

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): June 6, 2019

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36728
(Commission
File Number)

56-2590442
(IRS Employer
Identification No.)

465 State Route 17, Ramsey, New Jersey
(Address of principal executive offices)

07446
(Zip Code)

Registrant's telephone number, including area code: (201) 478-5552

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events

As previously disclosed, Adam Grossman, the President and Chief Executive Officer of ADMA Biologics, Inc., a Delaware corporation (the “Company”), and Brian Lenz, the Company’s Executive Vice President and Chief Financial Officer, plan to present at the Jefferies 2019 Healthcare Conference in New York, NY, on Thursday, June 6, 2019, and at the Raymond James Life Sciences and MedTech Conference in New York, NY, on Wednesday, June 19, 2019 at 10:20 AM ET at 9:00 AM ET (collectively, the “Investor Presentations”). The Investor Presentations will be webcast live and may be accessed under the “Investor Relations” tab on the Company’s website at www.admabiologics.com. Additionally, a copy of the slides comprising the Investor Presentations is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	ADMA Biologics, Inc. June 2019 Investor Presentations.

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.

June 6, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics

Groundbreaking Immunotechnology, One Connection at a Time

June 2019

Nasdaq: ADMA

FORWARD-LOOKING STATEMENTS

This presentation contains "forward-looking statements", pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about ADMA Biologics, Inc. ("we", "our" or the "Company"), including, without limitation, statements that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "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, the anticipated benefits and synergies of our June 2017 acquisition of certain assets from Biotest Pharmaceuticals Corporation ("BPC") (the "BPC Transaction"), including optimization of the combined businesses, operations and products and services, including liquidity, debt repayment and capital return expectations, as well as the capitalization, resources and ownership structure of the combined company, the nature, strategy and focus of the combined company and the management and governance structure of the combined company, our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products, the safety, efficacy and expected timing of, and our ability to, obtain and maintain regulatory approvals of our current products, product expansions into new fields of use, indications and product candidates, and the labeling or nature of any such approvals, our dependence upon our third-party and related party customers and vendors and their compliance with regulatory bodies, our ability to obtain adequate quantities of U.S. Food and Drug Administration (FDA)-approved plasma with proper specifications, our plans to increase our supplies of plasma, our ability to expand our plasma center network, regulatory processes, interpretations of final data of our products and product candidates, acceptability of any of our products for any purpose, by physicians, patients or payers, concurrence by the FDA with our conclusions and the satisfaction by us of its guidance, the likelihood and timing of FDA action with respect to any further filings by the Company, results of clinical development, the potential of specialty plasma-derived biologics to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease (PID), our ability to market and promote our products in the competitive environment and to generate meaningful revenues, potential clinical trial initiations, potential investigational new product applications, Biologics License Applications, 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, 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. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause our actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.



ADMA Biologics is a vertically integrated commercial biopharmaceutical company committed to manufacturing, marketing and developing specialty plasma-derived products for the immune-compromised and other patients at risk for infection.

It is our devotion to these underserved populations that fuels us, and our hands-on approach to production and development that sets us apart.

VERTICALLY-INTEGRATED COMMERCIAL BIOPHARMACEUTICAL COMPANY

- Operates an FDA-approved 400,000L capacity plasma therapeutics manufacturing facility with potential for expansion
- Products acquired: Nabi-HB® (Hepatitis B IG, Human) and BIVIGAM® (IVIG, Human)
- Control all aspects of drug substance manufacturing, regulatory compliance and business operations
- Ability to increase market share and grow revenue through anticipated product launches
- Plans to expand pipeline with differentiated immune globulin product candidates in development

BIVIGAM® NOW FDA APPROVED

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

ASCENIV™ NOW FDA APPROVED

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

REVENUE OPPORTUNITIES FROM MULTI-FACETED PLATFORM

- Three commercial U.S. FDA licensed products
- Contract manufacturing
- Intermediate paste sales
- ADMA Bio Centers plasma collection subsidiary provides source plasma to 3rd parties

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

CURRENT NEAR & MID-TERM OBJECTIVES

Our Top Priorities:

- Relaunch BIVIGAM® in the U.S.
- Launch ASCENIV™ in the U.S.
- Ensure that Warning Letter is closed-out
- Increase penetration and utilization of Nabi-HB®
- Ongoing continuous improvements to quality management systems and enhancements to manufacturing processes
 - Continue to release commercial drug product
- Enhance commercial team for upcoming product launches
- Meet with FDA to gain insights on potential clinical evaluation of ASCENIV™ with Respiratory Syncytial Virus (RSV) endpoints



Regulatory Update:

- BIVIGAM® Prior Approval Supplement (PAS) FDA approved on May 9, 2019
- ASCENIV™ FDA approved on April 1, 2019
- New license issued for manufacturing plant and ASCENIV™ (Department of Health and Human Services U.S. license No. 2019)
- Continue to manufacture and release NABI-HB® for commercial sale

Continue to Operate in Compliance and Increase Commercialization Activities and Production

EXPERIENCED MANAGEMENT TEAM AND BOARD OF DIRECTORS

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

BLOOD & PLASMA COMPOSITION

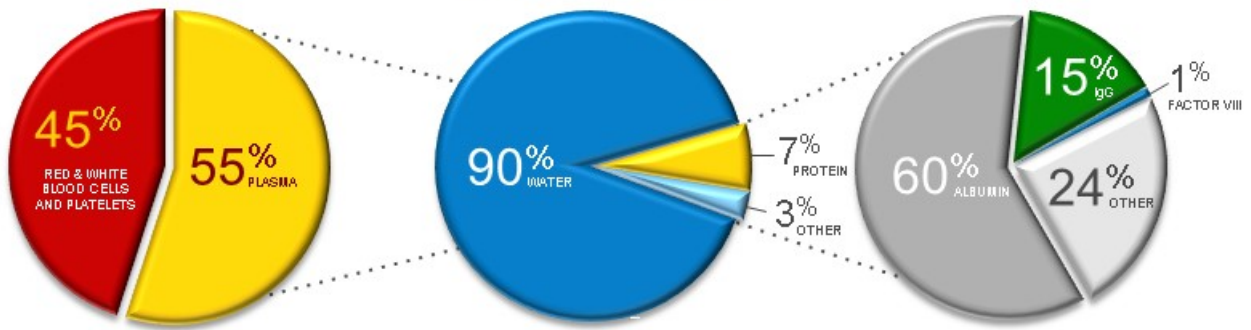
Blood Contains: Plasma, Red Cells, White Cells and Platelets

Plasma Contains: Protein and Water

Plasma Proteins Contain Many Therapeutic Benefits:

- Intravenous immunoglobulin (IVIg) is made from a key therapeutic protein in plasma: Immunoglobulin (IgG)
- IgG = naturally occurring polyclonal antibodies against bacteria, fungus and viruses
- Other therapeutic products made from plasma proteins include: albumin, coagulation factors, alpha-1, C-1 etc.

Composition of Blood



ADMA optimized IG manufacturing process to include validation for all intermediate fractions
Maximizing revenue from each L of plasma

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

- Successful plant inspections and drug approvals received
- Track record of receiving FDA approval for plasma collection centers
- ~400,000L annual capacity plasma fractionation and purification plant operating in FDA compliance
- ADMA Bio Centers subsidiary provides a portion of source plasma and long term supply contracts in place
- FDA licensed products including ASCENIV™ (Immune Globulin Intravenous – sIra, Human), Nabi-HB® (Hepatitis B Immune Globulin, Human) and BIVIGAM® (Immune Globulin Intravenous, Human)
- Strong patent portfolio across hyperimmune IG landscape including ASCENIV™
- Experienced with plasma products commercialization
- Acquired contractual agreement for manufacturing of immune globulin paste for a third party's licensed hyperimmune globulin
- Platform for developing additional hyperimmune and specialty IG products
- Additional potential contract manufacturing opportunities and sales of fractionation, intermediates to add accretive revenues



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

Market Opportunities

Plasma Products Portfolio Overview & Pipeline



Nasdaq: ADMA

GROWTH DRIVERS: PLASMA IG MARKET IS SIZEABLE & GROWING

IMMUNE GLOBULIN (IG or IVIG) is a pooled plasma product from healthy plasma donors, containing a range of polyclonal antibodies against common pathogens

IG IS USED TO TREAT A WIDE VARIETY OF DISORDERS

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

IG WIDELY MARKETED IN THE U.S.

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

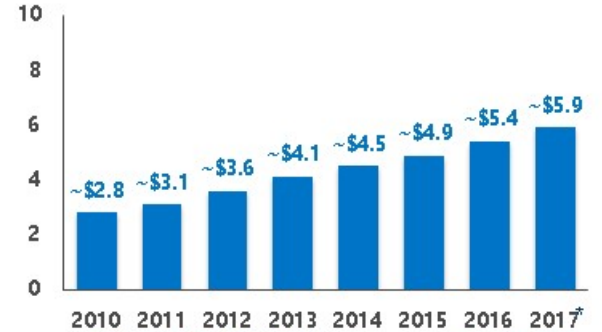
IG UTILIZATION INCREASING DUE TO

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

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

U.S. IG market (2010-17)

Billions of dollars



* Plus 2017 ~ \$300M Hyperimmune Globulin Sales

Projected ~6% year over year growth anticipated through 2025

Source: ADMA information, on file, AAAAI, FDA, Product prescribing information, United Healthcare, Aetna, L.E.K. Consulting research and analysis
Any market information for IVIG is not necessarily indicative of the expected market for ASCENIV™, BIVIGAM® or Nabi-HB®

COMMERCIAL PRODUCTS: ESTABLISHED BRANDS IN AN EXPANDING IG MARKET



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



BIVIGAM®
(Immune Globulin Intravenous, Human)
FDA-Approved protection against serious infections

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



Nabi-HB®
(Hepatitis B Immune Globulin, Human)
FDA-Approved to provide enhanced immunity against Hepatitis B

- Successfully used for over 17 years to protect against Hepatitis B infection among newly exposed individuals
- Manufactured from plasma obtained from vaccinated donors with high titers of human antibodies to Hepatitis B surface antigen, anti-HBs

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

IG IS WIDELY USED AND REIMBURSED

FDA-Approved Uses*	Possible Additional Reimbursed Evidence-Based Uses		
<ul style="list-style-type: none"> Primary immunodeficiency (PI) Multifocal motor neuropathy B-cell chronic lymphocytic leukemia Immune thrombocytopenic purpura Kawasaki syndrome Chronic inflammatory demyelinating polyneuropathy 	<ul style="list-style-type: none"> Acquired red cell aplasia Bone marrow transplantation Dermatomyositis Enteroviral meningoencephalitis Established bacterial sepsis Multiple sclerosis 	<ul style="list-style-type: none"> Multiple myeloma Myasthenia gravis Neonatal hemochromatosis Parvovirus B19 Pediatric HIV Post transfusion purpura 	<ul style="list-style-type: none"> Rasmussen's syndrome Renal transplant from liver donor Solid organ transplantation Staphylococcal toxic shock Systemic lupus erythematosus Toxic epidermal necrolysis

Payers appreciate and understand the proven, evidence-based benefits of IG

* Not all uses approved for all IG products by FDA.

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

PI IS A SIGNIFICANT MARKET OPPORTUNITY FOR ADMA

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

~50% are treated with IG

THE ADMA PORTFOLIO OF IG PRODUCTS

offers alternatives and can help treat major subsets of the PI population

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

Potential Target Population

Class	Est. Incidence (U.S.) Population	Target Population Numbers
Common Variable Immune Deficiency (CVID)	1 in 25,000 to 1 in 50,000 (7,000-14,000 patients)	2,000 to 5,000 patients
Severe Combined Immune Deficiency Syndrome (SCID)	New diagnoses of ~100 cases reported each year	500-1,000 patients on IVIG post transplant
Wiskott-Aldrich Syndrome (WAS)	4 in every 1,000,000 males has the disorder – sometimes not diagnosed until adulthood	600 patients on IVIG therapy
DiGeorge Syndrome (DGS)	1 in 4,000 births suffers from DGS (700-800 patients)	1,000 patients receive IVIG therapy
Ataxia Telangiectasia (AT)	1 in 40,000 to 1 in 100,000	3,000 to 8,000 patients
X-Linked Hyper IgM Deficiency (XHMD)	2 in every 1,000,000 males	350 patients receive IVIG therapy
X-Linked Agammaglobulinemia (XLA)	1 in 10,000 are diagnosed with XLA (35,000 patients)	3,500 patients are more susceptible to viral infections

Potential Relaunch of BIVIGAM™ & Launch of ASCENIV™ in 2H19 Positions ADMA to Penetrate the Growing IG Market & Service Tight Supply Needs for Clinicians & Patients

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

Risk Factors for Infection in PI

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



2013 IDF National PI Patient Treatment 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%

of PI patients reported being hospitalized in the prior 12 months due to lung impairments

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

SCREEN AND IDENTIFY HIGH-TITER DONORS

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



PROPRIETARY TESTING

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

TAILORED COMPOSITIONS

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



PATENTS ISSUED

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

Potential Target Populations for ASCENIV™

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

- HSCT/Bone Marrow Transplant
 - ~22,000 procedures/year performed in the U.S.
- Solid Organ Transplant (lung, heart, liver and multi-organ)
 - ~14,000 solid organ transplants/year (excluding kidney transplants) performed in the U.S.
- Cancer Patients Receiving Chemotherapy
 - ~650,000 patients/year receive chemotherapy in the U.S.
- Others At-Risk for RSV Infection

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

Potential Follow-On Specialty Plasma Products

By leveraging ADMA's IP, know-how and expertise, we may seek to expand our product portfolio with additional specialty IG products by building upon our core competency of identifying high-titer plasma donors and plasma products manufacturing expertise



We believe ADMA's IP and manufacturing capabilities establish a platform for developing future specialty IG products targeting problematic pathogens

ADMA PRODUCTS, PIPELINE AND ONGOING R&D

Product / Candidate	R&D Activity / Other Information	Pre-clinical	Phase I	Phase II	Phase III	BLA Submitted	FDA Approved / Marketed
BIVIGAM® Human, Immunoglobulin intravenous	Pediatric Indication / Manufacturing capacity expansion						
Nabi-HB® Hepatitis B, Hyperimmune Globulin	IM formulation						
ASCENIV™ Human, Immunoglobulin intravenous	IVIG prepared using ADMA's immunoglobulin patents						
Pathogens of interest - <i>S. pneumonia</i>*	Assay and specialty donor collection program						

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

Milestones & Financial Highlights

Nasdaq: ADMA



MILESTONES

Recently Completed

- Obtained FDA approval for BIVIGAM™ PAS
- ASCENIV™ (formerly RI-002) FDA approved
- License issued for manufacturing plant and ASCENIV™ (#2019)
- Completed ~\$52M public offering of common stock
- Secured up to \$85.0M in debt financing facility with Perceptive Advisors
 - \$72.5M currently outstanding; additional \$12.5M commitment at ADMA's option
- Successfully closed-out April 2018 FDA inspection
 - Inspection classification status improved to Voluntary Action Indicated (VAI)
- Obtained FDA approval for plasma collection center
- Achieved year-over-year revenue growth in 2018
- Extinguished approximately 19% of total outstanding common stock issued to BPC in June 2017 (8.6M shares)
- Four U.S. patents granted for compositions and methods for the treatment of immunodeficiency
- Patent Issued for *S. pneumonia* immune globulin

Other Significant Milestones and Achievements

- Completed acquisition and integration of strategic manufacturing assets and commercial products from BPC
- Phase III study ASCENIV™: Positive primary endpoint data
 - Secondary endpoint results announced from positive Phase III trial
 - Peer reviewed publication of final study analysis and results

Future & Ongoing Objectives 2019

- Relaunch BIVIGAM® in the U.S.
- Commercial launch of ASCENIV™
- Commercial sales of ASCENIV™
- Disclose potential product development pipeline consisting of additional specialty plasma and/or hyperimmune IG products
- Evaluate and implement strategy for potential manufacturing capacity expansion
- Expand plasma collection facility network

Financial Summary: 3/31/19 Results*

Cash and cash equivalents	\$16.5M
Total assets	\$78.1M
Total liabilities	\$68.1M
Total stockholders' equity	\$10.0M
Revenue	\$3.5M
Common stock outstanding	46.4M
Fully diluted common stock outstanding	53.9M

*Subsequent Events:

- Completed ~\$52M public offering of common stock
- Accessed \$27.5M from Perceptive Advisors' credit agreement as a result of FDA approval for ASCENIV™ on April 1, 2019
- Amended Perceptive Advisors' credit agreement with additional commitment of \$12.5M predicated upon BMIGAM® PAS approval at ADMA's option until March 31, 2020
- Received FDA approval for BMIGAM® May 9, 2019 / FDA approval for ASCENIV™ April 1, 2019

SUBSTANTIAL REVENUE OPPORTUNITIES AND PRODUCT DEVELOPMENT PLATFORM

DRUG MANUFACTURING COMMERCIAL & PIPELINE PRODUCTS

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

PLASMA COLLECTION

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

CONTRACT MANUFACTURING & TESTING

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

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