



ADMA Biologics Provides Corporate Update and Reports Third Quarter 2017 Financial Results

RAMSEY, N.J., Nov. 03, 2017 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ:ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that develops, manufactures and markets specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease ("PID") and the prevention and treatment of certain infectious immunological diseases, today provided a corporate update, including recent progress with its manufacturing and quality systems, and announced its financial results for the fiscal quarter ended September 30, 2017.

"Since completing the acquisition of certain assets of Biotest Pharmaceuticals Corporation's Therapy Business Unit ("BTBU"), we are pleased to report we continue to make progress with business integration, improving operating efficiencies, and remedying our outstanding U.S. Food and Drug Administration ("FDA") compliance issues," said Adam Grossman, President and Chief Executive Officer of ADMA.

Mr. Grossman continued, "Importantly, we remain on schedule to be FDA inspection-ready by year-end 2017. We have continued commercial production for Nabi-HB®, an FDA-approved hyperimmune globulin for the treatment of Hepatitis B during the third quarter of 2017 and further advanced our optimization program for our immunoglobulin manufacturing process, which is the process used for both Bivigam®, an FDA-approved immune globulin intravenous ("IGIV") for the treatment of primary humoral immunodeficiency and RI-002 our lead IGIV product candidate intended for immunodeficient patients. We are pleased with our operational progress, as we achieved year-over-year revenue growth of approximately 61 percent in the third quarter," concluded Mr. Grossman.

2017 YTD Achievements and Anticipated Goals

- Completed the acquisition of the BTBU, creating a U.S.-domiciled, vertically-integrated commercial drug manufacturer and provider of specialty- plasma biotherapeutics
- Generated accretive revenues from FDA-approved BTBU-acquired assets
- Continued the successful integration of BTBU operations into ADMA
- Established a timeline and engaged Subject Matter Experts to assist with the remediation of the FDA warning letter and compliance issues for the acquired Boca Raton, FL manufacturing facility (the "Boca Facility")
- Resumed commercial product manufacturing at the Boca Facility
- On track to be FDA "Inspection-Ready" by year-end 2017
- Initiated the buildout of our third ADMA BioCenter plasma collection facility
- Secured a second patent for immunotherapeutics methods for RI-002

Financial Results for the Three Months Ended September 30, 2017

ADMA reported total revenues of \$4.7 million for the third quarter ended September 30, 2017, as compared to \$2.9 million for the third quarter ended September 30, 2016, representing an increase of approximately 61%. This growth was primarily attributable to sales of Nabi-HB® as a result of the acquisition of certain BTBU assets, which included the commercial rights to Nabi-HB®.

The consolidated net loss for the quarter ended September 30, 2017 was \$15.2 million, or \$0.59 per basic and diluted share, as compared to a consolidated net loss of \$4.3 million, or \$0.34 per basic and diluted share, for the quarter ended September 30, 2016. The increase in net loss of \$10.9 million was primarily attributable to increased product revenue costs of \$9.6 million, which included manufacturing costs related to the Boca Facility, including third-party consultant fees of approximately \$2.0 million pertaining to the remediation efforts in response to the FDA warning letter. Additionally, the Company incurred increased selling, general and administrative expenses of \$2.4 million, which were primarily related to costs associated with the Boca Facility. These costs were partially offset by increased revenues of \$1.8 million. Included in the net loss for the third quarter ended September 30, 2017 were non-cash expenses of \$1.9 million for stock-based compensation, non-cash interest expense and depreciation and amortization.

Financial Results for the Nine Months Ended September 30, 2017

ADMA reported total revenues of \$10.8 million for the nine months ended September 30, 2017, as compared to \$7.3 million for the nine months ended September 30, 2016, representing a period-over-period increase of approximately 47%, which was driven by the sales of Nabi-HB® and increased plasma collection revenues.

The consolidated net loss for the nine months ended September 30, 2017 was \$30.8 million, or \$1.67 per basic and diluted share, as compared to a consolidated net loss of \$15.0 million, or \$1.26 per basic and diluted share, for the nine months ended September 30, 2016. The increase in net loss of \$15.8 million was primarily attributable to increased product revenue costs of \$12.9 million, which include manufacturing costs related to the Boca Facility, including third-party consultant fees of approximately \$2.5 million pertaining to the remediation efforts in response to the FDA warning letter, as well as increased selling, general and administrative expenses of \$7.7 million, which include transaction costs for the acquisition of the BTBU of \$3.9 million. These costs were partially offset by increased revenues of \$3.5 million for the quarter ended September 30, 2017. Included in the net loss for the nine months ended September 30, 2017 were non-cash expenses of \$2.8 million for stock-based compensation, depreciation and amortization and non-cash interest expense.

At September 30, 2017, ADMA had cash, cash equivalents and short-term investments of \$13.6 million, as compared to \$15.3 million at December 31, 2016. ADMA's net working capital as of September 30, 2017 was \$18.1 million, as compared to \$10.4 million as of December 31, 2016.

About ADMA Biologics, Inc. (ADMA)

ADMA is a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that develops, manufactures and markets specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease ("PID") and the prevention and treatment of certain infectious immunological 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 immunological 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. Patents 9,107,906 and 9,714,283 related to certain aspects of its product candidate, RI-002. 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," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "expect," "believe," "will," "is likely," "will likely," "should," "could," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements include, without limitation, the anticipated benefits and synergies of our recent acquisition of certain assets from Biotest Pharmaceuticals Corporation ("BPC") (the "BPC Transaction"), including optimization of the combined businesses, operations and products and services, including liquidity, debt repayment and capital return expectations, as well as the capitalization, resources and ownership structure of the combined company, the nature, strategy and focus of the combined company and the management and governance structure of the combined company, our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products and the success of such efforts, the timing and ability to conduct further testing of RI-002 in humans if needed, the safety, efficacy and expected timing of, and our ability to, obtain and maintain regulatory approvals of our current products and product candidates, and the labeling or nature of any such approvals, the timeframe within which we may receive approval from the U.S. Food and Drug Administration ("FDA"), if at all, of our Biologics License Application ("BLA") for RI-002, our ability to address the outstanding issues in the FDA's Complete Response Letter ("CRL"), as well as other deficiencies existing at the manufacturing facility we acquired in the BPC Transaction and the effect any adverse events on such manufacturing facility could have on us or our business, our ability to generate revenue, if any, from the potential commercialization of RI-002, if approved by the FDA, the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals, our ability to resume the manufacturing of Bivigam® once the deficiencies identified in the CRL, and the warning letter issued by the FDA to BPC on November 25, 2014 with respect to the outstanding issues at the manufacturing facility in Boca Raton, Florida which we acquired from BPC in June 2017, have been resolved by us to the satisfaction of the FDA, as well as a positive review of the optimized manufacturing process under a Prior Approval Supplement by the FDA our dependence upon our third-party and related party customers and vendors and their compliance with regulatory bodies our ability to obtain adequate quantities of FDA-approved normal source plasma and Respiratory Syncytial Virus ("RSV"), high-titer plasma with proper specifications, our plans to increase our supplies of plasma, the potential indications for our product candidates, our ability to expand our plasma center network, regulatory processes, interpretations of final data, possible characteristics of RI-002, acceptability of any of our products as

well as RI-002 for any purpose, by physicians, patients or payers, concurrence by the 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 Intravenous Immune Globulin ("IVIG") trials, improvements in clinical outcomes, the potential of RI-002 and Bivigam® to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease ("PIDD"), our ability to market and promote Nabi-HB® in the competitive environment and to generate meaningful revenues, 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, BLAs, expansion plans, our intellectual property position, including our expectations of the scope of patent protection with respect to RI-002, or other future pipeline product candidates, the achievement of clinical and regulatory milestones, our manufacturing capabilities, third-party contractor capabilities and strategy, our plans relating to manufacturing, supply and other collaborative agreements, our estimates regarding expenses, capital requirements and needs for additional financing, possible or likely reimbursement levels for our currently marketed products and if any, if and when RI-002 is approved for marketing, estimates regarding market size, projected growth and sales for our existing products as well as our expectations of market acceptance of RI-002, future economic conditions and performance, expectations for future capital requirements, commercialization efforts relating to our product candidates and the runway and limitation of our available cash and our ability to identify alternative sources of cash or the enforceability of our patent or its effectiveness in providing protection for any of our product candidates. Such forward-looking statements are also subject to many risks and uncertainties, including without limitation, 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, 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 any future plasma centers, 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 any new facilities 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 we express, and other risks and uncertainties as identified below. 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.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Nine Months Ended September 30, 2017 and 2016
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
REVENUES:				
Product revenue	\$ 4,693,703	\$ 2,902,155	\$ 10,650,558	\$ 7,226,368
License and other revenue	35,708	35,708	107,125	107,125
Total Revenues	<u>4,729,411</u>	<u>2,937,863</u>	<u>10,757,683</u>	<u>7,333,493</u>
OPERATING EXPENSES:				
Cost of product revenue (exclusive of amortization expense shown below)	11,291,116	1,735,771	17,241,422	4,346,433

Research and development	1,814,069	1,677,263	4,365,205	7,104,864
Plasma centers	1,582,694	1,482,586	4,662,340	4,057,306
Amortization of intangibles	273,878	-	346,899	-
Selling, general and administrative	4,195,414	1,779,115	12,908,448	5,211,148
TOTAL OPERATING EXPENSES	19,157,171	6,674,735	39,524,314	20,719,751
LOSS FROM OPERATIONS	(14,427,760)	(3,736,872)	(28,766,631)	(13,386,258)
OTHER INCOME (EXPENSE):				
Interest income	8,014	11,605	34,440	37,130
Interest expense	(782,969)	(605,972)	(2,043,982)	(1,611,411)
Other income	-	-	-	4,496
OTHER EXPENSE, NET	(774,955)	(594,367)	(2,009,542)	(1,569,785)
NET LOSS	\$ (15,202,715)	\$ (4,331,239)	\$ (30,776,173)	\$ (14,956,043)
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (0.59)	\$ (0.34)	\$ (1.67)	\$ (1.26)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	25,790,805	12,886,741	18,415,468	11,906,276

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

	September 30, 2017	December 31, 2016
	(Unaudited)	(Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 13,601,391	\$ 9,914,867
Short-term investments	-	5,390,184
Accounts receivable, net	1,499,809	1,018,027
Inventories	13,418,971	5,020,146
Prepaid expenses and other current assets	2,078,509	313,914
Assets held for sale	845,389	-
Total current assets	31,444,069	21,657,138
Property and equipment, net	29,755,541	2,000,784
Intangible assets, net	5,737,175	-
Goodwill	3,529,509	-
Assets to be transferred under purchase agreement	1,596,493	-
Deposits and other assets	750,693	27,163
TOTAL ASSETS	\$ 72,813,480	\$ 23,685,085
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 9,156,341	\$ 2,564,681
Accrued expenses	3,860,121	2,385,356
Current portion of notes payable	-	6,111,111
Current portion of deferred revenue	145,154	145,154
Other current liabilities	177,250	16,559
Total current liabilities	13,338,866	11,222,861
Notes payable, net of discount	14,534,340	12,321,640
End of term liability, notes payable	1,790,000	1,790,000
Deferred revenue, net of current portion	2,582,908	2,690,033
Note payable - related party, net of discount	14,834,696	-
Obligation to transfer assets under purchase agreement	12,621,844	-
Other non-current liabilities	118,318	117,813
TOTAL LIABILITIES	59,820,972	28,142,347
COMMITMENTS AND CONTINGENCIES	-	-
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred Stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common Stock - voting, \$0.0001 par value, 75,000,000 shares authorized, 17,202,244 and 12,886,741 shares issued and outstanding	1,722	1,289
Common Stock - non-voting, \$0.0001 par value, 8,591,160 shares	-	-

authorized, 8,591,160 and 0 shares issued and outstanding	859	-
Additional Paid-In Capital	150,700,918	102,476,267
Accumulated Deficit	(137,710,991)	(106,934,818)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>12,992,508</u>	<u>(4,457,262)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 72,813,480</u>	<u>\$ 23,685,085</u>

Source: ADMA Biologics, Inc.