million for depreciation and amortization.

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 proposed treatment of Primary Immune Deficiency Disease (PIDD) and the prevention and treatment of 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 has received U.S. Patent 9,107,906 relating to certain aspects of its product candidate. For more information, please visit www.admabiologics.com.

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," "intend," "target," "will," "is likely," "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 ability to develop, manufacture, and commercialize specialty plasma-based biologics for the proposed treatment of immune deficiencies and the prevention of certain infectious diseases, the success of our work with our third party vendors and the U.S. Food and Drug Administration in furtherance of and progress towards an approval of our Biologics License Application for specialty plasma-based biologics and the ability of such third parties to respond adequately or in a timely manner to the issues raised by the FDA, our ability to successfully pursue commercialization and prelaunch activities, the timeframe within which we may receive approval from the FDA for specialty plasma-based biologics, if at all, the potential of our specialty plasma-based biologics to provide meaningful clinical improvement for patients living with PIDD or other indications and our ability to realize increased prices for plasma growth in the plasma collection industry. These forward-looking statements also involve risks and uncertainties concerning our ability to complete and close the proposed transaction described herein, the expected closing date of such transaction, the anticipated benefits and synergies of such transaction, anticipated future combined businesses, operations, products and services, and liquidity, debt repayment and capital return expectations. Actual events or results may differ materially from those described in this document due to a number of important factors. These factors include, among others, the outcome of regulatory reviews of the proposed transaction; the ability of the parties to complete the transaction; the ability of ADMA to successfully integrate the to-be acquired therapy business, operations (including manufacturing and supply operations), sales and distribution channels, business and financial systems and infrastructures, research and development, technologies, products, services and employees; the ability of the parties to retain their customers and suppliers; the ability of the parties to minimize the diversion of their managements' attention from ongoing business matters; ADMA's ability to manage the increased scale, complexity and globalization of its business, operations and employee base post-closing, among others. 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 those 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, 2016 and 2015

	2016	2015
REVENUES:		
Product revenue	\$ 10,518,203	\$ 7,050,283
License and other revenue	142,834	127,350
Total Revenues	10,661,037	7,177,633
OPERATING EXPENSES:		
Cost of product revenue	6,360,761	4,311,461
Research and development	7,688,238	7,015,946
Plasma centers	5,447,691	4,618,065
General and administrative	8,494,742	6,745,968
TOTAL OPERATING EXPENSES	27,991,432	22,691,440
LOSS FROM OPERATIONS	(17,330,395)	(15,513,807)
OTHER INCOME (EXPENSE):		
Interest income	50,317	37,830
Interest expense	(2,239,569)	(1,842,716)
Other income	4,496	-
Change in fair value of stock warrants	-	67,860
Loss on extinguishment of debt	-	(719,097)
OTHER EXPENSE, NET	(2,184,756)	(2,456,123)
NET LOSS	\$ (19,515,151)	\$ (17,969,930)
NET LOSS PER COMMON SHARE,		
Basic and Diluted	\$ (1.61)	\$ (1.73)
WEIGHTED AVERAGE SHARES OUTSTANDING, Basic and Diluted	12,153,407	10,412,305

CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION:

	<u>*December 31, 2016</u>	<u>*December 31, 2015</u>
Assets		
Cash, cash equivalents and short-term investments	\$ 15,305,051	\$ 16,809,136
Total Assets	\$ 23,685,085	\$ 23,714,517
Accumulated deficit	\$ (106,934,818)	\$ (87,419,667)
Total Stockholders' (Deficiency) Equity	\$ (4,457,262)	\$ 820,974

***Condensed from audited financial statements**

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Source: ADMA Biologics, Inc.