UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2017

OR

□ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to ____

Commission file number 001-36728

ADMA BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

<u>Delaware</u> (State or Other Jurisdiction of Incorporation or Organization) <u>56-2590442</u> (I.R.S. Employer Identification No.)

<u>465 State Route 17, Ramsey, New Jersey</u> (Address of Principal Executive Offices) <u>07446</u> (Zip Code)

(201) 478-5552

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes \boxtimes No \square

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes \square No \square

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer □ Non-accelerated filer □ (Do not check if a smaller reporting company) Accelerated filer □ Smaller reporting company ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes 🗆 No 🗷

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

Emerging growth company

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

The number of shares outstanding of the issuer's common stock as of May 12, 2017 was 12,886,741.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

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Special Note Regarding Forward-Looking Statements

Some of the information in this quarterly report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. These statements include, among others, statements about:

- our ability to successfully consummate and close our proposed acquisition of certain assets from Biotest Pharmaceuticals Corporation, the expected closing date of which is conditioned upon several factors, including stockholder approval;
- our ability to successfully leverage the anticipated benefits and synergies of our proposed acquisition of certain assets from Biotest Pharmaceuticals Corporation, including maximizing the anticipated future combined businesses, operations, products and services, and liquidity, debt repayment and capital return expectations;
- our ability to successfully resubmit to the U.S. Food and Drug Administration, or FDA, our Biologics License Application, or BLA, for our lead product candidate, RI-002, once the deficiencies identified in the July 2016 Complete Response Letter, or CRL, have been resolved by us and/or our third party vendors to the satisfaction of the FDA, and other requests for information included therein have been provided by us;
- our plans to develop, market, launch and build our own commercial infrastructure and commercialize RI-002 and the success of such efforts;
- the expected timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including the timeframe within which we may receive approval from the FDA, if at all, of our BLA for RI-002 and the labeling or nature of any such approvals;
- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals;
- our dependence upon one manufacturer for RI-002 and the effect any adverse events on such manufacturer could have on us or our business;
- · our dependence upon our third-party contract manufacturers and vendors;
- our ability to obtain adequate quantities of FDA-approved normal source plasma and Respiratory Syncytical Virus, or RSV, hightiter plasma with proper specifications;
- · our plans to increase our supplies of plasma;
- · the potential indications for our product candidates;
- · potential investigational new product applications;
- the acceptability of RI-002 for any purpose by physicians, patients or payers;
- concurrence by FDA with our conclusions and the satisfaction by us of its guidance;
- the comparability of results of RI-002 to other comparably run injectable immune globulin clinical trials;
- the potential of RI-002 to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease, or PIDD;
- our intellectual property position, including our expectations of the scope of patent protection with respect to RI-002, or other future pipeline product candidates;



- our manufacturing capabilities, third-party contractor capabilities and strategy;
- · our plans relating to manufacturing, supply and other collaborative agreements;
- · our estimates regarding expenses, capital requirements and needs for additional financing;
- · possible or likely reimbursement levels, if any, if and when RI-002 is approved for marketing;
- estimates regarding market size, projected growth and sales as well as our expectations of market acceptance of RI-002; and
- expectations for future capital requirements.

These statements may be found under the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this quarterly report on Form 10-Q. Forward-looking statements typically are identified by the use of terms such as "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms, although some forward-looking statements are expressed differently. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to the factors referenced above.

In addition to the foregoing, you should also consider carefully the statements under the section entitled "Risk Factors" and other sections of this quarterly report on Form 10-Q, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

		March 31, 2017		December 31, 2016
		(Unaudited)		(Note 2)
ASSETS				
Current Assets:	¢	8,542,928	¢	9,914,867
Cash and Cash Equivalents Short-Term Investments	\$	8,542,928 245,000	\$	5,390,184
Accounts Receivable		839,938		1,018,027
Inventories		5,308,492		5,020,146
Prepaid Expenses		5,308,492 746,846		313,914
		15,683,204		21,657,138
Total Current Assets				
Property and Equipment at Cost, Net		1,882,151		2,000,784
Other Assets:		20.5(2		07.1(2
Deposits		29,563		27,163
Total Other Assets		29,563	-	27,163
TOTAL ASSETS	\$	17,594,918	\$	23,685,085
LIABILITIES AND STOCKHOLDERS' DEFICIENCY				
Current Liabilities:				
Accounts Payable	\$	3,904,445	\$	2,564,681
Accrued Expenses		2,224,719		2,385,356
Current Portion of Note Payable		6,666,667		6,111,111
Current Portion of Deferred Revenue		145,154		145,154
Current Portion of Leasehold Improvement Loan		16,935	_	16,559
Total Current Liabilities		12,957,920		11,222,861
Notes Payable, Net of Debt Discount		10,845,226		12,321,640
End of Term Liability, Notes Payable		1,790,000		1,790,000
Deferred Revenue, Net of Current Portion		2,654,325		2,690,033
Deferred Rent Liability		90,476		98,116
Leasehold Improvement Loan, Net of Current Portion		15,319		19,697
TOTAL LIABILITIES		28,353,266		28,142,347
COMMITMENTS AND CONTINGENCIES				
STOCKHOLDERS' DEFICIENCY				
Preferred Stock \$0.0001 par value 10,000,000 shares authorized,				
and 0 shares issued and outstanding as of March 31, 2017				
and December 31, 2016, respectively				
Common Stock \$0.0001 par value 75,000,000 shares				
authorized, and 12,886,741 shares issued and outstanding				
as of March 31, 2017 and December 31, 2016, respectively		1,289		1.289
Additional Paid-In Capital		102,712,144		102,476,267
Accumulated Deficit		(113,471,781)		(106,934,818)
TOTAL STOCKHOLDERS' DEFICIENCY		(10,758,348)		(4,457,262)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	\$	17,594,918	\$	23,685,085
IOTAL LIADILITIES AND STOCKHOLDERS DEFICIENCY	φ	17,374,718	φ	23,003,003

See Notes to (Unaudited) Condensed Consolidated Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months	Three Months Ended March 31			
	2017		2016		
REVENUES:					
Product revenue	\$ 2,593,163	\$	2,088,178		
License and other revenue	35,708		35,708		
Total Revenues	2,628,871		2,123,886		
OPERATING EXPENSES:					
Cost of product revenue	1,616,287		1,266,421		
Research and development	1,192,727		2,027,712		
Plasma centers	1,479,476		1,280,419		
General and administrative	4,277,384		1,707,870		
TOTAL OPERATING EXPENSES	8,565,874		6,282,422		
LOSS FROM OPERATIONS	(5,937,003)		(4,158,536)		
OTHER INCOME(EXPENSE):					
Interest income	18,568		13,508		
Interest expense	(618,528)		(467,441)		
OTHER EXPENSE,NET	(599,960)		(453,933)		
NET LOSS	\$ (6,536,963)	\$	(4,612,469)		
NET LOSS PER COMMON SHARE,					
Basic and Diluted	\$ (0.51)	\$	(0.43)		
WEIGHTED AVERAGE SHARES					
OUTSTANDING, Basic and Diluted	12,886,741		10,710,587		

See Notes to (Unaudited) Condensed Consolidated Financial Statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIENCY (Unaudited)

For the Three Months Ended March 31, 2017

	Common StockSharesAmount		Additional		Accumulated			
			Amount	Amount Paid-in Capital		Deficit		 Total
Balance - December 31, 2016	12,886,741	\$	1,289	\$	102,476,267	\$	(106,934,818)	\$ (4,457,262)
Stock-based compensation	—				235,877			235,877
Net loss	_				_		(6,536,963)	(6,536,963)
Balance - March 31, 2017	12,886,741	\$	1,289	\$	102,712,144	\$	(113,471,781)	\$ (10,758,348)

See Notes to (Unaudited) Condensed Consolidated Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	,	Three Months Ended March 31,			
		2017		2016	
CASH FLOWS FROM OPERATING ACTIVITIES:					
Net loss	\$	(6,536,963)	\$	(4,612,469)	
Adjustments to reconcile net loss to net					
cash used in operating activities:					
Depreciation and amortization		118,062		118,393	
Loss on disposal of fixed assets		4,155		—	
Stock-based compensation		235,877		422,180	
Amortization of debt discount		190,253		133,547	
Amortization of license revenue		(35,708)		(35,709)	
Changes in operating assets and liabilities:					
Accounts receivable		178,089		(19,482)	
Inventories		(288,346)		(603,466)	
Prepaid expenses		(432,932)		(633,883)	
Other assets		(2,400)			
Accounts payable		1,339,764		377,061	
Accrued expenses		(160,637)		(306,462)	
Deferred rent liability		(7,640)		(7,640)	
Net cash used in operating activities		(5,398,426)		(5,167,930)	
CASH FLOWS FROM INVESTING ACTIVITIES:		· · · · · ·	_	· · · · · · · · · · · · · · · · · · ·	
Sales of short-term investments		5,145,184		3,673,199	
Purchase of property and equipment		(3,584)		(17,437)	
Net cash provided by investing activities		5,141,600		3,655,762	
CASH FLOWS FROM FINANCING ACTIVITIES:		-,,			
Principal payments on note payable		(1,111,111)			
Payments of leasehold improvement loan		(4,002)		(3,659)	
Net cash used in financing activities		(1,115,113)		(3,659)	
NET DECREASE IN CASH AND CASH EQUIVALENTS		(1,371,939)		(1,515,827)	
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD		9,914,867		10,440,959	
CASH AND CASH EQUIVALENTS - END OF PERIOD	¢		¢		
CASH AND CASH EQUIVALENTS - END OF TEMOD	\$	8,542,928	\$	8,925,132	
SUPPLEMENTAL INFORMATION:					
Cash paid for interest	¢	124 170	¢	220.222	
	\$	424,470	\$	328,223	
Supplemental Disclosure of Noncash Financing Activities:					
Accrued equity issuance costs	\$		\$	3,554	

See Notes to (Unaudited) Condensed Consolidated Financial Statements.

1. ORGANIZATION AND BUSINESS

ADMA Biologics, Inc. ("ADMA" or the "Company") is a late stage biopharmaceutical company that develops, manufactures, and intends to commercialize specialty plasma-based biologics for the proposed treatment of immune deficiencies and prevention of certain infectious diseases. The Company's targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease or who may be immune-suppressed for medical reasons. Our 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. ADMA also operates through its wholly-owned subsidiary, ADMA Bio Centers Georgia, Inc. ("ADMA BioCenters"), a source plasma collection business with U.S. Food and Drug Administration ("FDA") approved facilities in Norcross, Georgia and Marietta, Georgia. Each facility holds certifications from the German Health Authority ("GHA") and the Korean Ministry of Food and Drug Safety ("MFDS"). ADMA BioCenters supplies ADMA with a portion of its raw material plasma for the manufacture of RI-002, ADMA's lead product candidate, which the Company is currently developing for the treatment of Primary Immune Deficiency Disease ("PIDD"). A Biologics License Application ("BLA") for RI-002 was submitted to the FDA and accepted for review during the third quarter of 2015. In July 2016, the FDA issued a Complete Response Letter ("CRL") to the Company for its BLA for RI-002. The CRL did not cite any concerns with the clinical safety and efficacy data for RI-002, 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 at ADMA's third-party contract manufacturers and vendors and requested documentation of corrections for a number of those issues. The FDA indicated in the CRL that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved. Since receiving the CRL, the Company has worked diligently with its contract fill and finisher as well as the contract testing laboratory. The Company has also continued to work with its third-party contract manufacturer, Biotest Pharmaceuticals Corporation ("BPC" or "Seller"), and on January 21, 2017, the Company signed a definitive acquisition agreement to acquire certain manufacturing and therapy-related assets from Biotest in Boca Raton, Florida, a wholly-owned subsidiary of Biotest Aktiengesellschaft ("Biotest"), in efforts to address the CRL and remediate the outstanding warning letter at the manufacturing facility. The acquisition of certain manufacturing and therapy-related assets of Biotest (the "Proposed Acquisition") is anticipated to close in June 2017. The Company and its vendors are awaiting certain feedback from the agency on submissions already made and the Company intends to provide a timeline for resubmission of the BLA for RI-002 as soon as practicable.

In May 2016, the Company completed an underwritten public offering of its common stock, raising gross proceeds of approximately \$14.1 million, and subsequently borrowed an additional \$4.0 million under its Loan and Security Agreement ("LSA") with Oxford Finance LLC ("Oxford"), which brought the total principal borrowed to \$20.0 million (See Footnote 3).

As of March 31, 2017, the Company had working capital of \$2.7 million, consisting primarily of \$8.5 million of cash and cash equivalents, \$0.3 million of short-term investments, \$0.8 million of accounts receivable, \$5.3 million of inventories, and \$0.7 million of prepaid expenses, offset primarily by the current portion of note payable due to Oxford of \$6.7 million, \$3.9 million of accounts payable, \$2.2 million of accrued expenses and \$0.1 million of deferred revenue. Based upon the Company's projected revenue and expenditures for 2017, including the fees associated with the Proposed Acquisition of certain BPC assets, regulatory and consulting fees for RI-002 associated with third-party manufacturers and ongoing discussions with the FDA, continuing implementation of the Company's commercialization and expansion activities and certain other assumptions, management currently believes that its cash, cash equivalents, short-term investments, projected revenue and accounts receivable are sufficient to fund ADMA's operations, as currently conducted, into the second half of 2017. These estimates may change based upon the timing of the closing of the Proposed Acquisition of certain BPC assets, whether or when the FDA approves RI-002, the timing of any required commercial manufacturing scale up activities or if any other assumptions of the Company change. This timing may also change based upon the timing of the completion of the Proposed Acquisition, anticipated in June 2017. Upon the closing of the Proposed Acquisition, BPC will be providing funds to ADMA consisting of: \$12.5 million in funding, \$15.0 million in debt financing and an additional \$12.5 million commitment towards a future equity financing is expected to be sufficient to fund operations into the first quarter of 2018. There is no assurance that we will be able to successfully close on the Proposed Acquisition. Other than the funding to be provided by BPC, the Company does not currently have arrangements to obtain additional financing. Furthermore, if the Company's assumptions underlying its estimated expenses and revenues are incorrect, it may have to raise additional capital sooner than anticipated. Due to numerous risks and uncertainties associated with the research and development and potential future commercialization of its product candidate, the Company is unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with its development activities. The Company's current estimates may be subject to change as circumstances regarding its business requirements evolve. The Company may decide to raise capital through public or private equity offerings or debt financings, or obtain a bank credit facility or corporate collaboration and licensing arrangements. The Company does not have any existing commitments for future external funding. The sale of additional equity or debt securities, if convertible, could result in dilution to the Company's stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict the Company's operations or other financing alternatives. Additional equity or debt financing, grants, or corporate collaboration and potential licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, the Company may be required to delay, reduce the scope of or eliminate the Company's research and development programs, reduce the Company's planned clinical trials and delay or abandon potential commercialization efforts of the Company's lead or other product candidates. The Company has reported losses since inception in June 2004 through March 31, 2017 of \$113.5 million. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities to fund its research and development, commercial programs and meet its obligations on a timely basis through the foreseeable future. As such, these factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts and the classification of liabilities that might be necessary from the outcome of this uncertainty.



ADMA's long-term liquidity will be dependent upon on its ability to raise additional capital, to fund its research and development and commercial programs and meet its obligations on a timely basis. If ADMA is unable to successfully raise sufficient additional capital, it will likely not have sufficient cash flow and liquidity to fund its business operations, forcing ADMA to curtail activities and potentially significantly reduce, or potentially cease, operations. Even if ADMA is 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 its common stock may decline.

There can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable. The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements.

2. <u>SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES</u>

Basis of presentation and principles of consolidation

The accompanying condensed consolidated financial statements include the accounts of ADMA and its wholly-owned subsidiaries, ADMA Plasma Biologics, Inc. and ADMA BioCenters. All significant intercompany transactions and balances have been eliminated in consolidation.

The condensed consolidated financial statements for the interim periods included herein are unaudited; however, they contain all adjustments (consisting of only normal recurring adjustments) which in the opinion of management are necessary to present fairly the condensed consolidated financial position of the Company and its wholly-owned subsidiaries as of March 31, 2017 and their results of operations for the three months ended March 31, 2017 and 2016, changes in stockholders' deficiency for the three months ended March 31, 2017 and 2016. The results of operations for the interim periods are not necessarily indicative of results that may be expected for any other interim periods or for the full year. These interim financial statements should be read in conjunction with the audited annual consolidated financial statements and notes thereto included in the Company's Annual Report for the year ended December 31, 2016 on Form 10-K, filed with the U.S. Securities and Exchange Commission (the "SEC") on February 24, 2017. The accompanying condensed consolidated balance sheet as of December 31, 2016, was derived from the 2016 audited consolidated financial statements.



The condensed consolidated financial statements have been prepared in accordance with Accounting Principles Generally Accepted in the United States of America ("GAAP") in accordance with the rules and regulations of the SEC for interim reporting. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in complete annual financial statements have been condensed or omitted.

Inventories

Plasma inventories (both plasma intended for resale and plasma intended for internal use in the Company's research and development and future anticipated commercialization activities of which certain quantities are labeled as normal source and Respiratory Syncytial Virus ("RSV"), high titer) are carried at the lower of cost or market value determined by the first-in, first-out method. Research and development plasma used in clinical trials was processed to a finished product and subsequently expensed to research and development. Inventory at March 31, 2017 and December 31, 2016 consists of high titer RSV plasma and normal source plasma.

Revenue recognition

Depending on the agreement with the customer, product revenues from the sale of human plasma collected at the Company's plasma collection centers are recognized at the time of transfer of title and risk of loss to the customer, which occurs at the time of shipment. Product revenues are recognized at the time of delivery if the Company retains the risk of loss during shipment. For the three months ended March 31, 2017, two of the Company's customers, SK Plasma Co., Ltd. ("SK") and BPC, represented 98% of the Company's total revenues, with BPC representing approximately 81% of the Company's total revenues and SK representing approximately 17% of the Company's total revenues.

Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement have been completed.

Revenues for the three months ended March 31, 2017 are comprised of product revenues from the sale of normal source human plasma collected from the Company's plasma collection centers segment and license and other revenues are primarily attributable to the outlicensing of RI-002 to Biotest to market and sell in Europe and selected countries in North Africa and the Middle East. Biotest and BPC, a subsidiary of Biotest, have provided the Company with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay the Company certain amounts in the future if certain milestones are achieved. Deferred revenue is recognized over the term of the Biotest license. Deferred revenue is amortized into income for a period of approximately 20 years, the term of the Biotest license agreement.

Use of estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include valuation of inventory, assumptions used in the fair value determination of stock-based compensation, warrants and the allowance for the valuation of future tax benefits.

Loss per common share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period.



Diluted net loss per share is calculated by dividing net loss attributable to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of common stock and dilutive common stock outstanding during the period. Potential common stock includes the shares of common stock issuable upon the exercise of outstanding stock options and warrants (using the treasury stock method). Potential common stock in the diluted net loss per share computation is excluded to the extent that it would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented. The aggregate number of potentially dilutive securities upon the exercise of outstanding warrants and stock options was 1.9 million and 1.8 million as of March 31, 2017 and 2016, respectively.

Stock-based compensation

The Company follows recognized accounting guidance which requires all stock-based payments, including grants of stock options, to be recognized in the statement of operations as compensation expense, based on their fair values on the grant date. The estimated fair value of stock options granted under the Company's 2007 Employee Stock Option Plan (the "2007 Plan") and the Company's 2014 Omnibus Incentive Compensation Plan (the "2014 Plan") is recognized as compensation expense over the option-vesting period.

During the three months ended March 31, 2017 and 2016, the Company granted stock options to purchase 182,000 and 85,984 shares of common stock, respectively, to its directors and employees.

Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU No. 2017-01, *Business Combinations – Clarifying the Definition of a Business*, which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. The Company does not expect this new guidance to have a material impact on its condensed consolidated financial statements.

In March 2016, the FASB, issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. The Company adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on its condensed consolidated financial statements for the first quarter of 2017.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact the standard may have on its condensed consolidated financial statements and related disclosures.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes*, which includes amendments that require deferred tax liabilities and assets be classified as non-current in a classified statement of financial position. The amendments in this ASU are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted as of the beginning of an interim or annual reporting period. The amendments may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The adoption of this ASU is not expected to have a material impact on the Company's condensed consolidated financial statements and related disclosures.



In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805), Simplifying the Accounting for Measurement-Period Adjustments*, which includes amendments that require an acquirer to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this ASU require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the changes to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in this ASU require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied prospectively to adjustments to provisional amounts that occur after the effective date of the ASU with earlier application permitted for financial statements that have not yet been made available for issuance. The Company adopted this standard and evaluated the impact the standard may have on its condensed consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory.* The standard requires entities to measure most inventory "at the lower of cost and net realizable value," thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures, one of which is net realizable value). The Company adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements for the first quarter of 2017.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is "substantial doubt about the entity's ability to continue as a going concern." The FASB believes that requiring management to perform the assessment will enhance the timeliness, clarity, and consistency of related disclosures and improve convergence with International Financial Reporting Standards ("IFRS") (which emphasize management's responsibility for performing the going-concern assessment). However, the time horizon for the assessment (look-forward period) and the disclosure thresholds under GAAP and IFRSs will continue to differ. The Company adopted this standard as of December 31, 2016 and the adoption of this standard did not have a material impact on its condensed consolidated financial statements for the first quarter of 2017.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, which requires that an entity recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to its customers. In order to achieve this core principle, an entity should apply the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. This update will replace existing revenue recognition guidance under GAAP, when it becomes effective for us beginning January 1, 2018, with early adoption permitted in the first quarter of 2017. The updated standard will permit the use of either the retrospective or cumulative effect transition method. The Company is currently evaluating the impact of this update on its condensed consolidated financial statements.

3. <u>DEBT</u>

Loan and Security Agreement

On June 19, 2015, the Company entered into an LSA with Oxford for up to \$21.0 million of debt financing in two term loan tranches. The first term loan tranche of \$16.0 million from the LSA (the "Term A Loan") was primarily used to repay the Company's previous debt facility with Hercules Technology Growth Capital, Inc. dated December 2012.

The outstanding term loans bear interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three-month U.S. LIBOR rate (as reported in *The Wall Street Journal*) on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.54% on the outstanding principal balance. The effective interest rate for the loan tranche of \$16.0 million, including backend fees is 11.40%. The Company began repaying the principal balance on February 1, 2017 for a period of 36 months, unless accelerated as a result of certain events of default. A final payment equal to 8.95% of the funded loan amount is due at the earlier of loan maturity or prepayment. All term loans mature no later than January 1, 2020. The loans are secured by the Company's assets, except for its intellectual property (which is subject to a negative pledge). The LSA contains customary representations, warranties and covenants, including limitations on incurring indebtedness, engaging in mergers or acquisitions and making investments, distributions or transfers.

In connection with the entry into 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. The Company recorded \$367,700 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: (i) volatility of 57% on the Company's common stock based upon a pro rata percentage of the Company' common stock's volatility and similar public companies' volatilities for comparison; (ii) an expected dividend yield of 0.0%; (iii) a risk-free interest rate of 1.99%; and (iv) a term of seven years.

In May 2016, the Company amended the LSA with Oxford (the "Amended LSA") which provided ADMA with an additional \$4.0 million term loan (the "Term B Loan"), the availability of which was conditioned on completing an equity financing of its common stock of at least \$10.0 million in gross proceeds no later than May 31, 2016. On May 3, 2016, the Company completed an underwritten public offering of its common stock, raising gross proceeds of approximately \$14.1 million and subsequently borrowed the additional \$4.0 million from Oxford under the Amended LSA, which brings the total principal amount borrowed to \$20.0 million. The effective interest rate for the loan tranche of \$4.0 million, including backend fees is 13.04%.

In the event the Company prepays a term loan for any reason, the Company is obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the applicable term loan prepaid. The Amended LSA further modified the fees payable by the Company on mandatory or voluntary prepayment of a term loan prior to its maturity date as follows: (i) for a prepayment made on or after the funding date of the applicable term loan through and including the first anniversary of its funding date, an amount equal to 3.00% of the principal amount of the term loan prepaid; (ii) for a prepayment made after the first anniversary of the funding date of the applicable term loan nurversary of such funding date, an amount equal to 2.00% of the principal amount of such term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid.

Pursuant to the Amended LSA, (i) the Company paid a total facility fee of \$125,000, consisting of \$105,000 previously paid and an additional \$20,000 paid on the date the Term B Loan was funded; (ii) certain adjustments were made to the time periods for any applicable prepayment fees; and (iii) certain defined terms were adjusted, including a new February 1, 2017 amortization date. The Amended LSA further provides for customary representations, warranties and covenants for the Company. Except as otherwise amended, the Amended LSA does not alter the terms of the LSA.



In connection with the Amended LSA, on May 13, 2016, the Company issued to Oxford a seven-year warrant, expiring on May 13, 2023, to purchase 24,800 shares of common stock at an exercise price of \$6.37 per share, equal to 3.95% of the amount drawn of such tranche, divided by the average reported closing price per share of common stock for the consecutive 10 trading days prior to the applicable draw in accordance with the Company's drawdown of the Term B Loan. The Company recorded \$86,300 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: volatility of 53.5% on the Company's common stock based upon a pro rata percentage of the Company's common stock's volatility and similar public companies' volatilities for comparison, an expected dividend yield of 0.0%, a risk-free interest rate of 1.51% and a term of seven years.

A summary of the Oxford loan balance is as follows:

		As of:		As of:
	Ma	rch 31, 2017	Decem	ber 31, 2016
Gross proceeds	\$	20,000,000	\$	20,000,000
Paydown of principal balance		(1,111,111)		
		18,888,889		20,000,000
Less: debt discount, net				
End of term fee		(1,026,468)		(1,155,157)
Warrants		(218,777)		(257,201)
Financing fees		(131,751)		(154,891)
Note payable	\$	17,511,893	\$	18,432,751

4. STOCKHOLDERS' EQUITY

On May 3, 2016, the Company completed an underwritten public offering of 2,176,154 shares of its common stock, for gross proceeds of approximately \$14.1 million. Net proceeds from this offering were approximately \$13.0 million, after payment of underwriting discounts and offering expenses of approximately \$1.1 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-200638) that was declared effective by the SEC on December 23, 2014.

Oxford Debt Financing Warrant Issuance

In May 2016, the Company issued to 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.

Equity incentive plan

The fair value of employee options granted was determined on the date of grant using the Black-Scholes option valuation model. The Black-Scholes model was developed for use in estimating the fair value of publicly traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. The Company's employee stock options have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value estimate. Because there has been minimal data for the Company's stock and very little historical experience with the Company's stock options, similar public companies and a pro rata percentage of the Company's common stock were used for calculating ADMA's volatility for comparison and expectations as to the assumptions required for fair value computation using the Black-Scholes methodology.



	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Expected term	5.8 - 6.3 years	5.8 - 6.3 years
Volatility	64%	52%
Dividend yield	0.0	0.0
Risk-free interest rate	2.29%	1.75-1.79%

The weighted average remaining contractual life of stock options outstanding and expected to vest at March 31, 2017 is 6.5 years. The weighted average remaining contractual life of stock options exercisable at March 31, 2017 is 5.6 years.

A summary of the Company's option activity under the 2007 Plan and 2014 Plan and related information is as follows:

		Three Months Ended March 31, 2017				
	Shares	A	eighted verage cise Price			
Outstanding at beginning of period	1,535,187	\$	7.90			
Forfeited	(19,814)	\$	9.02			
Expired	(6,250)	\$	9.00			
Granted	182,000	\$	5.00			
Outstanding at end of period and expected to vest	1,691,123	\$	7.57			
Options exercisable	1,227,873	\$	7.66			

Stock-based compensation expense for the three ended March 31, 2017 and 2016 is as follows:

	Three Months Ended March 31,					
	 2017		2016			
Research and development	\$ 52,983	\$	156,556			
Plasma centers	12,751		13,010			
General and administrative	170,143		252,614			
Total stock-based compensation expense	\$ 235,877	\$	422,180			

As of March 31, 2017, the total compensation expense related to unvested options not yet recognized totaled \$1,832,351. The weighted average vesting period over which the total compensation expense will be recorded related to unvested options not yet recognized at March 31, 2017 was approximately 2.3 years.

5. <u>RELATED PARTY TRANSACTIONS</u>

The Company leases an office building and equipment from Areth, LLC ("Areth") pursuant to a shared services agreement on a monthto-month basis of which terms were amended by the Company's Board of Directors in June 2016. Rent expense amounted to \$48,000 for the three months ended March 31, 2017 and \$24,112 for the three months ended March 31, 2016. Areth is a company controlled by Dr. Jerrold B. Grossman, the Company's Vice Chairman, and Adam S. Grossman, the Company's President and Chief Executive Officer, and the Company pays Areth monthly fees for the use of such office space and for other information technology, general warehousing and administrative services. The Company also reimburses its landlord for office and building related (common area) expenses, equipment and certain other operational expenses, which have been insignificant to the condensed consolidated financial statements for the three months ended March 31, 2017 and 2016. The Company maintains deposits and other accounts at Pascack Bankcorp, a bank of which Dr. Grossman served as a director through January 2016, and which was approximately 5%-owned by members of the Grossman family. Pascack Bankcorp was acquired by Lakeland Bancorp, Inc. in January 2016 and Dr. Grossman is currently a member of the Corporate Advisory Council of Lakeland Bancorp Inc.

6. COMMITMENTS AND CONTINGENCIES

General Legal Matters

The Company is and may become subject to certain legal proceedings and claims arising in connection with the normal course of its business. In the opinion of management, there are currently no claims that would have a material adverse effect on its consolidated financial position, results of operations or cash flows.

7. SEGMENTS

The Company is engaged in the development and commercialization of human plasma and plasma-derived therapeutics. The Company also operates ADMA BioCenters, consisting of two FDA-licensed source plasma collection facilities located in Georgia. The Company defines its segments as those business units whose operating results are regularly reviewed by the chief operating decision maker ("CODM") to analyze performance and allocate resources. The Company's CODM is its President and Chief Executive Officer.

The plasma collection centers segment includes the Company's operations in Georgia. The research and development segment includes the Company's plasma development operations in New Jersey.

Summarized financial information concerning reportable segments is shown in the following tables:

2,593,163 1,616,287 976 876	\$	_	\$	35,708	\$	2,628,871
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076 876				—		1,616,287
2/0,0/0		—		35,708		1,012,584
(502,600)		(1,192,727)		(4,241,676)		(5,937,003)
_		_		(599,960)		(599,960)
(502,600)		(1,192,727)		(4,841,636)		(6,536,963)
2,286,500		_		15,308,418		17,594,918
103,640		_		14,422		118,062
	(502,600) 2,286,500	(502,600) 	(502,600) (1,192,727)	(502,600) (1,192,727)	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

Three Months Ended March 31, 2016	Plas	ma Collection Centers	Research and Development		Corporate		Consolidated
Revenues	\$	2,088,178	\$ 	\$	35,708	\$	2,123,886
Cost of product revenue		1,266,421	_		_		1,266,421
Gross profit		821,757	_		35,708		857,465
Loss from operations		(458,662)	(2,027,712)		(1,672,162)		(4,158,536)
Other expense					(453,933)		(453,933)
Loss before income taxes		(458,662)	(2,027,712)		(2,126,095)		(4,612,469)
Total assets		2,595,429	_		17,089,491		19,684,920
Depreciation and							
amortization expense		105,189			13,204		118,393

The "Corporate" column above includes general and administrative overhead expenses. Total assets included in the "Corporate" column above includes assets related to corporate and support functions.

8. PROPOSED ACQUISITION OF CERTAIN ASSETS OF BPC

On January 21, 2017, the Company and its wholly-owned subsidiary, ADMA BioManufacturing, LLC, a Delaware limited liability company ("Buyer"), entered into a definitive Master Purchase and Sale Agreement (as amended, restated, supplemented, or otherwise modified from time to time (the "Purchase Agreement") with Seller, and for certain limited purposes set forth in the Purchase Agreement, Biotest, and Biotest US Corporation, a Delaware corporation and subsidiary of Biotest (together with Biotest, the "Biotest Guarantors"), pursuant to which Buyer has agreed to acquire certain assets and assume certain liabilities constituting the therapy business of Seller (the "Business"). The Business includes (a) a FDA-licensed immune globulin manufacturing and plasma products production facility of two buildings in Boca Raton, Florida, and the associated real property, (b) all exclusive rights to FDA licensed biologics products Nabi-HB®, BIVIGAM® and the investigational product CIVACIR®, (c) in-process inventory with an agreed-upon value of at least \$5.0 million, (d) certain other properties and assets used exclusively in the Business, and (e) certain additional assets which relate to both the Business and Seller's plasma business the arrangement with respect to which will be documented in a transition services agreement to be mutually agreed by the parties between the signing of the Purchase Agreement and the closing of the Proposed Acquisition.

Subject to the terms and conditions of the Purchase Agreement, (i) upon the closing, the Company has agreed to assume certain liabilities of Seller related to the Business, including, without limitation, related to (x) product liabilities, breach of warranty, product complaints, product returns, post-market commitments, recalls, adverse event reporting, product deviation reporting, lookbacks, market withdrawals and field corrections or similar claims for injury to person or property with respect to the Business or any product of the Business to the extent such liabilities relate to products manufactured and sold by Buyer after the closing (other than inventory transferred to the Company at the closing, which will be allocated 50% to Buyer and 50% to Seller if not traceable to acts or omissions of a particular party); and (y) other regulatory matters, whether related to the pre-closing or post-closing period and including any liabilities related to the products of the Business, the FDA warning letter (the warning letter issued by the FDA to Seller in connection with outstanding issues requiring remediation at the manufacturing facility in Boca Raton, Florida), noncompliance with applicable laws and legal proceedings related to the foregoing, but excluding such liabilities that arise out of any fraud, willful misconduct or intentional misrepresentation by Seller prior to the closing (the "Assumed Liabilities"); (ii) upon the closing, the Company has agreed to deliver to Seller an aggregate equity interest in the Company equal to 50%, less one share, of its issued and outstanding capital stock (calculated as of immediately following the closing and on a post-closing issuance basis) (the "Biotest Equity Interest"), consisting of (x) common stock representing 25% of the Company's issued and outstanding common stock, equal to 4.295,580 shares of common stock and (y) non-voting common stock equal to 8,591,160 shares of the Company's non-voting common stock representing the balance of the Biotest Equity Interest which is convertible into common stock of the Company upon the occurrence of certain specified events; (iii) upon the closing, the Company agreed to issue to Seller warrants, if any, necessary to acquire additional shares of the Company's capital stock equal to the excess, if any, of (x) the number of shares represented by rights, options and warrants issued by the Company between September 12, 2016 until the closing, over (y) 184,000 shares; and (iv) on January 1, 2019, pursuant to the terms of a separate purchase agreement to be entered into by the parties at the closing, the Company has agreed to sell, transfer and convey to Seller for no additional consideration, all of its right, title and interest in and to the Company's certain biocenter located in Norcross, Georgia and the Company's certain biocenter located in Marietta, Georgia, which are subject to a repurchase right in favor of the Company if within five years after January 1, 2019, the Biotest stockholders and its related entities own less than 20% of the Company's issued and outstanding capital stock. As part of the consideration, upon the closing, Seller will also be granted the right to designate one director and one observer to the Company's board of directors, and under certain circumstances, Seller will be granted the right to designate an additional director.

Additionally, on the closing date, Seller has agreed to (i) deliver to the Company a capital contribution of \$12.5 million in respect of the Biotest Equity Interest, which capital contribution will be contributed by Seller to Buyer; and (ii) fund a \$15.0 million unsecured subordinated loan to the Company, which (a) will bear interest at a rate of 6% per annum, payable semiannually in arrears, (b) has a term of five years and (c) will not be subject to any prepayment penalty or other breakage costs. Such loan will be subordinated to the Company's existing indebtedness as of the signing of the Purchase Agreement and any additional indebtedness approved by the Company's board of directors which is secured only by a mortgage on the owned real property acquired in connection with the transaction. Such loan will rank pari passu with all additional indebtedness approved by the Company's board of directors that is not secured only by a mortgage on such owned real property and if such additional indebtedness is secured, the loan from Seller will be secured on a pari passu basis with such additional indebtedness. At any time after the closing, if the Company undertakes an underwritten equity financing or a Private Investment in Public Equity, or PIPE, offering involving at least one unrelated third party, Biotest and/or Seller have agreed to participate pro rata in accordance with the Biotest Equity Interest up to an aggregate amount equal to \$12.5 million.

9. LEASE WITH HOME CENTER PROPERTIES, LLC

On February 17, 2017, ADMA BioCenters entered into a lease (the "Lease") with Home Center Properties, LLC, a Georgia limited liability company ("Landlord"), for approximately 12,167 square feet located at 166 Earnest W. Barrett Parkway, Marietta, Georgia 30066 (the "Premises"). As of March 31, 2017, ADMA BioCenters had not taken possession of the facility. The Lease term shall commence upon the substantial completion of the Landlord's work. Pursuant to the Lease, ADMA BioCenters will utilize the Premises as a facility specializing in the collection of human plasma and blood, general office administration and any other related use.

The Lease has an initial term of approximately eight years and nine months (the "Initial Term"), commencing upon substantial completion of "Landlord's Work" (as defined in the Lease) (the "Lease Commencement Date"), with rent payments commencing 150 days after the Lease Commencement Date. ADMA BioCenters' total monthly cost of the Premises (inclusive of Landlord's "Operating Costs", "Taxes" and "Insurance Charges" (as such terms are defined in the Lease)) will range from approximately \$20,000 to \$27,000 during the Initial Term; *provided*, *however*, *that*, provided ADMA BioCenters is not in default of the Lease beyond the expiration of any applicable notice and cure period, ADMA BioCenters shall not be obligated to make any rent payments for the first five calendar months of the Initial Term beginning on the Lease Commencement Date. Provided that the Lease is in full force and effect and provided there has been no "Event of Default" (as defined in the Lease) beyond the expiration of any applicable notice and cure period, ADMA BioCenters shall have the option to extend the term of the Lease for two additional periods of five years each (each, an "Extension Term"), each Extension Term on the same terms, covenants and conditions as the Lease, with the rent for each Extension Term to equal the mutually agreed fair market value of the Premises on the commencement of such Extension Term. The Lease also contains customary default provisions, representations, warranties and covenants.



Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This discussion, which refers to our historical results, should be read in conjunction with the other sections of this quarterly report, including "Risk Factors" and the consolidated financial statements and other consolidated financial information included in this quarterly report on Form 10-Q. The various sections of this discussion contain a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described throughout this quarterly report on Form 10-Q. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ materially.

Overview

We are a late-stage biopharmaceutical company that develops, manufactures, and intends to commercialize specialty plasmabased biologics for the proposed treatment of immune deficiencies and prevention of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immunesuppressed for medical reasons. Our product candidates are intended to be used by physician specialists focused on caring for immunecompromised patients with or at risk for certain infectious diseases.

Our Lead Product Candidate - RI-002

We are currently developing our lead product candidate, RI-002, for the treatment of PIDD, and have completed a pivotal Phase III clinical study. RI-002 is derived from human plasma blended from normal donors and donors tested to have high levels of neutralizing titers to RSV. RI-002 is manufactured using a process called fractionation, which purifies immune globulins, or IgG, from this blended plasma pool resulting in a final Intravenous Immune Globulin, or IVIG, product enriched with naturally occurring polyclonal anti-pathogen antibodies (e.g., streptococcus pneumonia, H. influenza type B, Cytomegalovirus or CMV, measles, tetanus, etc.). We use our proprietary RSV microneutralization assay to test for standardized levels of neutralizing antibodies to RSV in the final drug product.

In the third quarter of 2015, the FDA accepted for review our BLA for RI-002 for the treatment of PIDD. In July 2016, the FDA issued a CRL. The CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in the 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 relating to Chemistry, Manufacturing and Controls, or CMC, at our third-party contract manufacturers and vendors and requested documentation of corrections for a number of those issues. The FDA indicated in the CRL that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved. Since receiving the CRL, we have worked diligently with our contract fill and finisher as well as the contract testing laboratory. We have also continued to work with our third-party contract manufacturer, BPC, or Seller, and on January 23, 2017 we announced the signing of a definitive acquisition agreement to acquire certain manufacturing and therapy-related assets from BPC in Boca Raton, Florida, a wholly-owned subsidiary of Biotest Aktiengesellschaft, or Biotest, in efforts to address the CRL and remediate the outstanding warning letter and other matters at the manufacturing facility.

We continue to collaborate with our third-party manufacturers and vendors to identify solutions to outstanding issues identified in the CRL. We are currently preparing documentation for an additional submission to the FDA to address the CRL. We, along with our vendors, are awaiting certain feedback from the FDA regarding previous submissions and we intend to provide a timeline for resubmission of our BLA for RI-002 as soon as practicable. If RI-002 is approved by the FDA for PIDD, we intend to commercialize RI-002 for the treatment of PIDD and explore alternative processes to evaluate and seek approval for RI-002 for additional indications, patient populations and uses.

Evaluation of PIDD Patients

PIDD, a genetic disorder that causes a deficient or absent immune system, is caused by hereditary or genetic defects and can affect anyone regardless of age or gender. PIDD patients are more vulnerable to infections and more likely to suffer complications from these infections. IVIG is a plasma derived product that is used to prevent serious infections in patients with PIDD. It is comprised of polyclonal antibodies, which are proteins produced by B-cells that are used by the body's immune system to neutralize foreign objects such as bacteria and viruses. It is estimated that there are about 250,000 diagnosed PIDD patients in the U.S., approximately half of whom are treated with IVIG regularly. In the U.S., sales of immune globulin products for all its uses were reported to be approximately \$4.8 billion in 2014.



The RI-002 pivotal Phase III clinical trial was conducted as a single arm study in which patients were treated approximately once per month for a period of 12 months plus 90 days for follow up. Fifty-nine patients were enrolled in nine treatment centers in the U.S. The pivotal Phase III primary endpoint followed published FDA industry guidance, which provides for a reduction in the incidence of serious infections to less than one per year in each subject receiving IVIG. The secondary outcome was safety and included other pharmacokinetic, or PK, data collection points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion.

RI-002 demonstrated positive results in the Phase III study in patients with PIDD, meeting its primary endpoint, of no Serious Bacterial Infections, or SBI, reported. RI-002 was administered a total of 793 infusions with zero serious adverse events to 59 patients in nine treatment centers throughout the U.S. These results, included in the BLA, more than meet the requirement specified by FDA guidance of ≤ 1 SBI per patient-year.

On February 22, 2015, at the 2015 American Academy of Allergy, Asthma & Immunology Annual Meeting, scientific investigators reported on the secondary outcomes that included: a total of 93 days, or 1.66 days per patient per year lost from work or school due to infection; one hospitalization due to an infection of only five days duration in the entire study and IgG trough levels above those required by the FDA for IVIG products. Additionally, there was a marked increase in all of the measured specific anti-pathogen antibodies in PK subjects (n=31). The mean of maximum fold increases in specific antibody levels after infusion of RI-002 ranged from 1.9 fold (S. pneumonia type 19A) to 5.3 fold (RSV), which were statistically significant fold increases from the pathogen's specific measured baselines. The safety profile of RI-002 is comparable to that of other immunoglobulins.

Rationale for the Potential Evaluation in RSV Infected Patients

RSV is a common virus that ordinarily leads to mild, cold-like symptoms in healthy adults and children. In high-risk groups, such as the PIDD population and the other immune-compromised populations, RSV can lead to a more serious infection and may even cause death. The polyclonal antibodies which are present in RI-002 are expected to prevent infections in immune-compromised patients.

We previously conducted a randomized, double-blind, placebo-controlled Phase II clinical trial to evaluate RI-001, RI-002's predecessor product candidate, in immune-compromised, RSV-infected patients. This trial was conducted with 21 patients in the U.S., Canada, Australia, and New Zealand. The Phase II dose-ranging trial demonstrated a statistically significant improvement in the change from baseline RSV titers to day 18 in the high dose and low dose treatment groups when compared with placebo (p=0.0043 and p=0.0268, respectively). The mean fold increase for high dose was 9.24 (95% CI 4.07, 21.02) and the observed mean fold increase for low dose was 4.85 (95% CI 2.22, 10.59). The mean fold change for placebo treated patients was 1.42 (95% CI 0.64, 3.17). In addition, more patients in the high dose (85.7%) and low dose (42.9%) groups experienced greater than a four-fold increase from baseline to day 18 in RSV titer levels compared to placebo (0%). There were no serious drug-related adverse events reported during the trial.

From April 2009 through February 2011, RI-001 was also administered to 15 compassionate use patients where physicians requested access to the product for treating their patients with documented lower respiratory tract RSV infections due to the fact that these patients had failed conventional therapeutic interventions. Serum samples were obtained from 13 patients. Samples showed that patients demonstrated a four-fold or greater rise in RSV antibody titers from baseline. Serum samples were not obtained from two patients that received Palivizumab. All 11 patients who received RI-001 within 4.2 days after the onset of the diagnosis of RSV survived. The drug was well-tolerated in all 15 patients and there were no reports of serious adverse events attributable to RI-001. Data from our Phase II clinical trial, compassionate use experience and data obtained from the evaluation of RI-002 in the infected cotton rat animal model has been presented at various conferences during 2014, 2015 and 2016.

Based on these results, we intend to evaluate RI-002 for the treatment of RSV patients following FDA approval, if received, for treatment of PIDD.

Commercialization

While we are working towards remediating the warning letter and other deficiencies and eventually refiling the BLA resubmission for RI-002, we expect to continue our commercialization efforts and plan to increase our initiatives by hiring a small, specialty sales force to market Nabi-HBTM (Hepatitis B Immune Globulin, Human) upon closing the Proposed Acquisition anticipated in June 2017, and BivigamTM (Immune Globulin Intravenous, Human) upon its relaunch and RI-002 once approved by the FDA, to hospitals, physician offices/clinics, and other specialty treatment organizations. We anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources, and financial and operational management. If and when we receive FDA approval, we may also use a network of national distributors to assist with order fulfillment for RI-002 for use by healthcare professionals and hospitals.

Intellectual Property

During the second quarter of 2015, we received a notice of allowance from the U.S. Patent Office, or USPTO, for our RI-002 patent filed under U.S. patent application 14/592,721 entitled 'Compositions and Methods for the Treatment of Immunodeficiency,' which extends through January 2035. During the third quarter of 2015, our U.S. Patent 9,107,906 was issued by the USPTO. This patent describes methods by which the blending of plasma obtained from normal donors with plasma obtained from donors selected to have high levels of neutralizing titers to RSV form a unique antibody enriched plasma pool and provide for the standardization of the levels of anti-RSV antibodies in the RI-002 final product. Our proprietary microneutralization assay allows us to effectively identify and isolate donor plasma with high-titer RSV antibodies and to standardize RI-002's antibody profile, which we believe may enable us to garner a premium price.

Plasma Collection Facilities

Our wholly-owned subsidiary, ADMA Bio Centers Georgia, Inc., or ADMA BioCenters, operates two FDA-licensed, German Health Authority, or GHA, and Korean Ministry of Food and Drug Safety, or MFDS, certified source plasma collection facilities located in Norcross, Georgia and Marietta, Georgia, which provide us with a portion of our blood plasma for the manufacture of RI-002. 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' two Georgia facilities that is not used for making RI-002 is sold to third-party customers in the U.S., and other locations where we are approved globally under supply agreements or in the open "spot" market. We have entered into long-term manufacturing and licensing agreements with Biotest and their U.S. subsidiary, BPC, that provide for the exclusive manufacture of RI-002. At the same time, we granted Biotest an exclusive, royalty-bearing license to market and sell RSV antibody-enriched IVIG in Europe and in other selected territories in North Africa and the Middle East.

Financial Operations Overview

Revenues

Revenues for the three months ended March 31, 2017 are comprised of product revenues from the sale of normal source human plasma collected from our plasma collection centers segment and license and other revenues which are recorded as deferred revenue and amortized into income over the terms of the respective agreements. In exchange for the out-licensing of RI-002 to market and sell in Europe and selected countries in North Africa and the Middle East, BPC has provided us with certain services and a financial payment received in accordance with the related license agreement and is obligated to pay us certain amounts in the future if certain milestones are achieved.



A significant amount of our revenues are attributed to a single customer, BPC. For the three months ended March 31, 2017, two of our customers, SK Plasma Co., Ltd., or SK, and BPC, represented 98% of our total revenues, with BPC representing approximately 81% of our total revenues and SK representing approximately 17% of our total revenues. Product revenues from the sale of human plasma collected at our FDA-licensed plasma collection centers are recognized at the time of transfer of title and risk of loss to the customer, which occurs, depending on the agreement with the customer, at the time of shipment or at the time of delivery if we retain the risk of loss during shipment. Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement have been completed.

Research and Development Expenses

Research and development, or R&D, expenses, attributable to our R&D segment, consists of clinical research organization costs, clinical trial costs related to our clinical trial, consulting expenses relating to regulatory and medical affairs, quality assurance and control, manufacturing, assay development, ongoing testing costs, drug product manufacturing including the cost of plasma, plasma storage and transportation costs, as well as wages and benefits for employees, including stock-based compensation directly related to the R&D of RI-002. All R&D costs are expensed as incurred.

The process of conducting preclinical studies, clinical trials and regulatory activities necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, regulatory, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainties associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. For the three months ended March 31, 2017, R&D expenses decreased as compared to R&D expenses for the three months ended March 31, 2016 due to lower validation, testing and production costs related to RI-002. We anticipate that 2017 R&D expenses will continue to decrease, as compared to 2016, as a result of reduced testing and validation services related to RI-002 offset by increased costs related to regulatory activities in connection with the CRL. Once we have clarity for the timing of our expected BLA resubmission and anticipated RI-002 approval, we would then expect our R&D costs to increase.

General and Administrative Expenses

General and administrative, or G&A, expenses, consist of Proposed Acquisition fees, wages, stock-based compensation, benefits for senior management and staff unrelated to R&D, legal fees, accounting and auditing fees, commercialization and marketing activities, information technology, investor relations fees, rent, maintenance and utilities, insurance, travel and other expenses related to the general operations of our business. For the three months ended March 31, 2017, G&A expenses primarily increased as a result of fees incurred for the Proposed Acquisition, fees paid for legal, accounting, and financial advisory fees related to the issuance of a fairness opinion and due diligence fees. We expect that our G&A expenses will decrease as we continue to manage our costs through deferring certain pre-launch and commercial planning activities, while we focus on addressing the CRL. Once we have clarity for the timing of our expected BLA resubmission and anticipated RI-002 approval, we would then expect our G&A costs to increase.

Other Income and Expense

Interest income consists of interest earned on our cash and cash equivalents and short-term investments. Interest expense consists of interest incurred on our notes payable, as well as the amortization of end of term fees, back end fees, value of warrants issued, facility and financing fees. We anticipate other income and expense to remain consistent throughout 2017 as a result of our current outstanding debt and interest earned on investments.

Results of Operations

Three Months Ended March 31, 2017 Compared to Three Months Ended March 31, 2016

Summary table

The following table presents a summary of the changes in our results of operations for the three months ended March 31, 2017 compared to the three months ended March 31, 2016:

	Three Mo Mar	Percentage Increase/	
	2017	2016	(Decrease)
Revenues	\$ 2,628,871	2,123,886	24%
Cost of product revenue	\$ 1,616,287	1,266,421	28%
Gross profit	\$ 1,012,584	857,465	18%
Research and development expenses	\$ 1,192,727	2,027,712	-41%
Plasma center operating expenses	\$ 1,479,476	1,280,419	16%
General and administrative expenses	\$ 4,277,384	1,707,870	151%
Total operating expenses	\$ 8,565,874	6,282,422	36%
Other expense, net	\$ (599,960)	(453,933)	32%
Net loss	\$ (6,536,963)	(4,612,469)	42%
Net loss in plasma collection segment	\$ (502,600)	(458,662)	10%
Net loss attributable to research and			
development	\$ (1,192,727)	(2,027,712)	-41%

Revenues

We recorded total revenues of \$2,628,871 during the three months ended March 31, 2017 compared to \$2,123,886 during the three months ended March 31, 2017, which is attributable to our ADMA BioCenters plasma collection centers segment and derived from the sale of human source plasma collected in our FDA-licensed, GHA and MFDS-certified Georgia-based blood plasma collection centers, compared to product revenue of \$2,088,178 for the three months ended March 31, 2017 was primarily attributable to increased sales generated from our plasma supply agreement with SK, under which SK purchases normal source plasma from ADMA BioCenters. The normal source plasma and high-titer RSV plasma which we did not sell was allocated to inventory in anticipation of commercial manufacturing. For each of the three months ended March 31, 2017, and 2016, license and other revenue was \$35,708, which relates to services and financial payments provided by BPC and Biotest in accordance with our license agreement. We have not generated any revenue from our therapeutics research and development business.

Cost of Product Revenue

Cost of product revenue was \$1,616,287 for the three months ended March 31, 2017, and \$1,266,421 for the three months ended March 31, 2016. The increase in cost of product revenue of \$349,866 for the three months ended March 31, 2017 was directly related to the increase in product revenue for the three months ended March 31, 2016.

Research and Development Expenses

R&D expenses, which are attributable to our R&D segment, were \$1,192,727 for the three months ended March 31, 2017, a decrease of \$834,985 as compared to \$2,027,712 for the three months ended March 31, 2016. R&D expenses consist of clinical research organization costs, consulting expenses relating to regulatory affairs, quality control and manufacturing, assay development and ongoing testing costs, clinical trial costs and fees, drug product manufacturing, including the cost of plasma, plasma storage and transportation costs, as well as wages and benefits for staff directly related to the research and development of RI-002. R&D expenses decreased for the three months ended March 31, 2017, as compared to the three months ended March 31, 2016, primarily as a result of lower validation, testing and production costs related to RI-002 due to receipt of the CRL from the FDA during the third quarter of 2016.



Plasma Center Operating Expenses

Plasma center operating expenses were \$1,479,476 for the three months ended March 31, 2017, an increase of \$199,057 as compared to \$1,280,419 for the three months ended March 31, 2016. Plasma center operating expenses consist of: general and administrative plasma center costs; overhead comprised of rent, maintenance, utilities, wages, stock-based compensation and benefits for center staff, plasma collection supplies, plasma transportation and storage (off-site); advertising and promotion expenses; and computer software fees related to donor collections. The increase in plasma center expenses is attributable to hiring additional staff and increasing the hours of operations at our Marietta, Georgia location during the first quarter of 2017. We expect that as plasma collection increases, our operating expenses will also increase accordingly.

General and Administrative Expenses

G&A expenses were \$4,277,384 for the three months ended March 31, 2017, an increase of \$2,569,514 from \$1,707,870 for the three months ended March 31, 2016. G&A expenses consist of Proposed Acquisition fees, wages and stock-based compensation for our senior management and staff unrelated to research and development, professional fees for commercialization and marketing consulting, attorneys, accountants and auditors, investor relations, maintenance and utilities, insurance, information technology, travel and other expenses related to the general operations of the business. G&A expenses primarily increased as a result of fees incurred for the Proposed Acquisition, fees paid for legal, accounting, financial advisory fees related to the issuance of a fairness opinion and due diligence fees.

Total Operating Expenses

Total operating expenses were \$8,565,874 for the three months ended March 31, 2017, an increase of \$2,283,452 from \$6,282,422 for the three months ended March 31, 2016, primarily as a result of the increase in G&A expenses.

Other Income (Expense); Interest Expense

Other expense, net, was \$599,960 for the three months ended March 31, 2017, compared to \$453,933 for the three months ended March 31, 2016. The increase of \$146,027 is primarily related to increased interest expense due to an increase of \$4,000,000 to our current debt in the second quarter of 2016, which includes debt discounts amortization for our new lender's end of term fees, back end fees, value of warrants issued, facility and financing fees.

Net Loss

Net loss was \$6,536,963 for the three months ended March 31, 2017, an increase of \$1,924,494 from \$4,612,469 for the three months ended March 31, 2016, primarily as a result of the increase in G&A expenses.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities was \$5,398,426 for the three months ended March 31, 2017. The net loss for this period was higher than net cash used in operating activities by \$1,138,537, which was primarily attributable to an increase in prepaid expenses of \$432,932 for vendor payments related to insurance premiums, increased inventories of \$288,346 related to collection and purchases of normal source and RSV plasma, an increase in accounts payable of \$1,339,764 primarily related to legal, accounting and due diligence fees associated with the Proposed Acquisition, offset by decreases in accounts receivable of \$178,089 and accrued expenses of \$160,637. Net loss also included non-cash expenses of stock-based compensation of \$235,877, amortization of debt discount of \$190,253 and depreciation and amortization of \$118,062.

Net cash used in operating activities was \$5,167,930 for the three months ended March 31, 2016. The net loss for this period was lower than net cash used in operating activities by \$555,461, which was primarily attributable to an increase in prepaid expenses of \$633,883 for vendor payments related to insurance premiums, prepayments to third party manufacturing vendors for commercial manufacturing of RI-002, increased inventories of \$603,466 related to allocating additional plasma to inventory in preparation for commercial manufacturing activities anticipated in 2016, an increase in accounts payable of \$377,061 offset by a decrease in accrued expenses of \$306,462. Net loss also included non-cash expenses of stock-based compensation of \$422,180, and depreciation and amortization of \$251,940.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$5,141,600 for the three months ended March 31, 2017, which was related to the redemptions of short-term investments of \$5,145,184 and \$3,584 in purchases of computers and equipment.

Net cash provided by investing activities was \$3,655,762 for the three months ended March 31, 2016, which was related to the maturity of short-term investments of \$3,673,199 and \$17,437 in purchases of computers and equipment.

Net Cash Provided by Financing Activities

Net cash used in financing activities totaled \$1,115,113 for the three months ended March 31, 2017, which primarily consisted of repayments on the principal balance for our Loan and Security Agreement, or LSA, with Oxford Finance LLC, or Oxford, which the Company became obligated to begin repaying over 36 months beginning February 1, 2017.

Net cash used in financing activities totaled \$3,659 for the three months ended March 31, 2016, for payments on our leasehold improvement loan for ADMA BioCenters.

Liquidity and Capital Resources

Overview

As of March 31, 2017, we had working capital of \$2.7 million, consisting primarily of \$8.5 million of cash and cash equivalents, \$0.3 million of short term investments, \$0.8 million of accounts receivable, \$5.3 million of inventories and \$0.7 million of prepaid expenses, offset primarily by the current portion of the note payable due to Oxford of \$6.7 million, \$3.9 million of accounts payable, \$2.2 million of accrued expenses and \$0.1 million of deferred revenue.

We have had limited revenue from operations and we have incurred cumulative losses of \$113.5 million since inception. We have funded our operations to date primarily from equity investments, loans from venture debt lenders and loans from our primary stockholders. In May 2016, we completed an underwritten public offering of our common stock and we received net proceeds of approximately \$12.9 million. In May 2016, we amended our LSA with Oxford and borrowed an additional \$4.0 million. In March 2015, we received net cash proceeds of approximately \$10.2 million from an underwritten public offering from the sale of our common stock. Our funds are being used and have been used: to conduct clinical trials; to manufacture drug products; to collect and procure plasma; to test plasma donors for RSV titers; to file our BLA for RI-002; to conduct pre-launch activities; for commercialization and marketing activities; for the buildout and expansion of our plasma centers; for expenses related to our Proposed Acquisition of certain assets of BPC and the remainder for payment of existing accounts payable; for general and administrative, research and development expenses; and for other business activities and general corporate purposes.

Future Financing Needs

We expect to continue to spend substantial amounts on product development, quality and regulatory activities pre-launch and commercialization, procuring raw material plasma, manufacturing, conducting potential future clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We anticipate that, based upon our projected revenue and expenditures, our current cash and cash equivalents, short-term investments and accounts receivable will be sufficient to fund our operations into the second half of 2017. In June 2017, we anticipate closing the Proposed Acquisition with BPC, at which time BPC will provide us with funds consisting of: \$12.5 million in funding, \$15.0 million in debt financing and an additional \$12.5 million commitment towards a future equity financing, which funds are expected to be sufficient to fund operations into the first 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 capital by the end of the first quarter of 2018, and we cannot provide any assurance that we will be successful in doing so. Other than the funding to be provided by BPC upon closing the Proposed Acquisition, we currently do not have arrangements to obtain additional financing. There is no assurance that we will be able to successfully close the Proposed Acquisition. This time frame may change based upon the timing of our closing of the Proposed Acquisition, the quality management systems' remediation plans for the BPC operations, commercial manufacturing scale up activities, how aggressively we execute on our commercial initiatives and the resubmission of our BLA for RI-002 and when the FDA approves our BLA for RI-002, if at all. 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 of stockholders' interests. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan and financial performance and we could be forced to delay, discontinue or prevent product development, clinical trial or commercialization activities, delay or discontinue the approval of any of our potential products, or potentially cease operations. In addition, we could be forced to reduce or forego sales and marketing efforts and forego attractive business opportunities.

Furthermore, if our assumptions underlying our estimated expenses are incorrect, we may have to raise additional capital sooner than anticipated. Because of numerous risks and uncertainties associated with the research and development and potential future commercialization of our product candidate, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our anticipated clinical trials and development activities. Our current estimates may be subject to change as circumstances regarding our business requirements evolve. We may decide to raise capital through public or private equity offerings, 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, or we may decide to obtain debt financings or a bank credit facility or to enter into corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to our current stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other future financing alternatives. Additional equity or debt financing, grants, or corporate collaboration and potential licensing arrangements may not be available on acceptable terms, if at all.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned clinical trials and delay or abandon potential commercialization efforts of our lead product candidate or other product candidates.

Our long-term liquidity depends on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. We have reported losses since inception in June 2004 through March 31, 2017, and we have as of March 31, 2017, an accumulated deficit of \$113.5 million. We believe that we will continue to incur losses and negative cash flows from operating activities to fund our research and development, commercial programs and meet our obligations on a timely basis through the foreseeable future. As such, these conditions raise substantial doubt about our ability to continue as a going concern. If we are unable to successfully raise sufficient additional capital, we will likely not have sufficient cash flow and liquidity to fund our business operations as we currently operate, which may force us to delay, discontinue or prevent product development and clinical trial activities or the approval of any of our potential products, curtail our activities and potentially significantly reduce, or potentially cease operations.

Financial markets in the U.S., Canada, Europe and Asia continue to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, as well as severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be greatly reduced and local governments and many businesses are still suffering from the lack of consumer spending and the lack of liquidity in the credit markets. Instability in the credit and financial market conditions may negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of the adverse conditions in the U.S. and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flows or cash position.

Effect of Inflation

Inflation did not have a significant impact on our net sales, revenues or income from continuing operations in 2014, 2015 or 2016, or for the three months ended March 31, 2017.

Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU No. 2017-01, *Business Combinations – Clarifying the Definition of a Business*, which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. We do not expect this new guidance to have a material impact on our condensed consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 will be effective for us in the first quarter of 2017 and will be applied either prospectively, retrospectively or using a modified retrospective transition approach depending on the area covered in this update. We adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on our condensed consolidated financial statements and related disclosures during the first quarter of 2017.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. We are currently evaluating the impact the standard may have on our condensed consolidated financial statements and related disclosures.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes*, which includes amendments that require deferred tax liabilities and assets be classified as non-current in a classified statement of financial position. The amendments in this ASU are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted as of the beginning of an interim or annual reporting period. The amendments may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The adoption of this ASU is not expected to have a material impact on our condensed consolidated financial statements and related disclosures.

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805), Simplifying the Accounting for Measurement-Period Adjustments*, which includes amendments that require an acquirer to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this ASU require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the changes to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in this ASU require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied prospectively to adjustments to provisional amounts that occur after the effective date of the ASU with earlier application permitted for financial statements that have not yet been made available for issuance. We adopted this standard and evaluated the impact the standard may have on our condensed consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. The standard requires entities to measure most inventory "at the lower of cost and net realizable value," thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures, one of which is net realizable value). The standard is effective for us prospectively beginning January 1, 2017. We adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on our condensed consolidated financial statements during the first quarter of 2017.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is "substantial doubt about the entity's ability to continue as a going concern." The FASB believes that requiring management to perform the assessment will enhance the timeliness, clarity, and consistency of related disclosures and improve convergence with International Financial Reporting Standards, or IFRS (which emphasize management's responsibility for performing the going-concern assessment). However, the time horizon for the assessment (look-forward period) and the disclosure thresholds under Accounting Principles Generally Accepted in the U.S. of America, or GAAP, and IFRS will continue to differ. This guidance is effective for annual reporting periods ending after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption permitted. We adopted this standard as of December 31, 2016 and the adoption of this standard did not have a material impact on our condensed consolidated financial statements during the first quarter of 2017.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, which requires that an entity recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to its customers. In order to achieve this core principle, an entity should apply the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. This update will replace existing revenue recognition guidance under GAAP, when it becomes effective for us beginning January 1, 2018, with early adoption permitted in the first quarter of 2017. The updated standard will permit the use of either the retrospective or cumulative effect transition method. We are currently evaluating the impact of this update on our condensed consolidated financial statements.

Critical Accounting Policies and Estimates

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for qualifying public companies. 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 annual gross revenues exceed \$1 billion or we issue more than \$1 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. 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 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 have elected to take advantage of the benefits of this extended transition period. Our condensed consolidated 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 condensed consolidated 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 auditors provide an attestation report on our internal control over financial reporting.

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and assumptions, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

Some of the estimates and assumptions we have to make under GAAP require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations.

Stock-Based Compensation

Stock-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis.

We account for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing method. The noncash charge to operations for non-employee options with vesting is revalued at the end of each reporting period based upon the change in the fair value of the options and amortized to consulting expense over the related contract service period.

For purposes of valuing stock options granted to our employees, non-employees and directors and officers through the three months ended March 31, 2017, we used the Black-Scholes option pricing model. We granted options to purchase an aggregate of 182,000 shares of common stock during the three months ended March 31, 2017. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of our awards. The expected terms and contractual terms. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options was calculated by examining the pro rata historical volatilities for similar publicly traded industry peers and the trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions.

Research and Development Costs

Our R&D costs are expensed as incurred, including costs associated with (i) planning and conducting clinical trials, (ii) drug product manufacturing, including the cost of plasma, plasma storage and transportation costs; (iii) quality testing, validation, regulatory consulting and filing fees; and (iv) employees' compensation expenses directly related to R&D activities.

Revenue Recognition

Depending on the agreement with the customer, revenue from the sale of human plasma collected by ADMA BioCenters is recognized at the time of transfer of title and risk of loss to the customer, which usually occurs at the time of shipment. Product revenue is recognized at the time of delivery if we retain the risk of loss during shipment. Our product revenues are substantially attributable to two customers. One customer accounts for greater than 80% and another customer accounts for greater than 15% of our product revenues for the three months ended March 31, 2017. Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement with Biotest have been completed.

Accounting for Loan and Security Agreement

On June 19, 2015, we entered into a LSA with Oxford for up to \$21.0 million and refinanced our then existing debt. The first tranche of \$16.0 million from the Oxford loan was primarily used to repay our existing debt and the remaining \$5.0 million was available at our option upon RI-002's BLA being approved from the FDA no later than January 31, 2017, which funding would have also extended our interest only period for an additional six months pursuant to the May 2016 amendment to the LSA. The LSA bears interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three month U.S. LIBOR rate (as reported in *The Wall Street Journal*) on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.54% on the outstanding principal balance. We began repaying the principal balance on February 1, 2017 for a period of 36 months, unless accelerated as a result of certain events of default. A final payment equal to 8.95% of the funded loan amount is due at the earlier of loan maturity or prepayment. In the event of the six-month interest only extension, the final payment will be 9.95% of the funded loan, which shall also be due at the earlier of loan maturity or prepayment. In the event we elect to prepay the loan, we are obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the loan, with such percentage being: (i) for a prepayment made on or after the funding date of the applicable term loan through and including the first anniversary of its funding date, an amount equal to 3.00% of the principal amount of the term loan prepaid; (ii) for a prepayment made after the first anniversary of the funding date of the applicable term loan through and including the second anniversary of such funding date, an amount equal to 2.00% of the principal amount of such term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid. All term loans mature no later than January 1, 2020. The loans are secured by our assets, except for our intellectual property (which is subject to a negative pledge). The LSA contains customary representations, warranties and covenants, including limitations on incurring indebtedness, engaging in mergers or acquisitions and making investments, distributions or transfers.

In connection with the LSA, on June 19, 2015, we 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. We recorded \$367,700 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: (i) volatility of 57% on our common stock based upon a pro rata percentage of our common stock's volatility and similar public companies' volatilities for comparison; (ii) an expected dividend yield of 0.0%; (iii) a risk-free interest rate of 1.99%; and (iv) a term of seven years. As a result of prepaying our prior loan before maturity, we incurred a loss on extinguishment of debt of \$0.7 million comprised of debt issuance costs, debt discount related to the warrants issued to our prior lender, and a prepayment penalty.

In May 2016, we entered into an amendment to our LSA with Oxford, pursuant to which we borrowed an additional \$4.0 million, as an extension to the original LSA entered into on June 19, 2015, which brings the total principal borrowed to \$20.0 million. In connection therewith, we issued warrants to purchase an aggregate of up to 24,800 shares of our common stock at an exercise price equal to \$6.37, which will expire seven years after their issuance on May 13, 2023. We paid a total facility fee of \$125,000, consisting of \$105,000 previously paid and an additional \$20,000 paid on the date the \$4.0 million loan was funded.

Off-Balance Sheet Arrangements

We have entered into leases for our ADMA BioCenters' facilities in Norcross, Georgia and Marietta, Georgia. The Norcross, Georgia lease expires on September 30, 2023, and the Marietta, Georgia lease expires on January 31, 2024. There is a total minimum rent due under these leases of \$4.8 million through the end of the lease terms.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We designed our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms, and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Under the supervision of and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures as of March 31, 2017. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures as of March 31, 2017 are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures.

A control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended March 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met and therefore, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. We do not expect that our disclosure controls and procedures or our internal control over financial reporting are able to prevent with certainty all errors and all fraud.



PART II OTHER INFORMATION

Item 1. Legal Proceedings.

We are and may become subject to certain legal proceedings and claims arising in connection with the normal course of our business. In the opinion of management, there are currently no claims that would have a material adverse effect on our consolidated financial position, results of operations or cash flows.

Item 1A. Risk Factors.

There are numerous and varied risks that may prevent us from achieving our goals. We believe that the following are the material risks that we face. If any of the following risks actually occurs, our business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment. Additional risk factors relating to the Proposed Acquisition are described in the definitive merger proxy statement on Schedule 14A filed by the Company with the SEC on April 26, 2017.

Risks Relating to our Business

To date, we have generated limited product revenues, we 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 nearly all of our revenues from our plasma collections facilities derived from the sale of plasma, as well as our other plasma inventory sales. Unless and until we receive approval from the FDA and other regulatory authorities for our RI-002 product candidate, we do not expect to sell and generate revenue from the commercialization of RI-002 and we will be required to raise additional funds through the sale of equity and/or debt securities or otherwise to, among others, establish a commercial salesforce, infrastructure and recognize any significant sales.

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 during the second half of 2017, we will likely not have sufficient cash flow and liquidity to fund our business operations as we currently operate, forcing us to curtail our activities and potentially significantly reduce, or potentially 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 the our projected revenue and expenditures for 2017, including regulatory and consulting fees for RI-002 associated with third-party manufacturers and ongoing discussions with the FDA, continuing implementation of our commercialization and expansion activities and certain other assumptions, management currently believes that its cash, cash equivalents, short-term investments, projected revenue and accounts receivable are sufficient to fund our operations, as currently conducted, into the second half of 2017. These estimates may change based upon whether or when the FDA approves RI-002, the timing of any required commercial manufacturing scale up activities or if any of our other assumptions change. These estimates may also change based upon the timing of the completion of the Proposed Acquisition which is anticipated in June 2017. Upon the closing of the Proposed Acquisition, BPC will be providing funds to us consisting of: \$12.5 million in funding, \$15.0 million in debt financing and an additional \$12.5 million commitment towards a future equity financing is expected to be sufficient to fund operations into the first quarter of 2018. There is no assurance that we will be able to successfully close on the Proposed Acquisition. Other than the funding to be provided by BPC, 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 trial or commercialization activities, or the approval of any of our potential products. In addition, we could be forced to reduce or forego sales and marketing efforts and forego attractive business opportunities.



We are not currently 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 three months ended March 31, 2017 and 2016, we incurred net losses of \$6.5 million and \$4.6 million, respectively, and from our inception in 2004 through March 31, 2017, we have incurred an accumulated deficit of \$113.5 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:

- seek regulatory approval(s);
- · initiate commercialization and marketing efforts;
- · implement additional internal systems, controls and infrastructure;
- · hire additional personnel;
- · expand and build out of our plasma center network; and
- · integrate the assets which we intend to acquire in the Proposed Acquisition into our business post-closing.

We also expect to experience negative cash flow 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.

Relying exclusively on third-parties to manufacture and commercialize our product candidates exposes us to risks that may delay: testing, development, regulatory approval, commercialization and overall manufacturing of our product candidates.

We currently lack the internal resources to manufacture RI-002, our lead product candidate. Although we have agreements pertaining to the manufacture, testing, supply, storage and distribution of product supplies of RI-002, upon commercialization, it is possible that our manufacturing requirements may exceed the available supply allotments under our existing agreements. We rely on one third-party contractor to manufacture RI-002. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any;
- third-party manufacturers might be unable to manufacture our products in the volume and of the quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not perform as agreed, and operate their business independently from ADMA. Contract manufacturers are directly responsible for their own FDA current Good Manufacturing Practices, or cGMP, interactions and ADMA may not be privy to all ongoing discussions and information concerning products or process unrelated to ADMA. Additionally, contract manufacturers may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products;

- product manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, or DEA, and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards and our manufacturers may be found to be in noncompliance with certain regulations, which may impact our ability to manufacture our drug product candidates and may impact the regulatory status of ADMA and its product candidates; and
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. We may be required to pay fees or other costs for access to such improvements and additional clinical trials or other studies may be required.

Each of these risks could delay the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues. Our contract manufacturer announced in November 2014 that it received a warning letter from the FDA relating to an inspection at its Boca Raton, Florida location, which, we are informed, does not prevent the manufacturing or distribution of any of our contract manufacturer's commercial products. Failure to resolve any outstanding issues or any administrative actions or changes taken by FDA toward our contract manufacturers, vendors or us, could impact our ability to receive approval, including the timing thereof, for RI-002, 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.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Although our financial statements have been prepared on a going concern basis, we must raise additional capital during the second half of 2017 to fund our operations in order to continue as a going concern.

CohnReznick LLP, our independent registered public accounting firm for the fiscal year ended December 31, 2016, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2016, indicating that our current liquidity position raises 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 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 licensing partners. 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. The accompanying consolidated financial statements 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 in our company.

We anticipate that our principal sources of liquidity will only be sufficient to fund our activities as currently conducted and financial obligations into the second half of 2017. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional equity or debt capital by the end of the second half of 2017 in order to continue as a going concern, and we cannot provide any assurance that we will be successful in doing so. This time frame may change based upon the timing of our commercial manufacturing scale up activities and the timing of the closing of the Proposed Acquisition. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the second half of 2017. These assumptions may also change based upon the timing of the completion of the Proposed Acquisition, anticipated in June 2017, of which funds received from BPC at the closing of the Proposed Acquisition into the first 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 authorized.

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.

Our lead 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. We cannot provide any assurance or certainty regarding when we might complete the clinical trial process or receive regulatory approval for our BLA for RI-002. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials 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, or 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.

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 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 U.S., and therefore, may not have been performed in accordance with standards normally required by the FDA and other regulatory agencies.

Currently, our only viable product candidate is RI-002. 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.

At the present time, our entire focus is obtaining regulatory approval for RI-002, our only product candidate. If we cannot obtain regulatory approval for RI-002, our only source of revenue will be plasma collection and sales. 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 submit a BLA. To obtain required 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 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 BLA. Our BLA is dependent upon our third party manufacturer continuing operations and maintaining compliance with rules and regulations. 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 potential product candidate. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product beyond the plasma collected by ADMA BioCenters, and therefore without any source of additional revenues if and until another product candidate. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products. Foreign regulatory approval processes generally include all of the risks 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 U.S.

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 U.S. 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 U.S. 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 (e.g., 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 relating 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 and consultants to conduct our preclinical and clinical trials 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.

A single customer accounts for a significant amount of our revenues and, together with a second customer represent greater than 95% of our total revenues, and, therefore, the loss of such single customer could have a material adverse effect on our business, results of operations and financial condition.

A significant amount of our revenues are attributed to a single customer, BPC. For the three months ended March 31, 2017, two of our customers, SK and BPC, represented 98% of our total revenues, with BPC representing approximately 81% of our total revenues and SK representing approximately 17% of our total revenues. We believe SK will represent approximately less than 10% of our total revenues for 2017.

Our relationships with BPC and SK are arm's length commercial relationships. The loss of either or both of BPC and SK as a customer or a material change in the revenue generated by either or both of Biotest and SK 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 prices that are competitive with our competitors;
- · 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 either or both of BPC and SK could have a material adverse effect on our business and results of operations.

Relying exclusively on third parties to manufacture and commercialize our product candidates exposes us to risks that may delay: testing, development, regulatory approval, commercialization and overall manufacturing of our product candidates.

We have limited internal experience in manufacturing operations and have not historically established our own manufacturing facilities. We currently lack the internal resources to manufacture RI-002. Although we have agreements pertaining to the manufacture, testing, supply, storage and distribution of product supplies of RI-002, upon commercialization, it is possible that our manufacturing requirements may exceed the available supply allotments under our existing agreements. We currently rely on one third-party contractor to manufacture RI-002. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any;
- third-party manufacturers might be unable to manufacture our products in the volume and of the quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products;
- product manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA, and corresponding state
 agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do
 not have control over third-party manufacturers' compliance with these regulations and standards and our manufacturers may
 be found to be in noncompliance with certain regulations, which may impact our ability to manufacture our drug product; and
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. We may be required to pay fees or other costs for access to such improvements.

Each of these risks could delay the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues. Our contract manufacturer has announced that it received a warning letter from the FDA relating to an inspection at its Boca Raton, Florida location in August 2014 and that the warning letter does not prevent the manufacturing or distribution of any of its products. The receipt of the warning letter has not affected the manufacture or delivery to us of RI-002 by our contract manufacturer.



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 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 launching new products.

If physicians and patients do not accept and use our product, our ability to generate revenue from sales will be materially impaired.

Even if the FDA approves RI-002, physicians and patients may not accept and use it. Acceptance and use of our product will depend on a number of factors including:

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

Because we expect sales of RI-002, if approved, to generate substantially all of our product revenues other than the revenue attainable from the sale of plasma collected by ADMA BioCenters, the failure of this product 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 this quarterly report and our 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.

This quarterly report and our 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 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 that study represent the independent consultants' own methodologies, assumptions, research, analysis, projections, estimations, 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 such report. Readers should not place undue reliance on this information.

Our long-term success may depend on our ability to supplement our existing RI-002 product candidate through new product development or the in-license or acquisition of other new products, and if our business development efforts are not successful, our ability to achieve profitability may be negatively impacted.

Our current product development portfolio consists primarily of RI-002. We intend to seek to expand our current portfolio through new product development efforts or to in-license or acquire additional products. If we are not successful in developing or acquiring additional products, we will have to depend on our ability to raise capital for, and the successful development and commercialization of, RI-002 and the revenue we may generate from the sale of plasma attributable to the operations of ADMA BioCenters.

Our loan and security agreement with Oxford is subject to acceleration in specified circumstances, which may result in Oxford taking possession and disposing of any collateral. We became obligated to begin making payments of principal and interest on February 1, 2017, unless accelerated as a result of certain events of default or at our option.

On June 19, 2015, we entered into a Loan and Security Agreement, or LSA, with Oxford for up to \$21.0 million and refinanced our existing loan with Hercules Technology Growth Capital, Inc. or Hercules. The first tranche of \$16.0 million from the Oxford loan was primarily used to repay our existing facility with Hercules. In May 2016, we amended the LSA with Oxford and we borrowed an additional \$4.0 million, bringing the total principal amount borrowed to \$20.0 million. The LSA bears interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three month U.S. LIBOR rate (as reported in *The Wall Street Journal*) on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.54% on the outstanding principal balance. We became obligated to begin to repay the principal over 36 months beginning February 1, 2017, unless accelerated as a result of certain events of default. A final payment equal to 8.95% of the funded loan amount is due at the earlier of loan maturity or prepayment. In addition, a facility fee of \$105,000 was paid at closing. In the event we elect to prepay the loan, we are obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the loan, with such percentage being: (i) for a prepayment made on or after the funding date of the applicable term loan through and including the first anniversary of its funding date, an amount equal to 3.00% of the principal amount of the term loan prepaid; (ii) for a prepayment made after the first anniversary of the funding date of the applicable term loan through and including the second anniversary of such funding date, an amount equal to 2.00% of the principal amount of such term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid. The loan matures no later than January 1, 2020. The loan is secured by our assets, except for our intellectual property (which is subject to a negative pledge). Events of default under the agreement include, but are not limited to: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the LSA or other loan documents on a timely basis; (iii) failure to observe any covenant or secured obligation under the LSA or other loan documents, which failure, in most cases, is not cured within 10 days of written notice by lender; (iv) occurrence of any default under any other agreement between us and the lender, which is not cured within 10 days; (v) occurrence of an event that could reasonably be expected to have a material adverse effect; (vi) material misrepresentations; (vii) occurrence of any default under any other agreement involving indebtedness or the occurrence of a default under any agreement that could reasonably be expected to have a material adverse effect; and (viii) certain money judgments are entered against us or a certain portion of its assets are attached or seized. Remedies for events of default include acceleration of amounts owing under the LSA and Oxford taking immediate possession of, and selling, any collateral securing the loan.

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. Should we obtain regulatory approval for RI-002 or any future product we may develop, we will have to compete with existing 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 U.S. and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital 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 patent is 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 patent may be challenged, found to be over-broad or otherwise invalidated in subsequent proceedings before courts or the USPTO. Even if enforceable, we cannot provide any assurances that it 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 U.S. 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 our only product, 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 U.S. 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.

Continued instability in the credit and financial markets may negatively impact our business, results of operations and financial condition.

Financial markets in the U.S., Canada, Europe and Asia continue to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, as well as severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be greatly reduced and local governments and many businesses are still suffering from the lack of consumer spending and the lack of liquidity in the credit markets. As a clinical-stage biotechnology company, we rely on third parties for several important aspects of our business, including contract manufacturing of drug product, plasma collection supplies, transportation and storage of plasma, and conduct of our clinical trials. These third parties may be unable to satisfy their commitments to us due to tightening of global credit from time to time, which would adversely affect our business. The continued instability in the credit and financial market conditions may also negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of the adverse conditions in the U.S. and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

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

Our success will depend on the expansion of our commercial, manufacturing, 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.

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, particularly if we close and consummate the Proposed Acquisition. 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 located in Norcross and Marietta, Georgia, and if we cannot maintain FDA approval for these locations we may be adversely affected and potentially may not be able to sell and 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 cGMP, FDA and other government approvals. Failure to comply may result in enforcement action, which may significantly delay or suspend our operations for these locations.

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, alone or with collaborators.

Many of our business practices are subject to scrutiny by 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 U.S. are enforceable 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. There can be no assurance that our activities will not come under the scrutiny of 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 U.S., Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities (e.g., FDA in the U.S.), 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 offlabel 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 may be required to report detailed pricing information, net of included discounts, rebates and other concessions, to the Centers for Medicare & Medicaid Services, or 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 U.S., 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 U.S. 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 their 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 U.S. or the European Union, we could be adversely affected.

Also, under the U.S. Foreign Corrupt Practices Act, or FCPA, the U.S. has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the U.S., 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, or 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 program sthat 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.

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 goods sold. 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 profitability.

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 sales and profits. 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, or 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 (e.g., 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 FDAapproved 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 source plasma to manufacture RI-002. Therefore, we are reliant on purchasing normal source plasma to manufacture RI-002. We can give no assurances that normal source plasma will be available to us on commercially reasonable terms or at all. 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 goods. 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 on 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 depend 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 reimbursement. 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 U.S., where pricing levels for our products are substantially established by third-party payors, including Medicare, if payors 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 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 sprepare their approval applications. The FDA has issued several guidance documents to assist sponsors of biosimilar products in 2016. As a result of the biosimilar pathway in the U.S., 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 U.S. may adversely affect our business.

Through the March 2010 adoption of the healthcare reform law in the U.S., substantial changes are being made to the current system for paying for healthcare in the U.S., 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 that may cover the cost of our future products, including Medicaid, Medicare Parts B and D, and these efforts could have a materially adverse impact on our future financial prospects and performance. For example, with respect to Medicaid, 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 this 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, or AMP, or the AMP less Best Price, whichever is greater. Effective January 1, 2010, the healthcare reform law generally increases the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug product from a minimum of 15.1% to a minimum of 23.1% of the AMP, subject to certain exceptions, for example, for certain clotting factors, the increase is limited to a minimum of 17.1% of the AMP. 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, or 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.

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 U.S. As a result of loss of jobs, patients may lose medical insurance and be unable to purchase supply 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. While to date we cannot directly trace any material reduction in demand to the recession, if economic conditions do not improve, the impact may become material.

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

We are a late stage company with a history of operating losses that are expected to continue and we are unable to predict the extent of future losses, whether we will generate significant revenues or whether we will achieve or sustain profitability.

We are a late stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by similarly situated companies. For the three months ended March 31, 2017 and 2016, we incurred net losses of \$6.5 million and \$4.6 million, respectively, and from our inception in 2004 through March 31, 2017, we have incurred an accumulated deficit of \$113.5 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand commercial development, infrastructure, manufacturing and inventory planned requirements and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.



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, 2017 and 2016, we incurred research and development expenses of approximately \$1.2 million and \$2.0 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 anticipate that, based upon our projected revenue and expenditures, our current cash and cash equivalents, short term investments and accounts receivable will be sufficient to fund our operations, as currently conducted, into the second half of 2017. This time frame may change based upon the timing of the closing of our Proposed Acquisition, and how aggressively we execute on our operational initiatives. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the second half of 2017. These assumptions may also change based upon the timing of the completion of the Proposed Acquisition, anticipated in June 2017, of which funds received from BPC at the closing of the Proposed Acquisition are expected to be sufficient to fund operations into the first quarter of 2018. We have based this estimate, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration and licensing arrangements. If we are unable to raise additional capital, we will have to delay, curtail or eliminate our product development, 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 restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. 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, or FDIC, insurance limit. While we monitor daily the cash balances in the operating accounts 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 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, or SOX, 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 Exchange Act, we have been required to upgrade, and may need to implement further upgrades to our systems, including information technology, 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, 2016, we had Federal and state NOLs of \$87.8 million and \$75.2 million, respectively. The \$87.8 million and \$75.2 million in Federal and state NOLs, respectively, 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 utilize our NOLs fully. 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.

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:
- the closing and consummation, or failure thereof, of our Proposed Acquisition;
- · sales or potential sales of substantial amounts of our common stock;
- 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, reimbursement and sales of RI-002;
- · announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- · developments concerning our licensors or product manufacturers;
- 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.

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

As of March 31, 2017, almost all of our 12,886,741 outstanding shares of common stock, as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act or under registration statements we intend to file in the future. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

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.

Our affiliates control a substantial amount of our shares of common stock. Provisions in our certificate of incorporation, our by-laws 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 certificate of incorporation, our by-laws 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. Our directors and executive officers and their affiliates beneficially own approximately 51% of the outstanding shares of 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; and the ability of our board of directors to designate the terms of and issue change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock, and
- classification of our board of directors 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.

In addition, Section 203 of the Delaware General Corporation Law 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 forgoing 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.

If we fail to adhere to the strict listing requirements of 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 the NASDAQ Capital Market 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 continuing NASDAQ listing requirements could have an adverse impact on the value of and trading activity in our common stock. Although we currently satisfy the listing criteria for NASDAQ, if our stock price declines dramatically, we could be at risk of falling below NASDAQ continuing listing criteria.

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 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 annual gross revenues exceed \$1 billion or we issue more than \$1 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 and our stock price may be more volatile.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits

See the Exhibit Index immediately following the signature page of this quarterly report on Form 10-Q.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ADMA Biologics, Inc.

Date: May 12, 2017	By:	/s/ Adam S. Grossman Name: Adam S. Grossman Title: President and Chief Executive Officer
Date: May 12, 2017	By:	/s/ Brian Lenz Name: Brian Lenz Title: Vice President and Chief Financial Officer
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EXHIBIT INDEX

Description
Master Purchase and Sale Agreement dated January 21, 2017 by and among Biotest Pharmaceuticals Corporation, ADMA BioManufacturing, LLC, ADMA Biologics, Inc., Biotest AG and Biotest US Corporation (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on January 23, 2017).
Lease, effective as of February 17, 2017, by and between Home Center Properties, LLC and ADMA Bio Centers Georgia Inc. (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on February 24, 2017).
Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
Certification of Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
The following materials from ADMA Biologics, Inc.'s Form 10-Q for the quarter ended March 31, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of March 31, 2017 (Unaudited) and December 31, 2016, (ii) Condensed Consolidated Statements of Operations (Unaudited) for the three months ended March 31, 2017, (iii) Condensed Consolidated Statement of Changes in Stockholders' Deficiency (Unaudited) for the three months ended March 31, 2017, (iv) Condensed Consolidated Statements of Cash Flows (Unaudited) for the three months ended March 31, 2017, and 2016, and (v) Notes to (Unaudited) Condensed Consolidated Financial Statements.

^{*} Filed herewith.

^{**} Furnished herewith.

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam S. Grossman, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of ADMA Biologics, Inc. for the quarter ended March 31, 2017;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2017

By: /s/ Adam S. Grossman

Name: Adam S. Grossman Title: President and Chief Executive Officer (Principal Executive Officer)

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Lenz, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of ADMA Biologics, Inc. for the quarter ended March 31, 2017;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2017

By: /s/ Brian Lenz

 Name:
 Brian Lenz

 Title:
 Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of ADMA Biologics Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Adam S. Grossman, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2017

By: /s/ Adam S. Grossman

Name: Adam S. Grossman Title: President and Chief Executive Officer (Principal Executive Officer)

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of ADMA Biologics Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Lenz, Vice President and Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2017

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)