August 8, 2019

ADMA Biologics Reports Second Quarter and First Half 2019 Financial Results

RAMSEY, N.J. and BOCA RATON, Fla., Aug. 08, 2019 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases, today announced its financial results for the second quarter and six months ended June 30, 2019, and provided an update on its recent achievements, operations and upcoming milestones.

"We are pleased with our significant accomplishments reported during the second quarter of 2019, which include two United States Food and Drug Administration ("FDA") approvals, BIVIGAM® and ASCENIV™, as well as the FDA authorizations of product license transfers for BIVGAM® and Nabi-HB®," stated Adam Grossman, ADMA's President and Chief Executive Officer. "During the second quarter, we completed an equity financing of approximately $52 million in gross proceeds, which we expect to use to support the commercial inventory build and product launches for BIVIGAM® and ASCENIV™, expand the manufacturing capacity of our Boca Raton, FL facility, the procurement of raw materials, plasma center expansion, other capital expenditures and for general corporate purposes."

Recent Achievements

- Obtained FDA approval for ASCENIV™ (formerly RI-002)
- Received FDA approval for BIVIGAM®'s prior approval supplement
- Raised $51.75 million of gross proceeds through equity financing
- Received FDA approval for license transfers for BIVIGAM® and Nabi-HB®
- Expanded our sales and commercial team

Anticipated Milestones

- Commercial launches and sales of BIVIGAM® and ASCENIV™ in second half of 2019
- Expansion of our plasma collection network

Financial Results for the Three Months Ended June 30, 2019

ADMA reported total revenues of $6.6 million for the quarter ended June 30, 2019, as compared to $4.7 million for the quarter ended June 30, 2018, representing an increase of $1.9 million, or approximately 41%. The increase in revenues was primarily due to $2.4 million of contract manufacturing revenue in the second quarter of 2019, with no corresponding amount in the second quarter of 2018, partially offset by a $0.5 million decrease in Nabi-HB® revenues related to the timing of shipment requests from a key customer. The contract manufacturing revenue is related to an agreement we assumed from Biotest Pharmaceuticals Corporation ("BPC"). While we expect to generate additional

revenue under this contract during the second half of 2019, this contract is set to expire at the end of 2019.

The consolidated net loss for the quarter ended June 30, 2019 was $13.2 million, or $(0.25) per basic and diluted share, as compared to a consolidated net loss of $14.7 million, or $(0.35) per basic and diluted share, for the quarter ended June 30, 2018. The decrease in net loss of $1.5 million was primarily attributable to higher revenues and lower plasma center operating costs as a result of having one plasma collection center in operation in 2019 as compared to three during the same period last year, partially offset by higher selling, general and administrative costs, comprised of commercialization, marketing and prelaunch expenses for BIVIGAM® and ASCENIV™, as well as increased employee related expenses, including stock-based compensation, and to increased interest expense. Included in the net loss for the quarter ended June 30, 2019 were non-cash expenses of approximately $1.6 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

Financial Results for the Six Months Ended June 30, 2019

ADMA reported total revenues of $10.1 million for the six months ended June 30, 2019, as compared to $8.7 million for the six months ended June 30, 2018, representing an increase of $1.4 million, or approximately 16%. The increase in revenues was primarily attributable to the $2.4 million of contract manufacturing revenue generated during the second quarter of 2019, partially offset by a $0.9 million decrease in Nabi-HB revenues related to the timing of shipment requests from a key customer.

The consolidated net loss for the six months ended June 30, 2019 was $26.3 million, or $(0.53) per basic and diluted share, as compared to a consolidated net loss of $32.6 million, or $(0.74) per basic and diluted share, for the six months ended June 30, 2018. The decrease in net loss of $6.3 million was primarily attributable to higher revenues and lower manufacturing and plasma center operating costs, partially offset by higher selling, general and administrative costs, comprised of commercialization, marketing and prelaunch expenses for BIVIGAM® and ASCENIV™ as well as increased employee related expenses, including stock-based compensation, in addition to a non-cash gain of $11.5 million from the transfer of two of ADMA's plasma centers on January 1, 2019 as part of the consideration of the Biotest Therapy Business Unit ("BTBU") acquisition in June of 2017, largely offset by a loss on extinguishment of debt of $10.0 million related to the refinancing of ADMA's senior secured notes and higher interest expense. Included in the net loss for the six months ended June 30, 2019 were non-cash expenses of approximately $3.3 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

At June 30, 2019, ADMA had cash and cash equivalents of $73.6 million and accounts receivable of $5.1 million, as compared to $22.8 million and $1.4 million, respectively, at December 31, 2018. ADMA's net working capital as of June 30, 2019 was $93.8 million, as compared to $34.9 million as of December 31, 2018. In the second quarter of 2019, the Company completed an underwritten public offering of its common stock and received net proceeds of $48.4 million.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a vertically integrated biopharmaceutical manufacturer with three FDA approved commercial specialty plasma-based biologics. 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 and management of immune compromised patient populations. The target patient populations include immune compromised individuals who suffer from an underlying immune deficiency disease, or who may be immune compromised for other medical reasons. ADMA has received U.S. Patents 9,107,906, 9,714,283, 9,815,886, 9,969,793 and 10,259,865 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

About Primary Immune Deficiency Disease ("PI")

PI is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system. According to the World Health Organization, there are approximately 350 different genetic mutations encompassing PI. Some disorders present at birth or in early childhood, the disorders can affect anyone regardless of age or gender. Some affect a single part of the immune system, others may affect one or more components of the system. PI patients are vulnerable to infections and more likely to suffer complications from these infections as compared to individuals with a normal functioning immune system. The infections may occur in any part of the body. Because patients suffering from PI lack a properly functioning immune system, they typically receive monthly treatment with polyclonal immune globulin products. Without this exogenous antibody replacement, these patients would remain vulnerable to persistent and chronic infections. PI has an estimated prevalence of 1:1,200 in the United States, or approximately 250,000 people in the U.S.

About ASCENIV™ (Formerly referred to as RI-002)

ASCENIV™, Immune Globulin Intravenous, Human – slra 10% Liquid, is a plasma-derived, polyclonal, intravenous immune globulin ("IVIG"). ASCENIV™ is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886. ASCENIV™ is manufactured using our unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested using our proprietary microneutralization assay. ASCENIV™ contains naturally occurring polyclonal antibodies. ASCENIV™ is indicated for the treatment of Primary Humoral Immunodeficiency or Primary Immune Deficiency Disease ("PI") in adults and adolescents (12 to 17 years of age). ADMA received FDA approval for ASCENIV™ on April 1, 2019. Polyclonal antibodies are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses and prevent against infection and disease. ASCENIV™ prevented serious bacterial infection among fifty-nine patients treated for twelve months during the pivotal investigation. The most common adverse reactions to ASCENIV™ (≥5% of study subjects) were headache, sinusitis, diarrhea, gastroenteritis viral, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea. ADMA anticipates the commercial launch of ASCENIV™ during the second half of 2019. Certain data and other information about ASCENIV™ or ADMA Biologics and its products can be found on the Company's website at: www.admabiologics.com.

About BIVIGAM®

BIVIGAM® is an immune globulin intravenous (human), 10% liquid, indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, X-linked and congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These PIs are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as 250,000 people

in the U.S. have some form of Primary Humoral Immunodeficiency (“PI”). BIVIGAM® contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses, and help to protect PI patients against serious infections. BIVIGAM® is a purified, sterile, ready-to-use preparation of concentrated human Immunoglobulin (“IgG”) antibodies. Antibodies are proteins in the human immune system that work to defend against infections and disease. FDA’s initial approval for BIVIGAM® was received by BPC in December 2012, and production of BIVIGAM® was halted by BPC in December 2016. ADMA obtained ownership and all rights, title and interest in BIVIGAM® in June 2017 as part of the Biotest Therapy Business Unit (“BTBU”) acquisition in June 2017 and resumed the production of BIVIGAM® during the fourth quarter of 2017. The FDA approved BIVIGAM’s prior approval supplement to amend the biologics license application for the product on May 9, 2019 allowing the Company to resume supplying BIVIGAM® to the U.S. market. ADMA anticipates the commercial launch of BIVIGAM® during the second half of 2019. The FDA completed the license transfer for BIVIGAM® to ADMA on July 2, 2019. Certain data and other information about BIVIGAM® or ADMA Biologics and its products can be found on the Company’s website at: www.admabiologics.com.

About Nabi-HB®

Nabi-HB® is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB® is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB® is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen (“HBsAg”), prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. Hepatitis B is a potentially life-threatening liver infection caused by the Hepatitis B virus. It is a major global health problem and can cause chronic infection and put people at high risk of death from cirrhosis and liver cancer. Nabi-HB® has a well-documented record of long-term safety and effectiveness since its initial market introduction. FDA approval for Nabi-HB® was received on March 24, 1999. Biotest acquired Nabi-HB® from Nabi Biopharmaceuticals in 2007. ADMA obtained ownership and all rights, title and interest in Nabi-HB® in June 2017 as part of the BTBU acquisition and the FDA transferred the license to ADMA on July 2, 2019. Certain data and other information about Nabi-HB® or ADMA Biologics and its products can be found on the Company’s website at: www.admabiologics.com.

Cautionary Note Regarding 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, about ADMA Biologics, Inc. ("we“, “our” or the “Company”). Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain such words as “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 also include, but are not limited to, statements concerning our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products; the safety, efficacy and expected timing of, and our ability to, obtain and maintain regulatory approvals of our current products; product expansions into new fields of use, indications and product candidates, and the labeling or nature of any such approvals; our ability to

successfully pursue commercialization and prelaunch activities for our products; the potential of our specialty plasma-based biologics products and product candidates to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other indications; our ability to realize increased prices for plasma growth in the plasma collection industry; and our expectations for future capital expenditures and requirements. Actual events or results may differ materially from those described in this document due to a number of important factors. 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. 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. Forward-looking statements are subject to many risks, uncertainties and other factors 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, the risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
REVENUES:				
Product revenue	$ 6,525,233	$ 4,620,841	$ 10,018,114	$ 8,627,139
License revenue	35,709	35,709	71,417	71,417
Total Revenues	6,560,942	4,656,550	10,089,531	8,698,556
OPERATING EXPENSES:				
Cost of product revenue (exclusive of amortization expense shown below)	10,491,236	9,645,662	19,896,415	21,888,410
Research and development	516,986	1,040,427	1,387,621	2,005,998
Plasma center operating expenses	594,113	1,738,128	1,248,599	3,571,902
Amortization of intangible assets	211,234	211,234	422,469	422,469
Selling, general and administrative	6,086,047	5,438,480	11,681,517	10,759,661
Total operating expenses	17,899,616	18,073,931	34,636,621	38,648,440
LOSS FROM OPERATIONS	(11,338,674)	(13,417,381)	(24,547,090)	(29,949,884)
OTHER INCOME (EXPENSE):				
Interest and other income	209,808	33,070	337,207	59,616
Interest expense	(2,072,578)	(1,359,188)	(3,613,085)	(2,682,340)
Loss on extinguishment of debt	-	-	(9,962,495)	-
Gain on transfer of plasma center assets	-	-	11,527,421	-
Other (expense) income	(10,428)	(4,332)	(21,785)	2,635
Other expense, net	(1,873,198)	(1,330,450)	(1,732,737)	(2,620,089)
NET LOSS	$(13,211,872)	$(14,747,831)	$(26,279,827)	$(32,569,973)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.25)	$ (0.35)	$ (0.53)	$ (0.74)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	52,206,204	42,712,168	49,295,805	44,007,409

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2019	December 31, 2018
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 73,615,909	$ 22,754,852
Accounts receivable, net	5,086,663	1,392,441
Inventories	23,589,750	18,616,169
Prepaid expenses and other current assets	1,596,671	1,766,163
Total current assets	103,888,993	44,529,625
Property and equipment, net	29,444,489	30,115,730
Intangible assets, net	3,581,943	4,004,412
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	-	1,153,508
Restricted cash	-	4,000,000
Deposits and other assets	2,829,186	1,543,737
TOTAL ASSETS	$ 143,274,120	$ 88,876,521
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,788,144	$ 5,900,394
Accrued expenses and other current liabilities	2,974,476	3,551,835
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	223,114	29,983
Total current liabilities	10,128,568	9,625,046
Senior notes payable, net of discount	67,468,637	26,440,830
End of term liability, notes payable	-	2,760,000
Deferred revenue, net of current portion	2,332,949	2,404,365
Subordinated note payable, net of discount	14,890,711	14,874,184
Obligation to transfer assets under purchase agreement	-	12,621,844
Lease obligations, net of current portion	1,414,976	119,080
Other non-current liabilities	132,418	260,734
TOTAL LIABILITIES	96,368,259	69,106,083
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
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, 59,317,806 and 46,353,068 shares issued and outstanding	5,932	4,635
Additional paid-in capital	289,616,994	236,203,041
Accumulated deficit	(242,717,065)	(216,437,238)
TOTAL STOCKHOLDERS' EQUITY	46,905,861	19,770,438
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 143,274,120	$ 88,876,521

ADMA BIOLOGICS

Source: ADMA Biologics, Inc.