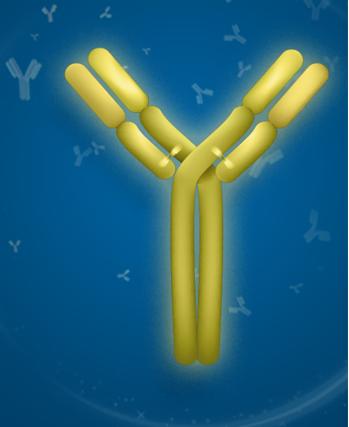
# **ADMA Biologics**

REALIZING THE POTENTIAL OF PLASMA-DERIVED THERAPIES WITH GROUNDBREAKING IMMUNOTECHNOLOGY

May 2020









# **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 milestones; the possibility of expanding our product portfolio with additional specialty immune globulin 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 FDA approved plasma with proper specifications; the likelihood and timing of U.S. Food and Drug Administration ("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 ("PI"); 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 continued safety and efficacy of, and our ability to, obtain and maintain regulatory approvals of our current products as well as, our plans to increase our supplies of plasma; our ability to expand our plasma center network; regulatory processes and 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 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

# **Industry 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** 

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** 



# **ADMA Investment Highlights**

# Unique and Different Supply-Chain Nuances and Regulatory Requirements

#### Long production cycletime – it can take 7 to 12

months for the end-to-end production, fill/finish, testing and release of a batch of IG

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; FDA performs release testing for each batch of ADMA's IG products

### Large inventories required

for raw material and in-process product are needed to ensure consistent and routine supply

**Raw material** US source plasma is in high demand globally with commodity-like pricing

Patent portfolio across hyperimmune IG landscape including the production of ASCENIV

**Working capital requirements** are substantial due to product production cycle and sales receivable cycle.

### **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
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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

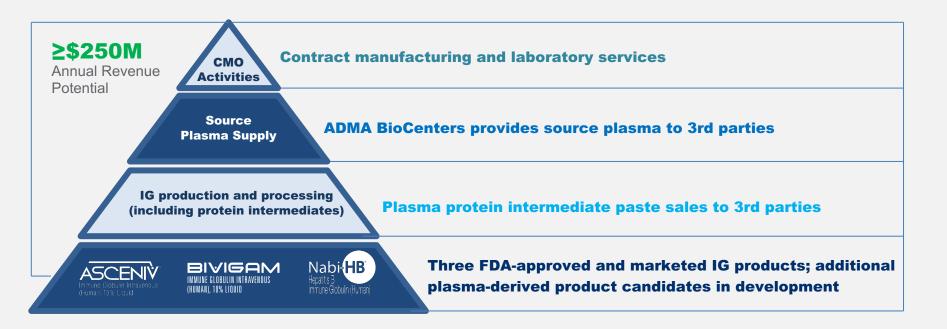
ADMA controls all aspects of manufacturing, regulatory affairs and quality assurance

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

ADMA Biologics has existing infrastructure and processes in place to manage plasma-derived products distinctive requirements



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



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

### ADMA BIOLOGICS

# **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

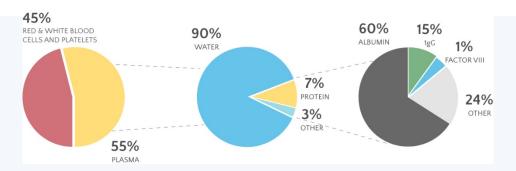
Many of these naturally occurring proteins are unable to be replaced by new, innovative therapies

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.

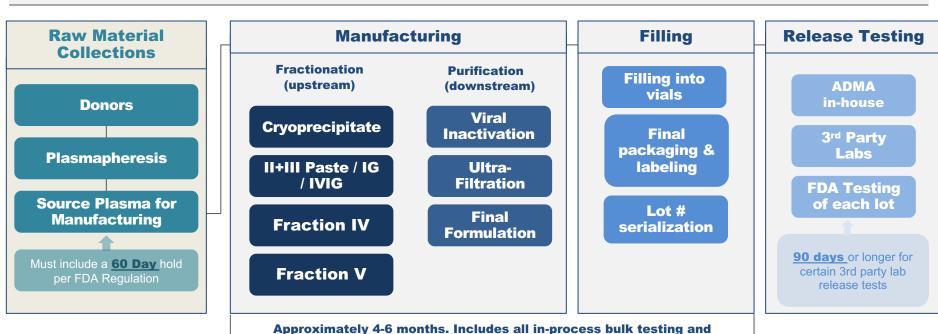


ADMA optimized IG manufacturing process and validation for intermediate fractions allows for the potential to maximize revenue from each L of plasma while producing life-sustaining and saving therapies



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

### COHN-ONCLEY COLD ETHANOL FRACTIONATION PROCESS



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

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



# COMMERCIAL OPPORTUNITY: PLASMA PRODUCTS PORTFOLIO







### 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

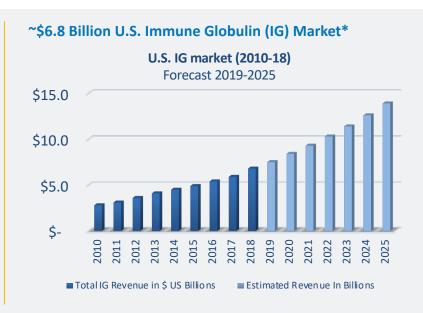
- Primary immune deficiencies
- Autoimmune diseases
- Immune-compromised patients
- Neuropathic diseases

# 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** 

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



#### **Competitive Landscape**

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

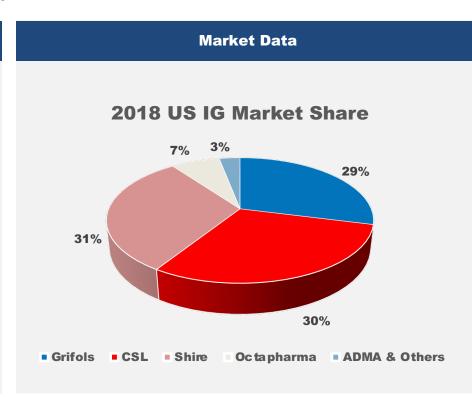
 CSL Behring, Grifols, Takeda (Shire), Octapharma account for approximately 90% of US market

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

### **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 donor

**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

### **Primary Immunodeficiency is a Significant Market Opportunity**

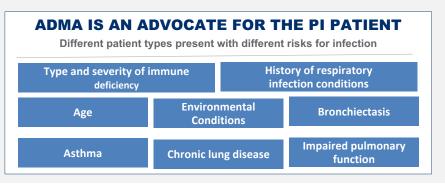


### **Primary Immunodeficiency: Epidemiology overview**

### 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 therapy	
DiGeorge Syndrome (DGS)	1 in 4,000 births suffers from DGS (700-800 patients)	1,000 patients receive IVIG therapy	
Ataxia Telangiectasia (AT)	1 in 40,000 to 1 in 100,000	3,000 to 8,000 patients	
X-Linked Hyper IgM Deficiency (XHMD)	2 in every 1,000,000 males	350 patients receive IVIG therapy	
X-Linked Agammagobulinanemia (XLA)	1 in 10,000 are diagnosed with XLA (35,000 patients)	3,500 patients are more susceptible to viral infections	

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





### **Commercial Products:**



## 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





**Professional Promotional Platform** 

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

### **Commercial Products:**





#### **ASCENIV**<sup>TM</sup>

(Immune Globulin Intravenous - slra, 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)



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



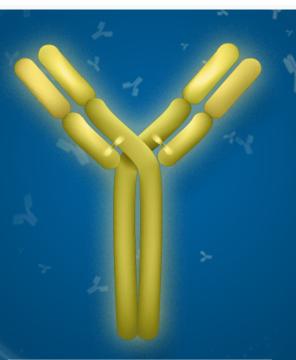


**Professional Promotional Platform** 

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



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



# 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.

# **PATENTS ISSUED** 9,107,906 - Composition 9,714,283 - Use

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

## **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

# Commercialization/Distribution Strategy for ADMA's Immunoglobulins



#### Distribution channel is well defined

- Inpatients hospital based
- Outpatients infusion center / physician office / homecare

# 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
- · Infectious diseases
- Hematology/oncology
- Critical care & emergency medicine

- ✓ INDEPENDENT INFUSION CENTERS
  - ✓ HOME CARE COMPANIES✓ INDEPENDENT GPOs















INFECTIOUS DISEASE



EMERGENCY MEDICINE



HEMATOLOGY/ONCOLOGY

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





# Plasma Product Manufacturing Overview





### **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**<sup>®</sup> (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 a few 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





# 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



# 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 to firm up the ability to ramp IG production and grow market share

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



# Milestones, Corporate and Financial Highlights



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

NAME	SELECTED CURRENT	OR PAST AFFILIATIONS			
Adam Grossman Founder, President, CEO & Director	MedImmune	GENESIS BPS Genes	is Bio-Pharmaceuticals, Inc.	N.C.S. NATIONAL HOSPITAL SPECIALTIES	American Red Cross
Brian Lenz, CPA Executive Vice President, Chief Financial Officer	KPMG	Bio NJ	<b>♥</b> CorMedi	x.	
James Mond, MD, PhD Executive Vice President, Chief Scientific Officer & Chief Medical Officer	S HENDY STAT INSTITUTE	NEXT Incorporated			
Steven Elms Chairman	<b>AISLING</b> Capital				
<b>Dr. Jerrold Grossman</b> Founder & Vice Chairman	GENESIS BPS	Genesis Bio-Pharmaceuticals, Inc.	NATIONAL HOSPITAL SPECIALTIES	Immuno™ Improving life through science	<b>△ New York</b> Blood Center
Lawrence Guiheen Director	Baxter	Plasma Protein Therapeurliss Association	KEDRIC BIOPHAR		
Dov Goldstein, MD Director	<b>AISLING</b> CAPITAL	HealthCare Ventures LLC	Vicuron	LOXO	SCHRÖDINGER.
Bryant Fong Director	BIOMARK CAPI	ITAL NEOS Therapeutics			





Current Financial Overview	1Q 2020	1Q 2019
Revenues	\$10.2M	\$3.5M
Total Operating Expenses	\$27.0M	\$16.7M
Loss per common share	\$(0.26)	\$(0.28)
Cash and cash equivalents	\$101.2M	
Total assets	\$210.5M	
Total liabilities	\$114.2M	
Total stockholders' equity	\$96.3M	
Common stock outstanding	86.3M	
Fully diluted common stock outstanding	95.5M	

# **Upcoming Milestones**



### **OBJECTIVES**

<b>™</b> Commercial launch and first sales of ASCENIV™
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



# 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



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# Thank You