

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): September 5, 2018

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36728
(Commission
File Number)

56-2590442
(IRS Employer
Identification No.)

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

07446
(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):

- 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 8.01. Other Events.

As previously disclosed, at 3:25 PM ET on September 5, 2018, members of the management team of ADMA Biologics, Inc., a Delaware corporation (the “Company”), plan to present at the 20th Annual Rodman & Renshaw Global Investment Conference in New York, New York (the “Investor Presentation”). The Investor Presentation will be webcast live and may be accessed under the “Investor Relations” tab on the Company’s website at www.admabiologics.com. Additionally, a copy of the slides comprising the Investor Presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	ADMA Biologics, Inc. September 2018 Investor Presentation.

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.

September 5, 2018

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics

Groundbreaking Immunotechnology, One Connection at a Time

September 2018

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 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.

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.

COMPLETED STRATEGIC TRANSACTION IN JUNE 2017 – COMMERCIAL OPERATIONS

- Operates a 400,000L capacity FDA-approved plasma products and production facility, and successfully closed-out April 2018 FDA compliance inspection of the facility. Facility status upgraded to “VAI” in September 2018
- Control all aspects of drug substance manufacturing, regulatory compliance and business operations
- Transaction resulted in our ability to increase margins/reduce costs
- Acquired two commercial products: Nabi-HB® (Hepatitis B IG, Human) and BIVIGAM® (IVIG, Human)
- 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 resubmission targeted for 2H 2018

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 BioCenters 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

Recent Regulatory Achievements

- October 25, 2018 Prescription Drug User Fee Act (PDFUA) target action date for BIVIGAM® relaunch
- Successfully closed-out April 2018 FDA compliance inspection of Boca Raton, FL facility
- Inspection classification status: Voluntary Action Indicated (VAI)

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
 - Optimized IG manufacturing process
 - Submitted PAS for BIVIGAM®
 - Relaunch BIVIGAM® in the U.S.
 - Resubmit the BLA for RI-002 for FDA review and approval
 - Obtain approval of third plasma center
 - Increase penetration and utilization of Nabi-HB®



Building 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					
Brian Lenz, CPA Chief Financial Officer					
James Mond, MD, PhD Chief Scientific Officer & Chief Medical Officer					
Steven Elms Chairman					
Dr. Jerrold Grossman Founder & Vice Chairman					
Lawrence Guiheen Director					
Eric Richman Director					
Dov Goldstein, MD Director					
Bryant Fong Director					

BLOOD & PLASMA COMPOSITION

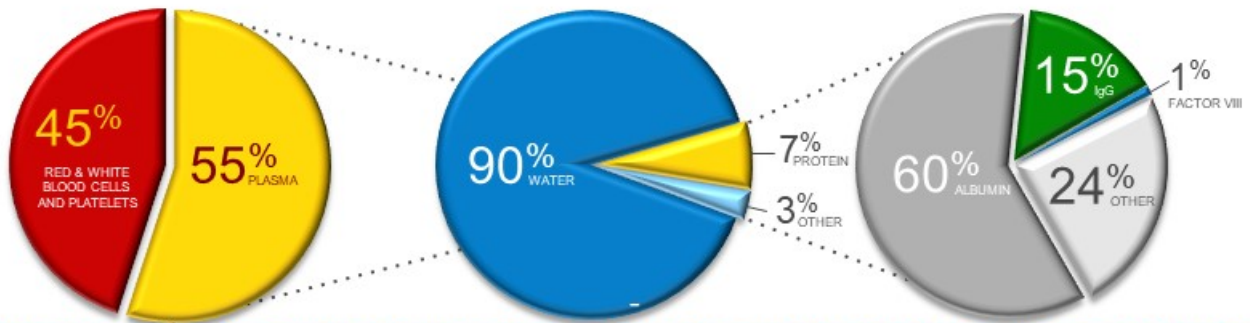
Blood Contains: Plasma, Red Cells, White Cells and Platelets

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.

- Plasma collection centers
- ~400,000L annual peak capacity plasma fractionation and purification plant
- 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 on track for resubmission in 3Q18, with first commercial sales anticipated in 1H19
- 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

Market Opportunities

Commercial Overview, RI-002 & Pipeline

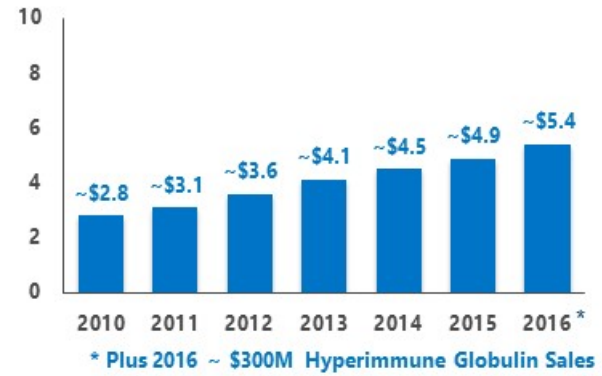
Nasdaq: ADMA

IMMUNE GLOBULIN (IG) (eg, Bivigam®) is a pooled plasma product from healthy plasma donors, containing a range of polyclonal antibodies against common pathogens

<p>IG IS USED TO TREAT A WIDE VARIETY OF DISORDERS</p> <ul style="list-style-type: none"> • Primary immune deficiencies • Autoimmune diseases • Immune-compromised patients • Neuropathic diseases 	<p>IG WIDELY MARKETED IN THE U.S.</p> <p>7 companies are currently marketing IG, including CSL Behring, Grifols and Shire</p>	<p>IG UTILIZATION INCREASING DUE TO</p> <ul style="list-style-type: none"> • New research and data • New markets (emerging countries) • Aging population
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~\$6 Billion U.S. Immune Globulin (IG) Market

U.S. IG market (2010-16)
Billions of dollars



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*	Additional Reimbursed Evidence-Based Uses		
<ul style="list-style-type: none"> Primary immunodeficiency (PID) Multifocal motor neuropathy B-cell chronic lymphocytic leukemia Immune thrombocytopenic purpura Kawasaki syndrome Chronic inflammatory demyelinating polyneuropathy 	<ul style="list-style-type: none"> Acquired red cell aplasia Bone marrow transplantation Dermatomyositis Enteroviral meningoencephalitis Established bacterial sepsis Multiple sclerosis 	<ul style="list-style-type: none"> Multiple myeloma Myasthenia gravis Neonatal hemochromatosis Parvovirus B19 Pediatric HIV Post transfusion purpura 	<ul style="list-style-type: none"> Rasmussen's syndrome Renal transplant from liver donor Solid organ transplantation Staphylococcal toxic shock Systemic lupus erythematosus Toxic epidermal 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

RI-002 Potential Target Population

~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

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 Agammaglobulinemia (XLA)	1 in 10,000 are diagnosed with XLA (35,000 patients)	3,500 patients are more susceptible to viral infections

The acquisition of BIVIGAM® is expected to result in a 10X increase in potential market penetration opportunity in PIDD

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

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



- 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
- Resubmission of BLA for RI-002 planned for 3Q 2018

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

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

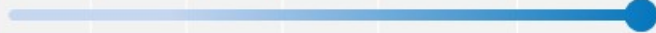

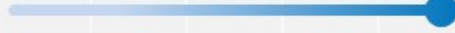


Potential Follow-On Specialty Plasma Products

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



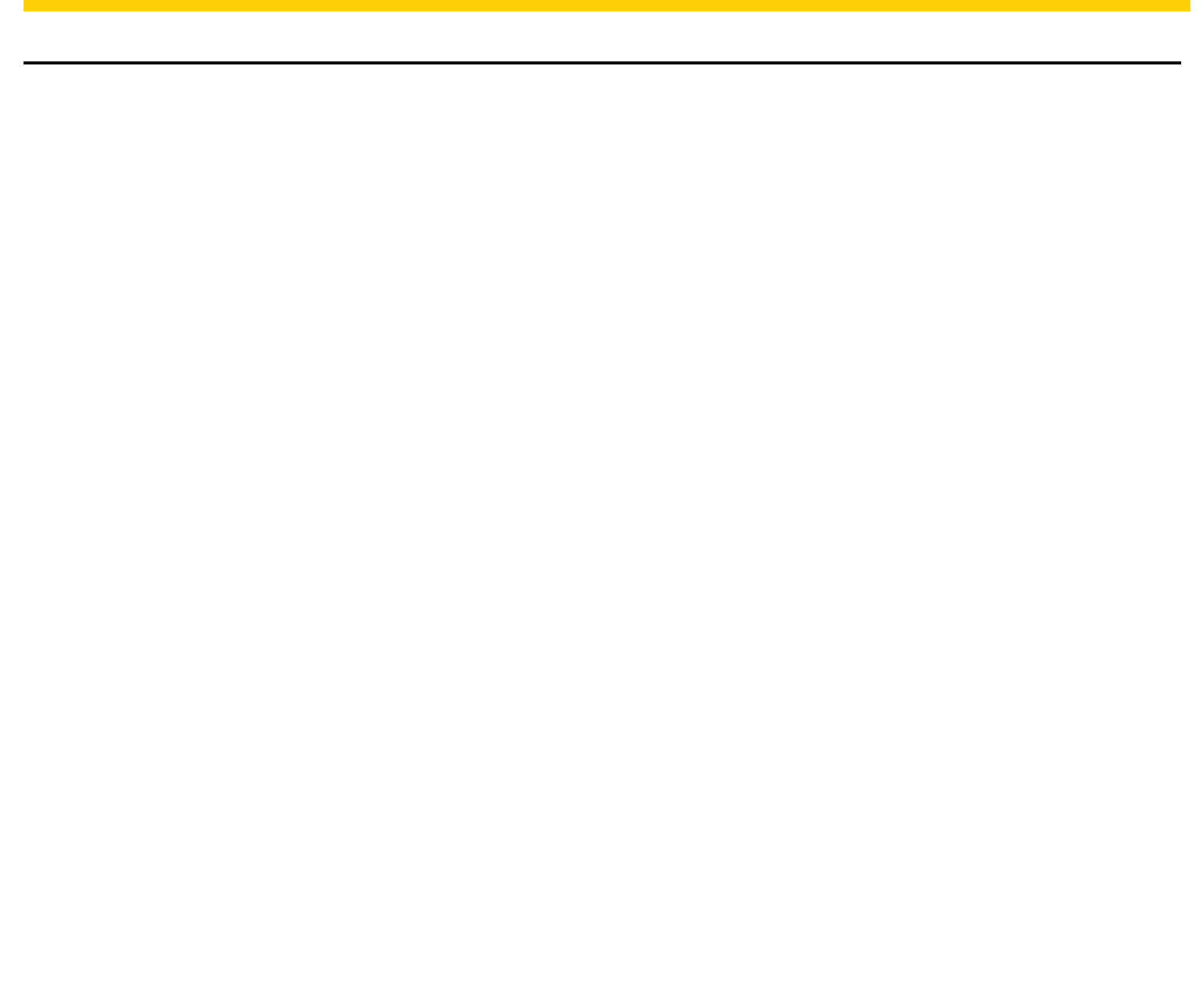
We believe ADMA's IP and manufacturing capabilities establish a platform for developing future specialty IG products targeting problematic pathogens

ADMA PRODUCTS, PIPELINE AND ONGOING R&D

Product / Candidate	R&D Activity / Other Information	Pre-clinical	Phase I	Phase II	Phase III	BLA Submitted	Marketed/ Phase IV
BIVIGAM® Human, Immunoglobulin intravenous	Pediatric Indication / Manufacturing Optimization						
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						

Milestones & Financial Highlights

Nasdaq: ADMA



MILESTONES

Completed in Last Twelve Months

- Successfully closed-out April 2018 FDA inspection
- Inspection classification status: VAI
- Submitted PAS for optimized BIVIGAM®/IVIG manufacturing process, received PDUFA target date of October 25, 2018
- Extinguished 8.6 million shares of non-voting common stock (~19%) issued to BPC in June 2017
- Upsized November 2017 and June 2018 equity offerings
- Year-over-year revenue growth
- Four U.S. patents granted for compositions and methods for the treatment of immunodeficiency
- BLA filed for 3rd ADMA BioCenter

Other Significant Milestones

- Completed acquisition and integration of strategic assets from BPC
- Phase III study RI-002: Positive primary endpoint data announced
- Secondary endpoint results announced from positive Phase III trial

Future & Ongoing Objectives

2H18:

- Respond to CRL and Resubmit BLA for RI-002
- PDUFA date supporting BIVIGAM® relaunch
- Work with FDA to close-out Warning Letter
- Obtain FDA approval for 3rd plasma collection center

1H19:

- Resume supply of BIVIGAM® no later than 1Q19
- PDUFA anticipated and with potential commercial sales of RI-002
- Disclose potential product development pipeline consisting of additional specialty hyperimmune IG products

2H19:

- Full commercial and promotional launch for RI-002
- Grow BIVIGAM® and Nabi-HB® revenues

Financial Summary: 06/30/18 Results

Cash, cash equivalents and short-term investments	\$55.2M
Total assets	\$117.8M
Total liabilities	\$66.0M
Total stockholders' equity	\$51.8M
Revenue	\$8.7M
Common stock outstanding	46.3M
Fully diluted common stock outstanding	51.1M

SUBSTANTIAL REVENUE OPPORTUNITIES AND PRODUCT DEVELOPMENT PLATFORM

DRUG MANUFACTURING COMMERCIAL & PIPELINE PRODUCTS

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

PLASMA COLLECTION

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

CONTRACT MANUFACTURING & TESTING

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

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

APPENDIX

Nasdaq: ADMA

OVERVIEW OF BPC ASSET ACQUISITION



Core assets acquired by ADMA from Biotest Pharmaceuticals Corporation (BPC):

- FDA-approved biologics plasma production fractionation facility responsible for RI-002 manufacturing
- FDA licensed products including Nabi-HB® (Hepatitis B Immune Globulin, Human) and BIVIGAM® (Immune Globulin Intravenous, Human)
- Contract manufacturing and services agreement for a third party's licensed Hyperimmune globulin product
- Cash consideration to ADMA totaling up to \$40 million from BPC
 - \$12.5 million in cash upon closing
 - \$15.0 million unsecured subordinated loan at a six (6%) percent per annum interest rate
 - Commitment to invest up to an additional \$12.5 million in future equity financings of ADMA

Consideration to BPC:

- Fifty percent less one share of ADMA's then-outstanding capital stock
- Right to nominate one director for election and to designate one observer to ADMA's Board
- Ownership of ADMA's 2 wholly-owned plasma centers, effective January 1, 2019
- Maintain existing distribution rights granted for RI-002 in Europe, Near and Middle East and selected other territories, receive right of first offer for distribution of potential future ADMA products
- Update – May 14, 2018: ADMA extinguished 8.6M shares of non-voting stock previously issued to BPC and BPC forfeited its right to nominate one director for election and to designate one observer to ADMA's Board

Transaction Closed June 6, 2017

Positive Effect on RI-002 Gross Margins