# 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): <u>January 13, 2020</u>

ADMA BIOLOGICS, INC.				
(E	xact name of registrant as specified in its cha	arter)		
Delaware 001-36728 56-2590442				
(State or other jurisdiction	(Commission	(IRS Employer		
of incorporation)	File Number)	Identification No.)		
465 State Route 17, Ramse	y, New Jersey	07446		
(Address of principal exec	rutive offices)	(Zip Code)		
Registrant	's telephone number, including area code: (20	<u>01) 478-5552</u>		
(Former	r name or former address, if changed since la	st report.)		
Check the appropriate box below if the Form 8-K filing is intende General Instruction A.2. below):	d to simultaneously satisfy the filing obligati	on of the registrant under any of the following provisions (see		
o Written communications pursuant to Rule 425 under the Securit	ies Act (17 CFR 230.425)			
$\square$ Soliciting material pursuant to Rule 14a-12 under the Exchange	e Act (17 CFR 240.14a-12)			
$\square$ Pre-commencement communications pursuant to Rule 14d-2(b)	) under the Exchange Act (17 CFR 240.14d-2	2(b))		
$\square$ Pre-commencement communications pursuant to Rule 13e-4(c)	under the Exchange Act (17 CFR 240.13e-4	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 grov Rule 12b-2 of the Securities Exchange Act of 1934 ( $\S 240.12b-2$ o Emerging growth company $\square$		e 405 of the Securities Act of 1933 (§230.405 of this chapter) or		
If an emerging growth company, indicate by check mark if the reg		ansition period for complying with any new or revised financial		

#### Item 7.01 Regulation FD.

ADMA Biologics, Inc., a Delaware corporation (the "Company") hereby furnishes the Corporate Presentation the Company expects to present to analysts and investors on or after January 13, 2020. The Company expects to use the Corporate Presentation, in whole or in part, and possibly with modifications, from time to time in connection with presentations to potential investors, strategic partners, industry analysts and others. The Corporate Presentation is attached hereto as Exhibit 99.1 and is incorporated by reference herein, and is available under the "Company Information" tab in the "Investors" section of the Company's website, located at www.admabio.com.

By furnishing this Current Report on Form 8-K and furnishing the information contained herein, the Company makes no admission as to the materiality of any information in this report that is required to be disclosed solely by reason of Regulation FD.

The information contained in the Corporate Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, except as may be required by the federal securities laws, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

The information furnished pursuant to this Current Report on Form 8-K, including Exhibit 99.1 hereto, shall not be considered "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 it be incorporated by reference into future filings by the Company under the Securities Act of 1933, as amended, or under the Exchange Act, unless the Company expressly sets forth in such future filings that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 <u>ADMA Biologics, Inc. January 2020 Corporate Presentation.</u>

#### **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 13, 2020 ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz Title: Executive Vice President and Chief Financial Officer





### **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," "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 forwardlooking 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 mile stones; 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 a dequate 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, the potential of specialty plasma-derived biologics to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease ("P!"); our ability to market and promote our products in the competitive environment and to generate meaningful revenues; our estimated revenue potential; 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 these 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





ADMA Biologics is an end-to-end commercial biopharmaceutical company committed to manufacturing, marketing and developing specialty plasma-derived products for the prevention and treatment of infectious diseases in the immune compromised and other patients at risk for infection



We believe our devotion to these underserved populations fuels us, and our hands-on approach to production and development sets us apart

### What We Do





#### PLASMA COLLECTION

ADMA BioCenters (FDA-licensed operation) & Long-term supply contracts in place



MANUFACTURING Plasma-Derived Biologics Production Facility

Immunoglobulins

Plasma Protein Intermediates



#### **TESTING &** VALIDATION QC/Scientific lab

ON-SITE: QC Testing Laboratory Cold-Chain Storage & Raw Material Management



### & MEDICAL AFFAIRS

Strategy and Operations In-house team Field Force Targeting Hospitals & Infusion Centers



#### DISTRIBUTION

Partnering Agreements to Service all Types of End Users and Sites of Care

End-to-end operations with capabilities to capitalize on the growing US plasma products market



### **ADMA Investment Highlights**

Operating in the plasma-derived therapeutics industry, a **unique area of healthcare** that has a **track record of long-term** growth and durability

**US Market Size 2018** 

IG=\$6.8B
Addressable

market growing to



Forecasted to Grow to

~\$13.9B by 2025 CAGR 10.9% 2020-2025



Very few players - consolidation has created opportunities for ADMA

Safety, efficacy & reimbursement

of plasma-derived products is established

Limited substitution for IG with any other therapy or product Low-risk of "generics"

or emerging markets providing plasma therapies to the US from lower-cost, non-US plasma Decades-long product lifecycles

Standard IG has no patent cliffs

Expanding market with projected increasing demand for IG

\*IgG 2025 Analysis of the Intravenous and Suboutaneous Immune Globulin (Igg) Market In the United States In 2018 and Forecast to 2025. Orange, CT: Marketing Research Bureau Inc., May 2019





### High Barriers to Entry: Manufacturing & Regulatory Compliance

# Significant CAPEX required to build a fractionation facility

with long timelines

To market plasma products for the US, **products must be made from US donor plasma** in FDA-approved biologics manufacturing plants

#### Regulatory Barriers -

Strict rules and regulations from FDA and State health departments in FDA- approved biologics manufacturing plants

Greenfield facilities to produce plasma-derived products cost hundreds of millions to billions of dollars to construct along with multiple years of project / regulatory timeline – which are historically extended

#### Patent portfolio across hyperimmune IG landscape including the production of ASCENIV

### Established platform for

developing additional hyperimmune specialty IG products and deriving revenue from contract manufacturing and services

#### **Commercial Sales & Production Ramp Underway**

### ADMA manufactures and markets 3 FDA-approved IG products in the US:

- . BIVIGAM® relaunched and marketed in 2019
- . ASCENIV™ first commercial sales in 2019
- NABI-HB® marketed in the US since 1999

Potential peak revenues of all ADMA's IG products and production process estimated at >\$250M annually as we ramp production over the next 3-5 years

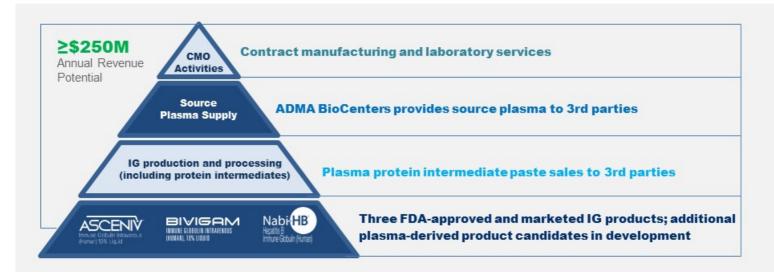
### ADMA controls all aspects of manufacturing, regulatory affairs and quality assurance

Opportunities to expand production capacity, increase production yield and revenue while enhancing margins

t



### ADMA Offers a Multi-Faceted Revenue-Generation Platform



Existing infrastructure supports manufacturing and commercial product opportunities to generate multiple meaningful sources of revenue



### **Introduction to Plasma-Derived Therapies and Production**

Plasma-derived therapeutics are essential, life-sustaining biologic drugs which replace absent proteins due to genetic and acquired disorders in hundreds of thousands of patients in the US

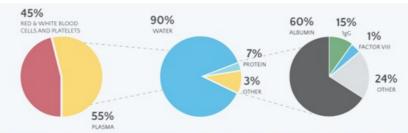
Many of these naturally occurring proteins are unable to be replaced by new, innovative therapies

Many patients require long-term treatments and some potentially for their entire life

Immunoglobulins (IG) or Intravenous Immune Globulin (IVIG) is a pooled plasma-derived product from healthy plasma donors, containing a range of polyclonal antibodies against common pathogens (e.g., bacteria, fungi, and viruses)

Only 6 companies currently produce IVIG approved for the US market, including CSL Behring, Grifols, Takeda, Octapharma, BPL and ADMA

Other therapeutic products made from plasma proteins include: albumin, coagulation factors, alpha-1, C-1 esterase, etc.

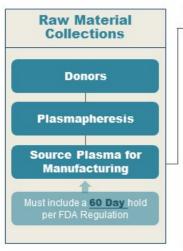


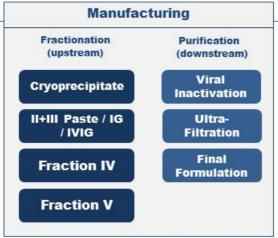
ADMA optimized IG manufacturing process and validation for intermediate fractions allows for the potential to maximize revenue from each L of plasma while producing life-sustaining and saving therapies



### **Overview: Production of Plasma-Derived Therapies**

### COHN-ONCLEY COLD ETHANOL FRACTIONATION PROCESS





**Filling Filling into** vials Final packaging & labeling Lot # serialization Approximately 4-6 months. Includes all in-process bulk testing and



Time for collection, manufacturing and release estimated at 7 to 12 months

batch record review and release by ADMA and any 3rd parties

Timing is not unique to ADMA - Other fractionators report similar production timelines



# Plasma Collection Centers: ADMA



# Plasma Centers are Essential to Ensure Raw Material Supply to Produce IG and Other Plasma Proteins

Expertise since 2011 - First ADMA BioCenter FDA-approved

- · Dedicated business unit with specialized staff and management oversight
- · Compliant with FDA and PPTA requirements

**Each center uses the latest technology** Haemonetics donor collection devices and donor tracking software

ADMA is a supplier to certain leading plasma companies through contracts and spot-market sales

### Collect hyperimmune and normal source plasma

**Hyperimmune plasma** means the plasma collected from donors is tested and confirmed to contain high-levels of antibodies against a specific pathogen and meets FDA requirements. Hyperimmune plasma collection requires FDA approval

**Normal source plasma** is plasma that is collected from donors and meets FDA requirements





### Expanding the ADMA BioCenter Network - 2020 Forward



### FDA-approved validation, SOPs, and training documentation in place

### **Opening additional**

centers – low regulatory risk and rapid time to first collections due to current FDA approval of documentation and methods

### **Vertical integration**

provides ADMA with increased speed to ramp to peak collection volumes in FDA-approved biologics manufacturing plants Plan to build between 5 to 10 new collection centers in total in various geographic locations across the US over the next 3 years

Use what we need, sell what we don't – decrease COGs, and generate additional revenue

#### Goals

Realize forecasted economies of scale as collections increase reducing the overall cost per L

Enhance efficiencies and ensure self-sufficiency into the future

Growth of the ADMA plasma collection network firms up the ability to ramp IG production and grow market share

Enhance economies of scale, speed to market, self-reliance, and increase market share





### ADMA: One of a Few Manufacturers of Specialty Immune Globulins in the US

#### Acquired the Boca Raton, FL facility June 2017

FDA product approvals and new license granted in 2019

#### FDA-approved products include:

BIVIGAM® (immune globulin intravenous, human)

ASCENIV™ (immune globulin intravenous – slra, human)

NABI-HB® (hepatitis B immune globulin, human)

Platform for developing additional hyperimmune and specialty IG products

**Additional potential:** contract manufacturing opportunities and sales of intermediate fractions to add accretive revenues





Fractionation plants are scarce with only four companies operating FDA-approved facilities in the US

### Leveraging Our Vertical Integration with End-to-End Control



### PLASMA DONORS & PLASMA COLLECTION

ADMA BioCenters & Long-term supply contracts

3rd Party collectors provide long term supply agreements

# MANUFACTURING Plasma-Derived Biologics Production Facility

Immunoglobulins: Fractionation & purification

Plasma protein intermediates

#### QC/ Scientific Laboratory

- · Raw materials
- · In process production
- · Final release
- Small scale process development
- Assay development and validation
- · Testing of raw materials

#### Aseptic Filling & Final Packaging

- In-house specialty team to oversee 3rd party operations
- Certain functions augmented by in-house staff
- Potential to bring certain activities completely inhouse with modest CAPEX
- Potential to improve final product yield, enhance margins and speed time to release product to market

End-to-end control of the supply chain and production process to produce our own products and leverage our expertise as a CMO for others



### ADMA's Plant - How Much Product Could Be Produced Annually?

400,000 L world-class plasma fractionation and purification plant

· Located in: Boca Raton, FL | Total Staff: ~350

ADMA's IG production process yields ~3.5 to 4g of IG per L of plasma processed

Total maximum production potential today: 400,000L x 3.5-4g per L = 1.4M to 1.6M grams of finished IG

• Potential for ≥\$250M revenue opportunity from IG

Plasma Intermediates are harvested with each batch of IG produced (e.g., Cryoprecipitate and Fraction V)

Potential for \$20M+ annual revenue opportunity



### World-class plasma fractionation facility and laboratories



# ADMA Is Well Positioned for Near and Long-Term Growth with Reasonable Investments in CAPEX

### SCALE PLASMA COLLECTION CENTER NETWORK WITH FORECASTED IG PRODUCTION RAMP

- Ramp plasma collection center build-out with forecasted plant processing throughput in a controlled and complaint manner
- Anticipated 3 5 years to ramp to peak production throughput in Boca Raton, FL facility
- Plan to build 5-10 centers over 3 years
- Each plasma center built can collect ~50,000L annually
- Plasma centers have traded in recent acquisitions for \$10M-\$15M per center when operating at peak collection capacity

#### ASSAY DEVELOPMENT

 More accurate biological assays means better control over the manufacturing process and potentially increased product yield



### INCREASE TOTAL PLANT PROCESSING CAPACITY

 Potential to increase the current IG process plasma pooling volume – could result in ~30 to 50% increase in total IG production capacity

#### ASEPTIC FILL-FINISH CAPABILITIES

- Potential to bring certain capabilities in-house for nominal capex which may offer:
  - · Reduced production life-cycle time
  - Limit losses inherent to biological drug production on older filling lines such as destructive weight checks
  - · Potential additional CMO revenue source

Goals: Enhance and improve production and supply-chain efficiencies to increase total production capacity, product yield and margin across the product mix



### 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 US

6 companies are currently producing IG for the US, including CSL Behring, Grifols, Takeda, Octapharma, BPL and ADMA

#### IG UTILIZATION INCREASING DUE TO

- · New research and data
- New markets (emerging countries)
- Aging population
- Utilization of new pharmaceuticals leading to increase in secondary immune deficiency



### Projected 10.9% CAGR anticipated through 2025

\*IgG 2025 Analysis of the Intravenous and Suboutaneous Immune Globulin (Igg) Market In the United States In 2018 and Forecast to 2025. Orange, CT: Marketing Research Bureau Inc., May 2019

### IG is Widely Used and Reimbursed Across Payer Mix



### FDA-Approved Uses\*

Primary immunodeficiency (PI)

Multifocal motor neuropathy

B-cell chronic lymphocytic leukemia

Immune thrombocytopenic purpura

Kawasaki syndrome

Chronic inflammatory demyelinating polyneuropathy

#### Possible 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

Solid organ transplantation

Staphylococcal toxic shock

Systemic lupus erythematosus

Toxic epidemal necrolysis

FDA-approved use and evidence based use is consistently expanding across therapeutic areas

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

### Primary Immunodeficiency is a Significant Market Opportunity

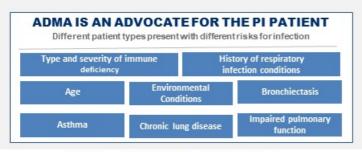


### Primary Immunodeficiency: Epidemiology overview

#### Over 350 genetic disorders are classified within PI

- ~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



#### Potential higher-risk 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 thera	
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 infection	

### **Partners With Patient Advocacy:**





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

### **Commercial Products:**





### **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





**Professional Promotional Platform** 

Ongoing reintroduction of BIVIGAM well-received in a high-demand IG market

### **Commercial Products:**





#### **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 sufficient levels of naturallyoccurring neutralizing antibody titers to Respiratory Syncytial Virus (RSV)





**Professional Promotional Platform** 

Novel IVIG with differentiation based on ADMA Biologics patented microneutralization screening assay, donor selection, and pooling process

### **Commercial Products:**





### NABI-HB®

(Hepatitis B Immune Globulin, Human)

### FDA-APPROVED TO PROVIDE ENHANCED IMMUNITY AGAINST HEPATITIS B

- Successfully used for over 20 years to protect against Hepatitis B infection among newly exposed individuals
- •Manufactured from plasma obtained from vaccinated donors with high titers of antibodies to Hepatitis B surface antigen, anti-HBs





**Professional Promotional Platform** 

Established brand with established distribution channels: Pull-through strategy based on driving increased utilization in sexual assault patients

### Commercialization/Distribution Strategy for ADMA's Immunoglobulins



#### Distribution channel is well defined

- Inpatients hospital based

#### Well established distribution organizations handle cold-chain products efficiently

- · Have existing product serialization tracking systems
- Have existing relationships with hospital pharmacy buyers and infusion center/homecare purchasing departments

#### ADMA's product portfolio offerings have overlapping prescriber call points

- Clinical immunologists

- Critical care & emergency medicine



















Identified and engaged with appropriate channel partners that align with our call plan and sites-of-service where there is demand across our immunoglobulin portfolio

### **US Plasma Products Competitive Landscape**



### **Competitive Landscape**

Presently, the US IG market is led by 4 major producers:

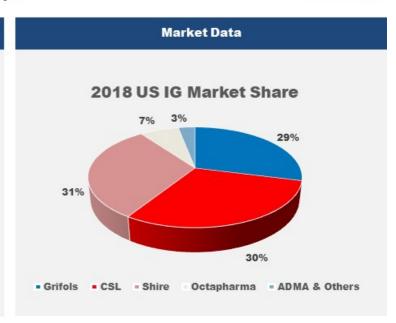
 CSL Behring, Grifols, Takeda (Shire), Octapharma account for approximately 90% of US market

Market is growing between ~6-11% annually

Growth has historically been through acquisition

Low-risk of "generics" or emerging markets providing plasma therapies to the US from lower-cost non-US plasma

Novel therapies in R&D and clinical trials are **unlikely to replace polyclonal IG** for immune compromised patients in the near- to long-term



Year-over-year growth driven by higher utilization of IG and acquisitions; low risk of generic intrusion or novel therapies to displace IG

Source: Marketing Research Bureau, 2018 US Fractionation Market Report, ADMA internal analysis



Creating & Unlocking Value:

# INTELLECTUAL PROPERTY AND R&D PIPELINE



# Despite Decades of IG Use, Patients and Treaters Continue to Advocate for Improved Therapies and Treatment Options

Despite standard immune globulin therapy, patients continue to experience recurrent respiratory infection and chronic lung disease<sup>4,9</sup>

>90%

of PI patients on standard IVIG experience recurrent respiratory tract infections<sup>10</sup>

In a 40-year study of 473 patients with PID7\*





4. Cinetto F, Scarpa R, Rattazzi M, Agostini C. The broad spectrum of lung diseases in primary antibody deficiencies. Eur Respir Rev. 2018;27(149). doi:10.1183/16000617.0019.2018. 7. Resnick ES, Moshier EL, Godbold IH, Cunningham Rundies C. Morbidity and mortality in common variable immune deficiency over 4 decades. Blood. 2012;119(7);1650.1657. 9. Baumann U, Bouters IM, Solier Palación P, Jolles S. The lung in primary immunedeficiencies: new concepts in infection and inflammation. Front Immunol. 2018;91837. Published 2018 Aug 8. doi:10.3389/immu.2018.01837. 10. Jolles S. Subclinical infection and dosing in primary immunodeficiencies. Clin Exp Immunol. 2014;178 (suppl 1):67-69. doi: 10.1111/cei. 12516.

### **IMMUNE DEFICIENCY FOUNDATION SURVEY**

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%

being hospitalized in the prior 12 months due to lung impairments

of PI patients reported

Source: 2013 IDF National Immunoglobulin Treatment SurveyThird National Survey of the Treatment Experiences and Preferences of Patients with Primary Immunodeficiency Diseases in 2013. A total of 4,000 patients with primary Immunodeficiency diseases (PI), who had reported either Intravenous immunoglobulin (IVIG) therapy or subcutaneous Immunoglobulin (SCIG) therapy, were selected from the IDF database for this survey.

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

### ADMA's Patented Immunotechnology is Used to Manufacture ASCENIV™





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

These patents include the use of IG for treatment and prevention of all viral induced respiratory infections

# Discover ADMA Biologics Patented Immunotechnology\*

### DESIGNED FOR THE IMMUNOCOMPROMISED

We manufacture, develop and commercialize specialized, targeted, plasma-derived therapeutics to extend and enhance the lives of individuals who are naturally or medically immunocompromised at risk for certain infections.



### Screen and identify high-titer donors

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



### Tailored compositions

Tailored plasma pools are derived from a unique blend of normal source plasma and plasma obtained from the selected donors.



### **Proprietary testing**

A proprietary microneutralization assay quantitatively measures titer levels of neutralizing RSV antibodies in plasma donor samples.

### **ADMA Biologics Pipeline**



### Potential additional target populations for ASCENIV™

As previously disclosed, we believe the published data and **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 US
- Solid Organ Transplant (lung, heart, liver and multi-organ)
  - ~14,000 solid organ transplants/year (excluding kidney transplants) performed in the US
- Cancer Patients Receiving Chemotherapy
  - ~650,000 patients/year receive chemotherapy in the US
- · 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

### **ADMA Biologics Pipeline**



### Patent No. 10,259,865 related to methods of treatment and prevention of *S. pneumonia* infection

- The patent (expiration date 2037) claims encompass methods of preparing immune globulin via harvesting plasma from S. pneumonia vaccinated, healthy adult human donors and pooling the harvested plasma as the source for manufacturing a hyperimmune anti-pneumococcal immune globulin
- The novel methods ensure the immune globulin will contain standardized, elevated opsonic antibodies to a plurality of S. pneumonia serotypes
- The issued claims also encompass hyperimmune anti-pneumococcal immune globulin
  - Donor stimulation and vaccination methods to ensure high titers in the plasma pool
  - · Methods of treating S. pneumonia infection and;
  - Methods of providing immunotherapy using the hyperimmune anti-pneumococcal immune globulin



Basic principles of immunology teach more antibody is better than less when treating or preventing infectious diseases

### **Our R&D Commitment:**

Doing Better For Donors

Doing Better For Patients

S. pneumonia:
Significant
problematic
pathogen even in
this age of vaccine
preventable
disease

Of vaccine eligible patients, less than 50% receive appropriate protection ADMA's patent and donor stimulation methods work to improve healthcare for donors and patients at risk for Pneumonia

ADMA BIOLOGICS

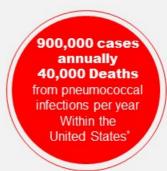
The plasma industry CAN DO BETTER! – Together we can provide healthcare benefits to donors and save patients' lives

We can make a difference in all aspects of the plasma products supply chain, thus improving healthcare for millions



### S. pneumonia: A Leading Cause of Illness and Death

- Is estimated to cause about 900,000 pneumococcal pneumonia infections within the United States per year, resulting in 450,000 hospitalizations\*
- Is the most common cause of community acquired pneumonia (CAP) in the United States<sup>1</sup>
- Emerging resistance to antibiotics is increasing
- Community acquired pneumonia is a frequent and severe infection and is the eighth most common cause of overall mortality in the United States\*
- Is an opportunistic pathogen that takes advantage of hosts with underdeveloped, weakened, and or deteriorating immune systems and has the greatest incidence rates in children under the age of two, the immunocompromised, and the elderly\*



In the US, all-cause pneumonia is the #1 cause of vaccine preventable illness and death Vaccines typically are ineffective in immune compromised patients

\*Brooks, L. R. K. & Mias, G. I. Streptococcus pneumoniae's Virulence and Host Immunity: Aging, Diagnostics, and Prevention. Front Immunol 9, 1366, doi:10.3389/firmmu.2018.01366 (2018).



Milestones, Corporate and Financial Highlights



# **Experienced Management Team and Board of Directors**

NAME	SELECTED CURRENT OR PAS	ST AFFILIATIONS			
Adam Grossman Founder, President, CEO & Director	MedImmune GEN	ESIS Gene	esis Bio-Pharmaceuticals, Inc.	S <sup>®</sup> AL HOSPITAL SPECIALTIES	American Red Cross
Brian Lenz, CPA Executive Vice President, Chief Financial Officer	КРМС	Bio \$NJ	<b>♥</b> CorMedix		
James Mond, MD, PhD Executive Vice President, Chief Scientific Officer & Chief Medical Officer	Services A	Incorporated	<b>(#)</b>		
Steven Elms Chairman		RECHT & QUIST	oxo		
Dr. Jerrold Grossman Founder & Vice Chairman	GENESIS Gener	is Bio-Pharmaceuticals, Inc.	national hospital specialties	immuno	▲ New York Blood Center
Lawrence Guiheen Director	Baxter	PUTA Pages Tompoutos Associates	KEDRION BIOPHARMA		
Eric Richman Director	PharmAthene	MedImmune	HealthCare Ventures LLC	LABCONN	ест 🕉.
Dov Goldstein, MD Director	AISLING CAPITAL	HealthCare Ventures LLC	Vicuron	(CO)	SCHRÖDINGER
Bryant Fong Director	BIOMARK CAPITAL	NEOS:			

### **Financials**



FY2018

\$17.0M

FY 2019

\$29.2M\*

4Q18

\$4.1M

Current Financial Overview	Nine Months 2019 Financial Results	Nine Months 2018 Financial Results	4Q19
Revenues	\$17.3M	\$12.9M	\$11.9M*
Total Operating Expenses	\$50.9M	\$56.7M	
Loss per common share	\$(0.72)	\$(1.06)	
Cash and cash equivalents	\$48.0M†		
Total assets	\$137.8M		
Total liabilities	\$101.7M		
Total stockholders' equity	\$36.1M		
Common stock outstanding	59.3M		
Fully diluted common stock outstanding	67.1M		

<sup>\*</sup>Preliminary, unaudited and subject to adjustment †Does not include \$12.5M tranche from Perceptive Credit Facility available to ADMA at its option until March 31, 2020

# **Upcoming Milestones**



### **OBJECTIVES**

Execute supply agreement to produce and sell intermediate fractions
☐ Continue production ramp for first full year of commercial sales across IG product portfolio
☐ Expand plasma collection facility network
☐ Evaluate and implement strategy for potential manufacturing capacity expansion
☐ Disclose potential product development pipeline consisting of additional specialty plasma and/or hyperimmune IG products



### **Investment and Corporate Highlights**



ADMA is well-positioned for success in a documented growing market with tight supply

3 FDA-approved commercial IG products with total IG manufacturing process revenue potential of ~\$250M annually

FDA compliant production facility with 400,000L processing capacity with potential for expansion

End-to-end control of supply chain offers opportunities for growth and efficiency enhancements improving margins

Year-over-year revenue growth and all 2019 milestones achieved

FDA licenses for source plasma collection centers as well as long-term supply agreements in place offers stability from fluctuating market pricing

Documented regulatory, clinical and manufacturing expertise in a consolidating and growing market both domestically and abroad

All 2019 milestones achieved with year-over-year growth across multiple revenue streams; servicing demand in a growing market, 3 FDA-approved products, compliant production facility with long-term supply agreements

