

ADMA BIOLOGICS, INC.  
Form S-3  
May 18, 2018

**As filed with the Securities and Exchange Commission on May 18, 2018.**

**Registration No. 333-**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM S-3  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

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**ADMA Biologics, Inc.**  
(Exact name of registrant as specified in its charter)

**Delaware**    **56-2590442**  
(State or other jurisdiction of    (I.R.S. Employer  
incorporation or organization) Identification Number)

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**465 State Route 17**  
**Ramsey, New Jersey 07446**  
**(201) 478-5552**  
(Address, including zip code, and telephone number, including area code,  
of registrant's principal executive offices)

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**Adam S. Grossman**  
**President and Chief Executive Officer**  
**ADMA Biologics, Inc.**  
**465 State Route 17**  
**Ramsey, New Jersey 07446**  
**(201) 478-5552**  
(Name, address, including zip code, and telephone number, including area code,

of agent for service)

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Copies to:

**David C. Schwartz, Esq.**  
**DLA Piper LLP (US)**  
**51 John F. Kennedy Parkway, Suite 120**  
**Short Hills, New Jersey 07078-2704**  
**(973) 520-2550**

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**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this Registration Statement, as determined by market conditions.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 (the "Securities Act"), other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer   
 Non-accelerated filer  Smaller reporting company   
 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 7(a)(2)(B) of the Securities Act.

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered(1)	Amount to be Registered(2)(3)	Proposed Maximum Offering Price Per Unit (2)(3)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
<b>Primary Offering:</b>				
Common stock, \$0.0001 par value per share			(2) —	
Preferred stock, \$0.0001 par value per share			(2) —	
Debt securities			(2) —	
Warrants			(2) —	
Units			(2) —	
<b>Primary Offering Total</b>			<b>\$ 100,000,000</b>	<b>\$ 12,450(4)</b>
<b>Secondary Offering:</b>				
Common stock, \$0.0001 par value per share	4,295,580	\$ 4.90 (5)	\$21,048,342 (5)	\$2,621 (5)
<b>Total</b>			<b>\$121,048,342</b>	<b>\$15,071 (6)</b>

(1) Securities registered hereunder may be sold separately, together or as units with other securities registered hereunder.

(2) With respect to the primary offering, such information is not required to be included pursuant to General Instruction II.D of Form S-3 under the Securities Act.

(3) With respect to the primary offering, we are registering hereunder such indeterminate number of each identified class of securities up to a proposed aggregate offering price of \$100,000,000, which may be offered by us from time to time in unspecified numbers and at indeterminate prices, and as may be issued upon conversion, exercise, redemption, repurchase or exchange of any securities registered hereunder, including under any applicable anti-dilution provisions. If any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be in such greater principal amount as shall result in an aggregate initial offering price not to exceed \$100,000,000, less the aggregate dollar amount of all securities previously issued hereunder. In addition, pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate

number of shares of common stock and preferred stock as may be issuable with respect to the securities being registered hereunder as a result of stock splits, stock dividends or similar transactions. In addition, with respect to the secondary offering, we are registering hereunder 4,295,580 shares of our common stock that the selling stockholder may sell from time to time.

- (4) Calculated pursuant to Rule 457(o) under the Securities Act, based on the proposed maximum aggregate offering price.
- (5) Pursuant to Rule 457(c) under the Securities Act, the offering price and registration fee are computed based on the average of the high and low prices reported for our common stock traded on The Nasdaq Capital Market on May 11, 2018.
- (6) The registration fee of \$15,071 is being paid at the time of this filing.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**The information in this prospectus is not complete and may be changed or supplemented. No securities described in this prospectus can be sold until the registration statement that we filed to cover the securities has become effective under the rules of the Securities and Exchange Commission. This prospectus is not an offer to sell the securities, nor is it a solicitation of an offer to buy the securities in any state where an offer or sale of the securities is not permitted.**

**Subject to Completion, dated May 18, 2018**

**Prospectus**

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**\$100,000,000**

**Common Stock, Preferred Stock,  
Debt Securities, Warrants and Units**

**4,295,580**

**Shares of Common Stock  
Offered by the Selling Stockholder**

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We may offer from time to time in one or more offerings up to an aggregate of \$100,000,000 of the common stock, preferred stock, debt securities, warrants or units described in this prospectus, separately or together in one or more combinations. The preferred stock, debt securities, and warrants may be convertible into or exercisable or exchangeable for common stock or preferred stock or other securities, as identified in the applicable prospectus supplement.

In addition, the selling stockholder may offer and sell, from time to time, subject to the provisions of that certain Stockholders Agreement, dated as of June 6, 2017, by and between the Company and Biotest Pharmaceuticals Corporation (“BPC”), as amended by that certain Share Transfer, Amendment and Release Agreement, dated as of May

14, 2018, by and among us, ADMA BioManufacturing, LLC, ADMA Bio Centers Georgia Inc., BPC, Biotest AG, Biotest US Corporation and The Biotest Divestiture Trust, up to an aggregate of 4,295,580 shares of voting common stock, \$0.0001 par value per share, referred to herein as “common stock”, under this prospectus. We will not receive any proceeds from sales of our common stock, if any, by the selling stockholder.

This prospectus provides a general description of the securities we or the selling stockholder may offer. This prospectus will allow us and the selling stockholder to offer for sale securities over time. Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus may add, update or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as the documents incorporated by reference herein and therein, before you invest in any of our securities. This prospectus may not be used to sell the securities unless accompanied by a prospectus supplement.

We may offer and sell the securities through underwriters, dealers or agents, or directly to purchasers, or through a combination of these methods. See “Plan of Distribution” beginning on page 38 of this prospectus.

Our common stock is listed on the Nasdaq Capital Market under the symbol “ADMA.” On May 15, 2018, the last reported sale price of our common stock was \$5.28 per share.

**Investing in our securities involves risk. See “Risk Factors” beginning on page 7 of this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as the documents incorporated by reference herein and therein, before you invest in any of our securities.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

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The date of this prospectus is \_\_\_\_\_, 2018

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission (the “SEC”) using a “shelf” registration process under the Securities Act of 1933, as amended (the “Securities Act”). Under this shelf registration process, we may offer and sell, from time to time, any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$100,000,000. In addition, the selling stockholder may offer and sell, from time to time, subject to the provisions of that certain Stockholders Agreement, dated as of June 6, 2017 (the “Stockholders Agreement”), by and between us and Biotest Pharmaceuticals Corporation (“BPC”), as amended by that certain Share Transfer, Amendment and Release Agreement, dated as of May 14, 2018, by and among us, ADMA BioManufacturing, LLC, ADMA Bio Centers Georgia Inc., BPC, Biotest AG, Biotest US Corporation and The Biotest Divestiture Trust, up to an aggregate of 4,295,580 shares of common stock under this prospectus.

This prospectus provides you with a general description of the securities we or the selling stockholder may offer. Each time we or the selling stockholder sell the securities, we will, to the extent required by law, provide a prospectus supplement that will contain specific information about the terms of the offering. We may also authorize one or more free writing prospectuses to be provided to you in connection with the offering. The prospectus supplement and any related free writing prospectus may add, update or change information contained in this prospectus. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. You should carefully read this prospectus, the applicable prospectus supplement, and any applicable free writing prospectus, as well as the information and documents incorporated herein and therein by reference and the additional information under the heading “Where You Can Find More Information,” before making an investment decision.

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained in, or incorporated by reference into, this prospectus and the applicable prospectus supplement, and any free writing prospectus we have authorized for use in connection with a specific offering. You must not rely upon any other information or representation.

This prospectus and any accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and any accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus, any accompanying prospectus supplement and any applicable free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus, any accompanying prospectus supplement or any applicable free writing prospectus is delivered, or securities sold, on a later date.

This prospectus may not be used by us to consummate sales of our securities unless it is accompanied by a prospectus supplement. To the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

This prospectus includes our trademarks, trade names and service marks, such as “Nabi-HB®” and “Bivigam®,” which are protected under applicable intellectual property laws and are the property of us or our subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, <sup>TM</sup> or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

## **PROSPECTUS Summary**

*This summary highlights selected information contained elsewhere in this prospectus or incorporated by reference into this prospectus. This summary does not contain all the information that you should consider before investing in our securities. You should carefully read this entire prospectus, the applicable prospectus supplement and any related free writing prospectus, including each of the documents incorporated herein or therein by reference, before making an investment decision. Unless the context otherwise requires, references in this prospectus to “we,” “us,” “our,” the “Company,” “ADMA Biologics” and “ADMA” refer to ADMA Biologics, Inc., a Delaware corporation, and its subsidiaries, ADMA Plasma Biologics, Inc., a Delaware corporation, ADMA Bio Centers Georgia Inc., a Delaware corporation (“ADMA BioCenters”), and ADMA BioManufacturing, LLC, a Delaware limited liability company (“ADMA BioManufacturing”).*

## ***Our Business***

We are a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of Primary Immune Deficiency Disease (“PIDD”) and the prevention and treatment of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. We currently have two marketed products: Nabi-HB, indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen (“HBsAg”); and Bivigam, indicated for the treatment of primary humoral immunodeficiency. We are also developing a pipeline of plasma-derived therapeutics, including our lead pipeline product candidate, RI-002 for the treatment of PIDD. Our products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases. Through ADMA BioCenters, we operate two U.S. Food and Drug Administration (the “FDA”)-licensed, German Health Authority (“GHA”) and Korean Ministry of Food and Drug Safety (“KMFDS”)-certified source plasma collection facilities located in the United States, which provide us with a portion of our blood plasma for the manufacture of our products and product candidates.

On June 6, 2017, we completed the acquisition of certain assets (the “Biotest Assets”) of the Therapy Business Unit (“BTBU”) of Biotest Pharmaceuticals Corporation (“BPC” and, together with Biotest AG, “Biotest”), which include two FDA-licensed products, Nabi-HB (Hepatitis B Immune Globulin, Human) and Bivigam (Immune Globulin Intravenous, Human), and a plasma fractionation facility located in Boca Raton, FL (the “Boca Facility”) (the “Biotest Transaction”). The Boca Facility is FDA-licensed and certified by the GHA. In addition to the manufacture and sale of Nabi-HB and Bivigam, we also provide contract manufacturing services for certain historical clients, including the sale of intermediate by-products. Immediately following the acquisition, the Biotest Assets were contributed into ADMA BioManufacturing.

On May 14, 2018, we, ADMA BioManufacturing and ADMA BioCenters entered into a Share Transfer, Amendment and Release Agreement with BPC, Biotest AG, Biotest US Corporation (“Biotest US”) and The Biotest Divestiture Trust (the “Biotest Trust”) (the “Biotest Transfer Agreement”) whereby BPC transferred to us, for no cash consideration, 8,591,160 shares of our non-voting common stock previously issued to BPC in connection with the Biotest Transaction and representing 100% of our issued and outstanding non-voting common stock (the “NV Biotest Shares”). Immediately upon transfer of the NV Biotest Shares to us, the shares were retired and are no longer available for issuance. The retired NV Biotest Shares comprised approximately 19% of our total outstanding common stock as of May 14, 2018. In exchange for the transfer and retirement of the NV Biotest Shares, we have (i) granted Biotest and its successors and assigns a release from all potential past, present and future indemnity claims arising under that certain Master Purchase and Sale Agreement, dated as of January 21, 2017 (as amended, restated, supplemented or otherwise modified from time to time, the “Purchase Agreement”), with BPC, and for certain limited purposes set forth in the Purchase Agreement, Biotest AG and Biotest US (together with Biotest AG, the “Biotest Guarantors”), and (ii) relinquished our rights to repurchase our two FDA-approved plasma collection centers required to be transferred to BPC on January 1, 2019. In addition, pursuant to the Biotest Transfer Agreement, BPC waived and terminated its rights to name a director and an observer to our Board of Directors (the “Board”). As BPC has made public statements regarding the U.S. Government required divestiture of all of BPC’s U.S. assets in connection with the sale of Biotest AG to CREAT Group Corporation, pursuant to the Biotest Transfer Agreement BPC, subject to the receipt of required regulatory approvals, has agreed to transfer its remaining 10,109,534 shares of the Company’s voting common stock, \$0.0001 par value per share (the “common stock”), to the Biotest Trust upon the earlier of (i) receipt of consent from the necessary governmental authorities and (ii) July 1, 2018 (provided that Biotest and the Biotest Trust have received all required regulatory approvals for the Biotest Trust to own and hold the common stock) (the “Voting Share Closing Date”). Furthermore, pursuant to the Biotest Transfer Agreement, the Biotest Trust has agreed to be bound by all obligations of, and will have all of the remaining rights of, BPC under that certain (i) Stockholders Agreement, dated as of June 6, 2017, by and between us and BPC, as amended by the Biotest Transfer Agreement, and (ii) Registration Rights Agreement, dated as of June 6, 2017, by and between us and BPC.

Concurrent with the closing of the Biotest Transaction, Biotest committed to an aggregate of \$40.0 million of funding for us. Upon the closing of the Biotest Transaction, we received \$27.5 million from Biotest, comprised of \$12.5 million in cash from BPC and a \$15.0 million subordinated note at 6% interest payable to BPC with a maturity of five years. At the closing of the Biotest Transaction, we delivered to BPC an aggregate equity interest equal to 50%, less one share, of our then-issued and outstanding capital stock comprised of 25%, or 4,295,580 shares, of our common stock, and 8,591,160 shares in the form of our non-voting common stock (calculated as of immediately following the closing and on a post-closing issuance basis). Biotest also participated in our November 2017 follow-on equity offering by investing \$12.5 million of the \$42.0 million of total gross proceeds from the offering.

For three years commencing December 6, 2017, subject to certain limited exceptions, under the Stockholders Agreement, sales by the Biotest Trust of our equity interests may not exceed 15% of our issued and outstanding common stock in any twelve-month period; provided, however, that if our market capitalization increases to double our market capitalization immediately following the closing of the Biotest Transaction, then the Biotest Trust may sell up to 20% of our issued and outstanding common stock in any twelve-month period; provided, further, that (x) if our market capitalization increases to triple our market capitalization immediately following the closing of the Biotest Transaction, or (y) upon the one-year anniversary of the Biotest Trust holding less than a 25% economic interest in us, then the Biotest Trust may sell its equity interests in us at any time (subject to applicable securities laws). Subject to the terms contained in the Biotest Transfer Agreement, for a 90-day period following the Voting Share Closing Date, the Biotest Trust has granted us a right of first negotiation for the purchase of the remaining shares of common stock then-held by the Biotest Trust.

### ***Our Marketed Products***

#### ***Nabi-HB***

Nabi-HB is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB is indicated for the treatment of acute exposure to blood containing HBsAg, prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. Hepatitis B is a potentially life-threatening liver infection caused by the Hepatitis B virus. It is a major global health problem. It can cause chronic infection and puts people at high risk of death from cirrhosis and liver cancer. Nabi-HB has a well-documented record of long-term safety and effectiveness since its initial market introduction. FDA approval for Nabi-HB was received on March 24, 1999. Biotest acquired Nabi-HB from Nabi Biopharmaceuticals in 2007. Under our leadership, production of Nabi-HB at the Boca Facility resumed during the third quarter of 2017. Subsequent to the end of 2017, we received authorization from the FDA for the release of our first commercial batch of Nabi-HB and also resumed commercial sales in the United States during the first quarter of 2018.

#### ***Bivigam***

Bivigam is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These primary immunodeficiencies (“PIs”) are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as one in every 1,200-2,000 people has some form of PI. Bivigam contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses, and help to protect PI patients against serious infections. Bivigam is a purified,

sterile, ready-to-use preparation of concentrated Immunoglobulin (“IgG”) antibodies. Antibodies are proteins in the human immune system that work to defend against disease. FDA approval for Bivigam was received on December 19, 2012, and sales commenced in the first quarter of 2013. In December 2016, BPC temporarily suspended the commercial production of Bivigam in order to focus on the completion of planned improvements to the manufacturing process. We resumed production of Bivigam utilizing our optimized intravenous immunoglobulin (“IVIG”) manufacturing process with two conformance lots in the fourth quarter of 2017 and a third conformance lot in the first quarter of 2018. We expect to file a Prior Approval Supplement (the “PAS”) with the FDA during the first half of 2018 to include the ADMA optimization improvements for Bivigam and are seeking FDA clearance which would enable us to relaunch this product no earlier than the second half of 2018. Upon FDA approval of the PAS, we anticipate the Bivigam conformance lots currently in inventory will be available for commercial sale.

***Our Lead Pipeline Product Candidate – RI-002***

We are currently developing our lead pipeline product candidate, RI-002, for the treatment of PIDD and have completed a pivotal Phase III clinical trial, which met the primary endpoint of no Serious Bacterial Infections reported. Secondary efficacy endpoints further demonstrated the benefits of RI-002 in the low incidence of infection, therapeutic antibiotic use, days missed from work/school/daycare, and unscheduled medical visits and hospitalizations. RI-002 is derived from human plasma blended from normal donors and from donors tested to have high levels of neutralizing titers to Respiratory Syncytial Virus (“RSV”). RI-002 is manufactured using a process known as fractionation, which purifies IgG from this blended plasma pool resulting in a final IVIG product enriched with naturally occurring polyclonal anti-pathogen antibodies, such as streptococcus pneumonia, H. influenza type B, Cytomegalovirus, measles and tetanus. We use our proprietary RSV microneutralization assay to test for standardized levels of neutralizing antibodies to RSV in the final drug product.

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for RI-002. In the third quarter of 2015, the FDA accepted for review our Biologics License Application for RI-002 (the “RI-002 BLA”) for the treatment of PIDD. In July 2016, the FDA issued a Complete Response Letter (the “CRL”), which reaffirmed the issues set forth in the November 2014 warning letter that had been issued by the FDA to Biotest related to certain issues identified at the Boca Facility (the “Warning Letter”), but did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in our RI-002 BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies related to Chemistry, Manufacturing and Controls (“CMC”) and Good Manufacturing Practices (“GMP”) at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of our RI-002 BLA until, among other things, these deficiencies are resolved. Upon the completion of the Biotest Transaction, we gained control over the regulatory, quality, general operations and drug substance manufacturing process, and our highest priority has been to remediate the outstanding compliance issues that were identified at the Boca Facility in the Warning Letter. We have been working with a consulting firm consisting of quality management systems and biologics production subject matter experts in order to improve the FDA inspection classification relative to the Warning Letter compliance issues as indicated in the CRL. We anticipate that we will be in a position to refile the RI-002 BLA in the second half of 2018, assuming certain FDA determinations are made concerning the Warning Letter and PAS for Bivigam. During the first quarter of 2018, we produced three RI-002 conformance lots using the optimized IVIG manufacturing process. Upon FDA approval of the RI-002 BLA, we anticipate that the RI-002 conformance batches currently in inventory will be available for commercial sale no earlier than the first half of 2019.

### ***Plasma Collection Facilities***

ADMA BioCenters operates three source plasma collection facilities located in the U.S., two of which are FDA-licensed, GHA and KMFDS-certified. ADMA BioCenters supplies us with a portion of our blood plasma for the manufacture of our products and product candidates. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our products or product candidates is sold to third-party customers in the United States, and other locations where we are approved globally under supply agreements or in the open “spot” market.

As part of the purchase price to acquire the Biotest Assets, we agreed to transfer ownership of two of our plasma collection facilities to BPC on January 1, 2019. We completed the construction of our third plasma collection facility, filed our Biologics License Application (the “BLA”) with the FDA and initiated collections for this facility in December 2017. We anticipate FDA approval of our third plasma collection facility to occur during the second half of 2018.

### ***Risk Factors***

Investing in our securities involves a significant degree of risk. See “Risk Factors” beginning on page 7 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities. These risks include among others:

- To date, we have generated limited product revenues, have a history of losses and will need to raise additional capital to operate our business, which may not be available on favorable terms, if at all.
- Failure to timely and effectively remediate the outstanding Warning Letter and other inspection issues and deficiencies at the Boca Facility will have a material adverse effect on our business. Failure of the FDA to adhere to its stated timelines in the Code of Federal Regulations, as well as any potential government shut-downs or unforeseen government office closings may affect our ability to resolve the Warning Letter and other inspection issues within the timelines provided.
- We may not realize the strategic and financial benefits currently anticipated from the Biotest Transaction.
- We may not be successful in integrating the Biotest Assets into our business.
- By completing the Biotest Transaction, we agreed to transfer assets that have historically generated substantially all of our revenue.
- Historically a single customer has accounted for a significant amount of our total revenue and, together with a second customer, represented 78% of our total revenue for the year ended December 31, 2017 and, collectively with two other customers, represented 90% of our total revenue for the three months ended March 31, 2018, and therefore the loss of such single customer could have a material adverse effect on our business, results of operations and financial condition.
- Our credit agreement (the “Credit Agreement”) with Marathon Healthcare Finance Fund, L.P. (“Marathon”) is subject to acceleration in specified circumstances, which may result in Marathon taking possession and disposing of any collateral.



- Business interruptions could adversely affect our business.
- The new biosimilar pathway established as part of the healthcare reform may make it easier for competitors to market biosimilar products.

### ***Corporate Information***

ADMA Biologics, Inc. was founded on June 24, 2004 as a New Jersey corporation and re-incorporated in Delaware on July 16, 2007. We operate through our wholly-owned subsidiaries ADMA BioManufacturing, ADMA Plasma Biologics and ADMA BioCenters. ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of the Biotest Assets. ADMA BioCenters is the Company's source plasma collection business which operates in the United States. Each operational biocenter, once approved, will have a license with the FDA and may obtain additional certifications from other regulatory agencies such as the GHA and the KMFDS. ADMA BioCenters supplies ADMA with a portion of its raw material plasma for the manufacture of its products and product candidates.

We maintain our headquarters at 465 State Route 17, Ramsey, NJ 07446. Our telephone number is (201) 478-5552. Our Florida campus is located at 5800 Park of Commerce Boulevard, Northwest, Boca Raton, FL 33487. The Florida telephone number is (561) 989-5800. We maintain a website at [www.admabiologics.com](http://www.admabiologics.com); however, the information on, or that can be accessed through, our website is not part of this prospectus or any accompanying prospectus supplement or related free writing prospectus.

## **RISK FACTORS**

*Investing in any securities offered pursuant to this prospectus, the applicable prospectus supplement and any related free writing prospectus involves a high degree of risk. You should carefully consider the risks described under “Risk Factors” in the applicable prospectus supplement, any related free writing prospectus and in our most recent Annual Report on Form 10-K, or any updates in our Quarterly Reports on Form 10-Q, together with all of the other information appearing in or incorporated by reference into this prospectus, the applicable prospectus supplement and any related free writing prospectus, before deciding whether to purchase any of the securities being offered. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.*

### **Risks Relating to our Business**

*To date, we have generated limited product revenues, have a history of losses and will need to raise additional capital to operate our business, which may not be available on favorable terms, if at all.*

To date, we have generated a substantial portion of our revenues from the sale of plasma by our plasma collections facilities. Following completion of the Biotest Transaction, we began generating revenues from the sale of Nabi-HB, and we recorded additional revenue in connection with a contract manufacturing agreement. Unless and until we receive approval from the FDA and other regulatory authorities for our RI-002 product candidate and other products and product candidates in our pipeline, we do not expect to sell and generate revenue from the commercialization of RI-002 and other products and product candidates in our pipeline, and we will be required to raise additional funds through the sale of our equity and/or debt securities in order to establish a commercial sales force, develop our commercial infrastructure and recognize any significant revenues.

Our long-term liquidity will depend upon our ability to raise additional capital, fund our research and development and commercial programs, establish and build out a commercial sales force and commercial infrastructure and meet our ongoing obligations. If we are unable to successfully raise additional capital prior to the end of 2018, we will likely not have sufficient cash flow and liquidity to fund our business operations as we currently operate, forcing us to potentially curtail our activities and significantly reduce or cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our common stock may decline. In addition, if we raise additional funds through license arrangements or through the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or assets or grant licenses on terms that are not favorable to us.

Based upon our projected revenue and expenditures for fiscal 2018, including regulatory and consulting fees for the remediation of the Warning Letter and ongoing discussions with the FDA, continuing implementation of our commercialization and expansion activities and certain other assumptions, we currently believe that our cash, cash equivalents, projected revenue and accounts receivable, along with the additional \$10.0 million we expect to be able to access through our existing senior credit facility will be sufficient to fund our operations, as currently conducted, into the fourth quarter of 2018. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing by the end of 2018. This timeframe may change based upon how quickly we are able to execute on our quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options available to us. These estimates may also change based upon whether or when the FDA approves RI-002 or if any of our other assumptions change. We currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution to stockholders. Failure to secure necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan and financial performance and could delay, discontinue or prevent product development, clinical trials, commercialization activities or the approval of any of our potential products. In addition, we could be forced to reduce or forgo sales and marketing efforts and forgo attractive business opportunities.

***Failure to timely and effectively remediate the outstanding Warning Letter and other inspection issues and deficiencies at the Boca Facility will have a material adverse effect on our business. Failure of the FDA to adhere to its stated timelines in the Code of Federal Regulations, as well as any potential government shut-downs or unforeseen government office closings may affect our ability to resolve the Warning Letter and other inspection issues within the timelines provided.***

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for RI-002. In response to our RI-002 BLA submission in 2015, in July 2016 the FDA issued the CRL. The CRL did not specify or request the need for any additional clinical trials or data; however, the CRL reaffirmed the issues set forth in the Warning Letter issued to Biotest relating to inspection issues identified at the Boca Facility. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies related to CMC and GMP at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of our RI-002 BLA until, among other things, these deficiencies are resolved. Following the completion of the Biotest Transaction, we gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and our highest priority has been to remediate the outstanding compliance issues at the Boca Facility as indicated in the Warning Letter. We have been working with a consulting firm consisting of quality management systems and biologics production subject matter experts with extensive experience in remediating compliance and inspection issues related to quality management systems that manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified CMC and current good manufacturing practice (“cGMP”) issues and deficiencies. We believe that we have been inspection-ready since the end of 2017 and expect to have the FDA inspection classification relative to the Warning Letter improved after the next inspection by the FDA, however there can be no assurances as to the timing by which the FDA may inspect the facility and/or make any determinations post-inspection concerning our compliance status. There can also be no assurances that our ongoing efforts to remediate the Warning Letter and other inspection issues and deficiencies at the Boca Facility will be effective or whether the FDA will accept these efforts. Failure to timely remediate the issues identified in the Warning Letter and other inspection issues and deficiencies and/or receive approval from the FDA, as well as passing an FDA inspection within this timeline, if at all, will have a material adverse effect on our business, prospects, financial condition and results of operations. Additionally, we are unable to control the timing of FDA inspections, responses, meeting requests, teleconference requests, requests for clarifications and similar regulatory communications as well as whether or not the FDA will change its requirements, guidance or expectations.

***We are currently not profitable and may never become profitable.***

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. For the years ended December 31, 2017 and 2016, we incurred net losses of \$43.8 and \$19.5 million, respectively, and for the three months ended March 31, 2018 and 2017, we incurred net losses of \$17.8 million and \$6.5 million, respectively. From our inception in 2004 through March 31, 2018, we have incurred an accumulated deficit of \$168.5 million. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital

expenditures and anticipate that our operating expenses will increase substantially in the foreseeable future as we:

- remediate the outstanding compliance deficiencies identified by the FDA in the CRL and Warning Letter at the Boca Facility;
- seek regulatory approval(s);
- initiate commercialization and marketing efforts;
- implement additional internal systems, controls and infrastructure;
- hire additional personnel;
- expand and build out our plasma center network; and
- continue to integrate the Biotest Assets into our business.

We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our securities.

***Although our financial statements have been prepared on a going concern basis, we must raise additional capital by the end of 2018 to fund our operations in order to continue as a going concern.***

CohnReznick LLP, our independent registered public accounting firm, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2017, indicating that our current liquidity position and history of losses raise substantial doubt about our ability to continue as a going concern. If we are unable to improve our liquidity position we may not be able to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements. We may also be forced to make reductions in spending, including delaying or curtailing our clinical development, trials or commercialization efforts, or seek to extend payment terms with our vendors and creditors. Our ability to raise or borrow the capital needed to improve our financial condition may be hindered by a variety of factors, including market conditions and the availability of such financing on acceptable terms, if at all. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. Our audited consolidated financial statements as of and for the year ended December 31, 2017 do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business, which could cause our security holders to suffer the loss of all or a substantial portion of their investment.

We anticipate that our principal sources of liquidity will only be sufficient to fund our activities, as currently conducted, into the fourth quarter of 2018. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing prior to the end of 2018. This time frame may change based upon how quickly we are able to execute on our quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options available to us. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional equity or debt capital, and we cannot provide any assurance that we will be successful in doing so. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the fourth quarter of 2018.

***We have a limited operating history upon which to base an investment decision.***

We have not demonstrated an ability to perform the functions necessary for the successful commercialization of RI-002. The successful development and commercialization of any product candidate will require us or our collaborators to perform a variety of functions, including:

- undertaking product development and clinical trials;
  - participating in regulatory approval processes;
  - formulating and manufacturing products; and
- conducting sales and marketing activities once product approval is received.

Our operations thus far provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

***Business interruptions could adversely affect our business.***

ADMA BioCenters operates FDA-licensed, GHA and KMFDS-certified source plasma collection facilities located in the United States, which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our products and product candidates is sold to third-party customers in the United States and other locations where we are approved globally under supply agreements or in the open "spot" market. Furthermore, we have completed the construction of our third plasma collection facility, and we filed our BLA with the FDA and initiated collections for this facility in

December 2017. Nabi-HB and Bivigam are manufactured at the Boca Facility, an FDA-licensed facility certified by the GHA. A portion of our revenues are dependent upon the continued operation of these facilities. Our operations are vulnerable to interruption by fire, weather related events such as hurricanes, wind and rain, other acts of God, electric power loss, telecommunications failure, equipment failure and breakdown, human error, employee issues and events beyond our control. We do not have detailed disaster recovery plans for our facilities nor do we have a backup manufacturing facility, other than our other facilities, or contractual arrangements with any other manufacturers in the event of a casualty to or destruction of any facility or if any facility ceases to be available to us for any other reason. If we are required to rebuild or relocate any of our facilities, a substantial investment in improvements and equipment would be necessary. We carry only a limited amount of business interruption insurance, which may not sufficiently compensate us for losses that may occur.

***Our lead pipeline product candidate, RI-002, requires extensive clinical data analysis and regulatory review and may require additional testing. Clinical trials and data analysis can be very expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for RI-002, or any of our product candidates do not provide positive results, we may be required to delay or abandon development of such product, which would have a material adverse impact on our business.***

Continuing product development requires additional and extensive clinical testing. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. While we have met the primary endpoint for our pivotal Phase III trial for RI-002, we cannot provide any assurance or certainty regarding when we might receive regulatory approval of our RI-002 BLA. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon our RI-002 BLA or repeat clinical trials. The commencement and completion of clinical trials for any current or future development product candidate may be delayed by several factors, including:

- unforeseen safety issues;

- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, the FDA or an independent institutional review board may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug (“IND”) submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. In the event we do not ultimately receive regulatory approval for RI-002, we may be required to terminate development of our only product candidate. Unless we acquire or develop other product candidates that are saleable, our business will be limited to plasma collection and sales, as well as sales of Nabi-HB and Bivigam.

***If the results of our clinical trials do not support our product candidate claims, completing the development of such product candidate may be significantly delayed or we may be forced to abandon development of such product candidate altogether.***

Even though our clinical trials for RI-002 have been completed as planned, we cannot be certain that their results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve a relatively small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results. In addition, certain portions of the clinical trial and product testing for RI-002 were performed outside of the United States, and therefore, may not have been performed in accordance with standards normally required by the FDA and other regulatory agencies.

***If we do not obtain the necessary U.S. or worldwide regulatory approvals to commercialize RI-002, we will not be able to sell RI-002.***



If we cannot obtain regulatory approval for RI-002, we will not be able to generate revenue from this product candidate. As a result, our sources of revenue may continue to be from a product mix consisting only of plasma collection and sales revenues, revenues generated from sales of our FDA-approved commercial products, revenues generated from ongoing contract manufacturing for third parties and revenues generated from the sales of manufacturing intermediates. We cannot assure you that we will receive the approvals necessary to commercialize RI-002 or any other product candidate we may acquire or develop in the future. In order to obtain FDA approval of RI-002 or any other product candidate requiring FDA approval, our clinical development must demonstrate that the product candidate is safe for humans and effective for its intended use, and we must successfully complete an FDA BLA review. Obtaining FDA approval of any other product candidate generally requires significant research and testing, referred to as preclinical studies, as well as human tests, referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the product approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidate;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject our RI-002 BLA. In addition, the FDA could determine that we must test additional subjects and/or require that we conduct further studies with more subjects. We may never obtain regulatory approval for RI-002, or any other future potential product candidate or label expansion activity. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without the ability to generate additional accretive revenues. There is no guarantee that we will ever be able to develop or acquire other product candidates. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products or product candidates outside the United States. Foreign regulatory approval processes generally include all of the risks and uncertainties associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the United States.

***Even if we receive approval from the FDA to market RI-002, our ability to market RI-002 for alternative applications could be limited.***

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the Internet and off-label promotion. The FDA generally does not allow drugs to be promoted for “off-label” uses — that is, uses that are not described in the product’s labeling and that differ from those that were approved by the FDA. Generally, the FDA limits approved uses to those studied by a company in its clinical trials. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. We have sought approval from the FDA to market RI-002 for the treatment of PIDD and, even if approved, we cannot be sure whether we will be able to obtain FDA approval for any desired future indications for RI-002.

While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product’s labeling, and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote our products is narrowly limited to those indications that are specifically approved by the FDA. “Off-label” uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label communications, such as truthful and non-misleading speech, may be protected under the First Amendment, the scope of any such protection is unclear, and there are still significant risks in this area as it is unclear how these court decisions will impact the FDA’s enforcement practices, and there is likely to be substantial disagreement and difference of opinion regarding whether any particular statement is truthful and not misleading. Moreover, while we intend to promote our products consistent with what we believe to be the approved indication for our drugs, the FDA may disagree. If the FDA determines that our promotional activities fail to comply with the FDA’s regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines related to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

***We depend on third-party researchers, developers and vendors to develop RI-002, and such parties are, to some extent, outside of our control.***

We depend on independent investigators and collaborators, such as universities and medical institutions, contract laboratories, clinical research organizations, contract manufacturers and consultants to conduct our preclinical, clinical trials, CMC testing and other activities under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign

as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our product-development programs, or if their performance is substandard, the approval of our FDA application(s), if any, and our introduction of new products, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed. Additionally, any change in the regulatory compliance status of any of our vendors may impede our ability to receive approval for our product candidates.

***Historically a single customer has accounted for a significant amount of our total revenue and, together with a second customer, represented 78% of our total revenue for the year ended December 31, 2017 and, collectively with two other customers, represented 90% of our total revenue for the three months ended March 31, 2018, and therefore the loss of such single customer could have a material adverse effect on our business, results of operations and financial condition.***

Historically, a significant amount of our total revenue is attributable to a single customer, BPC. For the year ended December 31, 2017, BPC and Sanofi Pasteur S.A. (“Sanofi”) represented 78% of our total revenue, with BPC representing 47% of our total revenue and Sanofi representing 31% of our total revenue. For the three months ended March 31, 2018, three customers represented an aggregate of 90% of our consolidated revenues, with BPC, McKesson Corporation and AmerisourceBergen representing 58%, 17% and 15%, respectively, of our consolidated revenues. For the three months ended March 31, 2017, sales to BPC represented 81% of our consolidated revenues, and sales to SK Plasma Co., Ltd. represented 17% of our consolidated revenues.

Although we expect this concentration to continue to decrease during 2018 as additional sales of Nabi-HB, revenues from our contract manufacturing services and sale of intermediate by-products are reflected in our consolidated financial statements, BPC is still expected to account for a significant portion of our total revenue in fiscal 2018.

The loss of BPC as a customer or a material change in the revenue generated by BPC could have a material adverse effect on our business, results of operations and financial condition. Factors that could influence our relationships with our customers include, among other things:

- our ability to sell our products at competitive prices;

- our ability to maintain features and quality standards for our products sufficient to meet the expectations of our customers; and

- our ability to produce and deliver a sufficient quantity of our products in a timely manner to meet our customers' requirements.

Additionally, an adverse change in the financial condition of BPC could have a material adverse effect on our business and results of operations.

***Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.***

Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue by us or by a third-party vendor in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully commercializing our current products and launching new products.

***If physicians and patients do not accept and use our current products or our future product candidates, our ability to generate revenue from these products will be materially impaired.***

Even if the FDA approves a product made by us, physicians and patients may not accept and use it. Acceptance and use of our products will depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
- cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- the effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of our current and future products to find market acceptance would harm our business and could require us to seek additional financing or make such financing difficult to obtain on favorable terms, if at all.

***Industry and other market data used in our periodic reports filed with the SEC and certain other materials, including those undertaken by us or our engaged consultants, may not prove to be representative of current and future market conditions or future results.***

Our periodic reports filed with the SEC and certain other materials include statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and surveys and studies we commissioned regarding the market potential for our current products as well as RI-002. Although we believe that such information has been obtained from sources believed to be reliable, neither the sources of such data, nor we, can guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. With respect to the information from third-party consultants, the results of this data represent the independent consultants' own methodologies, assumptions, research, analysis, projections, estimates, composition of respondent pool, presentation of data and adjustments, each of which may ultimately prove to be incorrect, and cause actual results and market viability to differ materially from those presented in any such report or other materials. Readers should not place undue reliance on this information.

***Our long-term success may depend on our ability to supplement our existing product portfolio through new product development or the in-license or acquisition of other new products and product candidates, and if our business development efforts are not successful, our ability to achieve profitability may be adversely impacted.***

Our current product development portfolio consists primarily of RI-002 and label expansion activities for Nabi-HB and Bivigam. We have initiated small scale preclinical activities to potentially expand our current portfolio through new product development efforts or to in-license or acquire additional products and product candidates. If we are not successful in developing or acquiring additional products and product candidates, we will have to depend on our ability to raise capital for, and the successful development and commercialization of, RI-002, as well as the revenue we may generate from the sale of Nabi-HB, Bivigam, contract manufacturing, and intermediates and plasma attributable to the operations of ADMA BioCenters, to support our operations.

***Our ADMA BioCenters facilities collect information from donors in the United States that subjects us to consumer and health privacy laws, which could create enforcement and litigation exposure if we fail to meet their requirements.***

Consumer privacy is highly protected by federal and state law. The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and their respective implementing regulations, impose, among other things, obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and business associates. A “covered entity” is the primary type of HIPAA-regulated entity. Health plans/insurers, health care providers engaging in standard transactions (insurance/health plan claims and encounters, payment and remittance advice, claims status, eligibility, enrollment/disenrollment, referrals and authorizations, coordination of benefits and premium payments), and health care clearinghouses (switches that convert data between standard and non-standard data sets) are covered entities. A “business associate” provides services to covered entities (directly or as subcontractors to other business associates) involving arranging, creating, receiving, maintaining, or transmitting protected health information (“PHI”) on a covered entity’s behalf. In order to legally provide access to PHI to service providers, covered entities and business associates must enter into a “business associate agreement” (“BAA”) with the service provider PHI recipient. Among other things, HITECH made certain aspects of the HIPAA’s rules (notably the Security Rule) directly applicable to business associates – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. The Department of Health and Human Services Office of Civil Rights (“OCR”) has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement, with one recent penalty exceeding \$5 million.

While we are not a covered entity or business associate subject to HIPAA, even when HIPAA does not apply, according to the U.S. Federal Trade Commission (the “FTC”), failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA Security Rule. In addition, states impose a variety of laws protecting consumer information, with certain sensitive information such as HIV/Sexually Transmitted Disease status subject to heightened standards. In addition, federal and state privacy, data security, and breach notification laws, rules and regulations, and other laws apply to the collection, use and security of personal information, including social security number, driver’s license numbers, government identifiers, credit card and financial account numbers. We could be subject to enforcement action and litigation exposure if we fail to adhere to these data privacy and security laws.

***We may not realize the strategic and financial benefits currently anticipated from the Biotest Transaction.***

We may not realize all of the strategic and financial benefits currently anticipated from the Biotest Transaction. For example, we may not realize the anticipated benefits of acquiring control of all aspects of RI-002 drug manufacturing, regulatory affairs and business operations. In addition, we may not be able to resolve the outstanding issues at the Boca Facility that resulted in the Warning Letter. As part of the remediation of the Warning Letter, in December 2016 BTBU temporarily suspended the production of Bivigam in order to focus on the completion of planned improvements to the manufacturing process. As a result, Bivigam was not available for sale or distribution throughout fiscal 2017. If we are unable to address the underlying concerns at the Boca Facility that resulted in the Warning Letter and the CRL in July 2016 that identified deficiencies and inspection issues related to certain of our third-party contract manufacturers, including BPC, and provide requested documentation of corrections for a number of these issues, we will not be able to apply for the PAS related to the manufacturing of Bivigam or reapply for FDA approval to market and sell RI-002, which could have a material adverse effect on us. Failure to resolve any outstanding issues or any administrative actions taken or changes made by the FDA toward our contract manufacturers, vendors or us could impact our ability to receive approval for RI-002, including the timing thereof, disrupt our business operations and the timing of our commercialization efforts and may have a material adverse effect on our financial condition and operating results.

Through the Biotest Transaction, we assumed a contract manufacturing agreement related to the fractionation of plasma provided by one of our third-party customers that includes certain minimum production requirements. If we are unable to meet our contractual obligations under this agreement, we may be liable for the payment of liquidated damages. If we are unable to resolve these issues, such failure could have a material adverse effect on us.

There is also uncertainty as to whether the combined business will be able to operate at a profitable level in the future given the relatively small size of the Biotest Assets and the competitive environment in which we operate. Furthermore, there is no assurance and no definitive timeline as to when or if the Warning Letter will be resolved by the FDA, and we have no assurances as to the timing by which the FDA may inspect the Boca Facility and/or make any determinations post-inspection concerning our compliance status. These factors could have a material adverse effect on us.

***We may not be successful in integrating the Biotest Assets into our business.***

The Biotest Transaction involves the integration of two businesses that previously have operated independently with principal offices in two distinct locations. We are expending significant management attention and resources to integrate the two companies following completion of the Biotest Transaction. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company's failure to achieve some or all of the anticipated benefits of the Biotest Transaction.

Potential difficulties that may be encountered in the integration process include, but are not limited to, the following:

- using our cash and other assets efficiently to develop the business on a post-Biotest Transaction basis;
- appropriately managing the liabilities of our Company on a post-Biotest Transaction basis;
- potential unknown or currently unquantifiable liabilities associated with the Biotest Transaction and the operations of our Company on a post-Biotest Transaction basis;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the Biotest Transaction; and
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performance shortfalls in one or both of the businesses as a result of the diversion of the applicable management's attention caused by completing the Biotest Transaction and integrating the business.

Delays in the integration process could adversely affect the combined company's business, financial results, financial condition and stock price following the Biotest Transaction. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration or that these benefits will be achieved within a reasonable period of time.

***By completing the Biotest Transaction, we agreed to transfer assets that have historically generated substantially all of our revenue.***

As part of the purchase price to acquire the Biotest Assets, we have agreed to transfer to BPC ownership of our two licensed plasma collection facilities in the United States and certain related assets and liabilities. These plasma collection facilities to be transferred have historically been the source of substantially all of our revenue. Although we have completed construction of a new plasma collection facility, there can be no assurances that we will generate similar revenues as historically reported from the plasma collection facilities we will transfer to BPC on January 1, 2019.

***The Biotest Transaction exposes us to liabilities, a release of claims and competition that could have a material adverse effect on our business, financial condition, results of operations and stock price.***

As part of the consideration for the Biotest Transaction, we agreed to assume certain liabilities of BPC related to BTBU. Because we agreed to assume liabilities related to the Biotest Assets, we are exposed to liabilities that are not within our control and we cannot predict the extent to which these liabilities may arise in the future. Any liabilities that may arise could have a material adverse effect on our business, financial condition, results of operations and stock price.

The Purchase Agreement contains indemnification undertakings by the parties thereto for certain losses, including, among other things, indemnification for any losses arising from breaches of its representations, warranties, covenants and agreements in the Purchase Agreement. In connection with the Biotest Transfer Agreement, we granted Biotest a full release from any and all past, present or future indemnification claims arising under or in connection with the Purchase Agreement. Significant indemnification claims by BPC or its affiliates or breaches by BPC or its affiliates of any indemnity obligations which would have been owed to us under the Purchase Agreement prior to the release granted in the Biotest Transfer Agreement could have a material adverse effect on our business, financial condition, results of operations and stock price.

As part of the consideration for the Biotest Transaction, the parties also agreed to a mutual release, pursuant to which the parties agreed not to bring any suit, action or claim for any breach or default under the existing manufacturing and supply agreement or master services agreement prior to the closing of the Biotest Transaction. This release remains effective from and after the closing of the Biotest Transaction. Without this release, we would have otherwise been permitted to bring a claim against BPC related to the Warning Letter that could have possibly entitled us to remedies in the event that we are unable to resolve the Warning Letter. The inability to seek these remedies could have a material adverse effect on our business, financial condition, results of operations and stock price.

In addition, while the Purchase Agreement contains certain non-compete clauses, such clauses do not prohibit either the Biotest Guarantors or their other affiliates from directly or indirectly (other than through BPC) competing with BTBU after the closing of the Biotest Transaction. Such competition could result in the loss of existing or new customers, price reductions, reduced operating margins and loss of market share, which could have a material adverse effect on our business, financial condition, results of operations and stock price.

***If our due diligence investigation for the Biotest Transaction was inadequate and/or the representations, warranties and indemnification given to us by BPC was inadequate, then it could result in a material adverse effect on our business.***

Even though we believe that we conducted a reasonable and customary due diligence investigation of BTBU and we received market representations, warranties and indemnities from Biotest and BPC, we cannot be sure that our due diligence investigation uncovered all material or non-material issues that may be present. There also can be no assurances that we received access to or had the ability to diligence certain information, as well as appropriate representations and or warranties, that it would be possible to uncover all material issues through customary due diligence, or that issues outside of our control will not later arise or that all material issues which could have been discovered would otherwise be covered by the representations and warranties of Biotest and BPC and therefore indemnifiable. In connection with the Biotest Transfer Agreement, we granted Biotest a full release from any and all past, present or future indemnification claims arising under or in connection with the Purchase Agreement. If we failed to identify any important issues, or if it were not possible to uncover all material issues, any such material issue could result in a material adverse effect on our business, financial condition, results of operations and stock price.

***Our credit agreement (the “Credit Agreement”) with Marathon Healthcare Finance Fund, L.P. (“Marathon”) is subject to acceleration in specified circumstances, which may result in Marathon taking possession and disposing of any collateral.***

On October 10, 2017, we entered into the Credit Agreement with Marathon which provides for a senior secured term loan facility in an aggregate amount of up to \$40.0 million (collectively, the “Credit Facility”), comprised of (i) a term loan in the principal amount of \$30.0 million (the “Tranche One Loan”), (ii) an additional term loan to be made in the maximum principal amount not to exceed \$10.0 million (the “Tranche Two Loan;” and, together with the Tranche One Loan, the “Loans”), which Tranche Two Loan availability is subject to the satisfaction of certain conditions. The Loans each have a maturity date of April 10, 2022 (the “Maturity Date”), subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default (as defined in the Credit Agreement). The Loans are secured by substantially all of our assets, including our intellectual property. Events of Default include, among others, non-payment of principal, interest, or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts and events constituting a change of control. In addition to an increase in the rate of interest on the Loans of 5% per annum, the occurrence of an Event of Default could result in, among other things, the termination of commitments under the Credit Facility, the declaration that all outstanding Loans are immediately due and payable in whole or in part, and Marathon taking immediate possession of, and selling, any collateral securing the Loans.

***Developments by competitors may render our products or technologies obsolete or non-competitive.***

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our current products, RI-002 (if we obtain regulatory approval) and any future product we may develop will have to compete with other marketed therapies. In addition, other companies may pursue the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, longer product development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations.

***If we are unable to protect our patents, trade secrets or other proprietary rights, if our patents are challenged or if our provisional patent applications do not get approved, our competitiveness and business prospects may be materially damaged.***

As we move forward in clinical development we are also uncovering novel aspects of our product and are drafting patents to cover our inventions. We rely on a combination of patent rights, trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. There can be no assurance that our patent, trade secret policies and practices or other agreements will adequately protect our intellectual property. Our issued patents may be challenged, found to be over-broad or otherwise invalidated in subsequent proceedings before courts or the United States Patent and Trademark Office. Even if enforceable, we cannot provide any assurances that they will provide significant protection from competition. The processes, systems, and/or security measures we use to preserve the integrity and confidentiality of our data and trade secrets may be breached, and we may not have adequate remedies as a result of any such breaches. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. There can be no assurance that the confidentiality, nondisclosure and non-competition agreements with employees, consultants and other parties with access to our proprietary information to protect our trade secrets, proprietary technology, processes and other proprietary rights, or any other security measures relating to such trade secrets, proprietary technology, processes and proprietary rights, will be adequate, will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

***We could lose market exclusivity of a product earlier than expected.***

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is realized during its market exclusivity period. In the United States and in some other countries, when market exclusivity expires and generic versions are approved and marketed or when biosimilars are introduced (even if only for a competing product), there are usually very substantial and rapid declines in a product's revenues.

Market exclusivity for our products is based upon patent rights and certain regulatory forms of exclusivity. The scope of our patent rights may vary from country to country and may also be dependent on the availability of meaningful legal remedies in a country. The failure to obtain patent and other intellectual property rights, or limitations on the use or loss of such rights, could be material to us. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and/or we (or our licensors) did not file in those markets. In addition, the patent environment can be unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once the data exclusivity period expires, generic versions can be approved and marketed.

Patent rights covering RI-002 may become subject to patent litigation. In some cases, manufacturers may seek regulatory approval by submitting their own clinical trial data to obtain marketing approval or choose to launch a generic product “at risk” before the expiration of our patent rights/or before the final resolution of related patent litigation. Enforcement of claims in patent litigation can be very costly and no assurance can be given that we will prevail. There is no assurance that RI-002, or any other of our products for which we are issued a patent, will enjoy market exclusivity for the full time period of the respective patent.

***Third parties could obtain patents that may require us to negotiate licenses to conduct our business, and there can be no assurance that the required licenses would be available on reasonable terms or at all.***

We may not be able to operate our business without infringing third-party patents. Numerous U.S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of immune globulins. In addition, many companies have employed intellectual property litigation as a way to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the United States and in foreign jurisdictions. If our products, methods, processes and other technologies are found to infringe third-party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology, process or product unless we obtain a license under the applicable third-party patent and pay royalties or are able to design around such patent. We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign our products or processes to avoid infringement. Even if we are able to redesign our products or processes to avoid an infringement claim, our efforts to design around the patent could require significant time, effort and expense and ultimately may lead to an inferior or more costly product and/or process. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently prohibit us, our licensees, if any, and our customers from making, using, selling, offering to sell or importing one or more of our products or practicing our proprietary technologies or processes, or could enter an order mandating that we undertake certain remedial activities. Any of these events could seriously harm our business, operating results and financial condition.

***If we are unable to successfully manage our growth, our business may be harmed.***

Our success will depend on the expansion of our commercial and manufacturing activities, supply of plasma and overall operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business could be harmed.

***The loss of one or more key members of our management team could adversely affect our business.***

Our performance is substantially dependent on the continued service and performance of our management team, who have extensive experience and specialized expertise in our business. In particular, the loss of Adam S. Grossman, our President and Chief Executive Officer, could adversely affect our business and operating results. We do not have "key person" life insurance policies for any members of our management team. We have employment agreements with each of our executive officers; however, the existence of an employment agreement does not guarantee retention of members of our management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our product candidates and diversion of management resources. Notwithstanding the foregoing, in the event Mr. Grossman is terminated for cause or resigns other than for good reason, then the standstill provisions contained in the Stockholders Agreement, which prohibits BPC or its transferee from, among other things, acquiring more than (i) 50%, less one share, of our issued and outstanding shares of capital stock on an as-converted basis, or (ii) 30% of the issued and outstanding shares of common stock, will terminate and be of no further force and effect. Such event could result in BPC or its transferee acquiring additional shares of our common stock or taking other actions with the goal of acquiring additional shares of our common stock.

***Cyberattacks and other security breaches could compromise our proprietary and confidential information which could harm our business and reputation.***

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. In addition, an employee, contractor, or other third party with whom we do business may attempt to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we have certain safeguards in place to reduce the risk of and detect cyber-attacks, including a company-wide cybersecurity policy, our information technology networks and infrastructure may be vulnerable to unpermitted access

by hackers or other breaches, or employee error or malfeasance. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information and subject us to additional costs, which could adversely affect our business.

***If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.***

We will need to hire additional qualified personnel with expertise in commercialization, sales, marketing, medical affairs, reimbursement, government regulation, formulation and manufacturing and finance and accounting. In particular, over the next 12-24 months, we expect to hire several new employees devoted to commercialization, sales, marketing, medical and scientific affairs, regulatory affairs, quality control, financial, general and operational management. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot assure you that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success and any failure to do so successfully may have a material adverse effect on us.

***We currently collect human blood plasma at our ADMA BioCenters facilities, and if we cannot maintain FDA approval for these facilities we may be adversely affected and may not be able to sell or use this human blood plasma for future commercial purposes.***

We intend to maintain FDA and other governmental and regulatory approvals of our ADMA BioCenters collection facilities for the collection of human blood plasma. These facilities are subject to FDA and other governmental and regulatory inspections and extensive regulation, including compliance with current cGMP, FDA and other government approvals. Failure to comply with applicable governmental regulations or to receive applicable approvals for our future facilities, including our third facility, may result in enforcement actions, such as adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of regulatory authority approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses, any of which may significantly delay or suspend our operations for these locations, potentially having a materially adverse effect on our ability to manufacture our products or offer for sale plasma collected at the affected site(s).

***We currently manufacture our current marketed products, pipeline products, and products for third parties in our manufacturing and testing facilities, and if we cannot maintain appropriate FDA status for these facilities, we may be adversely affected, and may not be able to sell, manufacture or commercialize these products.***

We currently operate under the Warning Letter due to issues identified by the FDA in their prior inspections while the Boca Facility was under Biotest's ownership and operational control. We engaged a consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems and which manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified CMC and cGMP issues and deficiencies. We believe that we have been inspection-ready since the end of 2017 and expect to have the FDA inspection classification relative to the Warning Letter improved after the next inspection by the FDA, however there can be no assurances as to the timing by which the FDA may make such a determination after any inspection.

***If we do not receive FDA approval for additional plasma collection centers, including our third center for which construction was completed in late 2017, before January 1, 2019, then we may be required to seek a waiver and extension from Biotest for the contractually required transfer of two of our facilities.***

We recently completed construction our third plasma center and plan to leverage our existing plasma center license in order to seek approval for this new facility with the FDA. The BLA for this facility was filed with the FDA in December 2017. If we do not receive FDA approval for this third plasma center on or before January 1, 2019, then we will be required to seek a waiver and extension from Biotest for our contractual obligation to transfer the two facilities under the Purchase Agreement. However, there can be no assurances that Biotest will waive or extend its rights with respect to such transfer. In the event Biotest refuses to waive and extend such right, we will be obligated to transfer the two facilities under the Purchase Agreement and risk not having an FDA-approved plasma center in the event of a delay or refusal to issue our future license for the new plasma center by the FDA. Any such delay or refusal to issue the license by the FDA could have a material adverse effect on our operations.

***We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.***

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, either alone or with collaborators.



***Many of our business practices are subject to scrutiny by federal and state regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.***

The laws governing our conduct in the United States are enforceable on the federal and state levels by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug, and Cosmetic Act, the Social Security Act (including the Anti-Kickback Law), the Public Health Service Act and the Federal False Claims Act, and any regulations promulgated under the authority of the preceding, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid and the Department of Health and Human Services and other regulatory authorities as well as by the courts. Similarly, the violation of applicable laws, rules and regulations of the State of Florida with respect to the manufacture of our products and product candidates may result in jail sentences, fines or exclusion from applicable state programs. There can be no assurance that our activities will not come under the scrutiny of federal and/or state regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the Anti-Kickback Law and similar state laws and regulations, the offer or payment of anything of value for patient referrals, or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease, or ordering of any time or service reimbursable in whole or in part by a federal health care program is prohibited. This places constraints on the marketing and promotion of products and on common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose products for patients, such as physicians and hospitals, and these practices can result in substantial legal penalties, including, among others, exclusion from the Medicare and Medicaid programs. Arrangements with referral sources such as purchasers, group purchasing organizations, physicians and pharmacists must be structured with care to comply with applicable requirements. Also, certain business practices, such as payments of consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Under the Patient Protection and Affordable Care Act and the companion Health Care and Education Reconciliation Act, which together are referred to as the “Healthcare Reform Law”, such payments by pharmaceutical manufacturers to U.S. healthcare practitioners and academic medical centers must be publicly disclosed. A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where such practices have been found to be improper incentives to use such products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable corporate conduct.

Failure to satisfy requirements under the Federal Food, Drug, and Cosmetic Act can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct. In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients, they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the United States, Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities such as the FDA in the United States, nor can companies promote unapproved products. In limited circumstances, companies may disseminate to physicians information regarding unapproved uses of approved products or results of studies involving investigational products. If such activities fail to comply with applicable regulations and guidelines of the various regulatory authorities, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if such activities are prohibited, it may harm demand for our products. Promotion of unapproved drugs or devices or unapproved indications for a drug or device is a violation of the Federal Food, Drug, and Cosmetic Act and subjects us to civil and criminal sanctions. Furthermore, sanctions under the Federal False Claims Act have recently been brought against companies accused of promoting off-label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud. The Healthcare Reform Law significantly strengthened provisions of the Federal False Claims Act, the Anti-Kickback Law that applies to Medicare and Medicaid, and other health care fraud provisions, leading to the possibility of greatly increased qui tam suits by relators for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect our business.

We are required to report detailed pricing information, net of included discounts, rebates and other concessions, to the Centers for Medicare & Medicaid Services (“CMS”) for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations. Inaccurate or incomplete reporting of pricing information could result in liability under the False Claims Act, the federal Anti-Kickback Law and various other laws, rules and regulations.

We will need to establish systems for collecting and reporting this data accurately to CMS and institute a compliance program to assure that the information collected is complete in all respects. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business. If we choose to pursue clinical development and commercialization in the European Union or otherwise market and sell our products outside of the United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which would preclude us from commercializing products in those markets.

In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the European Union, we could be adversely affected.

Also, under the U.S. Foreign Corrupt Practices Act, the United States has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the United States, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business. To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities such as the U.S. Health and Human Services Department Office of Inspector General (the “OIG”) have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. In the future, we may need to adopt healthcare compliance and ethics programs that would incorporate the OIG's recommendations, and train our applicable employees in such compliance. Such a program may be expensive and may not assure that we will avoid compliance issues.

We are also required to comply with the applicable laws, rules, regulations and permit requirements of the various states in which our business operates, including the State of Florida where our manufacturing facility is located. These regulations and permit requirements are not always in concert with applicable federal laws, rules and regulations regulating our business. Although compliant with applicable federal requirements, we may be required to comply with additional state laws, rules, regulations and permits. Failure to appropriately comply with such state requirements could result in temporary or long-term cessation of our manufacturing operations, as well as fines and other sanctions. Any such penalties may have a material adverse effect on our business and results of operations.

***The manufacturing processes for plasma-based biologics are complex and involve biological intermediates that are susceptible to contamination.***

Plasma is a raw material that is susceptible to damage and contamination and may contain human pathogens, any of which would render the plasma unsuitable as raw material for further manufacturing. For instance, improper storage of plasma, by us or third-party suppliers, may require us to destroy some of our raw material. If unsuitable plasma is not identified and discarded prior to the release of the plasma to the manufacturing process, it may be necessary to discard intermediate or finished product made from that plasma or to recall any finished product released to the market, resulting in a charge to cost of product revenue. The manufacture of our plasma products is an extremely complex process of fractionation, purification, filling and finishing. Our products can become non-releasable or otherwise fail to meet our stringent specifications or regulatory agencies' specifications through a failure in one or more of these process steps. We may detect instances in which an unreleased product was produced without adherence to our manufacturing procedures or plasma used in our production process was not collected or stored in a compliant manner consistent with our cGMP or other regulations. Such an event of noncompliance would likely result in our determination that the implicated products should not be released or maybe replaced or withdrawn from the market and therefore should be destroyed. Once manufactured, our plasma-derived products must be handled carefully and kept at appropriate temperatures. Our failure, or the failure of third parties that supply, ship or distribute our products, to properly care for our products may require that those products be destroyed. Even if handled properly, biologics may form or contain particulates or have other issues or problems after storage which may require products to be destroyed or recalled. While we expect to write off small amounts of work-in-progress in the ordinary course of business due to the complex nature of plasma, our processes and our products, unanticipated events may lead to write-offs and other costs materially in excess of our expectations and the reserves we have established for these purposes. Such write-offs and other costs could cause material fluctuations in our results of operations.

Furthermore, contamination of our products could cause investors, consumers, or other third parties with whom we conduct business to lose confidence in the reliability of our manufacturing procedures, which could adversely affect our revenues. In addition, faulty or contaminated products that are unknowingly distributed could result in patient harm, threaten the reputation of our products and expose us to product liability damages and claims from companies for whom we do contract manufacturing.

***Our ability to continue to produce safe and effective products depends on the safety of our plasma supply and manufacturing processes against transmittable diseases.***

Despite overlapping safeguards, including the screening of donors and other steps to remove or inactivate viruses and other infectious disease causing agents, the risk of transmissible disease through blood plasma products cannot be entirely eliminated. For example, since plasma-derived therapeutics involves the use and purification of human plasma, there has been concern raised about the risk of transmitting human immunodeficiency virus ("HIV"), prions, West Nile virus, H1N1 virus or "swine flu" and other blood-borne pathogens through plasma-derived products. There are also concerns about the future transmission of H5N1 virus, or "bird flu." In the 1980s, thousands of hemophiliacs worldwide were infected with HIV through the use of contaminated Factor VIII. Other producers of Factor VIII, though not us, were defendants in numerous lawsuits resulting from these infections. New infectious diseases emerge in the human population from time to time. If a new infectious disease has a period during which time the causative agent is present in the bloodstream but symptoms are not present, it is possible that plasma donations could be contaminated by that infectious agent. Typically, early in an outbreak of a new disease, tests for the causative agent do not exist. During this early phase, we must rely on screening of donors for behavioral risk factors or physical symptoms to reduce the risk of plasma contamination. Screening methods are generally less sensitive and specific than a direct test as a means of identifying potentially contaminated plasma units. During the early phase of an outbreak of a new infectious disease, our ability to manufacture safe products would depend on the manufacturing process' capacity to inactivate or remove the infectious agent. To the extent that a product's manufacturing process is inadequate to inactivate or remove an infectious agent, our ability to manufacture and distribute that product would be impaired. If a new infectious disease were to emerge in the human population, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to procure plasma, manufacture our products or both. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived products. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma used in the production of our products.

***We could become supply-constrained and our financial performance would suffer if we cannot obtain adequate quantities of FDA-approved source plasma with proper specifications.***

In order for plasma to be used in the manufacturing of our products, the individual centers at which the plasma is collected must be licensed by the FDA and approved by the regulatory authorities of any country in which we may wish to commercialize our products. When we open a new plasma center, and on an ongoing basis after licensure, it must be inspected by the FDA for compliance with cGMP and other regulatory requirements. An unsatisfactory inspection could prevent a new center from being licensed or risk the suspension or revocation of an existing license. We do not and will not have adequate plasma to manufacture our products. Therefore, we are reliant on the purchase of plasma from third parties to manufacture our products. We can give no assurances that appropriate plasma will be available to us on commercially reasonable terms, or at all, to manufacture our products. In order to maintain a plasma center's license, its operations must continue to conform to cGMP and other regulatory requirements. In the event that we determine that plasma was not collected in compliance with cGMP, we may be unable to use and may ultimately destroy plasma collected from that center, which would be recorded as a charge to cost of product revenue. Additionally, if non-compliance in the plasma collection process is identified after the impacted plasma has been pooled with compliant plasma from other sources, entire plasma pools, in-process intermediate materials and final products could be impacted. Consequently, we could experience significant inventory impairment provisions and write-offs which could adversely affect our business and financial results. We plan to increase our supplies of plasma for use in the manufacturing processes through increased purchases of plasma from third-party suppliers as well as collections from our existing ADMA BioCenters plasma collection centers. This strategy is dependent upon our ability to maintain a cGMP compliant environment in both plasma centers and to expand production and attract donors to both centers. There is no assurance that the FDA will inspect and license our unlicensed plasma collection centers in a timely manner consistent with our production plans. If we misjudge the readiness of a center for an FDA inspection, we may lose credibility with the FDA and cause the FDA to more closely examine all of our operations. Such additional scrutiny could materially hamper our operations and our ability to increase plasma collections. Our ability to expand production and increase our plasma collection centers to more efficient production levels may be affected by changes in the economic environment and population in selected regions where ADMA BioCenters operates its current or future plasma centers, by the entry of competitive plasma centers into regions where ADMA BioCenters operates such centers, by misjudging the demographic potential of individual regions where ADMA BioCenters expects to expand production and attract new donors, by unexpected facility related challenges, or by unexpected management challenges at selected plasma centers.

***Our ability to commercialize our products, alone or with collaborators, will depend in part upon the extent to which reimbursement will be available from governmental agencies, health administration authorities, private health maintenance organizations and health insurers and other healthcare payers, and also depends upon the approval, timing and representations by the FDA or other governmental authorities for our product candidates. As the FDA BLA review process is ongoing, we are subject to information requests and communications from the FDA on a routine basis and may not have clarity on any or all specific aspects of the approval timing, language, name, claims and any other future requirements that may be imposed by the FDA or other governmental agencies for marketing, authorization and ultimately financial reimbursement for patient utilization.***

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of coverage. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, as well as to the timing, language, specifications and other details pertaining to the approval of such products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such product. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced. Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products, such as plasma-derived products, are subject to price controls in several of the world's principal markets, including many countries within the European Union. In the United States, where pricing levels for our products are substantially established by third-party payers, including Medicare, if payers reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace, or where changes in reimbursement induce a shift in the site of treatment. The existence of direct and indirect price controls and pressures over our products could materially adversely affect our financial prospects and performance.

***The new biosimilar pathway established as part of the healthcare reform may make it easier for competitors to market biosimilar products.***

The Healthcare Reform Law introduced an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to an FDA-licensed biological product. A biological product may be demonstrated to be “biosimilar” if data show that, among other things, the product is “highly similar” to an already-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. The law provides that a biosimilar application may be submitted as soon as four years after the reference product is first licensed, and that the FDA may not make approval of an application effective until 12 years after the reference product was first licensed. Since the enactment of the law, the FDA has issued several guidance documents to assist sponsors of biosimilar products in preparing their approval applications. The FDA approved the first biosimilar product in 2015, and approved three biosimilar products in 2016. As a result of the biosimilar pathway in the United States, we expect in the future to face greater competition from biosimilar products, including a possible increase in patent challenges.

*The implementation of the Healthcare Reform Law in the United States may adversely affect our business.*

Through the March 2010 adoption of the Healthcare Reform Law in the United States, substantial changes are being made to the current system for paying for healthcare in the United States, including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. The changes contemplated by the Healthcare Reform Law are subject to rule-making and implementation timelines that extend for several years, and this uncertainty limits our ability to forecast changes that may occur in the future. However, implementation has already begun with respect to certain significant cost-saving measures under the Healthcare Reform Law, for example with respect to several government healthcare programs, including Medicaid and Medicare Parts B and D, that may cover the cost of our future products, and these efforts could have a material adverse impact on our future financial prospects and performance. For example, in order for a manufacturer's products to be reimbursed by federal funding under Medicaid, the manufacturer must enter into a Medicaid rebate agreement with the Secretary of the U.S. Department of Health and Human Services and pay certain rebates to the states based on utilization data provided by each state to the manufacturer and to CMS and pricing data provided by the manufacturer to the federal government. The states share these savings with the federal government, and sometimes implement their own additional supplemental rebate programs. Under the Medicaid drug rebate program, the rebate amount for most branded drug products was previously equal to a minimum of 15.1% of the Average Manufacturer Price ("AMP") or the AMP less Best Price, whichever is greater. Effective January 1, 2010, the Healthcare Reform Law generally increased the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug products from a minimum of 15.1% to a minimum of 23.1% of AMP, subject to certain exceptions. For non-innovator multiple source (generic) products, the rebate percentage is increased from a minimum of 11.0% to a minimum of 13.0% of AMP. In 2010, the Healthcare Reform Law also newly extended this rebate obligation to prescription drugs covered by Medicaid managed care organizations. These increases in required rebates may adversely affect our future financial prospects and performance. In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As the 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

Effective in 2011, the Healthcare Reform Law imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs. These fees may adversely affect our future financial prospects and performance. The Healthcare Reform Law established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2019.

The Healthcare Reform Law also creates new rebate obligations for our products under Medicare Part D, a partial, voluntary prescription drug benefit created by the U.S. federal government primarily for persons 65 years old and over. The Part D drug program is administered through private insurers that contract with CMS. Beginning in 2011,



the Healthcare Reform Law generally requires that in order for a drug manufacturer's products to be reimbursed under Medicare Part D, the manufacturer must enter into a Medicare Coverage Gap Discount Program agreement with the Secretary of the U.S. Department of Health and Human Services, and reimburse each Medicare Part D plan sponsor an amount equal to 50% savings for the manufacturer's brand name drugs and biologics which the Part D plan sponsor has provided to its Medicare Part D beneficiaries who are in the "donut hole" (or a gap in Medicare Part D coverage for beneficiaries who have expended certain amounts for drugs). The Part D plan sponsor is responsible for calculating and providing the discount directly to its beneficiaries and for reporting these amounts paid to CMS's contractor, which notifies drug manufacturers of the rebate amounts it must pay to each Part D plan sponsor. The rebate requirement could adversely affect our future financial performance, particularly if contracts with Part D plans cannot be favorably renegotiated or the Part D plan sponsors fail to accurately calculate payments due in a manner that overstates our rebate obligation. Regarding access to our products, the Healthcare Reform Law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research ("CER"). While the stated intent of CER is to develop information to guide providers to the most efficacious therapies, outcomes of CER could influence the reimbursement or coverage for therapies that are determined to be less cost-effective than others. Should any of our products be determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our future financial prospects and results.

There have been repeated attempts by Congress to repeal or change the Healthcare Reform Law. At this time, it remains unclear whether there will be any changes made to or any repeal or replacement of the Healthcare Reform Law, with respect to certain of its provisions or in its entirety.

***Developments in the worldwide economy may adversely impact our business.***

The difficult economic environment may adversely affect demand for our products. RI-002, our current product candidate, is expected to be sold to hospitals, specialty pharmacies and clinicians in the United States. As a result of loss of jobs, patients may lose medical insurance and be unable to purchase our products or may be unable to pay their share of deductibles or co-payments. Hospitals adversely affected by the economy may steer patients to less costly therapies, resulting in a reduction in demand, or demand may shift to public health hospitals, which may purchase at a lower government price.

**Risks Relating to our Finances, Capital Requirements and Other Financial Matters**

***We require additional funding and may be unable to raise capital when needed, which would force us to delay, curtail or eliminate one or more of our research and development programs or commercialization efforts.***

Our operations have consumed substantial amounts of cash since inception. For the three months ended March 31, 2018 and 2017, we had negative cash flows from operations of \$16.4 million and \$5.4 million, respectively, and for the years ended December 31, 2017 and 2016, we had negative cash flows from operations of approximately \$37.3 million and \$18.3 million, respectively. We expect to continue to spend substantial amounts on product development, including commercialization activities, procuring raw material plasma, manufacturing, conducting potential future clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We currently anticipate, based upon our projected revenue and expenditures, as well as the additional \$10.0 million we expect to be able to access under the Credit Agreement, that our current cash, cash equivalents and accounts receivable will be sufficient to fund our operations, as currently conducted, into the fourth quarter of 2018. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing prior to the end of 2018. This time frame may change based upon how quickly we are able to execute on our operational initiatives and the various financing options available to us. However, if the assumptions underlying our estimated expenses prove to be incorrect, we may have to raise additional capital sooner than we currently expect. Until such time, if ever, as we can generate a sufficient amount of product revenue to achieve profitability, we expect to continue to finance our operations through additional equity or debt financings or corporate collaboration and licensing arrangements. If we are unable to raise additional capital as needed, we will have to delay, curtail or eliminate our product development activities, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, as well as future commercialization efforts.

***Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that, among other restrictions, limit our ability to incur liens or additional debt, pay dividends, redeem or repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. In addition, if we raise additional funds through licensing arrangements or the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

***Our cash, cash equivalents and short-term investments could be adversely affected if the financial institutions in which we hold our cash, cash equivalents and short-term investments fail.***

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. While we monitor the cash balances in our operating accounts on a daily basis and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit cash fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

***If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.***

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules, our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we have been required to upgrade, and may need to implement further upgrades, to our financial, information and operating systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

***Our ability to use our net operating loss carryforwards (“NOLs”) may be limited.***

We have incurred substantial losses during our history. As of December 31, 2017, we had federal and state NOLs of \$125.3 million and \$201.5 million, respectively. These NOLs will begin to expire at various dates beginning in 2027, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code, changes in our ownership, in certain circumstances, will limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Internal Revenue Code imposes limitations on a company’s ability to use NOLs upon certain changes in such ownership. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership that we cannot predict or control that could result in further limitations being placed on our ability to utilize our federal NOLs.

***The recently passed Tax Cuts and Jobs Act (the “TCJA”) could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law the TCJA which significantly reforms the Internal Revenue Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses generated after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, immediate deductions for certain new investments instead of deductions for depreciation expense over time and modifying or repealing many business deductions and credits. Federal net operating losses arising in taxable years ending after December 31, 2017 will be carried forward indefinitely pursuant to the TCJA. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

**Risks Associated with our Common Stock**

***The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.***

Our stock price may experience substantial volatility as a result of a number of factors, including:

- sales or potential sales of substantial amounts of our common stock;
  
- our ability to successfully leverage the anticipated benefits and synergies from the Biotest Transaction, including optimization of the combined businesses, operations and products and services, including the nature, strategy and focus of the combined company and the management and governance structure of the combined company;
  
- delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials;
  
- delay in FDA approval for RI-002;
  
- the timing of acceptance, third-party reimbursement and sales of RI-002;
  
- our ability to resume the manufacturing of Bivigam once the deficiencies identified in the CRL have been resolved by us to the satisfaction of the FDA;
  
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
  
- developments concerning our licensors or third-party vendors;
  
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
  
- conditions in the pharmaceutical or biotechnology industries;
  
- governmental regulation and legislation;
  
- variations in our anticipated or actual operating results; and
  
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnology companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

***An investment in our common stock is extremely speculative and there can be no assurance of any return on any such investment.***

An investment in our common stock is extremely speculative and there is no assurance that investors will obtain any return on their investment. Investors will be subject to substantial risks involved in an investment in us, including the risk of losing their entire investment.

***Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the market price of our common stock.***

As of May 14, 2018 most of our 36,726,084 outstanding shares of Common Stock, as well as a substantial number of shares of our common stock underlying outstanding warrants, were available for sale in the public market, subject to certain restrictions with respect to sales of our common stock by our affiliates, either pursuant to Rule 144 under the Securities Act (“Rule 144”) or under effective registration statements. The 4,295,580 shares of common stock and the 8,591,160 NV Biotest Shares acquired by BPC in the Biotest Transaction were subject to a lock-up for six months after closing of the Biotest Transaction, which lock-up expired on December 6, 2017. For three years after the end of such six-month period, subject to certain limited exceptions, under the Stockholders Agreement, sales by BPC, or its transferee, of our equity interests may not exceed 15% of the issued and outstanding common stock of ADMA in any twelve-month period; provided, however, that if our market capitalization increases to double our market capitalization immediately following the closing of the Biotest Transaction, then BPC or its transferee may sell up to 20% of our issued and outstanding common stock in any twelve-month period; provided, further, that (x) if our market capitalization increases to triple our market capitalization immediately following the closing of the Biotest Transaction, or (y) upon the one-year anniversary of BPC or its transferee holding less than a 25% economic interest in us, then BPC or its transferee may sell its equity interests in us at any time (subject to applicable securities laws). On May 14, 2018, we, ADMA BioManufacturing and ADMA BioCenters entered into the Biotest Transfer Agreement with BPC, Biotest AG and the Biotest Trust whereby BPC transferred to us, for no cash consideration, the 8,591,160 NV Biotest Shares, representing 100% of our then-issued and outstanding non-voting common stock. Immediately upon transfer of the NV Biotest Shares to us, the shares were retired and are no longer available for issuance. At the closing of the Biotest Transaction, we entered into the Registration Rights Agreement with BPC, pursuant to which BPC, or its transferee, has, among other things, certain registration rights under the Securities Act with respect to its shares of our common stock, subject to certain transfer restrictions. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the market price of our common stock.

***Our affiliates control a substantial amount of our shares of common stock. Provisions in our Amended and Restated Certificate of Incorporation (the “A&R Certificate of Incorporation”), our Amended and Restated Bylaws (the “Bylaws”) and Delaware law might discourage, delay or prevent a change in control of our Company or changes in our management and, therefore, depress the trading price of our common stock.***

Provisions of our A&R Certificate of Incorporation, our Bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. As of March 31, 2018, BPC, our directors and executive officers and their affiliates beneficially owned in excess of 55% of the outstanding shares of our common stock. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings;
- the ability of our Board to institute a stockholder rights plan, also known as a poison pill, that would work to dilute our stock;
- classification of our Board and limitation on filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our Company; and
- authorization of the issuance of “blank check” preferred stock, with such designation rights and preferences as may be determined from time to time by the Board, without any need for action by stockholders.

In addition, Section 203 of the Delaware General Corporation Law (the “DGCL”) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition. In addition, as a result of the concentration of ownership of our shares of common stock, our stockholders may, from time to time, observe instances where there may be less liquidity in the public markets for our securities.

***We have never paid and do not intend to pay cash dividends in the foreseeable future. As a result, capital appreciation, if any, will be your sole source of gain.***

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***If we fail to adhere to the strict listing requirements of the Nasdaq Capital Market (“Nasdaq”), we may be subject to delisting. As a result, our stock price may decline and our common stock may be delisted. If our stock were no longer listed on Nasdaq, the liquidity of our securities likely would be impaired.***

Our common stock currently trades on Nasdaq under the symbol “ADMA.” If we fail to adhere to Nasdaq's strict listing criteria, including with respect to stock price, our market capitalization and stockholders’ equity, our stock may be delisted. This could potentially impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which may be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our common stock. We believe that current and prospective investors would view an investment in our common stock more favorably if it continues to be listed on Nasdaq. Any failure at any time to meet the Nasdaq continued listing requirements could have an adverse impact on the value of and trading activity of our common stock. Although we currently satisfy the listing criteria for Nasdaq, if our stock price declines dramatically, we could be at risk of failing to meet the Nasdaq continued listing criteria.

***Penny stock regulations may affect your ability to sell our common stock.***

Because the price of our common stock has historically traded below \$5.00 per share, our common stock may be considered penny stock and may be subject to Rule 15c-9 under the Exchange Act, which imposes additional sales practice requirements on broker dealers which sell these securities to persons other than established customers and accredited investors. Under these rules, broker-dealers who recommend penny stocks to persons other than established customers and “accredited investors” must make a special written suitability determination for the purchaser and receive the purchaser’s written agreement to a transaction prior to sale, which includes an acknowledgement that the purchaser’s financial situation, investment experience and investment objectives forming the basis for the broker-dealer’s suitability determination are accurately stated in such written agreement. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock and may make it more difficult for holders of our common stock to sell shares to third parties or to otherwise



dispose of them.

***We are an “emerging growth company,” and elect to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined by the Jumpstart Our Business Startups Act (the “JOBS Act”). The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for qualifying public companies. As an “emerging growth company,” we may, under Section 7(a)(2)(B) of the Securities Act, delay adoption of new or revised accounting standards applicable to public companies until such standards would otherwise apply to private companies. We may continue to take advantage of this extended transition period until the first to occur of the date that we (i) are no longer an “emerging growth company” or (ii) affirmatively and irrevocably opt out of this extended transition period.

We could be an emerging growth company until December 31, 2018, which is the last day of the fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our total annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we would cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an “emerging growth company” or affirmatively and irrevocably opt out of the exemption provided by Securities Act Section 7(a)(2)(B), upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard. As an emerging growth company, we are also exempt from the requirement to have our independent registered public accounting firm provide an attestation report on our internal control over financial reporting.

We cannot predict if investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our common stock, our stock price may be more volatile and our stock price may decline dramatically.

***Our Board may, without stockholder approval, issue and fix the terms of shares of preferred stock and issue additional shares of common stock adversely affecting the rights of holders of our common stock.***

Our A&R Certificate of Incorporation authorizes the issuance of up to 10,000,000 shares of “blank check” preferred stock, with such designation rights and preferences as may be determined from time to time by the Board. Currently, our A&R Certificate of Incorporation authorizes the issuance of up to 75,000,000 shares of common stock, of which 33,617,806 shares remain available for issuance and may be issued by us without stockholder approval, and up to 8,591,160 shares of non-voting common stock, all of which were reacquired by us in May 2018 pursuant to the Biotest Transfer Agreement and were subsequently retired and are no longer available for issuance.

## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the documents incorporated by reference into this prospectus and any prospectus supplement or free writing prospectus may contain “forward-looking statements” within the meaning of the safe harbor provisions of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These forward-looking statements only provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should”, “could”, “predicts” or the negative variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans and our expectations and timing related to the FDA approval and commercialization of our lead pipeline product candidate, RI-002. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995.

You should read carefully the risks described in the section entitled “Risk Factors” beginning on page 7 of this prospectus, and in any accompanying prospectus supplement or related free writing prospectus, together with all information incorporated by reference herein and therein, to better understand the significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these risks, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this prospectus or in any accompanying prospectus supplement or related free writing prospectus, or incorporated by reference herein and therein, and you should not place undue reliance on any forward-looking statements.

In addition to the risks described in the section entitled “Risk Factors” beginning on page 7 of this prospectus, many important factors may affect our ability to achieve our plans and objectives and to successfully develop and commercialize our product candidates. Our results may be affected by our ability to manage our financial resources, difficulties or delays in developing manufacturing processes for our product candidates, preclinical and toxicology testing and regulatory developments. Delays in clinical programs, whether caused by competitive developments, adverse events, patient enrollment rates, regulatory issues or other factors, could adversely affect our financial position and prospects. Prior clinical trial program designs and results are not necessarily indicative of future clinical trial designs or results. If our product candidates do not meet safety or efficacy endpoints in clinical evaluations, they will not receive regulatory approval and we will not be able to market them. The FDA may not approve our RI-002 BLA, our data, our results, or permit us to proceed. We may not be able to enter into any strategic partnership agreements. Operating expenses and cash flow projections involve a high degree of uncertainty, including variances in future spending rates due to changes in corporate priorities, the timing and outcomes of clinical trials, competitive developments and the impact on expenditures and available capital from licensing and strategic collaboration opportunities. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more of our drug development or discovery research programs and delay or abandon potential commercialization efforts. We may not ever have any products that generate

significant revenue. Therefore, current and prospective security holders are cautioned that there can be no assurance that the forward-looking statements included in this document will prove to be accurate.

You should read and interpret any forward-looking statements together with the following documents:

- our most recent Annual Report on Form 10-K, including the sections entitled “Business”, “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”;
- the risk factors contained in this prospectus under the caption “Risk Factors”; and
- and our other filings with the SEC.

Any forward-looking statements that we make in this prospectus speak only as of the date of such statements and we undertake no obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

## **USE OF PROCEEDS**

Unless the applicable prospectus supplement states otherwise, we anticipate that the net proceeds from our sale of any securities will be used for general corporate purposes, including working capital, capital expenditures at the Boca Facility, continued remediation and ongoing improvement and enhancements to our quality systems and GMP operations, retirement of debt and other business opportunities.

We believe it is prudent to have an effective shelf registration statement on file with the SEC to preserve flexibility to raise capital if and when needed. We have no specific plans to raise money at this time.

We will not receive the proceeds from any sale of our common stock made by the selling stockholder.

## **DESCRIPTION OF THE SECURITIES WE MAY OFFER**

The descriptions of the securities contained in this prospectus summarize the material terms and provisions of the various types of securities that we or the selling stockholder may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we so indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material U.S. federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may offer and sell from time to time, in one or more primary offerings, our common stock, preferred stock, debt securities, warrants or units, or any combination of the foregoing. The selling stockholder may offer and sell, from time to time, subject to the provisions of the Stockholders Agreement, up to 4,295,580 shares of our common stock in one or more secondary offerings.

In this prospectus, we refer to the common stock, preferred stock, debt securities, warrants or units, or any combination of the foregoing securities to be sold by us in a primary offering collectively as “securities.” The total dollar amount of all securities that we may issue under this prospectus, not including the total dollar amount of our common stock that may be offered by the selling stockholder, will not exceed \$100,000,000.

This prospectus may not be used by us to consummate a sale of securities unless it is accompanied by a prospectus supplement.

## **DESCRIPTION OF CAPITAL STOCK**

The following description of our common stock and preferred stock, together with the additional information we include in the applicable prospectus supplement, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. It may not contain all the information that is important to you. For the complete terms of our common stock and preferred stock, please refer to our A&R Certificate of Incorporation and Bylaws, which are incorporated by reference into the registration statement which includes this prospectus. The DGCL may also affect the terms of these securities.

### **General**

The total number of shares of capital stock that the Company has authorized is 93,591,160, divided into three classes consisting of (i) 75,000,000 shares of voting common stock, \$0.0001 par value per share, (ii) 8,591,160 shares of non-voting common stock, \$0.0001 par value per share, and (iii) 10,000,000 shares of preferred stock, par value per share \$0.0001. All references to “common stock” in this prospectus refer to our voting common stock. This prospectus does not cover, and may not be used to consummate sales of, our non-voting common stock.

As of May 15, 2018, there were 36,726,084 shares of common stock issued and outstanding and an additional 4,657,110 shares issuable upon exercise of outstanding options and warrants. Of the 4,657,110 shares of common stock issuable upon exercise of outstanding options and warrants, 3,418,184 shares are issuable to officers and directors and principal stockholders of the Company, 710,766 shares are issuable to other employees and a third-party consultant to the Company and 528,160 shares are issuable to current and former noteholders of the Company.

As of May 15, 2018, there were no shares of non-voting common stock issued and outstanding. On June 6, 2017, in connection with the closing of the Biotest Transaction, the 8,591,160 NV Biotest Shares were issued to BPC. On May 14, 2018, immediately upon transfer of the NV Biotest Shares to us in connection with the Biotest Transfer Agreement, the shares were retired and are no longer available for issuance.

As of May 15, 2018, there were no shares of preferred stock issued and outstanding.

## **Common Stock**

### ***Voting***

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of the Company’s stockholders. The holders of a majority of the outstanding shares of common stock constitute a quorum at a meeting of stockholders for the transaction of any business. Directors are elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Any other action is authorized by a majority of the votes cast, except where the DGCL prescribes a different percentage of votes and/or a different exercise of voting power.

### *Dividends*

Subject to applicable law and the rights, if any, of the holders of any outstanding series of preferred stock, dividends may be declared and paid on the common stock out of funds legally available therefor at such times and in such amounts as the Board, in its discretion, shall determine; provided, however, that simultaneously with the declaration and payment of any dividends on the non-voting common stock, a like dividend in form and amount per share shall also be declared and paid on the common stock (except that, if such dividend on the non-voting common stock is paid in the form of shares of common stock or non-voting common stock or rights or options to acquire common stock or non-voting common stock, the holders of shares of common stock shall receive equivalent shares of common stock or rights or options to acquire common stock, as the case may be).

### *Distributions Upon Dissolution, Liquidation or Winding Up*

Upon the dissolution, liquidation or winding up of the Company, subject to the rights, if any, of the holders of any outstanding series of preferred stock, the holders of the common stock shall be entitled to receive the assets of the Company available for distribution to its stockholders ratably in proportion to the number of shares of common stock held by them. The holders of common stock do not have cumulative or preemptive rights.

### **Non-Voting Common Stock**

#### *Voting*

Except as otherwise required by applicable law, shares of non-voting common stock shall have no voting power and the holders thereof, as such, are not entitled to vote on any matter that is submitted to a vote of the stockholders of the Company; provided, however, that for so long as any shares of non-voting common stock are outstanding, the Company shall not, without the prior vote of the holders of at least a majority of the shares of non-voting common stock then outstanding (voting separately as a single class), amend, alter or repeal, whether by merger, consolidation or otherwise (other than in connection with a Liquidation Event (as defined in the Stockholders Agreement), (i) Section 4.3 of the Company's A&R Certificate of Incorporation or (ii) any other provision of the A&R Certificate of Incorporation to alter or change the powers, preferences, or special rights of the shares of non-voting common stock in an adverse manner to the powers, preferences or special rights of the shares of common stock.

### *Dividends*



Subject to applicable law and the rights, if any, of the holders of any outstanding series of preferred stock, dividends may be declared and paid on the non-voting common stock out of funds legally available therefor at such times and in such amounts as the Board in its discretion shall determine; provided, however, that simultaneously with the declaration and payment of any dividends on the common stock, a like dividend in form and amount per share shall also be declared and paid on the non-voting common stock (except that, if (i) such dividend on the common stock is paid in the form of shares of common stock or rights or options to acquire common stock, (ii) the holders of non-voting common stock would own more than 30% of the outstanding common stock following the issuance of such common stock dividend and (iii) the Standstill Period (as defined in the Stockholders Agreement) has not expired or been earlier terminated pursuant to and in accordance with the terms and conditions of the Stockholders Agreement, the holders of shares of non-voting common stock shall receive equivalent shares of non-voting common stock or rights or options to acquire non-voting common stock, as the case may be).

### ***Distributions Upon Dissolution, Liquidation or Winding Up***

Upon the dissolution, liquidation or winding up of the Company, subject to the rights, if any, of the holders of any outstanding series of preferred stock, the holders of the non-voting common stock shall be entitled to receive the assets of the Company available for distribution to its stockholders ratably in proportion to the number of shares of common stock held by them following conversion of their shares of non-voting common stock into common stock, as provided in the A&R Certificate of Incorporation.

### ***Conversion Rights of Non-Voting Common Stock***

The non-voting common stock is convertible into common stock:

- upon the earliest to occur of (1) the expiration or earlier termination of the Standstill Period (as defined in the Stockholders Agreement), (2) immediately prior to the consummation of any Liquidation Event (as defined in the Stockholders Agreement) and (3) immediately prior to the taking of any action by the Board or earlier record date for any vote of stockholders in connection with any insolvency, voluntary or involuntary bankruptcy, liquidation or assignment for the benefit of creditors of the Company or termination of the Company's status as a reporting company under the Exchange Act;

- upon consummation of a Permitted Sale (as defined in the Company’s A&R Certificate of Incorporation);
- at the option of the holder thereof, if (1) it is the subject of a legally binding sale agreement to be sold in a transaction constituting a Permitted Sale, (2) it is required to be registered under the Securities Act pursuant to the terms of such sale agreement, (3) the common stock into which such share otherwise would automatically convert upon the consummation of such Permitted Sale constitutes a “Registrable Security” under the Registration Rights Agreement, (4) the holder delivers a legally binding agreement not to vote the common stock into which such share is converted until the earlier of the consummation of such Permitted Sale or the termination of the Standstill Period, and (5) the holder follows certain other notice procedures necessary to exercise its optional conversion rights;
- at the option of the holder thereof, if (1) it intends and irrevocably commits to the Company to use its reasonable efforts to sell such common stock in the public market within 60 days of such notice and such sale constitutes a Permitted Sale (a “Market Sale”); (2) it has executed and delivered to the Company a legally binding written agreement enforceable by the Company that, prior to the earlier of (A) the consummation of such Market Sale and (B) the expiration or earlier termination of the Standstill Period in accordance with and pursuant to the terms and conditions of the Stockholders Agreement, such holder shall not vote any of the common stock issued to such holder upon conversion of such converted share of non-voting common stock; (3) such Market Sales shall be conducted in compliance with all applicable requirements of the Securities Act; and (4) it follows certain other notice procedures necessary to exercise its optional conversion rights; or
- at the option of the holder thereof, if (1) the Company issues additional shares of common stock (a “Dilutive Issuance”), (2) as a result of such Dilutive Issuance, the percentage of the voting power of the Company represented by all shares of common stock held by BPC immediately following the Dilutive Issuance is lower than the voting percentage of all shares of common stock held by BPC immediately prior to the Dilutive Issuance, and (3) the holder follows certain other notice procedures necessary to exercise its optional conversion rights; provided, however, that the maximum number of shares of non-voting common stock that may be converted in respect of a Dilutive Issuance is the number of shares that, upon conversion, results in the voting percentage of all shares of common stock held by BPC immediately following such conversion being equal to the voting percentage of all shares of common stock held by BPC immediately prior to the Dilutive Issuance.

### **Preferred Stock**

No shares of preferred stock are currently outstanding, and the Company has no current plans to issue preferred stock. The issuance of shares of preferred stock, or the issuance of rights to purchase preferred stock, could be used to discourage an unsolicited acquisition proposal. For example, a business combination could be impeded by the issuance of a series of preferred stock containing class voting rights that would enable the holder or holders of such series to block any such transaction. Alternatively, a business combination could be facilitated by the issuance of a series of preferred stock having sufficient voting rights to provide a required percentage vote of the Company’s stockholders. In addition, under some circumstances, the issuance of preferred stock could adversely affect the voting power and other rights of the holders of common stock. Although prior to issuing any series of preferred stock the Board is required to make a determination as to whether the issuance is in the best interests of the Company’s stockholders, the board could act in a manner that would discourage an acquisition attempt or other transaction that some, or a majority, of the stockholders might believe to be in their best interests or in which the stockholders might receive a premium for their stock over prevailing market prices of such stock. The Board does not presently intend to seek stockholder approval prior to any issuance of currently authorized preferred stock, unless otherwise required by

law or applicable stock exchange requirements.

## Warrants

On October 10, 2017, the Company entered into the Credit Agreement with Marathon Healthcare Finance Fund, L.P. (“Marathon”) which provides for a senior secured term loan facility in an aggregate amount of up to \$40.0 million, comprised of (i) a term loan in the principal amount of \$30.0 million (the “Tranche One Loan”) and (ii) an additional term loan to be made in the maximum principal amount not to exceed \$10.0 million (the “Tranche Two Loan”), which Tranche Two Loan availability is subject to the satisfaction of certain conditions. As consideration for the Credit Agreement, the Company issued warrants to purchase an aggregate of 339,301 shares of the Company’s common stock to Marathon and certain of its affiliates (the “Tranche One Warrants”). The Tranche One Warrants have (i) an exercise price equal to \$3.09, which is the trailing 10-day volume weighted-average price of the Company’s common stock prior to October 10, 2017, and (ii) an expiration date of October 10, 2024. In the event that the Tranche Two Loan is issued to the Company, the Company shall issue an additional warrant to Marathon (the “Tranche Two Warrant”) to purchase such number of shares of common stock equal to 3.5% of the Tranche Two Loan, which shall have an exercise price equal to the trailing 10-day volume weighted-average price of the common stock prior to the issuance date of the Tranche Two Warrant and an expiration date equal to the seven year anniversary of the issuance of the Tranche Two Warrant.

In May 2016, the Company issued to Oxford Finance, LLC (“Oxford”) warrants to purchase an aggregate of up to 24,800 shares of the Company’s common stock at an exercise price equal to \$6.37 per share. The warrants became exercisable on May 13, 2016 for cash or by net exercise and will expire seven years after their issuance on May 13, 2023. In connection with a Loan and Security Agreement executed between the Company and Oxford (the “LSA”), on June 19, 2015, the Company issued to Oxford a seven year warrant, expiring on June 19, 2022, to purchase 74,309 shares of common stock at an exercise price of \$8.51 per share.

In connection with the Company's prior loan facility with Hercules Technology Growth Capital, Inc. ("Hercules"), on December 21, 2012, the Company issued to Hercules a warrant to purchase 31,750 shares of common stock with an exercise price of \$7.56, subject to customary anti-dilution adjustments. The Company also issued to Hercules a warrant to purchase 23,200 and 34,800 shares of common stock of the Company in February and December 2014, respectively, with an exercise price of \$7.50 per share. The warrant expires after 10 years and has piggyback registration rights with respect to the shares of common stock underlying the warrant.

### **Registration Rights**

At the closing of the Biotest Transaction, the Company entered into the Registration Rights Agreement with BPC, pursuant to which BPC, or its transferee, and/or its affiliate(s) have, among other things, certain registration rights under the Securities Act with respect to its shares of the Company's common stock, subject to certain transfer restrictions.

### **Indemnification of Directors and Officers**

The Company's directors and officers are indemnified as provided by the DGCL, the Company's A&R Certificate of Incorporation, and the Company's Bylaws. The Company has been advised that, in the opinion of the SEC, indemnification for liabilities arising under the Securities Act is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities is asserted by one of the Company's directors, officers, or controlling persons in connection with the securities being registered, the Company will, unless in the opinion of its legal counsel the matter has been settled by controlling precedent, submit the question of whether such indemnification is against public policy to a court of appropriate jurisdiction. The Company will then be governed by the court's decision.

We are party to indemnification agreements with each of our directors and officers. These agreements require us to, among other things, indemnify our directors and officers against certain liabilities which may arise by reason of their status or service as directors or officers to the fullest extent permitted by applicable laws. These indemnification provisions and the indemnification agreements are sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act. The Company also maintains director and officer liability insurance.

### **Delaware Anti-Takeover Law**

The Company is subject to the provisions of Section 203 of the DGCL. Section 203 prohibits publicly held Delaware corporations from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation’s voting stock. These provisions could have the effect of delaying, deferring or preventing a change of control of the Company or reducing the price that certain investors might be willing to pay in the future for shares of the Company’s stock.

### **Staggered Board; Removal of Directors; A&R Certificate of Incorporation**

The Company’s A&R Certificate of Incorporation divides the Company’s board of directors into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of the Company’s stockholders, with the other classes continuing for the remainder of their respective three year terms. Except as the DGCL may otherwise require, any newly created directorships or vacancies on the Board may be filled only by the board of directors, but subject to the rights of holders of any series of preferred stock and to the terms and conditions of the Stockholders Agreement.

The Company’s A&R Certification Incorporation provides that (i) all stockholder actions must be effected at a duly called meeting of the stockholders and (ii) stockholders may not adopt actions by written consent without a meeting.

The combination of these provisions will make it more difficult for the Company’s existing stockholders to replace the Board as well as for another party to obtain control of the Company by replacing the Board. Since the board of directors has the power to retain and discharge the officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the Board to issue preferred stock with voting or other rights or preferences that could impede any attempt to effect a change of control of the Company.

### **Transfer Agent**

Continental Stock Transfer & Trust Company, 17 Battery Place, New York, New York, serves as the transfer agent and registrar for the Company's stock.

### **DESCRIPTION OF DEBT SECURITIES**

We may issue from time to time, in one or more offerings, senior or subordinated debt securities covered by this prospectus. When we offer to sell a particular series of debt securities, we will describe the specific terms of the series in a supplement to this prospectus.

### **DESCRIPTION OF WARRANTS**

We may issue warrants to purchase our debt or equity securities or other rights, including rights to receive payment in cash or securities based on the value, rate or price of one or more specified commodities, currencies, securities or indices, or any combination of the foregoing. Warrants may be issued independently or together with any other securities and may be attached to, or separate from, such securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and a warrant agent. The terms of any warrants to be issued and a description of the material provisions of the applicable warrant agreement will be set forth in the applicable prospectus supplement.

### **DESCRIPTION OF UNITS**

As specified in the applicable prospectus supplement, we may issue units consisting of warrants, debt securities, shares of preferred stock, shares of common stock or any combination of such securities.

### **LEGAL OWNERSHIP OF SECURITIES**

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee maintain for this purpose as the “holders” of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as “indirect holders” of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

### **Book-Entry Holders**

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depository on behalf of other financial institutions that participate in the depository’s book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Securities issued in global form will be registered in the name of the depository or its nominee. Consequently, for securities issued in global form, we will recognize only the depository as the holder of the securities, and we will make all payments on the securities to the depository. The depository passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depository and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a book-entry security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depository’s book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not holders, of the securities.

### **Street Name Holders**

We may terminate a global security or issue securities in non-global form. In these cases, investors may choose to hold their securities in their own names or in “street name.” Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

### **Legal Holders**

Our obligations, as well as the obligations of any applicable trustee and of any third parties employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with depository participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of the indenture or for other purposes. In such an event, we would seek approval only from the holders, and not the indirect holders, of the securities. Whether and how the holders contact the indirect holders is up to the holders.

### **Special Considerations for Indirect Holders**

If you hold securities through a bank, broker or other financial institution, either in book-entry form or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders' consent, if ever required;



whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;

how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and

- if the securities are in book entry form, how the depository's rules and procedures will affect these matters.

## **Global Securities**

A global security is a security held by a depository that represents one or any other number of individual securities. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depository. Unless we specify otherwise in the applicable prospectus supplement, DTC will be the depository for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depository, its nominee or a successor depository, unless special termination situations arise. We describe those situations below under “—Special Situations When a Global Security Will Be Terminated.” As a result of these arrangements, the depository, or its nominee, will be the sole registered owner and holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depository or with another institution that does. Thus, an investor whose security is represented by a global security will not be a holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued in global form only, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

## Special Considerations for Global Securities

As an indirect holder, an investor's rights relating to a global security will be governed by the account rules of the investor's financial institution and of the depository, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depository that holds the global security.

If securities are issued only in the form of a global security, an investor should be aware of the following:

an investor cannot cause the securities to be registered in his or her name, and cannot obtain non global certificates for his or her interest in the securities, except in the special situations we describe below;

an investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe under "—Legal Holders" above;

an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book entry form;

an investor may not be able to pledge his or her interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;

the depository's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in a global security. We and any applicable trustee have no responsibility for any aspect of the depository's actions or for its records of ownership interests in a global security. We and the trustee also do not supervise the depository in any way;

the depository may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book entry system use immediately available funds, and your broker or bank may require you to do so as well; and

financial institutions that participate in the depository's book entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices and other matters relating to the securities. There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

### **Special Situations When A Global Security Will Be Terminated**

In a few special situations described below, the global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

The global security will terminate when the following special situations occur:

- if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;

- if we notify any applicable trustee that we wish to terminate that global security; or

- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the prospectus supplement. When a global security terminates, the depositary, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

## SELLING STOCKHOLDER

We are registering an aggregate of 4,295,580 shares of common stock to permit Biotest Pharmaceuticals Corporation, which we otherwise refer to herein as BPC or the selling stockholder, and its permitted assigns that receive their shares after the date of this prospectus, to resell the shares in the manner contemplated under “Plan of Distribution.” BPC became a stockholder of the Company in June 2017 as part of the Biotest Transaction. In connection with the Biotest Transaction, BPC received certain registration rights in the Registration Rights Agreement with respect to the 4,295,580 shares of common stock which are being registered.

The table below presents information regarding the beneficial ownership of outstanding shares of common stock by the selling stockholder and the shares that they may sell or otherwise dispose of from time to time under this prospectus. Information concerning the selling stockholder may change from time to time, and any changed information will be presented in a prospectus supplement if and when necessary and required. The shares set forth below may also be sold by certain transferees or successors-in-interest of the selling stockholder.

The number of shares of common stock in the column “Number of Shares Offered Hereby” represents all of the shares of common stock that the selling stockholder may offer under this prospectus. In addition, the table assumes that the selling stockholder will sell all of such shares. However, because the selling stockholder may offer from time to time all or some of their shares under this prospectus, or in another permitted manner, we cannot assure you as to the actual number of shares that will be sold or otherwise disposed of by the selling stockholder or that will be held by the selling stockholder after completion of such sales. We do not know how long the selling stockholder will hold the shares before selling them. For three years commencing December 6, 2017, subject to certain limited exceptions, under the Stockholders Agreement, sales by BPC, or its transferee, of our equity interests may not exceed 15% of our issued and outstanding common stock in any twelve-month period; provided, however, that if our market capitalization increases to double our market capitalization immediately following the closing of the Biotest Transaction, then BPC or its transferee may sell up to 20% of our issued and outstanding common stock in any twelve-month period; provided, further, that (x) if our market capitalization increases to triple our market capitalization immediately following the closing of the Biotest Transaction, or (y) upon the one-year anniversary of BPC or its transferee holding less than a 25% economic interest in us, then BPC or its transferee may sell its equity interests in us at any time (subject to applicable securities laws).

We have determined beneficial ownership in accordance with the rules of the SEC. The selling stockholder has the sole voting and investment power with respect to the shares set forth below. The percentage of beneficial ownership is based on an aggregate of 36,726,084 shares of common stock outstanding as of May 15, 2018.

Shares Beneficially  
Owned

Shares Beneficially  
Owned After Sale

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Name of Stockholder	Number	Percentage	Number of Shares Offered Hereby	of Shares Offered Hereby	
				Number	Percentage
Biotest Pharmaceuticals Corporation	10,109,534	27.5 %	4,295,580	5,813,954	15.8 %
Total	10,109,534	27.5 %	4,295,580	5,813,954	15.8 %

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## PLAN OF DISTRIBUTION

We or the selling stockholder may offer securities under this prospectus from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods or through underwriters or dealers, through agents and/or directly to one or more purchasers. The securities may be distributed from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Each time that securities covered by this prospectus are sold, we will provide a prospectus supplement or supplements that will describe the method of distribution and set forth the terms and conditions of the offering of such securities, including the offering price of the securities and the proceeds to us, if applicable.

Offers to purchase the securities being offered by this prospectus may be solicited directly. Agents may also be designated to solicit offers to purchase the securities from time to time. Any agent involved in the offer or sale of our securities will be identified in a prospectus supplement.

If a dealer is utilized in the sale of the securities being offered by this prospectus, the securities will be sold to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

If an underwriter is utilized in the sale of the securities being offered by this prospectus, an underwriting agreement will be executed with the underwriter at the time of sale and the name of any underwriter will be provided in the prospectus supplement that the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we, or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or

commissions from the underwriters and/or commissions from the purchasers for which they may act as agent. Unless otherwise indicated in a prospectus supplement, an agent will be acting on a best efforts basis and a dealer will purchase securities as a principal, and may then resell the securities at varying prices to be determined by the dealer.

Any compensation paid to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers will be provided in the applicable prospectus supplement. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We or the selling stockholder may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute to payments they may be required to make in respect thereof and to reimburse those persons for certain expenses.

The securities may or may not be listed on a national securities exchange. To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than were sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option, if any. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

If indicated in the applicable prospectus supplement, underwriters or other persons acting as agents may be authorized to solicit offers by institutions or other suitable purchasers to purchase the securities at the public offering price set forth in the prospectus supplement, pursuant to delayed delivery contracts providing for payment and delivery on the date or dates stated in the prospectus supplement. These purchasers may include, among others, commercial and savings banks, insurance companies, pension funds, investment companies and educational and charitable institutions. Delayed delivery contracts will be subject to the condition that the purchase of the securities covered by the delayed delivery contracts will not at the time of delivery be prohibited under the laws of any jurisdiction in the United States to which the purchaser is subject. The underwriters and agents will not have any responsibility with respect to the validity or performance of these contracts.

We may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

In compliance with the guidelines of the Financial Industry Regulatory Authority, Inc., or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate proceeds of the offering.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

The selling stockholder may also use any one or more of the following methods when selling shares of common stock:

- on The Nasdaq Capital Market (or any other exchange on which the shares may be listed);

- on the over-the-counter market;

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;



purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

In connection with the sale of our common stock or interests therein, the selling stockholder may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, the selling stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholder may also sell shares of our common stock short and deliver these securities to close out its short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholder may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities that require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholder from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. The selling stockholder reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from the offering by the selling stockholder.

The selling stockholder also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that such transactions meet the criteria and conform to the requirements of that rule.

The selling stockholder and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be “underwriters” within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. If the selling stockholder is an “underwriter” within the meaning of Section 2(11) of the Securities Act, it will be subject to the prospectus delivery requirements of the Securities Act.

## **General Information**

Underwriters, dealers and agents that participate in the distribution of our securities may be underwriters as defined in the Securities Act, and any discounts or commissions they receive and any profit they make on the resale of the offered securities may be treated as underwriting discounts and commissions under the Securities Act. Any underwriters or agents will be identified and their compensation described in a prospectus supplement. We may indemnify agents, underwriters, and dealers against certain civil liabilities, including liabilities under the Securities Act, or make contributions to payments they may be required to make relating to those liabilities. Our agents, underwriters, and dealers, or their affiliates, may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

Each series of securities offered by this prospectus may be a new issue of securities with no established trading market. Any underwriters to whom securities offered by this prospectus are sold by us for public offering and sale may make a market in the securities offered by this prospectus, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. No assurance can be given as to the liquidity of the trading market for any securities offered by this prospectus.

Representatives of the underwriters through whom our securities are sold for public offering and sale may engage in over-allotment, stabilizing transactions, syndicate short covering transactions and penalty bids in accordance with

Regulation M under the Exchange Act. Over-allotment involves syndicate sales in excess of the offering size, which creates a syndicate short position. Stabilizing transactions permit bids to purchase the offered securities so long as the stabilizing bids do not exceed a specified maximum.

Syndicate covering transactions involve purchases of the offered securities in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the representative of the underwriters to reclaim a selling concession from a syndicate member when the offered securities originally sold by such syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Such stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the offered securities to be higher than it would otherwise be in the absence of such transactions. These transactions may be effected on a national securities exchange and, if commenced, may be discontinued at any time.

Underwriters, dealers and agents may be customers of, engage in transactions with or perform services for, us and our subsidiaries in the ordinary course of business.

We will bear all costs, expenses and fees in connection with the registration of the securities as well as the expense of all commissions and discounts, if any, attributable to the sales of any of our securities by us.

## **WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and periodic reports, proxy statements and other information with the SEC. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549 on official business days during the hours of 10:00am and 3:00pm. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Many of our SEC filings are also available to the public from the SEC's Website at "<http://www.sec.gov>." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please contact Brian Lenz, our Chief Financial Officer, at the following address or telephone number: ADMA Biologics, Inc. 465 Route 17, Ramsey, New Jersey 07446, Attention: Brian Lenz, Vice President and Chief Financial Officer, (201) 478-5552. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

Copies of certain information filed by us with the SEC are also available on our website at [www.admabiologics.com](http://www.admabiologics.com). Information contained in, or accessible through, our website does not constitute a part of this prospectus or any accompanying prospectus supplement.

## **INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC allows us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information that is incorporated by reference is considered to be part of this prospectus, and the information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering of the securities.

- our Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 29, 2018;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed on May 14, 2018;
- our Current Reports on Form 8-K filed with the SEC on February 15, 2018, February 16, 2018, April 24, 2018, May 14, 2018 and May 16, 2018 (provided that any portions of such reports that are deemed furnished and not filed pursuant to instructions to Form 8-K shall not be incorporated by reference into this prospectus); and
- the description of common stock set forth in our Registration Statement on Form 8-A12B filed with the SEC on November 5, 2014 pursuant to Section 12(b) of the Exchange Act, including any amendment or report filed

for the purpose of updating such description.

Any statement contained in any document incorporated by reference herein will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any additional prospectus supplements modifies or supersedes such statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, a copy of any or all documents that are incorporated by reference into this prospectus, but not delivered with this prospectus, other than exhibits to such documents unless such exhibits are specifically incorporated by reference into the documents that this prospectus incorporates. To request such materials, please contact Brian Lenz, our Chief Financial Officer, at the following address or telephone number: ADMA Biologics, Inc. 465 Route 17, Ramsey, New Jersey 07446, Attention: Brian Lenz, Vice President and Chief Financial Officer, (201) 478-5552. A copy of all documents that are incorporated by reference into this prospectus can also be found on our website by accessing <http://ir.admabiologics.com/all-sec-filings>.

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. The selling stockholder will not make an offer of these shares in any jurisdiction where the offer is not permitted. You should not assume that information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

## **LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by DLA Piper LLP (US), Short Hills, New Jersey. Any underwriters will be advised about other issues relating to any offering by their own legal counsel.

## **EXPERTS**

The consolidated financial statements incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2017 have been audited by CohnReznick LLP, an independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference, which report includes an explanatory paragraph on the Company's ability to continue as a going concern. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

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**\$100,000,000**

**Common Stock, Preferred Stock,  
Debt Securities, Warrants and Units**

**4,295,580**

**Shares of Common Stock  
Offered by the Selling Stockholder**

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**Prospectus**

**, 2018**

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth an estimate of the costs and expenses payable by us in connection with the offering described in this registration statement. All of the amounts shown are estimates except the Securities and Exchange Commission registration fee:

Securities and Exchange Commission Registration Fee	\$ 15,071
Printing	15,000
Accounting Fees and Expenses	50,000
Transfer Agent and Registrar Fees	5,000
Legal Fees and Expenses	50,000
Miscellaneous	4,929
Total	\$ 140,000

**Item 15. Indemnification of Directors and Officers.**

Our directors and officers are indemnified as provided by the Delaware General Corporation Law, our Amended and Restated Certificate of Incorporation, and our Amended and Restated Bylaws. We have been advised that, in the opinion of the Securities and Exchange Commission, indemnification for liabilities arising under the Securities Act is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities is asserted by one of our directors, officers, or controlling persons in connection with the securities being registered, we will, unless in the opinion of our legal counsel the matter has been settled by controlling precedent, submit the question of whether such indemnification is against public policy to a court of appropriate jurisdiction. We will then be governed by the court's decision.

We are party to indemnification agreements with each of our directors and officers. These agreements require us to, among other things, indemnify our directors and officers against certain liabilities which may arise by reason of their status or service as directors or officers to the fullest extent permitted by applicable laws. These indemnification provisions and the indemnification agreements are sufficiently broad to permit indemnification of the our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act. The Company also maintains director and officer liability insurance.



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**Item 16.**

**Exhibits**

The exhibits to this Registration Statement are listed in the Exhibit Index to this Registration Statement, which Exhibit Index is hereby incorporated by reference.

**Item 17.**

**Undertakings**

The undersigned registrant hereby undertakes:

To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) to include any prospectus required by Section 10(a)(3) of the Securities Act; (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the "Commission"), pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement

That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

That, for the purpose of determining liability under the Securities Act to any purchaser:

- i. Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

- ii. Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

- 5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- i. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

- ii. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- iii. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of an undersigned registrant; and
- iv. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

That, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under Section 305(b)(2) of the Trust Indenture Act.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the Borough of Ramsey, State of New Jersey on May 18, 2018.

**ADMA BIOLOGICS, INC.**

By: /s/ Adam S. Grossman

Adam S. Grossman

President and Chief Executive Officer

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**POWER OF ATTORNEY**

KNOW BY ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Adam S. Grossman and Brian Lenz, and each of them, the undersigned's true and lawful attorneys-in-fact and agents, with full power of substitution and revocation, for and in the undersigned's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and any registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratify and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1933, as amended, this registration statement has been signed below by the following persons on behalf of the registrant and in the capacities indicated on the date listed below.

<b>Signature</b>	<b>Capacity</b>	<b>Date</b>
/s/ Adam S. Grossman Adam S. Grossman	President and Chief Executive Officer (Principal Executive Officer)	May 18, 2018
/s/ Brian Lenz Brian Lenz	Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	May 18, 2018
/s/ Steven A. Elms Steven A. Elms	Chairman of the Board of Directors	May 18, 2018
/s/ Dr. Jerrold B. Grossman Dr. Jerrold B. Grossman	Vice Chairman of the Board of Directors	May 18, 2018
/s/ Bryant E. Fong Bryant E. Fong	Director	May 18, 2018
/s/ Dov A. Goldstein, M.D. Dov A. Goldstein, M.D.	Director	May 18, 2018
/s/ Lawrence P. Guiheen Lawrence P. Guiheen	Director	May 18, 2018
/s/ Eric I. Richman Eric I. Richman	Director	May 18, 2018

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## INDEX TO EXHIBITS

The following exhibits are filed as part of, or incorporated by reference into this document:

<b>Exhibit No.</b>	<b>Description</b>
1.1**	Form of Underwriting Agreement.
4.1	<u>Specimen Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Current Report on Form 8-K/A, filed with the SEC on March 29, 2012).</u>
4.2	<u>Form of Warrant Agreement with Hercules Technology Growth Capital, Inc. (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1, filed with the SEC on February 11, 2013).</u>
4.3	<u>Form of Warrant Agreement with Oxford Finance LLC (incorporated herein by reference to Exhibit 4.6 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2016).</u>
4.4	<u>Warrant to Purchase Stock, dated October 10, 2017, issued by the Company to Marathon Healthcare Finance Fund, L.P. (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on October 11, 2017).</u>
4.5	<u>Form of Secured Term Loan Promissory Note issued to Hercules Technology Growth Capital, Inc. (incorporated herein by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1, filed with the SEC on February 11, 2013).</u>
4.6	<u>Form of Secured Term B Loan Promissory Note issued to Oxford Finance LLC (incorporated herein by reference to Exhibit 4.7 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2016).</u>
4.7	<u>Tranche One Term Note, dated October 10, 2017, issued by the Company to Marathon Healthcare Finance Fund, L.P. (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 11, 2017).</u>
5.1*	<u>Legal Opinion of DLA Piper LLP (US).</u>



23.1\* Consent of CohnReznick LLP.

23.2\* Consent of DLA Piper LLP (US) (included in Exhibit 5.1).

24.1\* Power of Attorney (included on signature page).

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\* Filed herewith.

\*\* To be filed by amendment or as an exhibit to a document incorporated by reference or deemed to be incorporated by reference in this registration statement, including a current report on Form 8-K, in connection with the offering of any securities, as appropriate.

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