

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): March 4, 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))

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 (i) Raymond James’ 40<sup>th</sup> Annual Institutional Investors Conference in Orlando, FL, on Monday, March 4, 2019 at 8:40 AM ET and (ii) Oppenheimer’s 29<sup>th</sup> Annual Healthcare Conference in New York, NY, on Tuesday, March 19, 2019 at 8:35 AM ET (together, the “Investor Presentations” and each, an “Investor Presentation”). 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](http://www.admabiologics.com). Additionally, a copy of the slides comprising each Investor Presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Please refer to Exhibit 99.1 for a discussion of certain forward-looking statements included therein and the risk and uncertainties related thereto.

**Item 9.01 Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">ADMA Biologics, Inc. March 2019 Investor Presentation.</a>

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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.

March 4, 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

**March 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 and product candidates, and the labeling or nature of any such approvals, the timeframe within which we may receive approval from the U.S. Food and Drug Administration ("FDA"), if at all, of our Biologics License Application ("BLA") for RI-002, our ability to address the outstanding issues in the FDA's Complete Response Letter (CRL), as well as other deficiencies existing at the manufacturing facility we acquired in the BPC Transaction, as well as a positive review of the optimized manufacturing process under a Prior Approval Supplement and related CRL responses by the FDA, 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, our plans to increase our supplies of plasma, the potential indications for our product candidates, our ability to expand our plasma center network, regulatory processes, interpretations of final data, possible characteristics of RI-002, acceptability of any of our products as well as RI-002 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 the clinical development, continuing demonstrations of safety, comparability of results of RI-002 to other comparably run Intravenous Immune Globulin (IVIG) trials, improvements in clinical outcomes, the potential of RI-002 and BIVIGAM® to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease (PIDD), our ability to market and promote Nabi-HB® in the competitive environment and to generate meaningful revenues, potential clinical trial initiations, potential investigational new product applications, BLAs, expansion plans, our intellectual property position, including our expectations of the scope of patent protection with respect to RI-002, 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, if any, if and when RI-002 is approved for marketing, estimates regarding market size, projected growth and sales for our existing products as well as our expectations of market acceptance of RI-002, future economic conditions and performance, expectations for future capital requirements, commercialization efforts relating to our product candidates 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 significant cost savings and differentiated immune product candidates

## RI-002: LEAD PIPELINE PRODUCT CANDIDATE

- Novel IVIG, manufactured using a unique, patented plasma pooling design

- Pivotal Phase III trial in PIDD met primary endpoint and reported positive secondary endpoints

- BLA resubmitted 3Q 2018 with Prescription Drug User Fee Act (PDUFA) action due date of April 2, 2019

## REVENUE OPPORTUNITIES FROM MULTI-FACETED PLATFORM

- Current commercial U.S. FDA licensed products

- Contract manufacturing and laboratory services agreements in place

- Intermediate paste sales

- ADMA Bio Centers plasma collection subsidiary provides source plasma to 3<sup>rd</sup> parties

- Additional plasma-based product candidates in development

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



## CURRENT NEAR & MID-TERM OBJECTIVES

### Regulatory Update

- Manufacturing plant FDA compliance status improved to Voluntary Action Indicated (VAI)
- FDA approval received for BIVIGAM® Prior Approval Supplement (PAS) Drug Product Fill/Finish
- Rapid response submitted January 4, 2019 to FDA for BIVIGAM® PAS Complete Response Letter (CRL) – Subsequently, FDA has provided information requests regarding the CRL resubmission and the Company has responded
- RI-002 BLA Resubmitted to FDA for approval - April 2, 2019 PDUFA target action date
- Continue to manufacture and release NABI-HB® for commercial sale

### Our Top Priorities:

- Obtain approval for BIVIGAM® in the U.S.
- Relaunch BIVIGAM® in the U.S.
- Obtain approval for RI-002
- Launch of RI-002
- 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



Focused on Engaging FDA to Complete Two Potential Product Candidate Approvals While Continuing to Operate in Compliance



# EXPERIENCED MANAGEMENT TEAM AND BOARD OF DIRECTORS

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

# BLOOD & PLASMA COMPOSITION

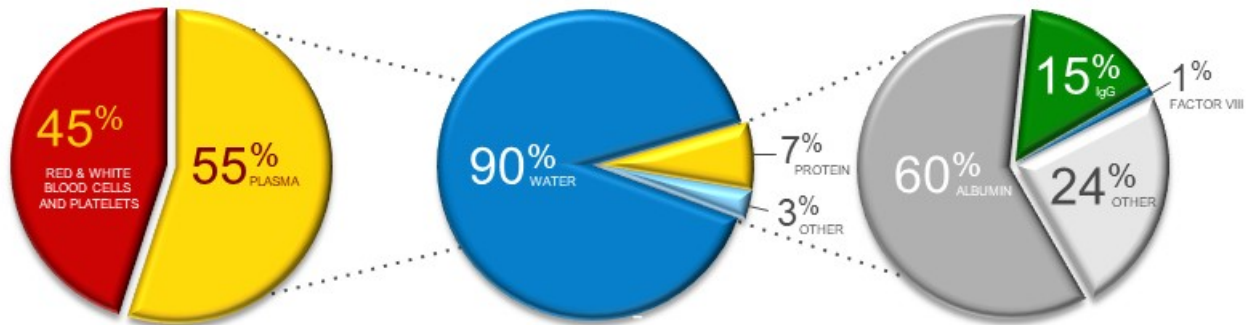
**Blood Contains:** Plasma, Red Cells, White Cells and Platelets

**Plasma Contains:** Protein and Water

**Plasma Proteins Contain Many Therapeutic Benefits**

- IVIG is made from a key therapeutic protein in plasma: 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 HANDFUL OF VERTICALLY INTEGRATED PLASMA PRODUCTS AND SPECIALTY IMMUNE GLOBULIN MANUFACTURERS IN THE U.S.

- 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
- Full regulatory, quality and compliance control of all products and operations
- FDA licensed products including Nabi-HB® (Hepatitis B Immune Globulin, Human) and BIVIGAM® (Immune Globulin Intravenous, Human)
- RI-002 BLA resubmitted 3Q18, with PDUFA target action date of April 2, 2019
- Strong patent portfolio across hyperimmune IG landscape
- Experienced plasma products commercialization team
- 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 to add accretive revenues



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

# Market Opportunities

## Commercial Overview, RI-002 & Pipeline

Nasdaq: ADMA

# GROWTH DRIVERS: PLASMA MARKET IS SIZEABLE

**IMMUNE GLOBULIN (IG) (e.g., BIVIGAM®)** 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

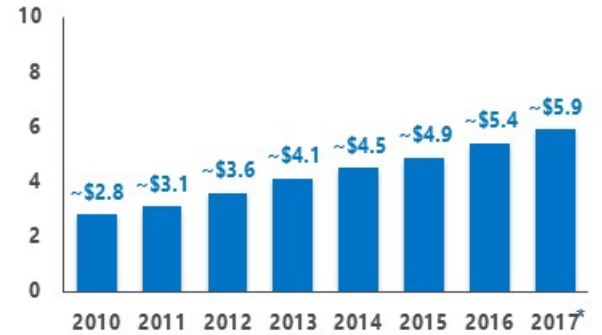
### IG UTILIZATION INCREASING DUE TO

- 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 5 to 7% year over year growth anticipated through 2027

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 RI-002, BIVIGAM® or Nabi-HB®





## **BIVIGAM®**

(Immune Globulin Intravenous, Human)

### **FDA-Approved protection against serious infections**

- Human intravenous immune globulin, 10% liquid
- Indicated for the treatment of patients with PIDD
- 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

Immediate commercial product opportunity with established immunoglobulin brands

# IG IS WIDELY USED AND REIMBURSED

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

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



# PIDD IS A SIGNIFICANT MARKET OPPORTUNITY FOR ADMA

## RI-002 Potential Target Population

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

~50% are treated with IG

### THE ADMA PORTFOLIO OF IG

PRODUCTS can help treat two major subsets of the PIDD population

**BIVIGAM®** targets the general population of 250,000 PIDD patients

**RI-002** could target the most at-risk and severely immune compromised population of PIDD patients (chart on right), if approved

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® offers opportunity to increase ADMA's market penetration in PIDD market by approximately 10X

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

## Risk Factors for Infection in PIDD

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



## 2013 IDF National PIDD Patient Treatment Survey

63%

of respondents reported having asthma, 13% have COPD

46%

of PIDD patients reported they suffer from chronic lung conditions

40%

of PIDD patients report lung infections and other infections in the prior 12 months

~5%

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

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



- Our lead product candidate, RI-002, is being developed for the treatment of PIDD
- Completed a pivotal Phase III clinical study, met primary endpoint and reported positive secondary endpoint(s)
- RI-002 is the basis for ADMA's patented methodology
- Resubmitted BLA for RI-002 in 3Q 2018, PDUFA target action date April 2, 2019

### The Donors Make The Difference

- RI-002 is manufactured using a plasma pool which is formed by using normal source plasma and plasma from donors tested to have high-titers to respiratory syncytial virus (RSV)
- We then use a process called fractionation, which purifies immune globulins (IgG)
- This blended plasma pool results in a final IVIG product containing naturally occurring polyclonal anti-pathogen antibodies

### Our IP & Process Sets Us Apart

- We use our proprietary, patented RSV microneutralization assay to test for appropriate levels of neutralizing antibodies to RSV in the donor plasma and in the final drug product
- Patent is titled "Compositions and Methods for Treatment of Immunodeficiency"
- Patent is first of its kind for use of polyclonal immunoglobulin for treatment of respiratory infections
- Expires in 2035

RI-002 demonstrated positive results and met its primary endpoint in the pivotal Phase III study in patients with PIDD

# DISCOVER THE DIFFERENCE OF ADMA'S PATENTED IMMUNOTECHNOLOGY

## 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

## TAILORED COMPOSITIONS

Tailored plasma pools are derived from a unique blend of normal source plasma and high-titer antibody rich plasma



## PATENTS ISSUED

9,107,906

9,714,283

9,815,886

9,969,793

Expiration 2035

### Potential Follow-On Indication Populations for RI-002

After initial FDA approval, ADMA may seek to expand the label for RI-002 to address these populations' unmet medical needs regarding RSV infection management

- HSCT/Bone Marrow Transplant
  - ~25,000 procedures/year performed in the U.S.
- Solid Organ Transplant (lung, heart, liver and multi-organ)
  - ~11,000 solid organ transplants/year (excluding kidney transplants) performed in the U.S.
- Cancer patients receiving chemotherapy
  - ~375,000 patients/year receive chemotherapy in the U.S. (winter months)

Published data suggests additional label expansion opportunities may be available for RI-002 RSV post approval for PIDD



## 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 Optimization						Awaiting FDA action on CRL responses for Prior Approval Supplement	
Nabi-HB® Hepatitis B, Hyperimmune Globulin	IM formulation							
RI-002 Human, Immunoglobulin intravenous	IG prepared from donors tested for high titers against RSV							
Pathogen of interest - New Product 1	Assay and specialty donor collection program							
Pathogen of interest - New Product 2	Assay and specialty donor collection program							



# Milestones & Financial Highlights

Nasdaq: ADMA



## **Recently Completed**

- Completed a \$72.5M debt financing facility with Perceptive Advisors
- Successfully closed-out April 2018 FDA inspection
  - Inspection classification status improved to VAI
- Submitted RI-002 CRL response and resubmitted BLA for review
  - Received PDUFA target action date of April 2, 2019
- Responded to CRL for BIVIGAM® PAS
- Obtained FDA approval for Kennesaw, GA 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

## **Other Significant Milestones and Achievements**

- Completed acquisition and integration of strategic manufacturing assets and commercial products from BPC
- Phase III study RI-002: 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**

- Obtain FDA approval for BIVIGAM® PAS
- Relaunch BIVIGAM® in the U.S.
- PDUFA target action date April 2, 2019 for RI-002
- Potential commercial sales of RI-002
- Disclose potential product development pipeline consisting of additional specialty plasma and/or hyperimmune IG products
- Work with FDA to close-out Warning Letter
- Commercial launch for RI-002
- Evaluate potential for manufacturing capacity expansion post product candidates' approvals

## Financial Summary: 09/30/18 Results

Cash, cash equivalents and short-term investments	\$42.4M
Total assets	\$106.3M
Total liabilities	\$69.1M
Total stockholders' equity	\$37.2M
Revenue	\$12.9M
Common stock outstanding	46.4M
Fully diluted common stock outstanding	51.2M

# SUBSTANTIAL REVENUE OPPORTUNITIES AND PRODUCT DEVELOPMENT PLATFORM

## DRUG MANUFACTURING COMMERCIAL & PIPELINE PRODUCTS

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

## PLASMA COLLECTION

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

## CONTRACT MANUFACTURING & TESTING

- CURRENT CONTRACT FOR HYPERIMMUNE GLOBULIN
- MONOCLONAL FACILITY
- FULL QC LABORATORY

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