

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): November 19, 2019

**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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	ADMA	Nasdaq Global Market

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.**

As previously disclosed, Adam Grossman, the President and Chief Executive Officer of ADMA Biologics, Inc., a Delaware corporation (the “Company”), plans to present at the Jefferies 2019 London Healthcare Conference in London, UK, on Wednesday, November 20, 2019 at 8:00 AM GMT (the “Investor Presentation”). The Investor Presentation will be webcast live and may be accessed under the “Investors” tab on the Company’s website at [www.admabiologics.com](http://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.

**Item 9.01 Exhibits.**

(d) Exhibits

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	<a href="#">ADMA Biologics, Inc. November 2019 Investor Presentation.</a>

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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.

November 19, 2019

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

## Jefferies 2019 London Healthcare Conference

November 20, 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. Such statements may contain the words "estimate," "project," "intend," "target," "anticipate," "plan," "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, statements relating to: our future and ongoing objectives; our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products; our belief that we are positioned to penetrate the growing immune globulin market; our plans to expand our pipeline with differentiated immune globulin product candidates in development; potential near and mid-term value creation through certain milestones; the possibility of expanding our product portfolio with additional specialty immune globulin 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 obtain adequate quantities of U.S. Food and Drug Administration ("FDA")-approved plasma with proper specifications; our plans to increase our supplies of plasma; our ability to expand our plasma center network, regulatory processes, interpretations of final data of our products and product candidates; acceptability of any of our products for any purpose, by physicians, patients or payers; possible additional reimbursed evidence-based uses for immune globulin products; estimates relating to our plasma processing capacity; the likelihood and timing of FDA action with respect to any further filings by the Company, results of clinical development, the potential of specialty plasma-derived biologics to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease ("PID"); our ability to market and promote our products in the competitive environment and to generate meaningful revenues; our projected year over year growth, anticipated through 2025; our ability to increase market share and grow revenue through anticipated product launches; potential clinical trial initiations; potential investigational new product applications, Biologics License Applications, and expansion plans; our intellectual property position, including our expectations of the scope of patent protection with respect to our products or other future pipeline product candidates; our belief that our intellectual property position and manufacturing capabilities establish a platform for developing future specialty immune globulin products; 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; potential contract manufacturing opportunities and sales of fractionation, intermediates to add accretive revenues; our estimates regarding expenses, capital requirements and needs for additional financing; possible or likely reimbursement levels for our currently marketed products and estimates regarding market size; projected growth and sales for our existing products as well as our expectations of market acceptance of BIVGAM<sup>®</sup> and ASCENIV<sup>™</sup>; future economic conditions and performance; expectations for future capital requirements; commercialization efforts relating to our products 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, except as otherwise required by the federal securities laws. 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.

Why does what we do matter? Because patients are counting on us.

## THREE APPROVED AND MARKETED PRODUCTS – MULTI-FACETED REVENUE PLATFORM

- Generated \$17M in revenues for full year 2018 and \$17.3M for first nine months of 2019
- BIVIGAM and ASCENIV now commercially available in the U.S.
- Revenues derived from commercial products, manufacturing intermediates, source plasma, CDMO/CMO activities

## SIGNIFICANT MARKET OPPORTUNITY

- Polyclonal Plasma Derived IG is a U.S. \$6B addressable market today; growing to over \$9B by 2025 (CAGR ~6%)
- 125,000 patients currently use IG routinely for PI
- IG is widely used and reimbursed in the U.S.
- Recent reports of tight IG supply in the U.S. leaving certain caregivers IG requirements underserved

## FDA APPROVED PLASMA THERAPEUTICS MANUFACTURING FACILITY

- 400,000L peak plasma processing capacity can yield ~1.5 million grams of finished immunoglobulin
- ADMA controls its manufacturing and regulatory compliance
- Facility provides further revenue generating opportunities through contract manufacturing and other initiatives

## CORPORATE AND FINANCIAL

- Multiple milestones recently achieved and YoY revenue growth
- Staffing to meet anticipated IG production ramp for all 3 ADMA brands
- Experienced leadership team

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

# BLOOD & PLASMA COMPOSITION

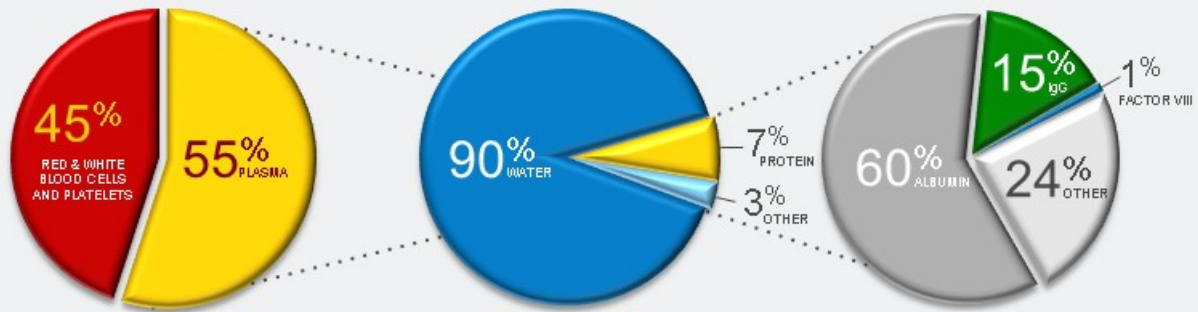
**Blood Contains:** Plasma, Red Cells, White Cells and Platelets

**Plasma Contains:** Protein and Water

**Plasma Proteins Contain Many Therapeutic Benefits:**

- Intravenous immunoglobulin (IVIg) is made from a key therapeutic protein in plasma: Immunoglobulin (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 includes validation for all intermediate fractions maximizing potential revenue from each L of plasma



# Plasma Products Portfolio & Pipeline

**ASCENIV**  
Immune Globulin Intravenous  
(Human) 10% Liquid

**BIVIGAM**  
IMMUNE GLOBULIN INTRAVENOUS  
(HUMAN), 10% LIQUID

**NabiHB**  
Hepatitis B  
Immune Globulin (Human)

Nasdaq: ADMA

# GROWTH DRIVERS: PLASMA IG MARKET IS SIZEABLE & GROWING

**IMMUNE GLOBULIN (IG or IVIG)** 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 Takeda

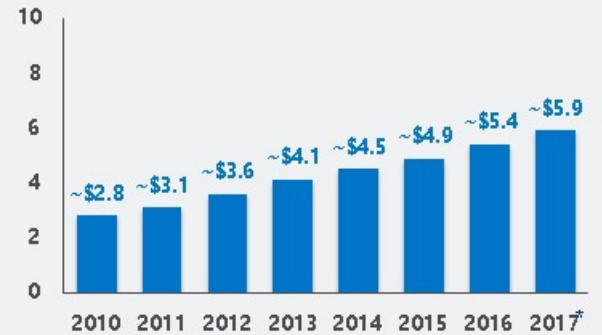
### IG UTILIZATION INCREASING DUE TO

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

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

### U.S. IG market (2010-17)

Billions of dollars



\* Plus 2017 ~ \$300M Hyperimmune Globulin Sales

Projected ~6% year over year growth anticipated through 2025

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 ASCENIV™, BIVIGAM® or Nabi-HB®

# IG IS WIDELY USED AND REIMBURSED

FDA-Approved Uses*	Possible Additional Reimbursed Evidence-Based Uses		
<p>Primary immunodeficiency (PI)</p> <p>Multifocal motor neuropathy</p> <p>B-cell chronic lymphocytic leukemia</p> <p>Immune thrombocytopenic purpura</p> <p>Kawasaki syndrome</p> <p>Chronic inflammatory demyelinating polyneuropathy</p>	<p>Acquired red cell aplasia</p> <p>Bone marrow transplantation</p> <p>Dermatomyositis</p> <p>Enteroviral meningoencephalitis</p> <p>Established bacterial sepsis</p> <p>Multiple sclerosis</p>	<p>Multiple myeloma</p> <p>Myasthenia gravis</p> <p>Neonatal hemochromatosis</p> <p>Parvovirus B19</p> <p>Pediatric HIV</p> <p>Post transfusion purpura</p>	<p>Rasmussen's syndrome</p> <p>Renal transplant from liver donor</p> <p>Solid organ transplantation</p> <p>Staphylococcal toxic shock</p> <p>Systemic lupus erythematosus</p> <p>Toxic epidermal necrolysis</p>

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

**ASCENIV**  
IMMUNE GLOBULIN INTRAVENOUS  
(HUMAN) 10% LIQUID

**ASCENIV™**  
(Immune Globulin Intravenous - sIra, Human)

**FDA-APPROVED PROTECTION AGAINST  
SERIOUS INFECTIONS**

- Indicated for the treatment of patients with PI
- Contains a wide spectrum of polyclonal antibodies against endemic pathogens
- Manufactured through ADMA's patented process using source plasma that is collected from donors screened using a microneutralization assay to detect and identify which donors possess naturally-occurring neutralizing antibody titers to Respiratory Syncytial Virus (RSV)

**BIVIGAM**  
IMMUNE GLOBULIN INTRAVENOUS  
(HUMAN), 10% LIQUID

**BIVIGAM®**  
(Immune Globulin Intravenous, Human)

**FDA-APPROVED PROTECTION AGAINST  
SERIOUS INFECTIONS**

- Indicated for the treatment of patients with PI
- Contains a wide spectrum of polyclonal antibodies against endemic pathogens

**Nabi-HB®**  
Hepatitis B  
Immune Globulin  
(Human)

**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

# PI IS A SIGNIFICANT MARKET OPPORTUNITY FOR ADMA

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

~50% are treated with IG

**THE ADMA PORTFOLIO OF IG PRODUCTS** offers alternatives and can help treat major subsets of the PI population

**At present, IVIG and IG products are listed in tight supply on drug shortage list**

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

**BIVIGAM® and ASCENIV™ Commercially Marketed Positions ADMA to Penetrate the Growing IG Market & Service Tight Supply Needs for Clinicians & Patients**

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



# ADMA IS AN ADVOCATE FOR THE PI PATIENT

*Different Patient Types Present with Different Risks for Infection*

## Risk Factors for Infection in PI

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



## Risk Factors for Infection in PI

**63%**  
of respondents reported having asthma, 13% have COPD

**46%**  
of PI patients reported they suffer from chronic lung conditions

**40%**  
of PI patients report lung infections and other infections in the prior 12 months

**~6%**  
of PI patients reported being hospitalized in the prior 12 months due to lung impairments

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

# DISCOVER THE NOVELTY OF ADMA'S PATENTED IMMUNOTECHNOLOGY USED TO MANUFACTURE ASCENIV™

## 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 in plasma donor samples

## TAILORED COMPOSITIONS

Tailored plasma pools are derived from a unique blend of normal source plasma and plasma obtained from the tested donors who have been selected due to their sufficient levels of RSV antibodies



## PATENTS ISSUED

9,107,906 - Composition  
9,714,283 - Use  
9,815,886 - Methods  
Expiration 2035

### Potential Target Populations for ASCENIV™

As previously disclosed, we believe the FDA approval of ASCENIV™ better positions ADMA to further its mission to evaluate ASCENIV™ in immune-compromised patients infected with or at-risk for Respiratory Syncytial Virus (RSV) infection.

- **HSCT/Bone Marrow Transplant**

- ~22,000 procedures/year performed in the U.S.

- **Solid Organ Transplant (lung, heart, liver and multi-organ)**

- ~14,000 solid organ transplants/year (excluding kidney transplants) performed in the U.S.

- **Cancer Patients Receiving Chemotherapy**

- ~650,000 patients/year receive chemotherapy in the U.S.

- **Others At-Risk for RSV Infection**

Published data suggests additional label expansion opportunities may be explored for ASCENIV™ now that it has FDA approval for PI



# cGMP Compliant Biologics Production Facility and QC Laboratory

## 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

# Milestones, Corporate Highlights and Financial Information

Nasdaq: ADMA

## RECENT MILESTONES & FUTURE OBJECTIVES

### RECENTLY COMPLETED

- ✓ Relunched BIVIGAM® with first commercial sales in the U.S.
- ✓ Obtained FDA approval for BIVIGAM® PAS
- ✓ First Commercial Sales of ASCENIV™
- ✓ Received FDA approval for ASCENIV™
- ✓ New license issued/transferred for manufacturing plant, BIVIGAM® and Nabi-HB® (#2019)
- ✓ Successfully closed-out April 2018 FDA inspection
  - Inspection classification status improved to Voluntary Action Indicated (VAI)
- ✓ Obtained FDA approval for plasma collection center
- ✓ Patent issued for *S. pneumonia* immune globulin

### FUTURE & ONGOING OBJECTIVES

- Ongoing commercial launches for BIVIGAM® and ASCENIV™
- Disclose potential product development pipeline consisting of additional specialty plasma and/or hyperimmune IG products
- Evaluate and implement strategy for potential manufacturing capacity expansion
- Expand plasma collection facility network

## Financial Summary: 9/30/19 Results

Cash and cash equivalents	\$48.0M
Total assets	\$137.8M
Total liabilities	\$101.7M
Total stockholders' equity	\$36.1M
Revenue (9 months)	\$17.3M
Common stock outstanding	59.3M
Fully diluted common stock outstanding	67.1M

\*Additional funding commitment of \$12.5M available through Perceptive Advisors at ADMA's option until March 31, 2020

# EXPERIENCED MANAGEMENT TEAM AND BOARD OF DIRECTORS

NAME	SELECTED CURRENT OR PAST AFFILIATIONS
<b>Adam Grossman</b> Founder, President, CEO & Director	    
<b>Brian Lenz, CPA</b> Executive Vice President, Financial Officer     Chief	  
<b>James Mond, MD, PhD</b> Executive Vice President, Scientific Officer & Chief Medical Officer     Chief	  
<b>Steven Elms</b> Chairman	  
<b>Dr. Jerrold Grossman</b> Founder & Vice Chairman	    
<b>Lawrence Guiheen</b> Director	  
<b>Eric Richman</b> Director	   
<b>Dov Goldstein, MD</b> Director	    
<b>Bryant Fong</b> Director	 



## SUBSTANTIAL REVENUE OPPORTUNITIES AND PRODUCT DEVELOPMENT PLATFORM

### DRUG MANUFACTURING COMMERCIAL & PIPELINE PRODUCTS

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

### PLASMA COLLECTION

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

### CONTRACT MANUFACTURING & TESTING

- CURRENT CONTRACT FOR HYPERIMMUNE GLOBULIN CMO
- FULL QC LABORATORY
- INTERMEDIATES FOR FURTHER MANUFACTURING

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

Thank You

Nasdaq: ADMA