UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 7, 2019

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-36728	56-2590442
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

465 State Route 17, Ramsey, New Jersey	07446
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (201) 478-5552

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

ADMA Biologics, Inc. (the "Company") has updated its investor presentation (the "Investor Presentation") and a copy of the slides comprising the Investor Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Investor Presentation may also be accessed under the "Investor Relations" tab on the Company's website at www.admabiologics.com.

In accordance with General Instruction B.2 on Form 8-K, the information set forth in this Item 7.01 and the Investor Presentation slides, attached to this report as Exhibit 99.1, are "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Please refer to Exhibit 99.1 for a discussion of certain forward-looking statements included therein and the risk and uncertainties related thereto.

Item 8.01 Other Events.

On January 7, 2019, the Company issued a press release announcing that the Company has submitted responses to the U.S. Food and Drug Administration ("FDA") Complete Response Letter received on December 19, 2018 for BIVIGAM®'s (Intravenous Immune Globulin [Human], 10%) ("BIVIGAM®") Prior Approval Supplement ("PAS"). The Company anticipates receiving an acknowledgement letter from the FDA within 30 days, and plans to provide appropriate updates on the progress of the BIVIGAM® PAS review.

The full text of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	ADMA Biologics, Inc. January 2019 Investor Presentation.
99.2	ADMA Biologics, Inc. Press Release, dated January 7, 2019.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

January 7, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer


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ADMA Biologics
Groundbreaking Immunotechnology, One Connection at a Time
January 2019
Nasdaq: ADMA

FORWARD-LOOKING STATEMENTS

This presentation 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"), including, without limitation, statements 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 also include, without limitation, the anticipated benefits and synergies of our June 2017 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, 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, as well as a positive review of the optimized manufacturing process under a Prior Approval Supplement and related CRL responses 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 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, 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. The forward-looking statements contained herein represent the Company's estimates and assumptions only as of the date of this presentation, and the Company undertakes no duty or obligation to update or revise publicly any forward-looking statements contained in this presentation. 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.

WHO WE ARE

OUR MISSION

ADMA Biologics is a vertically integrated commercial biopharmaceutical company committed to manufacturing, marketing and developing specialty plasma-derived products for the immune-compromised and other patients at risk for infection.

It is our devotion to these underserved populations that fuels us, and our hands-on approach to production and development that sets us apart.

CORPORATE HIGHLIGHTS

VERTICALLY-INTEGRATED COMMERCIAL BIOPHARMACEUTICAL COMPANY

Operates an FDA-approved 400,000L capacity plasma therapeutics manufacturing facility with potential for expansion

Products acquired: Nabi-HB® (Hepatitis B IG, Human) and BIVIGAM® (IVIG, Human)

Control all aspects of drug substance manufacturing, regulatory compliance and business operations

Ability to increase market share and grow revenue through anticipated product launches

Plans to expand pipeline with significant cost savings and differentiated immune product candidates

RI-002: LEAD PIPELINE PRODUCT CANDIDATE

- Novel IVIG, manufactured using a unique, patented plasma pooling design
- Pivotal Phase III trial in PIDD met primary endpoint and reported positive secondary endpoints
- BLA resubmitted 3Q 2018 with Prescription Drug User Fee Act (PDUFA) action due date of April 2, 2019

REVENUE OPPORTUNITIES FROM MULTI-FACETED PLATFORM

- Current commercial U.S. FDA licensed products
- Contract manufacturing and laboratory services agreements in place
- Intermediate paste sales
- ADMA Bio Centers plasma collection subsidiary provides source plasma to 3rd parties
- Additional plasma-based product candidates in development

- Multiple revenue sources, experienced executive leadership team
- Near and mid-term value creating milestones

CURRENT NEAR & MID-TERM OBJECTIVES

Regulatory Update

- Manufacturing plant FDA compliance status improved to Voluntary Action Indicated (VAI)
- FDA approval received for BIVIGAM® Prior Approval Supplement (PAS) Drug Product Fill/Finish
- Rapid response submitted January 4, 2019 to FDA for BIVIGAM® PAS Complete Response Letter (CRL)
- RI-002 BLA Resubmitted to FDA for approval - April 2, 2019 PDUFA target action date
- Continue to manufacture and release NABI-HB® for commercial sale

Our Top Priorities:

- Ongoing continuous improvements to quality management systems and enhancements to manufacturing processes
  - Continue to release commercial drug product
- Ensure that Warning Letter is closed-out
- Obtain approval for BIVIGAM® in the U.S.
- Relaunch BIVIGAM® in the U.S.
- Increase penetration and utilization of Nabi-HB®
- Obtain approval for RI-002 – expected 2Q19
- Launch of RI-002 – expected 2H 2019

Solidifying the foundation for corporate cultural change and operational excellence

EXPERIENCED MANAGEMENT TEAM AND BOARD OF DIRECTORS

NAME	SELECTED CURRENT OF PAST AFFILIATIONS
Adam Grossman Founder, President, CEO & Director	MedImmune; GENESIS BPS; Genesis Bio-Pharmaceuticals, Inc.; nhs NATIONAL HOSPITAL SPECIALTIES; American Red Cross
Brian Lenz, CPA Executive Vice President, Chief Financial Officer	KPMG; BioNJ; CorMedix
James Mond, MD, PhD Executive Vice President, Chief Scientific Officer & Chief Medical Officer	National Institutes of Health; BIOSNEXUS Incorporated;
Steven Elms Chairman	AISLING CAPITAL; HAMBRECHT & QUIST
Dr. Jerrold Grossman Founder & Vice Chairman	GENESIS BPS; Genesis Bio-Pharmaceuticals, Inc.; nhs NATIONAL HOSPITAL SPECIALTIES; immuno; New York Blood Center
Lawrence Guiheen Director	Baxter; PPTA; KEDRION BIOPHARMA
Eric Richman Director	PharmAthene; MedImmune; HealthCare Ventures LLC
Dov Goldstein, MD Director	AISLING CAPITAL; HealthCare Ventures LLC; Vicuron Pharmaceuticals
Bryant Fong Director	BIOMARK CAPITAL

BLOOD & PLASMA COMPOSITION

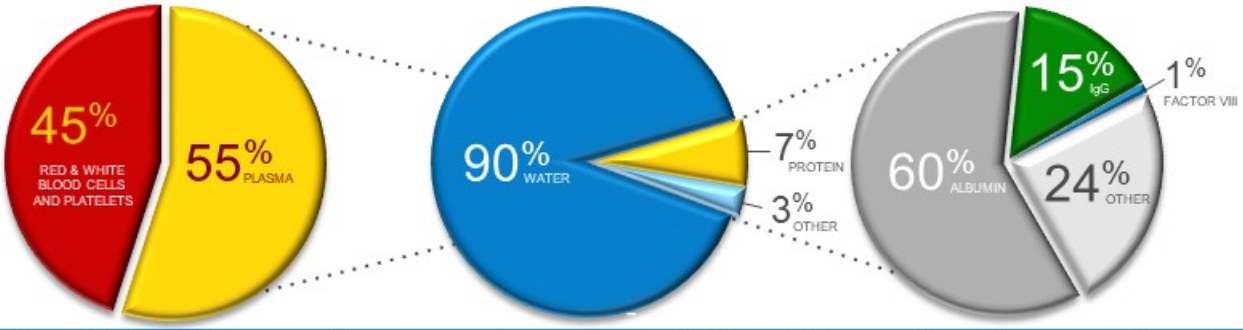
Blood Contains: Plasma, Red Cells, White Cells and Platelets

Plasma Contains: Protein and Water

Plasma Proteins Contain Many Therapeutic Benefits

- IVIG is made from a key therapeutic protein in plasma: IgG
- IgG = naturally occurring polyclonal antibodies against bacteria, fungus and viruses
- Other therapeutic products made from plasma proteins include: albumin, coagulation factors, alpha-1, C-1 etc.

Composition of Blood



ADMA optimized IG manufacturing process to include validation for all intermediate fractions
- Maximizing revenue from each L of plasma

ADMA IS ONE OF A HANDFUL OF VERTICALLY INTEGRATED PLASMA PRODUCTS AND SPECIALTY IMMUNE GLOBULIN MANUFACTURERS IN THE U.S.

- Track record of receiving FDA approval for plasma collection centers
- ~400,000L annual capacity plasma fractionation and purification plant operating in FDA compliance
- ADMA Bio Centers subsidiary provides a portion of source plasma
- Full regulatory, quality and compliance control of all products and operations
- FDA licensed products including Nabi-HB® (Hepatitis B Immune Globulin, Human) and BIVIGAM® (Immune Globulin Intravenous, Human)
- RI-002 BLA resubmitted 3Q18, with PDUFA target action date of April 2, 2019
- Strong patent portfolio across hyperimmune IG landscape
- Experienced plasma products commercialization team
- Acquired contractual agreement for manufacturing of immune globulin paste for a third party's licensed hyperimmune globulin
- Platform for developing additional hyperimmune and specialty IG products
- Additional potential contract manufacturing opportunities to add accretive revenues

Building blocks in place to support manufacturing and commercial product opportunities to generate meaningful sources of revenue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Market Opportunities
Commercial Overview, RI-002 & Pipeline
Nasdaq: ADMA

GROWTH DRIVERS: PLASMA MARKET IS SIZEABLE

IMMUNE GLOBULIN (IG) (e.g., BIVIGAM®) is a pooled plasma product from healthy plasma donors, containing a range of polyclonal antibodies against common pathogens

IG IS USED TO TREAT A WIDE VARIETY OF DISORDERS

- Primary immune deficiencies
- Autoimmune diseases
- Immune-compromised patients
- Neuropathic diseases

IG WIDELY MARKETED IN THE U.S.

7 companies are currently marketing IG, including CSL Behring, Grifols and Shire

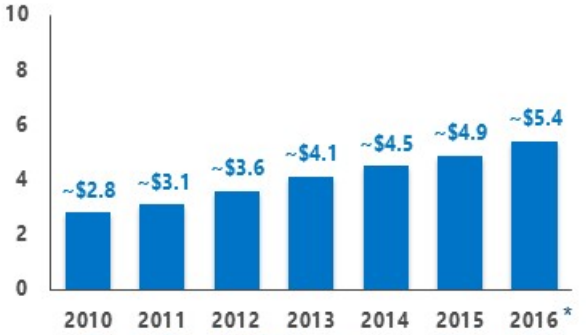
IG UTILIZATION INCREASING DUE TO

- New research and data
- New markets (emerging countries)
- Aging population

~$6 Billion U.S. Immune Globulin (IG) Market

U.S. IG market (2010-16)

Billions of dollars



*** Plus 2016 ~ $300M Hyperimmune Globulin Sales**

Projected 5 to 7% year over year growth anticipated through 2027

Source: ADMA information, on file, AAAAI, FDA, Product prescribing information, United Healthcare, Aetna, L.E.K. Consulting research and analysis
Any market information for IVIG is not necessarily indicative of the expected market for RI-002, BIVIGAM® or Nabi-HB®

COMMERCIAL PRODUCTS: ESTABLISHED BRANDS IN AN EXPANDING IG MARKET

BIVIGAM®
(Immune Globulin Intravenous, Human)
FDA-Approved protection against serious infections

- Human intravenous immune globulin, 10% liquid
- Indicated for the treatment of patients with PIDD
- Contains a wide spectrum of polyclonal antibodies against endemic pathogens

Nabi-HB®
(Hepatitis B Immune Globulin, Human)
FDA-Approved to provide enhanced immunity against Hepatitis B

- Successfully used for over 17 years to protect against hepatitis B infection among newly exposed individuals
- Manufactured from plasma obtained from vaccinated donors with high titers of human antibodies to Hepatitis B surface antigen, anti-HBs

Immediate commercial product opportunity with established immunoglobulin brands

IG IS WIDELY USED AND REIMBURSED

FDA-Approved Uses*

- Primary immunodeficiency (PIDD)
- Multifocal motor neuropathy
- B-cell chronic lymphocytic leukemia
- Immune thrombocytopenic purpura
- Kawasaki syndrome
- Chronic inflammatory demyelinating polyneuropathy

Additional Reimbursed Evidence-Based Uses

- Acquired red cell aplasia
- Bone marrow transplantation
- Dermatomyositis
- Enteroviral meningoencephalitis
- Established bacterial sepsis
- Multiple sclerosis
- Multiple myeloma
- Myasthenia gravis
- Neonatal hemochromatosis
- Parvovirus B19
- Pediatric HIV
- Post transfusion purpura
- Rasmussen's syndrome
- Renal transplant from liver donor
- Solid organ transplantation
- Staphylococcal toxic shock
- Systemic lupus erythematosus
- Toxic epidemal necrolysis

Payers appreciate and understand the proven, evidence-based benefits of IG

* Not all uses approved for all IG products by FDA.
Source: ADMA information, on file, AAAAI, FDA, Product prescribing information, United Healthcare, Aetna, L.E.K. Consulting research and analysis

PIDD IS A SIGNIFICANT MARKET OPPORTUNITY FOR ADMA

~250,000 PIDD PATIENTS in the U.S.

~50% are treated with IG

THE ADMA PORTFOLIO OF IG PRODUCTS can help treat two major subsets of the PIDD population

BIVIGAM® targets the general population of 250,000 PIDD patients

RI-002 could target the most at-risk and severely immune compromised population of PIDD patients (chart on right), if approved

RI-002 Potential Target Population

Class	Est. Incidence (U.S.) Population	Target Population Numbers
Common Variable Immune Deficiency (CVID)	1 in 25,000 to 1 in 50,000 (7,000-14,000 patients)	2,000 to 5,000 patients
Severe Combined Immune Deficiency Syndrome (SCID)	New diagnoses of ~100 cases reported each year	500-1,000 patients on IVIG post transplant
Wiskott-Aldrich Syndrome (WAS)	4 in every 1,000,000 males has the disorder – sometimes not diagnosed until adulthood	600 patients on IVIG therapy
DiGeorge Syndrome (DGS)	1 in 4,000 births suffers from DGS (700-800 patients)	1,000 patients receive IVIG therapy
Ataxia Telangiectasia (AT)	1 in 40,000 to 1 in 100,000	3,000 to 8,000 patients
X-Linked Hyper IgM Deficiency (XHMD)	2 in every 1,000,000 males	350 patients receive IVIG therapy
X-Linked Agammagobulinanemia (XLA)	1 in 10,000 are diagnosed with XLA (35,000 patients)	3,500 patients are more susceptible to viral infections

Potential relaunch of BIVIGAM® offers opportunity to increase ADMA's market penetration in PIDD market by approximately 10X

Source: ADMA information, on file, AAAAI, FDA, Product prescribing information, United Healthcare, Aetna, L.E.K. Consulting research and analysis

ADMA IS THE VOICE OF THE PIDD PATIENT

Risk Factors for Infection in PIDD

- Type and severity of immune deficiency
- Age
- Impaired pulmonary function
  - Bronchiectasis
  - Asthma
  - History of respiratory infection/environmental conditions
  - Chronic lung disease

2013 IDF National PIDD Patient Treatment Survey

63%

of respondents reported having asthma, 13% have COPD

46%

of PIDD patients reported they suffer from chronic lung conditions

40%

of PIDD patients report lung infections and other infections in the prior 12 months

~5%

of PIDD patients reported being hospitalized in the prior 12 months due to lung impairments

One infection is one too many!
Each time a PIDD patient gets a serious infection, irreparable damage occurs

LEADING A NEW PARADIGM IN IMMUNOTECHNOLOGY: RI-002

RI-002

- Our lead product candidate, RI-002, is being developed for the treatment of PIDD
- Completed a pivotal Phase III clinical study, met primary endpoint and reported positive secondary endpoint(s)
- RI-002 is the basis for ADMA's patented methodology
- Resubmitted BLA for RI-002 in 3Q 2018, PDUFA target action date April 2, 2019

The Donors Make The Difference

- RI-002 is manufactured using a plasma pool which is formed by using normal source plasma and plasma from donors tested to have high-titers to respiratory syncytial virus (RSV)
- We then use a process called fractionation, which purifies immune globulins (IgG)
- This blended plasma pool results in a final IVIG product containing naturally occurring polyclonal anti-pathogen antibodies

Our IP & Process Sets Us Apart

- We use our proprietary, patented RSV microneutralization assay to test for appropriate levels of neutralizing antibodies to RSV in the donor plasma and in the final drug product
- Patent is titled "Compositions and Methods for Treatment of Immunodeficiency"
- Patent is first of its kind for use of polyclonal immunoglobulin for treatment of respiratory infections
- Expires in 2035

RI-002 demonstrated positive results and met its primary endpoint in the pivotal Phase III study in patients with PIDD

DISCOVER THE DIFFERENCE OF ADMA'S PATENTED IMMUNOTECHNOLOGY

SCREEN AND IDENTIFY HIGH-TITER DONORS

Hyperimmune donors with high-titer antibodies to select pathogens are identified

PROPRIETARY TESTING

A proprietary microneutralization assay quantitatively measures titer levels of neutralizing RSV antibodies

TAILORED COMPOSITIONS

Tailored plasma pools are derived from a unique blend of normal source plasma and high-titer antibody rich plasma

PATENTS ISSUED

9,107,906
9,714,283
9,815,886
9,969,793
Expiration 2035

ADMA PIPELINE

Potential Follow-On Indication Populations for RI-002

After initial FDA approval, ADMA may seek to expand the label for RI-002 to address these populations' unmet medical needs regarding RSV infection management

- HSCT/Bone Marrow Transplant
  - ~25,000 procedures/year performed in the U.S.
- Solid Organ Transplant (lung, heart, liver and multi-organ)
  - ~11,000 solid organ transplants/year (excluding kidney transplants) performed in the U.S.
- Cancer patients receiving chemotherapy
  - ~375,000 patients/year receive chemotherapy in the U.S. (winter months)

Published data suggests additional label expansion opportunities may be available for RI-002 RSV post approval for PIDD

Potential Follow-On Specialty Plasma Products

By leveraging ADMA's IP, know-how and expertise, we may seek to expand our product portfolio with additional specialty IG products by building upon our core competency of identifying high-titer plasma donors and plasma products manufacturing expertise

We believe ADMA's IP and manufacturing capabilities establish a platform for developing future specialty IG products targeting problematic pathogens

ADMA PRODUCTS, PIPELINE AND ONGOING R&D

Product / Candidate	R&D Activity / Other Information	Pre-clinical	Phase I	Phase II	Phase III	BLA Submitted	FDA Approved / Marketed
BIVIGAM® Human, Immunoglobulin intravenous	Pediatric Indication / Manufacturing Optimization						Awaiting FDA action on CRL responses for Prior Approval Supplement
Nabi-HB® Hepatitis B, Hyperimmune Globulin	IM formulation						
RI-002 Human, Immunoglobulin intravenous	IG prepared from donors tested for high titers against RSV						
Pathogen of interest - New Product 1	Assay and specialty donor collection program						
Pathogen of interest - New Product 2	Assay and specialty donor collection program						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Milestones & Financial Highlights
Nasdaq: ADMA

MILESTONES

Recently Completed

- Successfully closed-out April 2018 FDA inspection
  - Inspection classification status improved to VAI
- Submitted RI-002 CRL response and resubmitted BLA for review
  - Received PDUFA target action date of April 2, 2019
- Responded to CRL for BIVIGAM® PAS
- Obtained FDA approval for Kennesaw, GA plasma collection center
- Achieved year-over-year revenue growth in 2018
- Extinguished approximately 19% of total outstanding common stock issued to BPC in June 2017 (8.6M shares)
- Four U.S. patents granted for compositions and methods for the treatment of immunodeficiency

Other Significant Milestones and Achievements

- Completed acquisition and integration of strategic manufacturing assets and commercial products from BPC
- Phase III study RI-002: Positive primary endpoint data
  - Secondary endpoint results announced from positive Phase III trial
  - Peer reviewed publication of final study analysis and results

Future & Ongoing Objectives

1H19:

- Work with FDA to close-out Warning Letter
- Obtain FDA approval for BIVIGAM® PAS
- Relaunch BIVIGAM® in the U.S.
- PDUFA target action date April 2, 2019 for RI-002
- Potential commercial sales of RI-002
- Disclose potential product development pipeline consisting of additional specialty plasma and/or hyperimmune IG products

2H19:

- Commercial launch for RI-002
- Increase BIVIGAM® and Nabi-HB® revenues
- Achieve year-over-year revenue growth in 2019

FINANCIAL INFORMATION

Financial Summary: 09/30/18 Results	
Cash, cash equivalents and short-term investments	$42.4M
Total assets	$106.3M
Total liabilities	$69.1M
Total stockholders' equity	$37.2M
Revenue	$12.9M
Common stock outstanding	46.4M
Fully diluted common stock outstanding	51.2M

SUBSTANTIAL REVENUE OPPORTUNITIES AND PRODUCT DEVELOPMENT PLATFORM

- FDA LICENSED FACILITY
- PROCESS VALIDATION
- EXISTING COMMERCIAL PRODUCTS
- PIPELINE USING IMMUNOTECHNOLOGY IP

- VERTICAL INTEGRATION
- ABILITY TO SUPPLY A PORTION OF THE INTERNAL NEEDS AND SELL TO 3rd PARTIES
- NORMAL SOURCE & HYPERIMMUNE COLLECTION ABILITIES

- CURRENT CONTRACT FOR HYPERIMMUNE GLOBULIN
- MONOCLONAL FACILITY
- FULL QC LABORATORY

- Multiple revenue sources, experienced executive leadership team
- Near and mid-term value creating milestones

ADMA Biologics Submits Response and Provides Supplemental Information to FDA for BIVIGAM® Complete Response Letter

RAMSEY, N.J. and BOCA RATON, FL., – January 7, 2019 – 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, announces that the Company has submitted responses to the U.S. Food and Drug Administration ("FDA") Complete Response Letter ("CRL") received on December 19, 2018 for BIVIGAM®'s (Intravenous Immune Globulin [Human], 10%) ("IVIG") Prior Approval Supplement ("PAS"). The Company anticipates receiving an acknowledgement letter from the FDA within 30 days, and plans to provide appropriate updates on the progress of the BIVIGAM® PAS review.

About ADMA Biologics, Inc. (ADMA)
ADMA Biologics is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-based biologics for the 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 other medical reasons. ADMA has received U.S. Patents 9,107,906, 9,714,283, 9,815,886 and 9,969,793 related to certain aspects of its lead product candidate, RI-002. For more information, please visit www.admabiologics.com.

About BIVIGAM®
BIVIGAM® is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These primary immunodeficiencies ("PI") 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 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 PIDD patients against serious infections. BIVIGAM® is a purified, sterile, ready-to-use preparation of concentrated polyclonal 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 Biotest Pharmaceuticals Corporation ("BPC" or "Biotest") on December 19, 2012, and production of BIVIGAM® was halted by Biotest in December 2016. ADMA Biologics obtained ownership and all rights, title and interest in BIVIGAM® on June 6, 2017 as part of the Biotest Therapy Business Unit ("BTBU") asset acquisition and resumed the production of BIVIGAM during the fourth quarter of 2017.

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 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 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 and product candidates, and the labeling or nature of any such approvals, the success of our work with our third party vendors and the U.S. Food and Drug Administration (the "FDA") 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 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 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. 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. 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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