### **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>December 1, 2021</u>

# ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)					
Delaware	001-36728	56-2590442			
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)			
465 State Route 17, Ramsey, New Jersey		07446			
(Address of principal executive offices)		(Zip Code)			
Registrant's	s telephone number, including area code: (201	<u>1) 478-5552</u>			
(Former	name or former address, if changed since las	st report.)			
Check the appropriate box below if the Form 8-K filing is intended General Instruction A.2. below):	d to simultaneously satisfy the filing obligatio	on of the registrant under any of the following provisions (see			
☐ 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(l	b) under the Exchange Act (17 CFR 240.14d-	-2(b))			
☐ Pre-commencement communications pursuant to Rule 13e-4(o	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	ADMA	Nasdaq Global Market			
Preferred Share Purchase Rights	-	Nasdaq Global Market			
Indicate by check mark whether the registrant is an emerging grow Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of Emerging growth company □  If an emerging growth company, indicate by check mark if the registrance accounting standards provided pursuant to Section 13(a) of the Exception 13(b).	f this chapter). istrant has elected not to use the extended trar				

#### Item 7.01 Regulation FD.

ADMA Biologics, Inc., a Delaware corporation (the "Company") hereby furnishes the Corporate Presentation the Company expects to present, 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 & Media" section of the Company's website, located at www. admabiologics.com.

By filing 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 ADMA Biologics, Inc. December 2021 Corporate Presentation.
 104 Cover Page Interactive Data File (formatted as Inline XBRL)

#### **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.

December 1, 2021 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. and its subsidiaries (collectively, "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," "potential," "possible," "forecast," "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; product expansions into new fields of use, indications, target populations 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; the likelihood and timing of FDA action with respect to any further filings by the Company; the expected financial, strategic and commercial benefits of the FDA's approval of our VanRx SA25 Workcell aseptic fill finish machine; 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"); expected market size growth in the U.S. immune globulin market through 2027; our ability to market and promote our products in the competitive environment and to generate meaningful revenues; our estimated revenue potential and related timing; certain revenue opportunities; our estimated revenue growth relative to our competitors; our production capacity and yield and ability to increase such capacity and yield; our ability to increase market share and grow revenue through anticipated product launches as well as expected peak market share; our ability to secure, build and obtain FDA approval for additional plasma collection centers and the timing related thereto; anticipated timing for achieving plasma supply self-sufficiency; estimated global supply and demand for plasma through 2027; the estimated value of our Boca Raton manufacturing facility: 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 our immune globulin products and intermediates; 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; 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



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

# **ADMA Investment Highlights**





- Differentiated U.S. Plasma Products Opportunity in a Large & Growing End-Market
- Vertically Integrated with Leading Technology, Supply Chain & Production Processes
- 3 Well-Defined & Largely De-Risked Pathway to Profitability & Unique Scarcity Value
- 4 Potential Upside Through Operating Leverage & New Product Pipeline Opportunities

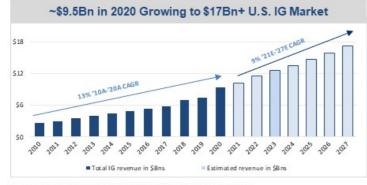


## Differentiated Opportunity in a Large & Growing Market



#### ADMA is 1 of 6 Manufacturers in a Growing, Supply-Constrained U.S. Immunoglobulin (IG) Market

- . One of six manufacturers in a historically undersupplied U.S. IG market
- . The only fully vertically integrated U.S.-domiciled fractionator
- Four major producers (Grifols, CSL Behring, Shire and Octapharma)
   collectively account for >94% of U.S. IG market
- Existing competitors are at or near capacity; ADMA is in early stages of its growth and production ramp-up



Source: The Plasma Proteins Market In The United States 2020, Marketing Research Bureau Inc., July 202:

# ADMA Has Three FDA-Approved Products & Diversified Revenue Streams

- · Comprehensive suite of three U.S. FDA-approved commercial IVIG products:
  - ✓ Standard IVIG (BIVIGAM), including a range of vial sizes and configurations
- ✓ Hyperimmune IG portfolio, comprised of ASCENIV and Nabi-HB
- ASCENIV is a novel IG and the only product in its class produced by blending normal plasma with hyperimmune plasma using ADMA's patented methods
- Nabi-HB has been used for over 20 years to protect against hepatitis B infection among newly exposed individuals







Six diversified revenue streams with the potential to add a seventh with third-party CMO fill-finish capabilities



# Vertically Integrated with Leading Technology, Supply Chain & Production Processes



#### **End-to-End Control of Supply Chain**

- . End-to-end control of supply chain from plasma collection through plasma fractionation, purification, fill-finish and testing
- · Among an elite group of U.S.-based biologic drug manufacturers with comprehensive in-house control of critical manufacturing and testing functions
- · Operating in cGMP compliance with validated methods
- Successful implementation of supply chain enhancements largely de-risks production scale-up and growth outlook



#### Plasma Supply Self-Sufficiency Anticipated by YE2023

- · Contractually obligated third-party supply agreements expected to complement and bridge to plasma supply selfsufficiency by YE2023
- 10+FDA-licensed plasma collection facilities anticipated to be fully FDA approved by YE2023
- · Well-positioned infrastructure to support near term revenue growth and ensure continuity of product supply into the supply-constrained U.S. IG market



#### In-House Fill-Finish Functions

- · FDA approved In-house aseptic fill-finishing capabilities
- · Ongoing exploration of potentially accretive third-party fill-finish opportunities
- · VanRx anticipated to meet all internal production needs with additional idle capacity, potentially adding new third-party revenues



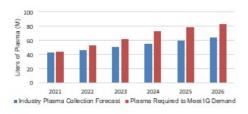


# Well-Defined and De-Risked Pathway to Profitability & Unique Scarcity Value



# Complex Manufacturing Process Validated and U.S. FDA Approved

- Capital requirements, regulatory approvals and manufacturing leadtime prohibit manufacturers from quickly increasing output and filling demand in endmarket supply
- Unique and complex manufacturing process with a long production cycle (7-12 months)
- Market demand forecasted to outpace industry supply for the foreseeable future



#### Adhere to Strict Regulatory Requirements With Data, Compliant SOPs and Processes In-Place

- Strict regulatory requirements for plasma-derived therapeutics governed by the FDA and state health departments
- Validation, product registration and ultimate commercialization takes ~3 to 5+ years – all current and complete
- ADMA operates in cGMP compliance across its manufacturing footprint as perrecent FDA inspections and approvals



Boca Raton facility and all rights to BIVIGAM DMA works - ADMA si iligently to bring nanufacturing for the or acility into FDA manufact ompliance for BIVIG FDA Biologics
al inspection completed achieved VAI acompliance status

#### Significant Scarcity Value for ADMA's Plant

 ADMA estimates, based upon publicly disclosed fractionator transactions, Boca Plant valuation estimated at \$400M+ and ~5 years to complete registrations, clinical trials and construction of a cGMP-compliant fractionation plant and fill-finish facility of equivalent capacity to ADMA's





Source: Wall Street research



# Potential Upside Through Operating Leverage & New Product Pipeline Opportunities



# Fractionation Facility Has 600,000 L Annual Plasma Processing Capacity, Supporting a ~\$300M+ Revenue Opportunity

- Well-defined pathway to \$300M+ revenues by 2025
- Fastest revenue growth profile forecasted within the plasma therapeutics landscape
- Potential capacity upside with modest capital investment requirements
- Expected to benefit from market share gains as well as end-market IG growth





#### Robust and Growing IP Estate to Support Potentially Attractive New Product Opportunities

- IP issued to screen hyperimmune donors, tailor compositions and form plasma pools – IP protection through 2035
- Attractive label expansion opportunities for specialty IGs targeting patient populations with high unmet need; robust and growing IP estate to support exploration of additional indications
- Published data supports potential evaluation of ASCENIV in immunecompromised patients infected with or at-risk for respiratory syncytial virus (RSV) infection and other respiratory viral pathogens in primary and secondary immune-deficient populations

#### ADMA's Patented Immunotechnology



Screen and identify high-titer RSV plasma donors

Hyperimmune donors with sufficient antibodies to select pathogens are identified



#### Tailored compositions

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

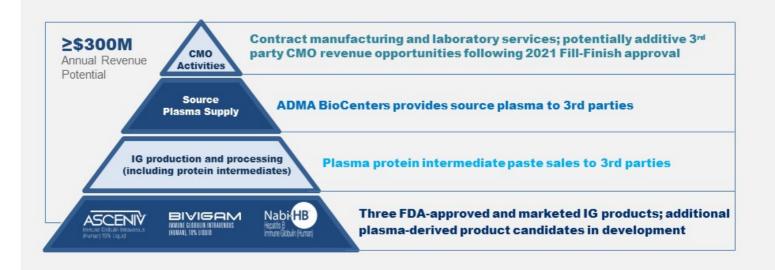


#### Proprietary testina

proprietary iicroneutralization assay uantitatively measures ter levels of neutralizing SV antibodies in plasma onor samples

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





Existing infrastructure supports manufacturing and commercial product opportunities to generate multiple meaningful sources of revenue collectively amounting to ≥\$300M









## Introduction to Plasma-Derived Therapies and Immunoglobulins (IG)



#### Plasma Therapeutics



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

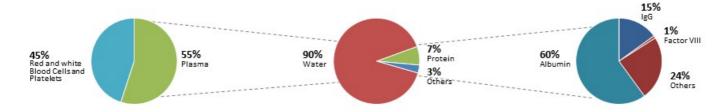
Many of these naturally occurring proteins are unable to be replaced by new, innovative therapies

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

#### Immunoglobulins (IG)



- Immunoglobulins (IG) or Intravenous Immune Globulins (IVIG) are pooled plasma-derived products 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 U.S. market, including CSL Behring, Grifols, Takeda, Octapharma, BPL and ADMA
- Other therapeutic products made from plasma proteins include: albumin, coagulation factors, alpha-1 and C-1 esterase, among others



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

## Plasma IG Market Is Sizeable & Growing



#### **Drivers of IG Market Growth**

#### **Aging Population**

- Geriatric population more susceptible to rare diseases treatable by IG products
- Global population of 65+ expected to nearly double by 2050

#### Rise of Use of IGs in Medicine

- Surge in awareness related to treatment of rare diseases with IG products
- · Widening scope of indications treatable with IG products

#### Improved Diagnostics

- · Improvements in diagnostics leading to increased rates of PI diagnoses
- Condition remains under-diagnosed; average PI diagnosis still takes 12.4 years

#### Increased Use of Immunosuppressive Therapeutics

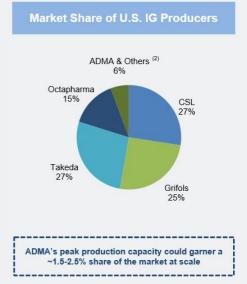
Increased utilization of immuno-oncology agents and other immunosuppressive therapeutics necessitating antibody supplementation

#### Increase in Number of Plasma Collection Centers

- · Growing number of plasma collection centers worldwide
- Increase in public and private associations that spread awareness and information related to plasma collections

#### ~\$9.5Bn U.S. IG Market in 2020 Set to Grow to \$17Bn+(1)





### Current \$9.5Bn U.S. IG market expected to grow to \$17.2Bn by 2027

Source: Marketing Research Bureau, 2020 U.S. Fractionation Market Report, ADMA internal analysis

1. The Plasma Proteins Market In The United States 2020, Marketing Research Bureau Inc., July 2021

2. Others include Kedrion and BPL

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



#### Primary Immunodeficiency (PI) Overview (1)

- · PI is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system due to either a lack of necessary antibodies or a failure of these antibodies to function properly
- Estimated prevalence of 1:1,200 in the U.S., or approximately 250,000 people
- NIH estimates 500,000 undiagnosed PI patients in the U.S.
- Over 400 genetic defects are responsible for PI
- Patients typically receive monthly outpatient infusions of IVIG therapy
- Without this exogenous antibody immune support, these patients would be susceptible to a wide variety of infectious diseases

#### Potential Higher-Risk Target Populations (1)

Chris	Pir Incidence (n.7.)	Est. Prevalence
Common variable immune deficiency (CVID)	1 in 25,000 to 1 in 50,000	2,000 to 5,000 patients
Severe combined immune deficiency (SCID) syndrome	-100 new cases each year	500-1,000 patients on IVIG post-transplant
Wiskott-Aldrich syndrome (WAS)	-4 in every 1,000,000 males	600 patients on IVIG therapy
DiGeorge syndrome (DGS)	1 in 4,000 births	1,000 patients on 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 on IVIG therapy
X-linked agammagobulinanemia (XLA)	1 in 10,000	3,500 patients more susceptible to viral infections

#### Despite Decades of IG Use, Improved Therapies Still Needed

Despite standard IG therapy, patients continue to experience recurrent respiratory infection and chronic lung disease (2)(3)

In a 40 year study of 473 patients with PI on standard IVIG (3)

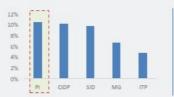


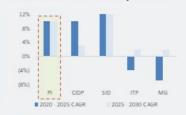


bronchiectasis

#### ~10% Volume Growth Projected for IG to Treat PI (6)

2015 - 2017 IG Volume Growth By Indication 2020 - 2030 IG Volume Growth By Indication





PI is a prevalent and under-diagnosed disorder long-treated with IG therapy, but a continual need for improved options remains

- Centers for Disease Control, National Institute of Health
   The broad spectrum of lung diseases in primary antibody deficiencies. Sur Rospin Rev. 2018.
   Morbidity and mortality in common variable immune deficiency over 4 decades.

# IG is Widely Used and Reimbursed Across Payer Mix



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

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.

### BIVIGAM® Overview





#### **BIVIGAM: FDA-Approved Protection Against Serious Infections**



- · Plasma-derived IVIG that contains a broad range of antibodies similar to those found in normal human plasma
- · Indicated for the treatment of patients with primary immunodeficiency (PI)
- ADMA received FDA approval for manufacturing BIVIGAM in May 2019 and recorded first commercial sale in August 2019

Approved and Reintroduced in May 2019 by ADMA

#### The Reintroduction of BIVIGAM RESULTS FROM ADMA'S STRONG EXECUTION AND REGULATORY EXPERTISE FDA Compliance Production ADMA FDA Suspended Compliance July Aug 2016 2017 2018 2019 2021 Production of BIVIGAM is voluntarily ADMA works ADMA obtains FDA approval for FDA Biologics Boca Rator diligently to op suspended by previous owner due to manufacturing and compliance issues production processes and bring the facility into FDA compliance achieved VAI status

#### Proven Efficacy in Treating Patients with PI

#### IN A 1-YEAR STUDY OF PATIENTS WITH PI, BIVIGAM met all primary endpoints (1)(2)



### Demonstrated protection from serious bacterial infections (SBIs)

- . 0.037 rate of SBIs per year\*
- During the 12-month study period, 2 serious acute bacterial infections occurred in 2 patients with an onset date between the first infusion of BIVIGAM and the first follow-up visit
- 197 total infections in 58 patients were reported (3.7 infections PPPY)
- 86% of patients were administered antibiotics (39.1 days PPPY)



#### Reduced health-related burdens

- · Low rate of hospitalizations (0.21 days / PPPY)
- 2 patients (3.4%) hospitalized for a total of 11 days (0.06%)
- Fewer missed days of school / work (2.3 days / PPPY)
- 21 patients (36%) with total of 122 days (0.6%)
- \*Target was 1 SBI / year; 99% C1 of 0.136 SBI / patient/year; of 63 adult patients in the enrolled in the study, 58 were included in efficiency analysis PPPY= per patient per year.

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

BIVIGAM Presenting Information, Book Raton, FL: ADMA Biologics; 2019
 A new intravenous immunoclobulin (BIVIGAM) for primary humoral immunoclotid ancy. Expert Rev Clin Immunol. 2014.

### **ASCENIV™** Overview





#### **ASCENIV: FDA-Approved Protection Against Serious Infections**



- Novel IVIG with differentiation based on patented methods for donor selection and pooling process blending normal source and hyperimmune RSV plasma
- Indicated for the treatment of patients with primary immunodeficiency (PI)
- ADMA received FDA approval in April 2019 and recorded first commercial sale in October 2019

Approved and introduced in April 2019 by ADMA

#### THE PRODUCTION OF ASCENIV

ONLY IVIG PRODUCT MANUFACTURED USING PATENTED DONOR SCREENING AND PLASMA POOLING METHODS (1)

- Manufactured through a patented process using source plasma, which is acquired from donors screened using a microneutralization assay to detect and identify which donors possess naturally occurring neutralizing antibody titers to respiratory syncytal virus (RSV)
- Plasma pool is derived from a minimum of 1,000 unique donors and blends normal source plasma with RSV plasma
- Plasma collected from U.S. FDA-licensed plasma collection centers
- \_

Meets potency requirements for 21CFR640

Proven Efficacy in Treating Patients with PI (2)

IN A 1-YEAR STUDY OF PATIENTS WITH PI, ASCENIV reported zero serious bacterial infections (SBIs)\*

Patients and physicians can count on ASCENIV to reduce infection-related quality-of-life impact

- Zero hospitalizations due to infection
  - One patient from the study group was hospitalized because of a postoperative local wound infection from elective surgery
  - <1 unscheduled medical visits PPPY</p>
  - 24 out of 59 patients (41%) had a total of 54 unscheduled medical visits due to infections
  - 1.7 missed days of work/school/activity PPPY due to infection
  - 23 patients (39%) had a total of 93 missed days of work/ school/activity due to infections out of a total of 21,535 patient days (<0.5%)</li>
  - · 32.9 days of antibiotic use PPPY
  - 37 patients (63%) used antibiotics due to infection (includes therapeutic use)





ADMA Biologics patents issued 9,107,906 – 9,714,283 – 9,815,886
 ASCENIV Prescribing Information, ADMA Biologics, 2019

### Nabi-HB® Overview





#### Nabi-HB: FDA-Approved for Enhanced Immunity Against Hepatitis-B



· Successfully used for over 20 years to protect against hepatitis B infection among newly exposed individuals (post-exposure prophylaxis PEP)

· Manufactured from plasma obtained from vaccinated donors with high titers of antibodies to hepatitis B surface antigen, anti-HBs

Received FDA approval in March 1999 under Nabi Biopharma; recorded first commercial sale under ADMA in April 2018

Approved in March 1999 (via Nabi); marketed by ADMA beginning in June 2017

#### THE THREAT OF HEPATITIS B

#### Poses An Immediate Threat to Sexual Assault Patients

- HBV is 50-100x more infectious than HIV (1)
- The risk of blood-borne infections being transmitted after a sexual assault is greater than with consensual sex (1)(2)
- Incidence of HBV exposure during sexual assault is unknown since the HBV status of perpetrators is rarely known (3)

Once someone is exposed to HBV, it may take hold and develop into potentially deadly chronic liver disease <sup>(4)</sup>

#### Seroprotection Remains a Serious Issue

- The HBV vaccine series alone takes up to 2 weeks to achieve initial serum levels and 3 doses (across 6 months) to provide seroprotection in ~90% of patients (1)(5)(8)
- · Waning antibody levels may compromise seroprotection over time
- Among immunocompetent HBV vaccine responders, protection lasts 15 to 20 years (1)

~67% of U.S. adults 19-49 years old do not have adequate HBV vaccination coverage (1)

#### Proven Efficacy in Treating Hepatitis B

NABI-HB PROVIDES PROTECTION AGAINST HEPATITIS B INFECTION WITHIN 24 HOURS OF ADMINISTRATION (7)

Highly protective potency with Nabi-HB (7)

- · Each milliliter of Nabi-HB contains >312 IU/mL of anti-HBs
- The potency of each milliliter of Nabi-HB exceeds the potency of anti-HBs in a U.S. reference hepatitis B immune globulin
- The U.S. reference has been tested against the WHO standard and found to be equal to 208 IU/mL



#### Delivers highly effective protection (7)

- · Nabi-HB is 75% effective in preventing an HBV carrier state in those at risk following sexual exposure to persons with acute hepatitis B
- If administered as a single dose within 2 weeks of exposure

**75**% Effective



EFFICACY WHEN ADMINISATERED AS A SINGLE DOSE WITHIN 2 WEEKS OF EXPOSURE

Anti HBs = anti hepatitis B surface antibodies; IU = international units; WHO = World Health Organization; HBIG = hepatitis immunoglobulin; HBV = hepatitis B virus; HIV-human immunodeficiency virus.

#### Established brand and distribution channels driving increased utilization in PEP and sexual assault patients

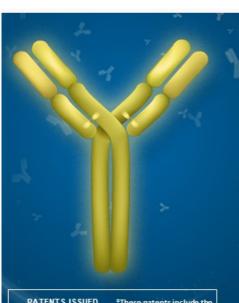
- Centers for Disease Control and Prevention.
   Middlesses London Health Unit. Post acrossine management: hepatitis B, hepatitis C and HIV 3. Roberts and hebated Cinical Procedures in Emergency Medicine and Acute Care
   World Health Organization

- Do patients who received only two doses of hepatitis B vaccine need a booste? Objec Clin J Med 2014
   PDR: presorber's digital inference. Enger's (hepatitis B vaccine recombinant) drug summary
   Date on file. ADMA B drogics



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





PATENTS ISSUED \*These patents include the 9,107,906 - Composition 9,714,283 - Use 9,815,886 - Methods Expiration 2035 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.

## **Pipeline & Label Expansion Opportunities**



#### 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™

-1

# Commercialization/Distribution Strategy for ADMA's Immunoglobulins



#### Distribution channel is well defined

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

# ✓ INDEPENDENT INFUSION CENTERS ✓ HOME CARE COMPANIES ✓ INDEPENDENT GPOS



# 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

# BioCare SD\*



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

- Clinical immunologists
- Infectious diseases
- · Hematology/oncology
- · 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







- World-class, cGMP-compliant plasma fractionation facility and laboratories in Boca Raton, FL; acquired in June 2017
- Recent FDA compliance inspection completed in August 2021
- · One of few FDA-approved fractionation facilities in the U.S.
- Total staff: ~350
- Annual capacity of up to 600,000 liters, or ~2.4M grams of finished IG, supporting a \$300M+
  revenue opportunity
- Yield of ~3.5-4 g / L and revenue / liter of \$600-\$800
- Patented immunotechnology to screen hyperimmune donors, tailor plasma pool compositions and conduct proprietary antibody detection testing
- · Capable of full product transfers as well as initial phase plasma product concept development
- · In-house fill-finish capabilities following the 2021 FDA approval of the VanRx machine
- Plasma Intermediates are harvested with each batch of IG produced (e.g., Cryoprecipitate and Fraction V). Potential for up to \$20M annual revenue opportunity



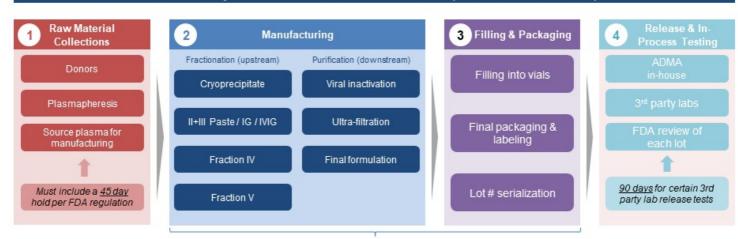


Fractionation plants are scarce with only a few companies operating FDA-approved facilities in the U.S.

# **Production of Plasma-Derived Therapies**



#### Cohn-Oncley Cold Ethanol Fractionation Process (Estimated 7-12 Months)



Approximately <u>4-6 months</u> – includes all in-process bulk testing and batch record review and release by ADMA and any 3rd parties

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

### Contract Manufacturing Opportunities: Fill-Finish, Packaging and Serialization

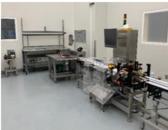


#### Fill-Finish Capabilities

- ✓ In-house fill-finish capabilities with the 2021 FDA approval of the VanRx SA25 workcell
- ✓ In-house specialty team to oversee third-party operations
- ✓ Potential to improve final product yield and enhance margins, speed and time to release product to market

#### Product Labeling, Packaging and Serialization





#### VanRx Machine Brings Fill-Finish Capabilities In-House

New VanRx SA25 aseptic fill-finish machine received FDA approval



#### Internal fill-finish production capabilities expected to result in:



Greater product supply consistency



Significantly improved gross margins



Significantly improved operational efficiencies



Reduced manufacturing cycle times



Plasma Collection Centers: ADMA



### ADMA BioCenters Overview: Advancing Towards Plasma Self-Sufficiency



- Plasma collection centers are essential to ensure raw material supply to produce IG and other plasma proteins
- ADMA BioCenters currently consists of a network of 9 plasma collection centers in various stages of approval and development
- Total staff: ~150
- First center opened in 2011; network now includes <u>6 fully</u> <u>operational BioCenters</u> in Tennessee, South Carolina and Georgia
- On track to have 10+ FDA approved centers by 2023 to achieve substantial plasma supply self-sufficiency
- ADMA BioCenters collects hyperimmune and normal source plasma
- In addition to providing plasma supply for ADMA products, collected plasma is sold through supply contracts to leading plasma companies



Plasma centers are essential to ensure raw material supply to produce IG and other plasma proteins; Supply self-sufficiency forecasted to be achieved by 2023

## **Expanding the ADMA BioCenter Network - 2021 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 have 10 or more collection centers in approved in various geographic locations across the U.S. by 2023

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 O	R PAST AFFILIATIONS			
Adam Grossman Founder, President, CEO & Director	MedImmune	GENESIS	Genesis Bio-Pharmaceuticals, Inc.	national Hospital Speci	American ALTIES Red Cross
Brian Lenz, CPA Executive Vice President, Chief Financial Officer	КРМС	Bio \$NJ	<b>♥</b> CorMedix		
Steven Elms Chairman	AISLING CAPITAL	HAMBRECHT & QUIST Investment Banking for the New Economy	roxo		
Dr. Jerrold Grossman Founder & Vice Chairman	GENESIS	Genesis Bio-Pharmaceuticals, Inc.	NATIONAL HOSPITAL SPECIALTIES	immun	DiICt
Lawrence Guiheen Director	Baxter	Pasma Praesis Therapeutica Association	KEDRION		
Martha Demski Director	BIO PHARMA	equillium.	CHIMERIX	ADAMAS	BANK OF AMERICA
Bryant Fong Director	BIOMARK CAPITA	AL NEOS			
Young Kwon, Ph.D. Director	LIGHTSTON	E Momenta	Biogen	ALCHEMAB THERAPEUTICS	

# **Financials**



Current Financial Overview	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Revenues	\$54.6M	\$28.3M
Net Loss	\$(55.0M)	\$(56.3M)
Loss per common share	\$(0.44)	\$(0.68)
Cash and cash equivalents	\$34.4M	\$59.7M
Total assets	\$238.7M	\$190.0M
Total liabilities	\$135.9M	\$118.6M
Total stockholders' equity	\$102.8M	\$71.4M
Common stock outstanding	195.8M	94.5M
Fully diluted common stock outstanding	212.6M	103.9M

Cash Balance Excludes Gross Proceeds of \$57.5M From Equity Financing Completed October 2021

# **Upcoming Milestones**



#### **OBJECTIVES**

Execute on supply chain robustness for increased BIVIGAM® plasma pool scale

Execute on supply chain robustness for aseptic fill/finish machine

Expand our BioCenters plasma collection facility network to a total of 10 or more

Expand commercial production and penetration of our marketed IVIG product portfolio

Disclose potential product development pipeline consisting of additional specialty plasma and/or hyperimmune IG products

### **ADMA Investment Highlights**



Unique and Different Supply-Chain Nuances and Regulatory Requirements

#### Long production cycle-

**time** – 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 U.S., **products must be made from U.S. 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** U.S. 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 U.S.:

- 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 processes to reach ≥\$300M as we ramp production

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

