

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): October 2, 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 Capital 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 Disclosure.

As previously disclosed, Adam Grossman, President and Chief Executive Officer of ADMA Biologics, Inc., a Delaware corporation (the "Company"), and Brian Lenz, the Company's Executive Vice President and Chief Financial Officer, plan to present a corporate overview at the 2019 Cantor Global Healthcare Conference in New York City, on Wednesday, October 2, 2019 at 10:40 AM ET (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. Additionally, a copy of the slides comprising the Investor Presentation is included as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information set forth in this Item 7.01 and the Investor Presentation slides included in 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 into 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 risks and uncertainties related thereto.

Item 9.01 Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	ADMA Biologics, Inc. October 2019 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.

October 2, 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

October 2019

Nasdaq: ADMA



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," "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, our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products; 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 dependence upon our third-party and related party customers and vendors and their compliance with regulatory bodies; 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; 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 clinical development, and 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; 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 BIVIGAM® and ASCENIV™; 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.



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.

ADMA Biologics was founded to address unmet needs for immune compromised patient populations

We are committed to providing products which address the clinical needs of providers and patients

We understand the commitment and resources required to operate an effective manufacturing organization operating in cGMP compliance

All members of the Executive Management team and Board of Directors have worked in the Pharmaceutical and Biotechnology industry

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 differentiated immune globulin product candidates in development

BIVIGAM® NOW FDA APPROVED

- Indicated for the treatment of patients with primary immune deficiency disease (PI)
- FDA approved on May 9, 2019

ASCENIV™ NOW FDA APPROVED

- Novel IVIG, manufactured using a unique, patented plasma pooling methodology
- Pivotal Phase III trial in PI met primary endpoint and reported positive secondary endpoints
- FDA approved on April 1, 2019 for patients with PI

REVENUE OPPORTUNITIES FROM MULTI-FACETED PLATFORM

- Three commercial U.S. FDA licensed products
- Contract manufacturing
- Intermediate paste sales
- ADMA Bio Centers plasma collection subsidiary provides a portion of vertical raw material supply and plasma for sale to 3rd parties

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

EXPERIENCED MANAGEMENT TEAM AND BOARD OF DIRECTORS

NAME	SELECTED CURRENT OR PAST AFFILIATIONS				
Adam Grossman Founder, President, CEO & Director					
Brian Lenz, CPA Executive Vice President, Chief Financial Officer					
James Mond, MD, PhD Executive Vice President, 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

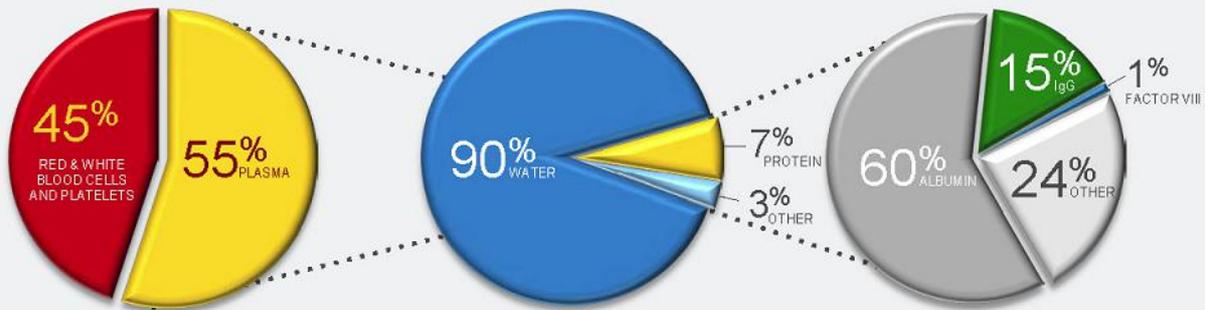
Blood Contains: Plasma, Red Cells, White Cells and Platelets

Plasma Contains: Protein and Water

Plasma Proteins Contain Many Therapeutic Benefits:

- 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 to include validation for all intermediate fractions maximizing revenue from each L of plasma

ADMA IS ONE OF A FEW COMMERCIAL MANUFACTURERS OF PLASMA PRODUCTS AND SPECIALTY IMMUNE GLOBULINS IN THE U.S.

- Successful plant inspections and drug approvals received
- 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 and long term supply contracts in place
- FDA licensed products including ASCENIV™ (Immune Globulin Intravenous – sIra, Human), Nabi-HB® (Hepatitis B Immune Globulin, Human) and BIVIGAM® (Immune Globulin Intravenous, Human)
- Strong patent portfolio across hyperimmune IG landscape including ASCENIV™
- Experienced with plasma products commercialization
- 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 and sales of fractionation, intermediates to add accretive revenues



Building blocks in place to support manufacturing and commercial product opportunities to generate meaningful sources of revenue

Market Opportunities

PLASMA PRODUCTS PORTFOLIO OVERVIEW & PIPELINE

ASCENIV
Immune Globulin Intravenous
(Human), 10% Liquid

BIVIGAM
IMMUNE GLOBULIN INTRAVENOUS
(HUMAN), 10% LIQUID

Nabi-HB
-hepatitis B
immune Globulin (human)

Nasdaq: ADMA

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.

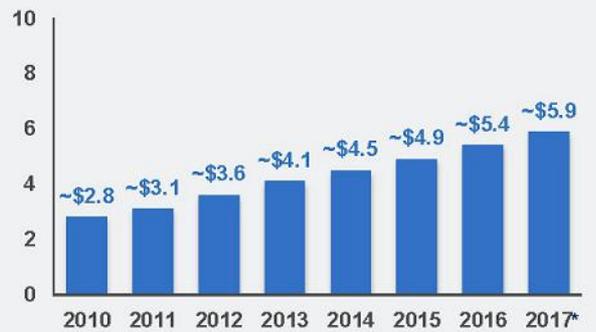
7 companies are currently marketing IG, including CSL Behring, Grifols and Takeda

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®

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

Expanding Our IG Portfolio of Product Offerings Alternatives to Clinicians
and Patients with PI and Those at Risk for Infection

FDA-Approved Uses*	Possible Additional Reimbursed Evidence-Based Uses		
<ul style="list-style-type: none"> Primary immunodeficiency (PI) 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

~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

Relaunch of BIVIGAM™ & Anticipated Launch of ASCENIV™ in 4Q19
Positions ADMA to Penetrate the Growing IG Market & Service Tight Supply Needs for Clinicians & Patients

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 selected donors



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

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

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 capacity expansion						
Nabi-HB® Hepatitis B, Hyperimmune Globulin	IM formulation						
ASCENIV™ Human, Immunoglobulin intravenous -slra	IVIG prepared using ADMA's immunoglobulin patents						
Pathogens of interest - <i>S. pneumonia</i>*	Assay and specialty donor collection program						

*(*S. pneumonia*, U.S. Patent No.10,259,865 issued on April 16, 2019 for composition and treatment modalities for immune compromised from vaccinated donors)

Milestones & Financial Highlights

Nasdaq: ADMA

RECENTLY COMPLETED

- ✓ Relunched BIVIGAM® with first commercial sales in the U.S.
- ✓ Obtained FDA approval for BIVIGAM® PAS
- ✓ ASCENIV™ (formerly RI-002) FDA approved
- ✓ 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

- Commercial launch and first sales of 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: 6/30/19 Results

Cash and cash equivalents	\$73.6M
Total assets	\$143.3M
Total liabilities	\$96.4M
Total stockholders' equity	\$46.9M
Revenue (6 months)	\$10.1M
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

SUBSTANTIAL REVENUE OPPORTUNITIES AND PRODUCT DEVELOPMENT PLATFORM

DRUG MANUFACTURING COMMERCIAL & PIPELINE PRODUCTS

- FDA LICENSED FACILITY
- PROCESS VALIDATION
- 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 CMO
- FULL QC LABORATORY
- INTERMEDIATES FOR FURTHER MANUFACTURING

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