

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 September 30, 2018

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)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)
Organization)

56-2590442

(I.R.S. Employer Identification No.)

465 State Route 17, Ramsey, New Jersey
(Address of Principal Executive Offices)

07446
(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 No

Indicate by check mark whether the registrant has submitted electronically 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 No

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

As of November 5, 2018, there were 46,351,243 shares of the issuer's common stock outstanding.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

INDEX

PART I FINANCIAL INFORMATION

Item 1.	Financial Statements	
	Condensed Consolidated Balance Sheets as of September 30, 2018 (Unaudited) and December 31, 2017	1
	Condensed Consolidated Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2018 and 2017	2
	Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited) for the Nine Months Ended September 30, 2018	3
	Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2018 and 2017	4
	Notes to (Unaudited) Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations.	23
Item 3.	Quantitative and Qualitative Disclosures About Market Risk.	36
Item 4.	Controls and Procedures.	36

PART II OTHER INFORMATION

Item 1.	Legal Proceedings.	37
Item 1A.	Risk Factors.	37
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds.	62
Item 3.	Defaults Upon Senior Securities.	62
Item 4.	Mine Safety Disclosures.	62
Item 5.	Other Information.	62
Item 6.	Exhibits.	62

SIGNATURES

63

This Quarterly Report on Form 10-Q includes our trademarks, trade names and service marks, such as “Nabi-HB®” and “BIVIGAM®” which are protected under applicable intellectual property laws and are the property of ADMA Biologics, Inc., or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

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 leverage the anticipated benefits and synergies from our June 6, 2017 acquisition of certain assets of Biotest Pharmaceuticals Corporation (the “Biotest Transaction”), including optimization of the combined businesses, operations and products and services, as well as the nature, strategy and focus of the combined company and the management and governance structure of the combined company;
- our ability to resume the manufacturing and commercialization of BIVIGAM once the deficiencies identified in a November 2014 warning letter (the “Warning Letter”) with respect to the outstanding issues at the plasma fractionation facility in Boca Raton, FL acquired in the Biotest Transaction have been resolved by us to the satisfaction of the U.S. Food and Drug Administration (the “FDA”), as well as a positive review of the optimized manufacturing process for BIVIGAM submitted to the agency as a Prior Approval Supplement;
- our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current and future products and the success of such efforts;
- the safety, efficacy and expected timing of and our ability to obtain and maintain regulatory approvals for our current products and product candidates, including the timeframe within which we may receive approval from the FDA, if at all, of our Biologics License Application resubmission for our lead pipeline product candidate, RI-002 (“RI-002”), and the labeling or nature of any such approvals, as well as our ability to maintain an acceptable compliance status to continue operations;
- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals;
- our dependence upon our third-party and related-party customers and vendors and their compliance with regulatory bodies;
- our ability to obtain adequate quantities of FDA-approved 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 any of our products, including RI-002, for any purpose by physicians, patients or payers;
- concurrence by the FDA with our conclusions and the satisfaction by us of its guidance;
- the comparability of results of our immune globulin products to other comparably run Intravenous Immune Globulin clinical trials;
- the potential of RI-002 and BIVIGAM to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease;
- our ability to market and promote Nabi-HB in a highly competitive environment and to generate meaningful revenues from this product;

- our intellectual property position and the defense thereof, including our expectations regarding 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 the need for and availability of additional financing;
- possible or likely reimbursement levels for our currently marketed products and, if any, if and when RI-002 is approved for marketing;
- estimates regarding market size, projected growth and sales of our existing products as well as our expectations of market acceptance of RI-002;
- future economic conditions or performance; 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 thereof or other variations thereof or comparable terminology. 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. Any forward-looking statement included or incorporated by reference in this Quarterly Report on Form 10-Q reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions related to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements speak only as of the dates such statements are made.

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. Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statements and we undertake no obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018	December 31, 2017
	(Unaudited)	(Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 42,367,489	\$ 43,107,574
Accounts receivable, net	4,126,794	3,880,154
Inventories	13,877,434	12,628,181
Prepaid expenses and other current assets	2,131,035	2,050,740
Restricted cash	—	1,500,000
Total current assets	62,502,752	63,166,649
Property and equipment, net	30,362,629	30,466,858
Intangible assets, net	4,215,646	4,849,350
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	1,204,391	1,496,410
Restricted cash	4,000,000	4,000,000
Deposits and other assets	530,173	510,057
TOTAL ASSETS	\$ 106,345,100	\$ 108,018,833
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,267,683	\$ 5,920,873
Accrued expenses and other current liabilities	4,453,027	3,376,476
Current portion of deferred revenue	142,834	142,834
Current portion of capital lease obligation	29,443	—
Total current liabilities	9,892,987	9,440,183
Notes payable, net of discount	26,153,543	25,368,458
End of term liability, notes payable	2,760,000	2,760,000
Deferred revenue, net of current portion	2,440,074	2,547,199
Note payable - related party, net of discount	14,865,981	14,842,396
Obligation to transfer assets under purchase agreement	12,621,844	12,621,844
Capital lease obligation	126,765	—
Other non-current liabilities	277,692	105,996
TOTAL LIABILITIES	69,138,886	67,686,076
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred Stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock - voting, \$0.0001 par value, 75,000,000 shares authorized, 46,351,243 and 36,725,499 shares issued and outstanding	4,635	3,673
Common Stock - non-voting, \$0.0001 par value, 8,591,160 shares authorized, 0 and 8,591,160 shares issued and outstanding	—	859
Additional Paid-In Capital	235,600,830	191,022,018
Accumulated Deficit	(198,399,251)	(150,693,793)
TOTAL STOCKHOLDERS' EQUITY	37,206,214	40,332,757
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 106,345,100	\$ 108,018,833

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three Months Ended September		Nine Months Ended September	
	30,		30,	
	2018	2017	2018	2017
REVENUES:				
Product revenue	\$ 4,194,602	\$ 4,693,703	\$ 12,821,741	\$ 10,650,558
License and other revenue	35,708	35,708	107,125	107,125
Total Revenues	<u>4,230,310</u>	<u>4,729,411</u>	<u>12,928,866</u>	<u>10,757,683</u>
OPERATING EXPENSES:				
Cost of product revenue (exclusive of amortization expense shown below)	9,164,109	11,291,116	31,052,519	17,241,422
Research and development	1,317,234	1,814,069	4,071,040	4,365,205
Plasma center operating expenses	1,973,338	1,582,694	5,545,240	4,662,340
Amortization of intangibles	211,235	273,828	633,704	346,849
Selling, general and administrative	5,355,794	4,195,464	15,367,647	12,908,498
Total operating expenses	<u>18,021,710</u>	<u>19,157,171</u>	<u>56,670,150</u>	<u>39,524,314</u>
LOSS FROM OPERATIONS	<u>(13,791,400)</u>	<u>(14,427,760)</u>	<u>(43,741,284)</u>	<u>(28,766,631)</u>
OTHER INCOME (EXPENSE):				
Interest income	75,581	8,014	135,197	34,440
Interest expense	(1,402,475)	(782,969)	(4,084,815)	(2,043,982)
Other expense	(17,191)	—	(14,556)	—
Other expense, net	<u>(1,344,085)</u>	<u>(774,955)</u>	<u>(3,964,174)</u>	<u>(2,009,542)</u>
NET LOSS	<u>\$ (15,135,485)</u>	<u>\$ (15,202,715)</u>	<u>\$ (47,705,458)</u>	<u>\$ (30,776,173)</u>
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$ (0.33)</u>	<u>\$ (0.59)</u>	<u>\$ (1.06)</u>	<u>\$ (1.67)</u>
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	<u>46,350,392</u>	<u>25,790,805</u>	<u>44,796,986</u>	<u>18,415,468</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

For the Nine Months Ended September 30, 2018

	Common Stock				Additional Paid-in Capital	Accumulated Deficit	Total
	Voting Shares	Amount	Non-Voting Shares	Amount			
Balance - January 1, 2018	36,725,499	\$ 3,673	8,591,160	\$ 859	\$ 191,022,018	\$ (150,693,793)	\$ 40,332,757
Stock-based compensation	—	—	—	—	1,627,756	—	1,627,756
Issuance of common stock, net of offering expenses	9,623,430	962	—	—	42,943,869	—	42,944,831
Stock options exercised	2,314	—	—	—	6,328	—	6,328
Retirement of non-voting common stock	—	—	(8,591,160)	(859)	859	—	—
Net loss	—	—	—	—	—	(47,705,458)	(47,705,458)
Balance - September 30, 2018	<u>46,351,243</u>	<u>\$ 4,635</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 235,600,830</u>	<u>\$ (198,399,251)</u>	<u>\$ 37,206,214</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (47,705,458)	\$ (30,776,173)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,522,496	1,231,265
Loss on disposal of fixed assets	13,200	4,155
Stock-based compensation	1,627,756	1,052,970
Amortization of debt discount	808,671	555,568
Amortization of license revenue	(107,125)	(107,125)
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable	(246,640)	(481,782)
Inventories	(1,249,253)	(201,472)
Prepaid expenses and other current assets	(80,295)	(969,042)
Other assets	(20,116)	(723,530)
Accounts payable	(653,190)	5,228,096
Accrued expenses	1,013,003	1,277,700
Other current and non-current liabilities	191,393	(3,775)
Net cash used in operating activities	<u>(43,885,558)</u>	<u>(23,913,145)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Sales of short-term investments	—	5,390,184
Purchase of property and equipment	(1,276,594)	(666,457)
Cash acquired in acquisition transaction	—	12,500,000
Net cash (used in) provided by investing activities	<u>(1,276,594)</u>	<u>17,223,727</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	—	(4,444,444)
Proceeds from issuance of common stock, net of offering expenses	42,944,831	—
Proceeds from the exercise of stock options	6,328	7,504
Proceeds from issuance of related party note payable	—	15,000,000
Payment of debt issuance costs	—	(174,839)
Payments on capital lease obligations	(9,395)	—
Payments of leasehold improvement loan	(19,697)	(12,279)
Net cash provided by financing activities	<u>42,922,067</u>	<u>10,375,942</u>
Net (decrease) increase in cash and cash equivalents	(2,240,085)	3,686,524
Cash and cash equivalents, including restricted cash - beginning of period	48,607,574	9,914,867
Cash and cash equivalents, including restricted cash - end of period	<u>\$ 46,367,489</u>	<u>\$ 13,601,391</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND BUSINESS

ADMA Biologics, Inc. (“ADMA” or the “Company”) is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of Primary Immune Deficiency Disease (“PID”) and the prevention and treatment of certain infectious diseases. The Company’s targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. ADMA operates through its wholly-owned subsidiaries ADMA BioManufacturing, LLC (“ADMA BioManufacturing”) and ADMA Bio Centers Georgia Inc. (“ADMA Bio Centers”). ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of the Biotest Therapy Business Unit (“BTBU”) from Biotest Pharmaceuticals Corporation (“BPC” and, together with Biotest AG, “Biotest”) as more fully described below. ADMA Bio Centers is the Company’s source plasma collection business, with facilities located in Norcross, GA, Marietta, GA and Kennesaw, GA. All three of the Company’s plasma collection facilities have approved licenses with the U.S. Food and Drug Administration (the “FDA”) and the Norcross, GA and Marietta, GA facilities have certifications from the German Health Authority (the “GHA”) and the Korean Ministry of Food and Drug Safety.

As discussed in Note 3, on June 6, 2017, ADMA completed the acquisition of certain assets (the “Biotest Assets”) of BTBU, which include two FDA-licensed products, Nabi-HB (Hepatitis B Immune Globulin, Human) and BIVIGAM (Immune Globulin Intravenous, Human), and a plasma fractionation manufacturing facility located in Boca Raton, FL (the “Boca Facility”) (the “Biotest Transaction”). In addition to Nabi-HB and BIVIGAM, BTBU provides contract manufacturing services for certain clients and also generates revenues from the sale of intermediate by-products which result from the immunoglobulin production process. The Boca Facility is FDA-licensed and certified by the GHA. Immediately following the closing of the Biotest Transaction, the Biotest Assets were contributed into ADMA BioManufacturing.

Nabi-HB is a hyperimmune globulin that is rich in antibodies to the hepatitis B virus. Nabi-HB is indicated for the treatment of acute exposure to blood containing hepatitis B surface antigen (“HBsAg”), prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. FDA approval for Nabi-HB was received on March 24, 1999. Under ADMA’s leadership, the production of Nabi-HB resumed during the third quarter of 2017, resulting in subsequent commercial sales.

BIVIGAM is indicated for the treatment of primary humoral immunodeficiency. FDA approval for BIVIGAM was received on December 19, 2012, and sales commenced in the first quarter of 2013. In December 2016, Biotest temporarily suspended the commercial production of BIVIGAM in order to focus on the completion of planned improvements to the manufacturing process. ADMA resumed production of BIVIGAM during the fourth quarter of 2017. The Company submitted a Prior Approval Supplement (the “PAS”) for BIVIGAM to amend the FDA-approved Biologics License Application (“BLA”) for BIVIGAM and once approved, ADMA intends to relaunch BIVIGAM in the United States. The Prescription Drug User Fee Act (“PDUFA”) target action date for the PAS is December 18, 2018. The BIVIGAM inventory of three conformance batches produced in the fourth quarter of 2017 and the first quarter of 2018 was used in connection with, and as the basis for, the prepared and submitted PAS, which was accepted for review by the FDA in July 2018. Upon approval of the PAS by the FDA, the Company intends to relaunch BIVIGAM. This relaunch is expected to take place during the first half of 2019, at which time the Company believes the conformance lots currently in inventory can be labeled and released for commercial sale. The anticipated relaunch of BIVIGAM is dependent upon the timing of certain FDA decisions, production slots available with the Company’s contract fill/finish provider, approvals that may need to be obtained for product labeling as well as other commercial requirements and regulatory factors.

Prior to the closing of the Biotest Transaction in June 2017, BTBU was the Company’s third-party manufacturer for RI-002. In the third quarter of 2015, the FDA accepted for review the Company’s BLA for RI-002 (the “RI-002 BLA”) for the treatment of PID. In July 2016, the FDA issued a Complete Response Letter (the “CRL”) to the Company for the RI-002 BLA. Although the CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in the RI-002 BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002, the CRL reaffirmed the issues set forth in the November 2014 warning letter (the “Warning Letter”) that had been issued by the FDA to Biotest related to certain compliance issues identified at the Boca Facility, and also identified certain outstanding inspection issues and deficiencies at the Boca Facility and certain of the Company’s third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved. Upon the completion of the Biotest Transaction, ADMA gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and the Company’s highest priority has been the remediation of the outstanding compliance issues that were identified at the Boca Facility in the Warning Letter. The Company has worked with a consulting firm consisting of quality management systems and biologics production subject matter experts in order to improve the FDA inspection classification relative to the Warning Letter compliance issues as indicated in the CRL. Based on communication received from the FDA in July 2018 following the April 2018 FDA compliance inspection of the Boca Facility, the Company has determined that this inspection of the Boca Facility has been successfully closed out and the site’s compliance status has subsequently been improved to Voluntary Action Indicated, as indicated on the FDA’s website inspection database. The Company responded to the CRL and resubmitted the RI-002 BLA on September 28, 2018. As part of the RI-002 BLA resubmission, ADMA produced three conformance batches of inventory during the first quarter of 2018, which was used in connection with such BLA submission. The Company believes that this RI-002 inventory can be used for commercial sale once the RI-002 BLA is approved by the FDA. In October 2018, the FDA acknowledged receipt of the Company’s RI-002 BLA resubmission and set a target action date under PDUFA of April 2, 2019. Upon approval of the RI-002 BLA by the FDA, the Company intends to commercialize RI-002 with a full commercial launch anticipated for the second half of 2019.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

As of September 30, 2018, the Company had working capital of \$52.6 million, including \$42.4 million of cash and cash equivalents. Based upon the Company's current projected revenue and expenditures, including capital expenditures and regulatory and consulting fees for the remediation of the Warning Letter and ongoing discussions with the FDA, as well as continuing implementation of the Company's commercialization and expansion activities and certain other assumptions, the Company's management currently believes that its cash, cash equivalents, projected revenue and accounts receivable, along with the additional \$10.0 million it is able to access under its senior credit facility, will be sufficient to fund ADMA's operations, as currently conducted, into the second quarter of 2019. In order to have sufficient cash to fund its operations thereafter and to continue as a going concern, the Company will need to raise capital prior to the end of the second quarter of 2019. These estimates may change based upon how quickly the Company is able to execute on its quality management systems' remediation plans for the ADMA BioManufacturing operations, timing of receipt of communications, determinations and feedback from the FDA regarding inspectional outcomes and remediation activities undertaken to date, commercial manufacturing ramp-up activities, timing of any potential product approvals and the various financing options available to the Company. The Company currently has no firm commitments for additional financing, and there can be no assurances that the Company will be able to secure additional financing on terms that are acceptable to the Company, or at all. Furthermore, if the Company's assumptions underlying its estimated expenses and revenues are incorrect, it may have to raise additional capital sooner than currently anticipated.

Due to numerous risks and uncertainties associated with ongoing remediation efforts, regulatory review cycles and the research and development and potential future commercialization of its products and product candidates, 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 sale of additional equity or debt securities, if convertible, could result in dilution to the Company's stockholders and, in such event, the value and potential future market price of its common stock may decline. The incurrence of additional indebtedness would result in increased fixed obligations and could also result in covenants that would restrict the Company's operations or other financing alternatives. Failure to secure any necessary financing in a timely manner and on commercially reasonable terms could have a material adverse effect on the Company's business plan and financial performance and it could be forced to delay or discontinue its product development, clinical trial or commercialization activities, delay or discontinue the approval efforts for any of the Company's potential products or potentially cease operations. The Company has reported losses since inception in June 2004 through September 30, 2018 of \$198.4 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 and commercial programs and to 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 related to the recoverability and classification of asset carrying amounts and the classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In June 2018, the Company completed an underwritten public offering of its common stock and received net proceeds of \$42.9 million (see Note 5).

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. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board (the "FASB").

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 29, 2018. These condensed consolidated interim financial statements have been prepared in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X, and therefore omit or condense certain footnotes and other information normally included in consolidated interim financial statements prepared in accordance with U.S. GAAP. All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2018 and its results of operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017.

During the three and nine months ended September 30, 2018 and 2017, comprehensive loss was equal to the net loss amounts presented for the respective periods in the accompanying condensed consolidated statements of operations. In addition, certain prior year balances have been reclassified to conform to the current presentation. Specifically, Other current liabilities at December 31, 2017 of approximately \$58,000 have been reclassified into Accrued expenses and other current liabilities in the accompanying consolidated balance sheets. Operating results for interim periods are not necessarily indicative of the results that may be expected for the full fiscal year.

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 the fair value of assets acquired and liabilities assumed in a business combination, the valuation of inventory and assumptions used in the fair value determination of stock-based compensation and the allowance for the valuation of future tax benefits.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Business combinations

The Company accounts for business combinations using the acquisition method of accounting in accordance with FASB ASC 805, *Business Combinations*. Identifiable assets acquired, liabilities assumed, and contingent consideration are recorded at their acquisition date fair values. Any change in the fair value of the acquisition-related contingent consideration subsequent to the acquisition date, including changes from events after the acquisition date, is recognized in the period of the estimated fair value change. Goodwill represents the excess of the purchase price over the fair value of identifiable assets acquired and liabilities assumed as a result of the business combination. Identifiable assets with finite lives are amortized over their useful lives. Acquisition related costs are expensed as incurred.

Fair value of financial instruments

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents and accounts payable, are shown at cost which approximates fair value due to the short-term nature of these instruments. The debt outstanding under the Company's senior secured term loan (see Note 4) approximates fair value due to the variable interest rate on this debt. With respect to the related party note payable in the amount of \$15.0 million as of September 30, 2018 which is held by a principal stockholder of the Company and was issued concurrent with an acquisition transaction with an affiliate of such stockholder (see Note 4), the Company has concluded that an estimation of fair value for this note is not practicable.

Accounts receivable

Accounts receivable are reported at realizable value, net of allowances for contractual credits and doubtful accounts, which are recognized in the period the related revenue is recorded. At September 30, 2018, four customers accounted for an aggregate of 93% of the Company's total accounts receivable, and at December 31, 2017, two customers accounted for approximately 79% of the Company's total accounts receivable.

Inventories

Inventories, including plasma intended for resale and plasma intended for internal use in the Company's research and development and future anticipated commercialization activities, are carried at the lower of cost or net realizable value determined by the first-in, first-out method. Research and development plasma used in engineering lots or clinical trials is processed to a finished product and subsequently expensed to research and development.

Although the Company expects that the BIVIGAM and RI-002 inventory produced during 2017 and 2018 will ultimately be available for commercial sale, due to uncertainties at the time of production surrounding the timing and outcome of any FDA determinations concerning the Warning Letter and the PAS that must be approved and/or closed-out by the FDA prior to this inventory being available for commercial sale, all costs related to the production of BIVIGAM during the nine months ended September 30, 2018 in the amount of \$1.1 million have been charged to cost of product revenue in the accompanying consolidated statement of operations. In addition, the costs related to the manufacture of conformance lots of RI-002 during the nine months ended September 30, 2018 in the amount of \$2.9 million were also charged to cost of product revenue.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill at September 30, 2018 and December 31, 2017 was \$3.5 million. All of the Company's goodwill is attributable to its ADMA BioManufacturing business segment.

Goodwill is not amortized, but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. The Company has the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill and other intangible assets. If the Company concludes that this is the case, then it must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value, not to exceed the total amount of goodwill allocated to that reporting unit. The Company performs its annual goodwill impairment test as of October 1 of each year.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the three and nine months ended September 30, 2018 and 2017, the Company determined that there was no impairment of its long-lived assets.

Revenue recognition

Revenue from the sale of Nabi-HB is recognized when the product reaches the customer's destination. Nabi-HB revenue is recorded net of estimated customer prompt pay discounts and contractual allowances in accordance with managed care agreements, including wholesaler chargebacks, rebates, customer returns and other wholesaler fees. For sales of intermediates, title typically transfers when the product is delivered to a third party warehouse. With all other contract manufacturing, the title transfers to the customer when they take possession of the product from the Boca Facility. As the Company maintains a significant risk of loss throughout the contract manufacturing process, contract manufacturing revenue is not recognized until the product is released and title transfers to 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 generally occurs at the time of delivery.

License and other revenues are primarily attributable to the out-licensing of RI-002 to Biotest to market and sell this product in Europe and selected countries in North Africa and the Middle East. Biotest has 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.

For the nine months ended September 30, 2018, three customers represented an aggregate of 90% of the Company's consolidated revenues, with BPC representing 54% of the Company's consolidated revenues and the other two customers representing an aggregate of 35% of the Company's consolidated revenues. For the nine months ended September 30, 2017, sales to BPC represented 68% of the Company's consolidated revenues, and another customer represented 8% of the Company's consolidated revenues.

Cost of product revenue

Cost of product revenue includes expenses related to process development as well as scientific and technical operations when these operations are attributable to marketed products. When the activities of these operations are attributable to new products in development, the expenses are classified as research and development expenses.

Expenses associated with remediating the issues identified in the Warning Letter for the three and nine months ended September 30, 2018 were approximately \$0.1 million and \$1.3 million, respectively, and are reflected in cost of product revenue in the accompanying consolidated statements of operations. For the three and nine months ended September 30, 2017, these expenses totaled \$2.0 million and \$2.5 million. In addition, for the nine months ended September 30, 2018, all operating expenses associated with the Boca Facility, other than the Nabi-HB production that was capitalized into inventory, have been expensed as incurred.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Loss per common share

Basic loss per common 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. For purposes of computing basic and diluted loss per common share, the non-voting class of common stock (see Notes 3 and 5) is included in the common stock outstanding as the characteristics of the non-voting class are substantially the same as the voting class of common stock.

Diluted loss per common 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 shares of common stock and dilutive common stock outstanding during the period. Potentially dilutive common stock includes the shares of common stock issuable upon the exercise of outstanding stock options and warrants, using the treasury stock method. Potentially dilutive common stock is excluded from the diluted loss per common share computation to the extent that it would be anti-dilutive. As a result, no potentially dilutive securities are included in the computation of any of the accompanying diluted loss per share amounts as the Company reported a net loss for all periods presented. For the nine months ended September 30, 2018 and 2017, the following securities were excluded from the calculation of diluted loss per common share because of their anti-dilutive effects:

	For the Three and Nine Months Ended September 30,	
	2018	2017
Stock options	4,278,324	3,282,792
Warrants	528,160	188,859
	4,806,484	3,471,651

Stock-based compensation

The Company follows recognized accounting guidance which requires all equity-based payments, including grants of stock options, to be recognized in the statements of operations as compensation expense based on their fair values at the date of grant. The Company uses the Black-Scholes option pricing model to determine the fair value of options granted. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term (see Note 5).

During the three and nine months ended September 30, 2018, the Company granted options to purchase an aggregate of 61,800 and 1,044,700 shares of common stock, respectively, to its directors and employees, and during the nine months ended September 30, 2018, the Company granted options to purchase 20,000 shares of common stock to a third party service provider. During the three and nine months ended September 30, 2017, the Company granted options to purchase an aggregate of 86,000 and 1,942,595 shares of common stock, respectively, to its directors and employees.

Income Taxes

The accounting and reporting requirements with respect to accounting for income taxes require an asset and liability approach. Deferred income tax assets and liabilities are computed for differences between the financial statement and tax bases of assets and liabilities that will result in future taxable or deductible amounts, based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred income tax assets to the amount expected to be realized.

In accordance with U.S. GAAP, the Company is required to determine whether a tax position of the Company is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. Derecognition of a tax benefit previously recognized could result in the Company recording a tax liability that would reduce net assets. Based on its analysis, the Company has determined that it has not incurred any liability for unrecognized tax benefits as of September 30, 2018 and December 31, 2017. The Company is subject to income tax examinations by major taxing authorities for all tax years since 2013 and its tax returns may be subject to review and adjustment at a later date based on factors including, but not limited to, on-going analyses of and changes to tax laws, regulations and interpretations thereof. No interest expense or penalties have been recognized as of September 30, 2018 and December 31, 2017. During the three and nine months ended September 30, 2018 and 2017, the Company recognized no adjustments for uncertain tax positions.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

On December 22, 2017, the Tax Cuts and Jobs Act (the “TCJA”) was enacted, which included a reduction of the corporate income tax rate from 35% to 21%. This portion of the TCJA resulted in a reduction to the Company’s net deferred tax assets before valuation allowance of \$17.2 million for the year ended December 31, 2017, with a corresponding \$17.2 million reduction in the Company’s valuation allowance, resulting in no net impact to the Company’s tax provision. The Company expects to complete its analysis related to the TCJA and its impact on the Company’s consolidated financial statements, including the re-measurement of deferred tax assets and liabilities for the change in the corporate income tax rate, during the fourth quarter of 2018. However, the Company does not expect that the completion of this analysis will have a material impact on its consolidated financial statements.

Recent Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Modification Accounting for Share-Based Payment Arrangements*, which amends the scope of modification accounting for share-based payment arrangements. The ASU provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718, *Compensation – Stock Compensation*. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. Adoption of this new guidance in 2018 did not have a material impact on the Company’s condensed consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (“ASU 2016-02”), 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. Based on the lease agreements the Company had in place as of September 30, 2018, and after giving effect to the Company’s obligation to transfer ownership of two of its plasma collection centers to Biotest on January 1, 2019 (see Note 3), the Company does not believe this new standard will have a material impact on its consolidated financial statements and related disclosures.

In May 2014, the FASB issued new guidance related to revenue recognition, ASU 2014-09, *Revenue from Contracts with Customers* (“ASC 606”), which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new guidance requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASC 606 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The new guidance became effective in calendar year 2018. Two methods of adoption are permitted: (a) full retrospective adoption, meaning the standard is applied to all periods presented; or (b) modified retrospective adoption, meaning the cumulative effect of applying the new guidance is recognized at the date of initial application as an adjustment to the opening retained earnings balance.

In March 2016, April 2016 and December 2016, the FASB issued ASU No. 2016-08, *Revenue From Contracts with Customers (ASC 606): Principal Versus Agent Considerations*, ASU No. 2016-10, *Revenue From Contracts with Customers (ASC 606): Identifying Performance Obligations and Licensing*, and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts with Customers*, respectively, which further clarify the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers*, narrow-scope improvements and practical expedients which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards became effective for the Company beginning in the first quarter of 2018.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ADMA adopted the new revenue recognition standard and related updates effective January 1, 2018, using the modified retrospective method of adoption. Adoption of the new revenue recognition guidance did not have a material impact on the Company's consolidated financial statements.

3. ACQUISITION

On June 6, 2017, ADMA completed the acquisition of the Biotest Assets from BPC. As a result of this transaction, the Company acquired Nabi-HB, BIVIGAM, the Boca Facility and certain other assets of BTBU. The acquisition of the Biotest Assets expanded the Company's product offering with two FDA-approved products while providing direct control over the manufacturing and regulatory processes impacting the Company's RI-002 product candidate, including remediation of the Warning Letter as well as certain other remediation matters affecting the Boca Facility. Pursuant to the acquisition, the Company issued to Biotest 4,295,580 voting shares of its common stock and 8,591,160 shares of non-voting common stock (the "NV Biotest Shares"). The Company will also transfer ownership of two of its plasma centers to Biotest on January 1, 2019 as additional consideration, which are reflected as non-current assets in the accompanying consolidated balance sheets at September 30, 2018 and December 31, 2017 in the amount of \$1.2 million and \$1.5 million, respectively.

As a result of the foregoing transaction, BPC became a principal stockholder and Biotest became a related party of the Company (see Note 9). Therefore, all transactions with Biotest subsequent to June 6, 2017, including product and license revenues attributable to Biotest (see Note 2), are related party transactions. The results from BTBU's operations are included in the Company's consolidated financial statements from the date of acquisition.

The following unaudited pro forma summary presents consolidated information of the Company as if the business combination had occurred on January 1, 2017. The pro forma information is presented for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved had the acquisition been consummated as of that time or that may result in the future.

	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2017
Revenues:		
As reported	\$ 4,729,411	\$ 10,757,683
Pro forma	\$ 4,729,411	\$ 29,021,453
Net loss		
As reported	\$ (15,202,715)	\$ (30,776,173)
Pro forma	\$ (15,202,715)	\$ (40,029,464)
Basic and diluted net loss per share:		
As reported	\$ (0.59)	\$ (1.67)
Pro forma	\$ (0.59)	\$ (1.55)

On May 14, 2018, the Company, ADMA BioManufacturing and ADMA Bio Centers entered into a Share Transfer, Amendment and Release Agreement with BPC, Biotest AG, Biotest US Corporation and The Biotest Divestiture Trust (the "Biotest Trust") (the "Biotest Transfer Agreement") whereby BPC transferred to the Company, for no cash consideration, the NV Biotest Shares. Immediately upon transfer of the NV Biotest Shares to the Company, the shares were retired and are no longer available for issuance. The retired NV Biotest Shares comprised approximately 19% of the total outstanding common stock of the Company as of May 14, 2018. In exchange for the transfer and retirement of the NV Biotest Shares, the Company (i) granted Biotest and its successors and assigns a release from all potential past, present and future indemnity claims arising under the Master Purchase and Sale Agreement, dated as of January 21, 2017, and (ii) relinquished its rights to, under certain circumstances, repurchase the two FDA-approved plasma collection centers required to be transferred to BPC on January 1, 2019. In addition, pursuant to the Biotest Transfer Agreement, BPC waived and terminated its rights to name a director and an observer to the Company's Board of Directors (the "Board"). As BPC has made public statements regarding the U.S. Government required divestiture of all of BPC's U.S. assets in connection with the sale of Biotest AG to CREAT Group Corporation, pursuant to the Biotest Transfer Agreement BPC transferred its remaining 10,109,534 shares of the Company's common stock to the Biotest Trust on July 24, 2018, and the Biotest Trust is bound by all obligations of and has all of the remaining rights of BPC under that certain (i) Stockholders Agreement dated as of June 6, 2017, by and between the Company and BPC, as amended by the Biotest Transfer Agreement, and (ii) Registration Rights Agreement, dated as of June 6, 2017, by and between the Company and BPC, as amended by the Biotest Transfer Agreement. Furthermore, subject to the terms contained in the Biotest Transfer Agreement, for a 90-day period following BPC's transfer of the remaining shares of ADMA common stock to the Biotest Trust, the Biotest Trust granted the Company a right of first negotiation for the purchase of the remaining shares of common stock held by the Biotest Trust, which right expired on October 22, 2018.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

4. DEBT

Senior Notes Payable

A summary of outstanding senior notes payable is as follows:

	September 30, 2018	December 31, 2017
Notes payable:	\$ 30,000,000	\$ 30,000,000
Less:		
Debt discount	(3,846,457)	(4,631,542)
Senior notes payable	\$ 26,153,543	\$ 25,368,458

On October 10, 2017 (the “Marathon Closing Date”), the Company entered into a Credit Agreement (the “Credit Agreement”) with Marathon Healthcare Finance Fund, L.P. (“Marathon” or the “Lender”) and Wilmington Trust, National Association, as the administrative agent for the Lender (the “Administrative Agent”). The Credit Agreement provides for a senior secured term loan facility in an aggregate amount of up to \$40.0 million (collectively, the “Credit Facility”), comprised of (i) a term loan made on the Marathon Closing Date in the principal amount of \$30.0 million evidenced by a secured promissory note (the “Tranche One Note”), and (ii) an additional term loan evidenced by a secured promissory note to be made in the maximum principal amount not to exceed \$10.0 million (the “Tranche Two Note” and, together with the Tranche One Note, the “Notes”), which Tranche Two Note availability is subject to the satisfaction of certain conditions, including, but not limited to, those described below. The Notes each have a maturity date of April 10, 2022 (the “Maturity Date”), subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default (as defined in the Credit Agreement).

Borrowings under the Credit Agreement bear interest at a rate per annum equal to LIBOR plus 9.50% with a 1% LIBOR floor; provided, however, that in the event that the Company achieves sales of not less than \$61.7 million for the 2018 calendar year and the Tranche Two Loan has been funded, then the interest rate on the borrowings under the Credit Agreement will decrease to LIBOR plus 7.75% with a 1% LIBOR floor. During an Event of Default under the Credit Agreement, the outstanding amount of indebtedness under the Credit Agreement will bear interest at a rate per annum equal to the interest rate then applicable to the borrowings under the Credit Agreement plus 5% per annum. Quarterly cash interest payments are due the first business day of each March, June, September and December, beginning on December 1, 2017. During the nine months ended September 30, 2018, the interest rate on the Tranche One Note ranged from 10.99% to 11.82%.

The Company will pay Marathon a facility fee in an amount equal to 9.20% of the amount of the Tranche One Note, payment of which is deferred until the Maturity Date pursuant to the terms of the Credit Agreement. Commencing on October 10, 2020, and on the first business day of each month, the Company is required to make principal payments on the Tranche One Note (and Tranche Two Note in the event it shall have been funded) in equal monthly installments over 18 months, subject to certain conditions in the Credit Agreement. The outstanding principal amount of the Notes, together with all accrued interest thereon, is due on the Maturity Date.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Credit Agreement contains market representations and warranties, affirmative covenants, negative covenants, financial covenants, and conditions that are customarily required for similar financings. The affirmative covenants, among other things, require the Company to undertake various reporting requirements. The negative covenants restrict or limit the ability of the Company and its subsidiaries to, among other things, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes or changes to the Company's business activities; sell or otherwise dispose of assets; repurchase stock, pay dividends; repay certain other indebtedness; engage in certain affiliate transactions; or enter into any other agreements that restrict the Company's ability to make loan repayments.

The Credit Agreement also required the establishment of a debt service reserve account, and the Company is required to maintain a certain minimum level of liquidity at all times. Liquidity is defined in the Credit Agreement as cash held in the debt service reserve account and any other deposit account subject to a control agreement with the Administrative Agent, and the required liquidity amount is reflected as restricted cash in the accompanying consolidated balance sheets as of September 30, 2018 and December 31, 2017. The minimum liquidity requirement was \$4.0 million and \$5.5 million as of September 30, 2018 and December 31, 2017, respectively. On May 31, 2018, the Credit Agreement was amended to reduce the minimum liquidity requirement to \$5.25 million, and \$250,000 was released from the debt service reserve account to the Company on June 25, 2018. On June 26, 2018, the Lender and the Administrative Agent acknowledged that the Company had met the requirements regarding its leased properties as set forth in Credit Agreement, and an additional \$1.25 million was released from the debt service reserve account to the Company.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the accompanying consolidated balance sheets and statements of cash flows:

	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 42,367,489	\$ 43,107,574
Restricted cash included in current assets	—	1,500,000
Restricted cash included in long-term assets	4,000,000	4,000,000
Total cash, cash equivalents and restricted cash as shown in the consolidated statements of cash flows	<u>\$ 46,367,489</u>	<u>\$ 48,607,574</u>

The Credit Agreement also contains customary Events of Default which include, among others, non-payment of principal, interest or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts and events constituting a change of control. The occurrence of an Event of Default could result in, among other things, the termination of commitments under the Credit Facility and the declaration that all outstanding Loans are immediately due and payable in whole or in part. At September 30, 2018 and December 31, 2017, the Company was in compliance with all of the covenants contained in its senior lending agreements.

Related Party Note Payable

A summary of the outstanding related party note payable is as follows:

	September 30, 2018	December 31, 2017
Biotest - Gross proceeds	\$ 15,000,000	\$ 15,000,000
Less:		
Debt discount	(134,019)	(157,604)
Note payable - related party	<u>\$ 14,865,981</u>	<u>\$ 14,842,396</u>

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In connection with the acquisition of the Biotest Assets (see Note 3), ADMA BioManufacturing issued a subordinated note payable to Biotest and in connection therewith received cash proceeds of \$15.0 million. The note bears interest at a rate of 6.0% per annum and matures on June 6, 2022. The Company is obligated to make semi-annual interest payments, with all principal and unpaid interest due at maturity. The note is subordinate to all amounts outstanding under the Credit Agreement. In the event of default, all principal and unpaid interest is due on demand. The subordinated note also contains several non-financial covenants with which the Company was in compliance as of September 30, 2018.

On July 20, 2018, in connection with the U.S. Government required divestiture of all of BPC's U.S. assets in connection with the sale of Biotest AG to CREAT Group Corporation, Biotest AG, BPC, ADMA BioManufacturing and the Company entered into an Assignment and Assumption Agreement whereby BPC transferred to Biotest AG all of its obligations, rights, title and interest in the subordinated loan agreement under which the Company borrowed \$15.0 million from BPC.

5. STOCKHOLDERS' EQUITY

Preferred Stock

The Company is currently authorized to issue up to 10 million shares of preferred stock, \$0.0001, par value per share. There were no shares of preferred stock outstanding at September 30, 2018 and December 31, 2017.

Common Stock

As of September 30, 2018 and December 31, 2017, the Company was authorized to issue 75,000,000 shares of its common stock, and 46,351,243 and 36,725,499 shares of common stock, respectively, were outstanding. After giving effect to shares reserved for the issuance of warrants and stock options, as of September 30, 2018, 23,842,273 shares of common stock were available for issuance.

On May 14, 2018, pursuant to the Biotest Transfer Agreement, all 8,591,160 shares of the Company's non-voting common stock (see Note 3) were transferred from Biotest to the Company and the shares were immediately retired and are no longer available for issuance.

In June 2018, the Company completed an underwritten public offering of 9,623,430 shares of common stock for gross proceeds of \$46.0 million. The Company received net proceeds from this offering, after underwriters' commissions and other offering expenses, of \$42.9 million. The net proceeds have been and will continue to be used, among other things, (i) for continued remediation and ongoing improvements and enhancements at the Boca Facility, (ii) to submit the PAS for, and relaunch of, BIVIGAM, (iii) to resubmit the RI-002 BLA, (iv) for expenses associated with obtaining with FDA approval of ADMA's third plasma collection facility, and (v) for general corporate purposes and other capital expenditures.

Equity Incentive Plan

The fair value of stock options granted under the Company's 2007 Employee Stock Option Plan (the "2007 Plan") and the ADMA Biologics, Inc. 2014 Omnibus Incentive Compensation Plan, as amended and restated (the "2014 Plan"), 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 certain subjective assumptions including the expected stock price volatility. The stock options granted to employees and directors have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value estimate. The following assumptions were used to determine the fair value of options granted during the nine months ended September 30, 2018 and 2017:

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	Nine Months Ended September 30,	
	2018	2017
Expected term	5.8 - 6.3 years	5.8 - 6.3 years
Volatility	54-57%	58-64%
Dividend yield	0.0	0.0
Risk-free interest rate	2.40-2.97%	1.60-2.29%

The weighted average remaining contractual life of stock options outstanding and expected to vest at September 30, 2018 is 7.7 years. The weighted average remaining contractual life of stock options exercisable at September 30, 2018 is 6.2 years.

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

	Nine Months Ended September 30, 2018	
	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	3,276,043	\$ 5.52
Forfeited	(46,285)	\$ 4.05
Expired	(12,446)	\$ 8.03
Granted	1,064,700	\$ 3.99
Exercised	(3,688)	\$ 3.14
Outstanding at end of period and expected to vest	<u>4,278,324</u>	<u>\$ 5.15</u>
Options exercisable	<u>2,026,707</u>	<u>\$ 6.51</u>

During the nine months ended September 30, 2018, an aggregate of 1,959 option shares were exercised in cashless exercise transactions resulting in the issuance of an aggregate of 585 shares of common stock, and 1,729 option shares were exercised for cash. Stock-based compensation expense for the three and nine months ended September 30, 2018 and 2017 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 84,588	\$ 141,405	\$ 246,231	\$ 262,822
Plasma centers	7,836	10,341	22,682	36,288
Selling, general and administrative	444,651	331,946	1,245,702	726,062
Cost of product revenue	40,506	22,038	113,141	27,798
Total stock-based compensation expense	<u>\$ 577,581</u>	<u>\$ 505,730</u>	<u>\$ 1,627,756</u>	<u>\$ 1,052,970</u>

As of September 30, 2018, the Company had \$4.7 million of unrecognized compensation expense related to options granted under the Company's equity incentive plans, which is expected to be recognized over a weighted-average period of 2.7 years.

6. INVENTORIES

The following table provides the components of inventories:

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Raw materials	\$ 10,247,437	\$ 10,143,149
Work-in-progress	1,440,168	1,265,339
Finished goods	2,189,829	1,219,693
Total inventories	<u>\$ 13,877,434</u>	<u>\$ 12,628,181</u>

Inventories are stated at the lower of cost or net realizable value with cost being determined on the first-in, first-out method. Finished goods inventories as of September 30, 2018 is comprised of Nabi-HB, a portion of which is recorded at fair value as part of the purchase price allocation of the Biotest Assets acquired, and plasma collected at ADMA Bio Centers which is expected to be sold. Raw materials includes materials expected to be used in the production of Nabi-HB, BIVIGAM and RI-002. All other activities and materials associated with the production of inventories used in research and development activities are expensed as incurred.

7. INTANGIBLE ASSETS

Intangible assets at September 30, 2018 and December 31, 2017 consist of the following:

	<u>September 30, 2018</u>			<u>December 31, 2017</u>		
	<u>Cost</u>	<u>Accumulated Amortization</u>	<u>Net</u>	<u>Cost</u>	<u>Accumulated Amortization</u>	<u>Net</u>
Trademark and other intangible rights related to Nabi-HB	\$ 4,100,046	\$ 780,961	\$ 3,319,085	\$ 4,100,046	\$ 341,670	\$ 3,758,376
Rights to intermediates	907,421	172,842	734,579	907,421	75,618	831,803
Customer contract	1,076,557	914,575	161,982	1,076,557	817,386	259,171
	<u>\$ 6,084,024</u>	<u>\$ 1,868,378</u>	<u>\$ 4,215,646</u>	<u>\$ 6,084,024</u>	<u>\$ 1,234,674</u>	<u>\$ 4,849,350</u>

All of the Company's intangible assets were acquired in the Biotest Transaction. Amortization expense related to these intangible assets for the three and nine months ended September 30, 2018 was \$0.2 million and \$0.6 million, respectively. Amortization expense for the three and nine months ended September 30, 2017 was \$0.3 million. Estimated aggregate future aggregate amortization expense for the next five years is expected to be as follows:

Remainder of 2018	\$ 211,435
2019	844,938
2020	715,352
2021	715,352
2022	715,352

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

8. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment and related accumulated depreciation are summarized as follows:

	September 30, 2018	December 31, 2017
Manufacturing and laboratory equipment	\$ 7,386,573	\$ 7,148,405
Office equipment and computer software	1,598,565	1,086,756
Furniture and fixtures	1,136,623	1,136,623
Construction in process	1,460,984	738,093
Leasehold improvements	1,650,029	1,642,903
Land	4,339,441	4,339,441
Buildings and building improvements	15,670,559	15,660,559
	<u>33,242,774</u>	<u>31,752,780</u>
Less: Accumulated depreciation	(2,880,145)	(1,285,922)
Total property, plant and equipment, net	<u>\$ 30,362,629</u>	<u>\$ 30,466,858</u>

Fixed assets are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset's estimated useful life. Land is not depreciated. The buildings were assigned a useful life of 30 years. Property and equipment other than land and buildings have useful lives ranging from 3 to 10 years. Leasehold improvements are amortized over the lesser of the lease term or their estimated useful lives.

The Company recorded depreciation expense on property and equipment for the three and nine months ended September 30, 2018 of \$0.6 million and \$1.9 million, respectively, which includes \$0.1 million and \$0.3 million, respectively, of depreciation expense on the plasma assets to be transferred (see Note 3). Depreciation expense for the three and nine months ended September 30, 2017 was \$0.6 million and \$0.9 million, respectively.

9. RELATED PARTY TRANSACTIONS

The Company leases an office building and equipment from Areth, LLC ("Areth") on a month-to-month basis pursuant to a shared services agreement, effective as of January 1, 2016, as amended effective September 25, 2017 and September 27, 2018 (the "Areth Agreement"). Monthly rent on this facility is \$10,000. Rent expense under the Areth Agreement for the three and nine months ended September 30, 2018 was \$30,000 and \$90,000, respectively. Rent expense for the three and nine months ended September 30, 2017 was \$48,000 and \$144,000, respectively. Areth is a company controlled by Dr. Jerrold B. Grossman, the Company's Vice Chairman of the Board, and Adam Grossman, the Company's President and Chief Executive Officer.

As part of the Biotest Transaction, the Company issued a \$15.0 million subordinated note payable to Biotest (see Note 4), and recognized interest expense on this note for the three and nine months ended September 30, 2018 in the amount of \$0.2 and \$0.7 million, respectively. Interest expense on this note for the three and nine months ended September 30, 2017 was \$0.2 million and \$0.3 million, respectively.

For the three and nine months ended September 30, 2018 and 2017, the Company recognized revenues under its out-licensing agreements with Biotest of approximately \$36,000 and \$107,000, respectively. Deferred revenue of \$2.6 million and \$2.7 million as of September 30, 2018 and December 31, 2017, respectively, is related to these agreements.

Biotest is the Company's largest customer for the sale of normal source plasma. Plasma sales to Biotest for the three and nine months ended September 30, 2018 were \$2.2 million and \$7.0 million, respectively. For the three and nine months ended September 30, 2017, plasma sales to Biotest were \$2.8 million and \$7.3 million, respectively. Accounts receivable includes \$1.0 million and \$1.2 million due from Biotest as of September 30, 2018 and December 31, 2017, respectively. Additionally, Biotest is a supplier of plasma to ADMA. For the three and nine months ended September 30, 2018, the Company purchased \$1.7 million and \$2.5 million, respectively, of plasma from Biotest. Plasma purchases from Biotest for the three and nine months ended September 30, 2017 were \$1.4 million and \$1.7 million, respectively. Included in accounts payable is \$1.8 million and \$0.1 million due to Biotest as of September 30, 2018 and December 31, 2017, respectively. The following table summarizes the related party balances with Biotest:

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Sale and purchase of plasma				
Product revenue	\$ 2,207,312	\$ 2,808,640	\$ 7,009,380	\$ 7,262,915
Purchases	1,694,999	1,411,500	2,529,788	1,735,640
License revenue	35,708	35,708	107,125	107,125
Interest expense	230,000	230,000	682,500	290,000

	September 30,	December 31,
	2018	2017
Accounts receivable	\$ 1,005,971	\$ 1,245,677
Accounts payable	1,791,354	139,939
Accrued expenses	19,661	314,820
Note payable, net of discount	14,865,981	14,842,396
Accrued interest	292,500	65,000
Deferred revenue	2,582,908	2,690,033

In connection with the acquisition of the Biotest Assets, the Company entered into a Transition Services Agreement with BPC pursuant to which each of the Company and BPC agreed to provide transition services to the other party, including services related to finance, human resources, information technologies, leasing of equipment and clinical and regulatory services for a period of up to 24 months after the June 6, 2017 closing date, as well as agreements to lease certain laboratory space within the Boca Facility to BPC for a period of up to 24 months after the closing date of the acquisition transaction. As of September 30, 2018 and December 31, 2017, approximately \$20,000 and \$0.3 million, respectively, was payable by the Company to BPC for services rendered and expenses incurred on behalf of the Company related to these agreements. This amount is reflected in accrued expenses in the accompanying consolidated balance sheets. The services component of amounts billed to the Company by BPC for the three months and nine months ended September 30, 2018 was not material to the Company's consolidated financial statements.

Under the terms of the acquisition of the Biotest Assets, the Company will transfer ownership of two plasma collection centers to BPC on January 1, 2019. The Company has estimated the fair value of these assets to be \$12.6 million, and the obligation to transfer these assets to Biotest is reflected in non-current liabilities in the accompanying consolidated balance sheet as of September 30, 2018 and December 31, 2017.

10. COMMITMENTS AND CONTINGENCIES

General Legal Matters

From time to time the Company is or may become subject to certain legal proceedings and claims arising in connection with the normal course of its business. Management does not expect that the outcome of any such claims or actions will have a material effect on the Company's liquidity, results of operations or financial condition.

Contract manufacturing agreement

In connection with the acquisition of the Biotest Assets, the Company acquired all of the rights and assumed all of the obligations under an existing agreement with a third party related to the fractionation of plasma provided by the third party. This contract, as amended from time to time, maintains minimum production requirements as well as a payment due to the counterparty to the contract of \$1.5 million per year if the minimum volume is not manufactured in that year and no other breach or default under the contract has occurred.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Post-marketing commitments

In connection with the approval of the BLA for BIVIGAM, on December 19, 2012 Biotest committed to perform two additional post-marketing studies, a pediatric study to evaluate the efficacy and safety of BIVIGAM in children and adolescents, and a post-authorization safety study to further assess the potential risk of hypotension and hepatic and renal impairment in BIVIGAM-treated patients with primary humoral immunodeficiency. These studies are still pending completion, ADMA has assumed the remaining obligations, and the costs of the studies will be expensed as incurred as research and development expenses. The Company currently expects both studies to be completed by the end of 2021. However, the timing of the completion of these studies is dependent upon the availability of BIVIGAM and the completion of the planned manufacturing process improvements.

Other commitments

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of September 30, 2018. The Company does not anticipate recognizing any significant losses relating to these arrangements.

11. SEGMENTS

The Company is engaged in the manufacture, marketing and development of specialty plasma-derived biologics. The Company's operating segments reflect the consummation of the Biotest Transaction on June 6, 2017 (see Notes 1 and 3), and the nature of its operations subsequent to the close of the transaction. The Company's ADMA BioManufacturing segment reflects the Company's immune globulin manufacturing and development operations in Boca Raton, FL, acquired on June 6, 2017 (see Note 3). The Plasma Collection Centers segment consists of three FDA-licensed source plasma collection facilities located in Georgia. The Corporate segment includes general and administrative overhead expenses. 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. Summarized financial information concerning reportable segments is shown in the following tables:

Three Months Ended September 30, 2018

	<u>ADMA BioManufacturing</u>	<u>Plasma Collection Centers</u>	<u>Corporate</u>	<u>Consolidated</u>
Revenues	\$ 1,985,630	\$ 2,208,972	\$ 35,708	\$ 4,230,310
Cost of product revenue	7,671,279	1,492,830	—	9,164,109
Loss from operations	(10,214,933)	(1,257,196)	(2,319,271)	(13,791,400)
Interest and other expense, net	(255,410)	849	(1,089,524)	(1,344,085)
Net loss	(10,470,343)	(1,256,347)	(3,408,795)	(15,135,485)
Total assets	56,123,178	5,524,105	44,697,817	106,345,100
Depreciation and amortization expense	651,317	191,547	4,193	847,057

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Nine Months Ended September 30, 2018

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	\$ 5,796,597	\$ 7,025,144	\$ 107,125	\$ 12,928,866
Cost of product revenue	26,334,602	4,717,917	—	31,052,519
Loss from operations	(32,656,560)	(3,238,013)	(7,846,711)	(43,741,284)
Interest and other expense, net	(732,623)	(22)	(3,231,529)	(3,964,174)
Net loss	(33,389,183)	(3,238,035)	(11,078,240)	(47,705,458)
Capital expenditures	772,339	504,255	—	1,276,594
Depreciation and amortization expense	1,922,448	581,059	18,989	2,522,496

Three Months Ended September 30, 2017

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	\$ 1,879,921	\$ 2,813,782	\$ 35,708	\$ 4,729,411
Cost of product revenue	9,552,128	1,738,988	—	11,291,116
Loss from operations	(10,532,500)	(507,900)	(3,387,360)	(14,427,760)
Interest and other expense, net	(237,548)	—	(537,407)	(774,955)
Net loss	(10,770,048)	(507,900)	(3,924,767)	(15,202,715)
Total assets	55,452,496	3,517,274	13,843,710	72,813,480
Depreciation and amortization expense	723,098	102,263	10,710	836,071

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Nine Months Ended September 30, 2017

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	\$ 2,419,144	\$ 8,231,414	\$ 107,125	\$ 10,757,683
Cost of product revenue	12,050,984	5,190,438	—	17,241,422
Loss from operations	(13,650,801)	(1,621,364)	(13,494,466)	(28,766,631)
Interest and other expense, net	(299,535)	—	(1,710,007)	(2,009,542)
Net loss	(13,950,336)	(1,621,364)	(15,204,473)	(30,776,173)
Depreciation and amortization expense	881,496	309,606	40,163	1,231,265
Capital expenditures	360,000	291,194	15,263	666,457

12. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the nine months ended September 30, 2018 and 2017 is as follows:

	2018	2017
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	\$ 3,063,219	\$ 1,217,524
Noncash Financing and Investing Activities:		
Equipment acquired reflected in accounts payable and accrued liabilities	\$ 533,921	\$ 1,363,563
Equipment acquired through capital lease	\$ 165,644	\$ —
Assets acquired through the issuance of common stock and liabilities assumed	\$ —	\$ 60,161,629

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

The following discussion, which refers to our historical results, should be read in conjunction with the other sections of this Quarterly Report on Form 10-Q, including “Risk Factors” and our unaudited consolidated financial statements and the notes thereto appearing elsewhere herein, and in conjunction with the Management’s Discussion and Analysis of Financial Condition and Results of Operations set forth in our Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 29, 2018 (the “2017 10-K”). 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 or referenced within this Quarterly Report on Form 10-Q. See “Special Note Regarding Forward-Looking Statements.” Our actual results may differ materially.

OVERVIEW

Our Business

ADMA Biologics, Inc. (the “Company”, “ADMA”, “we”, “us” or “our”) is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of Primary Immune Deficiency Disease (“PID”), and the prevention and treatment of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. We currently have two approved products: Nabi-HB, which is currently marketed and indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen (“HBsAg”); and BIVIGAM, which is indicated for the treatment of primary humoral immunodeficiency. We are also developing a pipeline of plasma-derived therapeutics, including our lead pipeline product candidate, RI-002, for the treatment of PID. RI-002 is currently under FDA review with a target action due date under the Prescription Drug User Fee Act (“PDUFA”) of April 2, 2019. Our products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases. Through our wholly-owned subsidiary, ADMA Bio Centers Georgia, Inc. (“ADMA Bio Centers”), we operate three U.S. Food and Drug Administration (the “FDA”)-licensed source plasma collection facilities located in the United States, two of which are certified by the German Health Authority (“GHA”) and Korean Ministry of Food and Drug Safety (“KMFDS”).

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

On May 14, 2018, we, ADMA BioManufacturing and ADMA Bio Centers entered into a Share Transfer, Amendment and Release Agreement with BPC, Biotest AG, Biotest US Corporation and The Biotest Divestiture Trust (the “Biotest Trust”) (the “Biotest Transfer Agreement”) whereby BPC transferred to us, for no cash consideration, 8,591,160 shares of our non-voting common stock, previously issued to BPC in connection with the Biotest Transaction and representing 100% of our issued and outstanding non-voting common stock (the “NV Biotest Shares”) and 19% of our total outstanding common stock, \$0.0001 par value per share (the “Common Stock”), as of May 14, 2018. Immediately upon transfer of the NV Biotest Shares to us, the shares were retired and are no longer available for issuance. In exchange for the transfer and retirement of the NV Biotest Shares, we have (i) granted Biotest and its successors and assigns a release from all potential past, present and future indemnity claims arising under that certain Master Purchase and Sale Agreement, dated as of January 21, 2017 (as amended, restated, supplemented or otherwise modified from time to time, the “Purchase Agreement”), with BPC, and for certain limited purposes set forth in the Purchase Agreement, Biotest AG and Biotest US (together with Biotest AG, the “Biotest Guarantors”), and (ii) relinquished our rights to repurchase our two FDA-approved plasma collection centers required to be transferred to BPC on January 1, 2019. In addition, pursuant to the Biotest Transfer Agreement, BPC waived and terminated its rights to name a director and an observer to our Board of Directors (the “Board”). As BPC has made public statements regarding the U.S. Government required divestiture of all of BPC’s U.S. assets in connection with the sale of Biotest AG to CREAT Group Corporation, pursuant to the Biotest Transfer Agreement BPC, on July 24, 2018 BPC transferred its remaining 10,109,534 shares of our Common Stock to the Biotest Trust, and the Biotest Trust is bound by all obligations of and has all of the remaining rights of BPC under that certain (i) Stockholders Agreement dated as of June 6, 2017, by and between us and BPC, as amended by the Biotest Transfer Agreement, and (ii) Registration Rights Agreement, dated as of June 6, 2017, by and between us and BPC, as amended by the Biotest Transfer Agreement. Furthermore, subject to the terms contained in the Biotest Transfer Agreement, for a 90-day period following the date of the transfer of the remaining ADMA shares to the Biotest Trust, the Biotest Trust has granted us a right of first negotiation for the purchase of the remaining shares of Common Stock held by the Biotest Trust, which right expired on October 22, 2018.

Our Marketed Products

Nabi-HB

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

BIVIGAM

BIVIGAM is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These primary immunodeficiencies (“PIs”) are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as one in every 1,200-2,000 people has some form of PI. BIVIGAM contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses, and help to protect PI patients against serious infections. BIVIGAM is a purified, sterile, ready-to-use preparation of concentrated Immunoglobulin G (“IgG”) antibodies. Antibodies are proteins in the human immune system that work to defend against disease. FDA approval for BIVIGAM was received on December 19, 2012, and sales commenced in the first quarter of 2013. In December 2016, BPC temporarily suspended the commercial production of BIVIGAM in order to focus on the completion of planned improvements to the manufacturing process. We resumed production of BIVIGAM utilizing our optimized intravenous immunoglobulin (“IVIG”) manufacturing process with two conformance lots in the fourth quarter of 2017 and a third conformance lot in the first quarter of 2018. We filed a Prior Approval Supplement (the “PAS”) with the FDA during the first half of 2018 to include the ADMA optimization improvements for BIVIGAM, and the PAS was accepted for review by the FDA in July 2018, and the Prescription Drug User Fee Act (“PDUFA”) target action date for the PAS is December 18, 2018. The BIVIGAM inventory of three conformance batches produced in the fourth quarter of 2017 and the first quarter of 2018 was used in connection with, and as the basis for, the prepared and submitted PAS. Upon FDA approval of the PAS, we anticipate being in a position to relaunch BIVIGAM during the first half of 2019, at which time we believe the conformance lots currently in inventory can be labeled and released for commercial sale. The anticipated relaunch of BIVIGAM is dependent upon the timing of certain FDA decisions, production slots available with our contract fill/finish provider, approvals that may need to be obtained for product labeling as well as other commercial requirements and regulatory factors.

Our Lead Pipeline Product Candidate – RI-002

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

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for RI-002. In the third quarter of 2015, the FDA accepted for review our Biologics License Application (“BLA”) for RI-002 (the “RI-002 BLA”) for the treatment of PIDDD. In July 2016, the FDA issued a Complete Response Letter (the “CRL”), which reaffirmed the issues set forth in the November 2014 Warning Letter that had been issued by the FDA to Biotest related to certain issues identified at the Boca Facility (the “Warning Letter”), but did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in our RI-002 BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies related to Chemistry, Manufacturing and Controls and Good Manufacturing Practices at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of our RI-002 BLA until, among other things, these deficiencies are resolved. Upon the completion of the Biotest Transaction, we gained control over the regulatory, quality, general operations and drug substance manufacturing process and our highest priority has been to remediate the outstanding compliance issues that were identified at the Boca Facility in the Warning Letter.

Compliance Status Update for RI-002 CRL Response and BLA Resubmission

We have been working with a consulting firm consisting of quality management systems and biologics production subject matter experts in order to improve the FDA inspection classification relative to the Warning Letter compliance issues as indicated in the CRL. Based on official communication received in an Establishment Inspection Report from the FDA in July 2018 following the April 2018 FDA compliance inspection of the Boca Facility, we have determined that the April 2018 inspection has been successfully closed out and the site’s compliance status has subsequently been improved to Voluntary Action Indicated (“VAI”), as indicated on the FDA’s website inspection database. We believe that this VAI compliance classification is acceptable for the FDA to grant approvals for new applications. As such, we responded to the CRL and resubmitted the RI-002 BLA on September 28, 2018. As part of the RI-002 BLA resubmission, we produced three conformance batches of inventory during the first quarter of 2018, which was used in connection with such BLA submission. We believe that this RI-002 inventory can be used for commercial sale once the RI-002 BLA is approved by the FDA. In October of 2018, the FDA acknowledged receipt of our RI-002 BLA resubmission and set a target action date under PDUFA of April 2, 2019. Upon approval of the RI-002 BLA by the FDA, we intend to commercialize RI-002 with a full commercial launch anticipated for the second half of 2019.

Plasma Collection Facilities

ADMA Bio Centers, our wholly-owned subsidiary, currently operates three FDA-licensed source plasma collection facilities located in the United States, two of which are GHA and KMFDS-certified. ADMA Bio Centers provides us with a portion of our blood plasma for the manufacture of our products and product candidates. A typical plasma collection center, such as those operated by ADMA Bio Centers, 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 Bio Centers’ facilities that is not used to manufacture our products or product candidates is sold to third-party customers in the United States, and other locations where we are approved globally under supply agreements or in the open “spot” market. As part of the purchase price to acquire the Biotest Assets, we agreed to transfer ownership of two of our plasma collection facilities to BPC on January 1, 2019.

RESULTS OF OPERATIONS

Critical Accounting Policies and Estimates

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 Accounting Principles Generally Accepted in the United States of America ("U.S. 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 U.S. 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. For a detailed discussion on the application of these and our other accounting policies, see Note 2 to the Consolidated Financial Statements included in the 2017 10-K.

Revenue Recognition

Revenues for the three and nine months ended September 30, 2018 are comprised of (i) revenues from Nabi-HB, (ii) product revenues from the sale of human plasma collected from our plasma collection centers segment; and (iii) license and other revenues primarily attributable to the out-licensing of RI-002 to Biotest to market and sell this product in Europe and selected countries in North Africa and the Middle East. Biotest has provided us with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay us certain amounts in the future if certain milestones are achieved. Deferred revenue is amortized into income for a period of approximately 22 years, the term of the Biotest license agreement.

Revenue from the sale of Nabi-HB is recognized when the product reaches the customer's destination. Nabi-HB revenue is recorded net of estimated customer prompt pay discounts and contractual allowances in accordance with managed care agreements, including wholesaler chargebacks, rebates, customer returns and other wholesaler fees.

Product revenues from the sale of human plasma collected at our plasma collection centers are recognized at the time of transfer of title and risk of loss to the customer, which generally occurs at the time of delivery.

For the nine months ended September 30, 2018, three customers represented an aggregate of 90% of our consolidated revenues, with BPC, Amerisource Bergen ("AB") and McKesson Corporation ("McKesson") representing 54%, 16% and 20%, respectively, of the Company's consolidated revenues. For the nine months ended September 30, 2017, sales to BPC represented 68% of the Company's consolidated revenues, and sales to SK Plasma Co., Ltd. ("SK") represented 8% of our consolidated revenues.

Accounts Receivable

Accounts receivable are reported at realizable value, net of allowances for contractual credits and doubtful accounts, which are recognized in the period the related revenue is recorded. At September 30, 2018, four customers represented an aggregate of 93% of our total accounts receivable, with McKesson, AB, BPC and Sanofi Pasteur S.A. ("Sanofi") representing approximately 35%, 25%, 22% and 11%, respectively, of our consolidated accounts receivable. At December 31, 2017, Sanofi and BPC represented 48% and 30%, respectively, of our total accounts receivable.

Cost of Product Revenue

Cost of product revenue includes expenses related to process development as well as scientific and technical operations when these operations are attributable to marketed products. When the activities of these operations are attributable to new products in development, the expenses are classified as research and development expenses. Expenses associated with remediating the issues identified in the Warning Letter for the three and nine months ended September 30, 2018 of approximately \$0.1 million and \$1.3 million, respectively, are expensed as incurred and are reflected in cost of product revenue. In addition, for the nine months September 30, 2018, all operating expenses associated with the Boca Facility, other than the limited Nabi-HB production that was capitalized into inventory, were expensed as incurred.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the grantee's requisite vesting period on a straight-line basis. For the purpose of valuing stock options granted to our employees, directors and officers, we use the Black-Scholes option pricing model. During the three and nine months ended September 30, 2018, we granted options to purchase an aggregate of 61,800 and 1,044,700 shares of Common Stock, respectively, to our directors and employees, and during the nine months ended September 30, 2018, we granted options to purchase 20,000 shares of Common Stock to a third party service provider. During the three and nine months ended September 30, 2017, we granted options to purchase an aggregate of 86,000 and 1,942,595 shares of Common Stock, respectively, to our directors and employees.

Research and Development Expenses

Our research and development ("R&D") costs are expensed as incurred, including costs associated with (i) planning and conducting clinical trials; (ii) plasma storage and transportation costs for RI-002 (iii) quality testing, validation, regulatory consulting and filing fees; and (iv) employees' compensation expenses directly related to R&D activities.

Impairment of Long-Lived Assets

We assess the recoverability of our long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the three and nine months ended September 30, 2018 and 2017, we determined that there was no impairment of our long-lived assets.

Goodwill is not amortized, but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. We have the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill and other intangible assets. If we were to conclude that this is the case, then we must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value, with the impairment loss recognized not to exceed the total amount of goodwill allocated to that reporting unit. We did not recognize any impairment charges related to goodwill for the nine months ended September 30, 2018.

Recent Accounting Pronouncements

On April 5, 2012, the Jumpstart Our Business Startups Act (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 of 1933, as amended (the "Securities Act"). However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our total annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we would cease to be an emerging growth company prior to the end of such five-year period. 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 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 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.

In May 2017, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2017-09, *Modification Accounting for Share-Based Payment Arrangements*, which amends the scope of modification accounting for share-based payment arrangements. The ASU provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718, *Compensation – Stock Compensation*. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. Adoption of this new guidance in 2018 did not have a material impact on our condensed consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (“ASU 2016-02”), 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. Based on the lease agreements we had in place as of September 30, 2018, and after giving effect to our obligation to transfer ownership of two of our plasma collection centers to BPC on January 1, 2019 (see Note 3 to the consolidated financial statements), we do not believe this new standard will have a material impact on our consolidated financial statements and related disclosures.

In May 2014, the FASB issued new guidance related to revenue recognition, ASU 2014-09, *Revenue from Contracts with Customers* (“ASC 606”), which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new guidance requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASC 606 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The new guidance became effective in calendar year 2018. Two methods of adoption are permitted: (a) full retrospective adoption, meaning the standard is applied to all periods presented; or (b) modified retrospective adoption, meaning the cumulative effect of applying the new guidance is recognized at the date of initial application as an adjustment to the opening retained earnings balance.

In March 2016, April 2016 and December 2016, the FASB issued ASU No. 2016-08, *Revenue From Contracts with Customers (ASC 606): Principal Versus Agent Considerations*, ASU No. 2016-10, *Revenue From Contracts with Customers (ASC 606): Identifying Performance Obligations and Licensing*, and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts with Customers*, respectively, which further clarify the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers*, narrow-scope improvements and practical expedients that provide clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards became effective for the Company in the first quarter of 2018.

We adopted the new standard and related updates effective January 1, 2018, using the modified retrospective method of adoption. Adoption of the new revenue recognition guidance did not have a material impact on our condensed consolidated financial statements.

Three Months Ended September 30, 2018 Compared to Three Months Ended September 30, 2017

The following table presents a summary of the changes in our results of operations for the three months ended September 30, 2018, our third fiscal quarter, compared to the three months ended September 30, 2017:

	Three Months Ended September 30,		
	2018	2017	
Revenues	\$ 4,230,310	\$ 4,729,411	\$ (499,101)
Cost of product revenue (exclusive of amortization expense shown below)	9,164,109	11,291,116	(2,127,007)
Gross loss	(4,933,799)	(6,561,705)	1,627,906
Research and development expenses	1,317,234	1,814,069	(496,835)
Plasma center operating expenses	1,973,338	1,582,694	390,644
Amortization of intangibles	211,235	273,828	(62,593)
Selling, general and administrative expenses	5,355,794	4,195,464	1,160,330
Loss from operations	(13,791,400)	(14,427,760)	636,360
Interest expense	(1,402,475)	(782,969)	(619,506)
Other income, net	58,390	8,014	50,376
Net loss	<u>\$ (15,135,485)</u>	<u>\$ (15,202,715)</u>	<u>\$ 67,230</u>

Revenues

We recorded total revenues of \$4.2 million during the three months ended September 30, 2018, as compared to \$4.7 million during the three months ended September 30, 2017, a decrease of \$0.5 million, or approximately 11%. The decrease is due to a \$0.6 million decrease in source plasma revenue from our ADMA Bio Centers operations, which was partially offset by a \$0.1 million increase in Nabi-HB revenue. The decrease in source plasma revenue is mainly due to the timing of shipments to certain customers in accordance with their agreements with us.

Cost of Product Revenue

Cost of product revenue was \$9.2 million for the three months ended September 30, 2018, as compared to \$11.3 million for the three months ended September 30, 2017, a decrease of \$2.1 million. The decrease is mainly due to a \$1.8 million reduction in facility remediation costs, as the compliance status of the Boca Facility was upgraded as a result of the FDA inspection that took place in April 2018. In addition, we experienced a \$0.7 million decrease in cost of product revenue related to Nabi-HB, as the Nabi-HB inventory sold in the third quarter of 2017 was carried at a higher value as a result of the Biotest Transaction (see Note 6 to the consolidated financial statements), resulting in higher cost of revenue in 2017. These decrease in cost of product revenue were partially offset by an increase in unabsorbed manufacturing costs related to the Boca Facility.

Research and Development Expenses

R&D expenses totaled \$1.3 million for the three months ended September 30, 2018, as compared to \$1.8 million for the three months ended September 30, 2017. The decrease is primarily due to fewer employees associated with R&D activities as we continue to focus more of our business on commercial operations in 2018 as compared to 2017. As a result of the Biotest Transaction, a number of ADMA employees that were previously contributing in R&D functions are now contributing more of their time to an FDA-approved facility generating commercial revenues.

Plasma Center Operating Expenses

Plasma center operating expenses were \$2.0 million for the three months ended September 30, 2018, as compared to \$1.6 million for the three months ended September 30, 2017. 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 operating expenses is mainly attributable to the opening of our third plasma center in Kennesaw, GA in December 2017.

Amortization of Intangibles

Amortization expense pertains to the amortization of intangible assets acquired in the Biotest Transaction (see Note 3 to the consolidated financial statements), and was \$0.2 million for the three months ended September 30, 2018, as compared to \$0.3 million for the three months ended September 30, 2017.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses were \$5.4 million for the three months ended September 30, 2018, an increase of \$1.2 million from the three months ended September 30, 2017. The increase was primarily due to increased headcount and related expenses of approximately \$0.6 million, increased legal and professional fees of \$0.2 million, branded prescription drug fees in 2018 of \$0.2 million, an increase in insurance expense of \$0.1 million and increased marketing costs in preparation for commercialization of BIVIGAM and RI-002 of \$0.1 million.

Loss from Operations

Our operating loss was \$13.8 million for the three months ended September 30, 2018, as compared to \$14.4 million for the three months ended September 30, 2017. The decrease in operating loss was mainly due to the reductions in cost of product revenue and R&D expenses, partially offset by increased SG&A and plasma center operating expenses and lower total revenues.

Interest Expense

Interest expense was \$1.4 million for the three months ended September 30, 2018, as compared to \$0.8 million for the three months ended September 30, 2017. The increase is due to higher outstanding debt in 2018 resulting from the refinancing of our senior debt in the fourth quarter of 2017 (see “Liquidity and Capital Resources”), as well as the increase in the interest rate on our senior debt and an increase in amortization of debt discount.

Net Loss

Our net loss was \$15.1 million for the three months ended September 30, 2018, as compared to \$15.2 million for the three months ended September 30, 2017, as the improvement in operating loss was offset by the increase in interest expense.

Nine Months Ended September 30, 2018 Compared to Nine Months Ended September 30, 2017

As a result of the Biotest Transaction, our operating results include the results of BTBU effective as of June 6, 2017. Therefore, our results of operations for the nine months ended September 30, 2018 are not comparable to the results of operations for the nine months ended September 30, 2017. The following table presents a summary of the changes in our results of operations for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017:

	Nine Months Ended September 30,		
	2018	2017	
Revenues	\$ 12,928,866	\$ 10,757,683	\$ 2,171,183
Cost of product revenue (exclusive of amortization expense shown below)	31,052,519	17,241,422	13,811,097
Gross (loss) profit	(18,123,653)	(6,483,739)	(11,639,914)
Research and development expenses	4,071,040	4,365,205	(294,165)
Plasma center operating expenses	5,545,240	4,662,340	882,900
Amortization of intangibles	633,704	346,849	286,855
Selling, general and administrative expenses	15,367,647	12,908,498	2,459,149
Loss from operations	(43,741,284)	(28,766,631)	(14,974,653)
Interest expense	(4,084,815)	(2,043,982)	(2,040,833)
Other income, net	120,641	34,440	86,201
Net loss	<u>\$ (47,705,458)</u>	<u>\$ (30,776,173)</u>	<u>\$ (16,929,285)</u>

Revenues

Revenues for the nine months ended September 30, 2018 were \$12.9 million, as compared to \$10.8 million during the nine months ended September 30, 2017, an increase of \$2.2 million, or approximately 20%. The increase is due to an increase in revenue attributable to the assets acquired in the Biotest Transaction of \$3.4 million, partially offset by a decrease in product revenue attributable to our plasma collection centers of \$1.2 million due to the timing of shipments to certain customers, and to increased competition from other local plasma donation centers which have opened in close proximity to our more established centers.

Cost of Product Revenue

Cost of product revenue was \$31.1 million for the nine months ended September 30, 2018, as compared to \$17.2 million for the nine months ended September 30, 2017. The increase is mainly attributable to our acquisition of the Boca Facility in June 2017, while our 2018 results include a full nine months of operating activities at the Boca Facility. As a result, we experienced a \$10.4 million increase in unabsorbed manufacturing costs related to the Boca Facility in 2018 as compared to 2017. We also incurred approximately \$2.9 million of costs related to the production of RI-002 and \$1.5 million of costs related to the production of BIVIGAM and the related intermediates, partially offset by lower facility remediation expenses in the amount of \$0.9 million.

Although we expect that the BIVIGAM and RI-002 conformance lots produced in 2017 and 2018 will be approved by the FDA and released for commercial sale, due to uncertainties at the time this inventory was produced surrounding the Warning Letter, the PAS related to improvements in the manufacturing process and the RI-002 BLA that must be approved by the FDA prior to this inventory being available for commercial release and sale, we have not capitalized these costs into inventory.

Research and Development Expenses

R&D expenses totaled \$4.1 million for the nine months ended September 30, 2018, as compared to \$4.4 million for the nine months ended September 30, 2017. The decrease is due to fewer employees whose activities are associated with R&D activities as we continue to focus more of our business on commercial operations in 2018 compared to 2017, partially offset by increased testing expense related to RI-002.

Plasma Center Operating Expenses

Plasma center expenses were \$5.5 million for the nine months ended September 30, 2018, as compared to \$4.7 million for the nine months ended September 30, 2017. The increase is mainly attributable to the opening of our third plasma center in Kennesaw, GA in December 2017.

Selling, General and Administrative Expenses

SG&A expenses were \$15.4 million for the nine months ended September 30, 2018, an increase of \$2.5 million from the nine months ended September 30, 2017. The increase reflects a full nine months of operations at the Boca Facility, as compared to four months of operating activity at the Boca Facility in 2017, resulting in higher expenses of \$6.3 million, partially offset by \$3.9 million of 2017 acquisition transaction expenses not present in 2018.

Amortization of Intangibles

Amortization expense was \$0.6 million for the nine months ended September 30, 2018, as compared to \$0.3 million for the nine months ended September 30, 2017, and reflects nine months of expense in 2018 and four months of expense in 2017.

Loss from Operations

Our operating loss was \$43.7 million for the nine months ended September 30, 2018, as compared to \$28.8 million for the nine months ended September 30, 2017. The increase in operating loss was mainly due to the \$13.8 million increase in cost of product revenue associated with the Boca Facility and, to a lesser extent, the increases in other operating expenses, partially offset by the \$2.2 million increase in total revenues.

Interest Expense

Interest expense was \$4.1 million for the nine months ended September 30, 2018, as compared to \$2.0 million for the nine months ended September 30, 2017. The increase is due to higher outstanding debt in 2018 resulting from the refinancing of our senior debt in the fourth quarter of 2017 and the \$15.0 million note issued to BPC in June 2017, as well as the increase in the interest rate on our senior debt and increased amortization of debt discount.

Net Loss

Our net loss was \$47.7 million for the nine months ended September 30, 2018, as compared to \$30.8 million for the nine months ended September 30, 2017, an increase of \$16.9 million, which is mainly due to the increase in operating loss and, to a lesser extent, the increase in interest expense.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2018, we had working capital of \$52.6 million, including cash and cash equivalents of \$42.4 million, and stockholders' equity of \$37.2 million, as compared to working capital of \$53.7 million, including cash and cash equivalents of \$43.1 million, and stockholders' equity of \$40.3 million as of December 31, 2017. We have had limited revenue from operations and have incurred an accumulated deficit of \$198.4 million since inception. For the nine months ended September 30, 2018 and 2017, we had negative cash flows from operations of \$43.9 million and \$23.9 million, respectively, and for the years ended December 31, 2017 and 2016 we had negative cash flows from operations of \$37.3 million and \$18.3 million, respectively. We have funded our operations to date primarily from the sale of our equity and debt securities, acquisition proceeds from the Biotest Transaction and loans from our principal stockholders.

We expect to continue to spend substantial amounts on product development, quality assurance, regulatory affairs, procurement of raw material plasma, manufacturing, marketing, sales and conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, some of which may be required by the FDA. We currently anticipate, based upon our projected revenue and expenditures, that our cash, cash equivalents, projected revenue and accounts receivable, along with the \$10.0 million we are able to access under the Credit Agreement (as defined below), will be sufficient to fund our operations, as currently conducted, into the second quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional capital prior to the end of the second quarter of 2019. This time frame may change based upon how quickly we are able to execute on our quality management systems' enhancement plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options available to us. We currently have no firm commitments for additional financing, and we cannot provide any assurance that we will be able to secure additional financing on terms that are acceptable to us, or at all. Failure to secure any necessary financing in a timely manner and on commercially reasonable terms could have a material adverse effect on our business plan and financial performance and we could be forced to delay or discontinue our product development, clinical trial or commercialization activities, delay or discontinue the approval efforts for any of our potential products, or potentially cease operations. In addition, we could also be forced to reduce or forgo sales and marketing efforts and forgo attractive business opportunities.

Furthermore, if the 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 candidates, 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 and 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. We may also decide to obtain additional debt financing or a bank credit facility, subject to the restrictions contained in the Credit Agreement, 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 additional indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other future financing alternatives.

Our long-term liquidity depends upon our ability to raise additional capital, fund our research and development and commercial programs and achieve commercial status for our products and product candidates in order to generate sufficient revenues to cover our operating expenses and meet our obligations on a timely basis. We believe that we will continue to incur losses and negative cash flows from operating activities through the foreseeable future. As such, these conditions raise substantial doubt about our ability to continue as a going concern.

On June 18, 2018, we completed an underwritten public offering of 9,623,430 shares of our Common Stock for gross proceeds of \$46.0 million. We received net proceeds from this offering, after underwriters' commissions and other offering expenses, of \$42.9 million. The net proceeds have been and will continue to be used, among other things, (i) for continued remediation and ongoing improvement and enhancements at the Boca Facility, (ii) to submit the PAS for, and relaunch of, BIVIGAM, (iii) to resubmit the RI-002 BLA, (iv) for expenses associated with obtaining with FDA approval of ADMA's third plasma collection facility, and (v) for general corporate purposes and other capital expenditures.

On November 13, 2017, we completed an underwritten public offering of 19,523,255 shares of Common Stock for gross proceeds of \$42.0 million. Net proceeds from this offering, after payment of underwriting discounts and offering expenses of \$2.8 million, were \$39.2 million. The proceeds from this offering were used for (i) the purchase of raw material inventory and the ramp-up of our manufacturing capabilities, (ii) continued remediation of the issues identified in the CRL and the Warning Letter and completion of our internal quality management systems overhaul, (iii) capital expenditures for the Boca Facility, (iv) product launch and medical education campaigns, (v) the build-out of our third plasma collection facility, (vi) research and development activities for our plasma collection programs and specialty plasma products, and (vii) working capital needs and general corporate purposes, including expenses associated with improving the FDA inspection classification relative to the Warning Letter, filing the PAS and obtaining marketing clearance for the relaunch of BIVIGAM and refiling the RI-002 BLA.

On October 10, 2017 (the "Marathon Closing Date"), we entered into a Credit Agreement (the "Credit Agreement") with Marathon Healthcare Finance Fund, L.P. ("Marathon" or the "Lender") and Wilmington Trust, National Association, as the administrative agent for the Lender (the "Administrative Agent"). The Credit Agreement provides for a senior secured term loan facility in an aggregate amount of up to \$40.0 million (collectively, the "Credit Facility"), comprised of (i) a term loan made on the Marathon Closing Date in the principal amount of \$30.0 million (the "Tranche One Loan"), and (ii) an additional term loan to be made in the maximum principal amount not to exceed \$10.0 million (the "Tranche Two Loan" and, together with the Tranche One Loan, the "Loans"), which Tranche Two Loan availability is subject to the satisfaction of certain conditions, including, but not limited to, those described below. The Loans each have a maturity date of April 10, 2022 (the "Maturity Date"), subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default (as defined in the Credit Agreement).

On the Marathon Closing Date, we used approximately \$17.0 million of the Tranche One Loan to retire and pay in full our previously existing credit facility, as amended, with Oxford Finance, LLC ("Oxford") and all of the obligations thereunder, including the end-of-term liability of \$1.8 million and prepayment penalties of \$0.2 million. We also (i) used \$5.5 million of the Tranche One Loan to pre-fund a debt service reserve account in accordance with the terms of the Credit Agreement, and (ii) paid diligence fees, legal and other expenses associated with the Credit Facility in the amount of approximately \$1.5 million, which fees exclude a deferred facility fee to Marathon equal to 9.20% of the Tranche One Loan payable at maturity. The remaining \$6.0 million of proceeds was used for the continued remediation of the issues identified in the CRL and the Warning Letter and for general corporate purposes.

The obligation of Marathon to make the Tranche Two Loan is subject to the satisfaction of certain conditions related to FDA approval for specified products and our financial condition, including, without limitation, the following: (a) (i) the FDA must validate the improved manufacturing process of BIVIGAM and (ii) not less than \$0.5 million in net revenue must be generated in calendar year 2018 from the sale in the United States of BIVIGAM; or (b) (i) the FDA must approve the commercialization of RI-002 and (ii) not less than \$0.5 million in net revenue must be generated in calendar year 2019 from the sale in the United States of RI-002.

On the Marathon Closing Date, we issued a promissory note in favor of the Administrative Agent in the principal amount of \$30.0 million (the “Tranche One Note”), evidencing our indebtedness resulting from the Tranche One Loan. Borrowings under the Credit Agreement bear interest at a rate per annum equal to LIBOR plus 9.50% with a 1% LIBOR floor; provided, however, that in the event that we achieve sales of not less than \$61.7 million for the 2018 calendar year and the Tranche Two Loan has been funded, then the interest rate on the borrowings under the Credit Agreement will decrease to LIBOR plus 7.75% with a 1% LIBOR floor. During an Event of Default under the Credit Agreement, the outstanding amount of indebtedness under the Credit Agreement will bear interest at a rate per annum equal to the interest rate then applicable to the borrowings under the Credit Agreement plus 5% per annum. Quarterly cash interest payments are due the first business day of each March, June, September and December, beginning on December 1, 2017. During the nine months ended September 30, 2018, the interest rate on the Tranche One Note ranged from 10.99% to 11.82%.

We will pay Marathon a facility fee in an amount equal to 9.20% of the amount funded, payment of which is deferred until the Maturity Date pursuant to the terms of the Credit Agreement. Commencing on October 10, 2020, and on the first business day of each month, we are required to make principal payments on the Tranche One Loan (and Tranche Two Loan in the event it shall have been funded) in equal monthly installments over 18 months, subject to certain conditions in the Credit Agreement. The outstanding principal amount of the Loans, together with all accrued interest thereon, is due on the Maturity Date.

Our obligations under the Credit Agreement are secured by a first-priority lien and security interest in substantially all of our assets, including a mortgage on the Boca Facility, and those of our subsidiaries as well as all of the equity interests in each subsidiary.

The Credit Agreement contains market representations and warranties, affirmative covenants, negative covenants, financial covenants, and conditions that are customarily required for similar financings. The affirmative covenants, among other things, require us to undertake various reporting requirements. The negative covenants restrict or limit our and our subsidiaries’ ability to, among other things, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes or changes to our business activities; sell or otherwise dispose of assets; repurchase stock, pay dividends; repay certain other indebtedness; engage in certain affiliate transactions; or enter into any other agreements that restrict our ability to make loan repayments. In addition, the terms of the Credit Agreement required the establishment of a debt service reserve account, and we are required to maintain a certain minimum level of liquidity at all times. Liquidity is defined in the Credit Agreement as cash held in the debt service reserve account and any other deposit account subject to a control agreement with the Administrative Agent, and the required liquidity amount is reflected as restricted cash in the accompanying consolidated balance sheets as of September 30, 2018 and December 31, 2017. The minimum liquidity requirement was \$4.0 million and \$5.5 million as of September 30, 2018 and December 31, 2017, respectively. On the Marathon Closing Date, \$5.5 million of the Tranche One Note proceeds was deposited into the debt service reserve account. On May 31, 2018, the Credit Agreement was amended to reduce the minimum liquidity requirement to \$5.25 million, and \$250,000 was released from the debt service reserve account to us on June 25, 2018. On June 26, 2018, the Lender and the Administrative Agent acknowledged that the Company had met the requirements regarding our leased properties as set forth in the Credit Agreement, and an additional \$1.25 million was released from the debt service reserve account to us.

The Credit Agreement also contains customary Events of Default which include, among others, non-payment of principal, interest or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts and events constituting a change of control. The occurrence of an Event of Default could result in, among other things, the termination of commitments under the Credit Facility and the declaration that all outstanding Loans are immediately due and payable in whole or in part.

In June 2017, we received \$27.5 million in connection with the Biotest Transaction, comprised of \$12.5 million in cash from BPC and an unsecured subordinated 6% note payable to Biotest in the amount of \$15.0 million. Also in June 2017, BPC provided us with a firm equity commitment to invest up to an additional \$12.5 million in future equity financings of the Company, and this equity commitment was satisfied in its entirety in the foregoing November 2017 public offering of Common Stock. In July 2018, BPC transferred to Biotest AG all of its obligations, rights, title and interest in the unsecured subordinated \$15.0 million note.

Cash Flows

The following table sets forth a summary of our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	\$ (43,885,558)	\$ (23,913,145)
Net cash (used in) provided by investing activities	(1,276,594)	17,223,727
Net cash provided by financing activities	42,922,067	10,375,942
Net change in cash and cash equivalents	(2,240,085)	3,686,524
Cash and cash equivalents, including restricted cash - beginning of period	48,607,574	9,914,867
Cash and cash equivalents, including restricted cash - end of period	<u>\$ 46,367,489</u>	<u>\$ 13,601,391</u>

Net Cash Used in Operating Activities

Cash used in operations for the nine months ended September 30, 2018 was \$43.9 million, an increase of \$20.0 million from the same period of a year ago, mainly due to the higher net loss in 2018. The following table illustrates the primary components of our cash flows from operations:

	Nine Months Ended September 30,	
	2018	2017
Net loss	\$ (47,705,458)	\$ (30,776,173)
Non-cash expenses, gains and losses	4,864,998	2,736,833
Changes in accounts receivable	(246,640)	(481,782)
Changes in inventories	(1,249,253)	(201,472)
Changes in prepaid expenses and other current assets	(80,295)	(969,042)
Changes in accounts payable and accrued expenses	359,813	6,505,796
Other	171,277	(727,305)
Cash used in operations	<u>\$ (43,885,558)</u>	<u>\$ (23,913,145)</u>

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2018 was \$1.3 million, consisting of capital expenditures at the Boca Facility and final build-out costs of our third plasma center. Although we have no specific material commitments for capital expenditures as of September 30, 2018, we expect our total capital expenditures will be between \$1.0 million and \$2.0 million for the remainder of fiscal 2018.

Net cash provided by investing activities was \$17.2 million for the nine months ended September 30, 2017, primarily consisting of a \$12.5 million equity infusion from BPC in accordance with the terms of the Biotest Transaction and \$5.4 million from the liquidation of short-term investments, partially offset by capital expenditures of \$0.7 million.

Net Cash Provided by Financing Activities

Cash provided by financing activities during the nine months ended September 30, 2018 was \$42.9 million, which was a result of the net proceeds received from the June 2018 public offering of our Common Stock. Net cash provided by financing activities totaled \$10.4 million for the nine months ended September 30, 2017, consisting primarily \$15.0 million of proceeds from the issuance of a subordinated note payable to Biotest in accordance with the terms of the Biotest Transaction, partially offset by \$4.4 of principal payments under our previously existing senior credit facility.

Effect of Inflation

Inflation or changing prices did not have a significant impact on our net sales, revenues or net loss in 2017, 2016 and 2015, or for the nine months ended September 30, 2018.

Off-Balance Sheet Arrangements

None.

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 Securities Exchange Act of 1934, as amended, (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 (the “SEC”) 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 September 30, 2018. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures as of September 30, 2018 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 principal executive officer and principal 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. 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.

Changes in Internal Control Over Financial Reporting

As we continue with the integration of the business processes and information systems in effect prior to the closing of the Biotest Transaction with those of ADMA BioManufacturing, we are modifying our internal control over financial reporting to address the integrated operations. The integration plan and related internal control modifications are expected to continue through our current fiscal year. Other than these integration-related changes, there have been no changes in our internal control over financial reporting during the quarter ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

We 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.

Risks Relating to our Business

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

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

Our long-term liquidity will depend upon our ability to raise additional capital, fund our research and development and commercial programs, establish and build out a commercial sales force and commercial infrastructure and meet our ongoing obligations. If we are unable to successfully raise additional capital prior to the end of the second quarter of 2019, we will likely not have sufficient cash flow and liquidity to fund our business operations as we currently operate, forcing us to potentially curtail our activities and significantly reduce or cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our Common Stock may decline. In addition, if we raise additional funds through license arrangements or through the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or assets or grant licenses on terms that are not favorable to us.

Based upon our projected revenue and expenditures for fiscal 2018, including regulatory and consulting fees for the remediation of the Warning Letter and ongoing discussions with the FDA, continuing implementation of our commercialization and expansion activities and certain other assumptions, we currently believe that our cash, cash equivalents, projected revenue and accounts receivable, along with the additional \$10.0 million we expect to be able to access through our existing senior credit facility will be sufficient to fund our operations, as currently conducted, into the second quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing before the end of the second quarter of 2019. This timeframe may change based upon how quickly we are able to execute on our quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options available to us. These estimates may also change based upon whether or when the FDA approves RI-002 or if any of our other assumptions change. We currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution to stockholders. Failure to secure necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan and financial performance and could delay, discontinue or prevent product development, clinical trials, commercialization activities or the approval of any of our potential products. In addition, we could be forced to reduce or forgo sales and marketing efforts and forgo attractive business opportunities.

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

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for RI-002. In response to our RI-002 BLA submission in 2015, in July 2016 the FDA issued the CRL. The CRL did not specify or request the need for any additional clinical trials or data; however, the CRL reaffirmed the issues set forth in the Warning Letter issued to Biotest relating to inspection issues identified at the Boca Facility. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies related to Chemistry, Manufacturing and Controls (“CMC”) and Good Manufacturing Practices (“GMP”) at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of our RI-002 BLA until, among other things, these deficiencies are resolved. Following the completion of the Biotest Transaction, we gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and our highest priority has been to remediate the outstanding compliance issues at the Boca Facility as indicated in the Warning Letter. We have been working with a consulting firm consisting of quality management systems and biologics production subject matter experts with extensive experience in remediating compliance and inspection issues related to quality management systems that manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified CMC and current good manufacturing practice (“cGMP”) issues and deficiencies. We believe that we have successfully closed out the April 2018 FDA inspection of the Boca Facility, however there can be no assurances as to the timing by which the FDA may make any determinations post-inspection concerning our compliance status. There can also be no assurances that our ongoing efforts to remediate the Warning Letter and other inspection issues and deficiencies at the Boca Facility will be effective or whether the FDA will accept these efforts. Failure to timely remediate the issues identified in the Warning Letter and other inspection issues and deficiencies and/or receive approval from the FDA would have a material adverse effect on our business, prospects, financial condition and results of operations. Additionally, we are unable to control the timing of FDA inspections, responses, meeting requests, teleconference requests, requests for clarifications and similar regulatory communications as well as whether or not the FDA will change its requirements, guidance or expectations.

We are currently not profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. For the years ended December 31, 2017 and 2016, we incurred net losses of \$43.8 and \$19.5 million, respectively, and for the nine months ended September 30, 2018 and 2017, we incurred net losses of \$47.7 million and \$30.8 million, respectively. From our inception in 2004 through September 30, 2018, we have incurred an accumulated deficit of \$198.4 million. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our operating expenses will increase substantially in the foreseeable future as we:

- remediate the outstanding compliance deficiencies identified by the FDA in the CRL and Warning Letter at the Boca Facility;
- seek regulatory approval(s);
- initiate commercialization and marketing efforts;
- implement additional internal systems, controls and infrastructure;

- hire additional personnel;
- expand and build out our plasma center network; and
- continue to integrate the Biotest Assets into our business.

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

Although our financial statements have been prepared on a going concern basis, we must raise additional capital before the end of the second quarter of 2019 to fund our operations in order to continue as a going concern.

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

We anticipate that our principal sources of liquidity will only be sufficient to fund our activities, as currently conducted, into the second quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing prior to the end of the second quarter of 2019. This time frame may change based upon how quickly we are able to execute on our quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options available to us. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional equity or debt capital, and we cannot provide any assurance that we will be successful in doing so. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the end of the second quarter of 2019.

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

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

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

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

Business interruptions could adversely affect our business.

ADMA Bio Centers operates FDA-licensed, GHA and KMFDS-certified source plasma collection facilities located in the United States, which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. Plasma collected from ADMA Bio Centers' facilities that is not used to manufacture our products and product candidates is sold to third-party customers in the United States and other locations where we are approved globally under supply agreements or in the open "spot" market. Furthermore, we have completed the construction of our third plasma collection facility, initiated collections for this facility in December 2017, and we received our FDA license for this facility in October 2018. Nabi-HB and BIVIGAM are manufactured at the Boca Facility, an FDA-licensed facility certified by the GHA. A portion of our revenues are dependent upon the continued operation of these facilities. Our operations are vulnerable to interruption by fire, weather related events such as hurricanes, wind and rain, other acts of God, electric power loss, telecommunications failure, equipment failure and breakdown, human error, employee issues and events beyond our control. We do not have detailed disaster recovery plans for our facilities nor do we have a backup manufacturing facility, other than our other facilities, or contractual arrangements with any other manufacturers in the event of a casualty to or destruction of any facility or if any facility ceases to be available to us for any other reason. If we are required to rebuild or relocate any of our facilities, a substantial investment in improvements and equipment would be necessary. We carry only a limited amount of business interruption insurance, which may not sufficiently compensate us for losses that may occur.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We depend on independent investigators and collaborators, such as universities and medical institutions, contract laboratories, clinical research organizations, contract manufacturers and consultants to conduct our preclinical, clinical trials, CMC testing and other activities under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our product-development programs, or if their performance is substandard, the approval of our FDA application(s), if any, and our introduction of new products, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed. Additionally, any change in the regulatory compliance status of any of our vendors may impede our ability to receive approval for our product candidates.

Historically a single customer has accounted for a significant amount of our total revenue and, together with a second customer, represented 78% of our total revenue for the year ended December 31, 2017 and, collectively with two other customers, represented an aggregate of 90% of our total revenue for the nine months ended September 30, 2018. Therefore, the loss of such single customer could have a material adverse effect on our business, results of operations and financial condition.

Historically, a significant amount of our total revenue is attributable to a single customer, BPC. For the year ended December 31, 2017, BPC and Sanofi represented 78% of our total revenue, with BPC representing 47% of our total revenue and Sanofi representing 31% of our total revenue. For the nine months ended September 30, 2018, three customers represented an aggregate of 90% of our consolidated revenues, with BPC, McKesson Corporation and AmerisourceBergen representing 54%, 20% and 16%, respectively, of our consolidated revenues. For the nine months ended September 30, 2017, sales to BPC represented 68% of our consolidated revenues, and sales to SK represented 8% of our consolidated revenues.

Although we expect this concentration to continue to decrease during 2018 as additional accretive revenues are generated from the Biotest Assets, BPC is still expected to account for a significant portion of our total revenue in fiscal 2018.

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

- our ability to sell our products at competitive prices;
- our ability to maintain features and quality standards for our products sufficient to meet the expectations of our customers; and
- our ability to produce and deliver a sufficient quantity of our products in a timely manner to meet our customers' requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. In addition, an employee, contractor, or other third party with whom we do business may attempt to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we have certain safeguards in place to reduce the risk of and detect cyber-attacks, including a company-wide cybersecurity policy, our information technology networks and infrastructure may be vulnerable to unpermitted access by hackers or other breaches, or employee error or malfeasance. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information and subject us to additional costs, which could adversely affect our business.

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

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

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

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

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

We currently operate under the Warning Letter due to issues identified by the FDA in their prior inspections while the Boca Facility was under Biotest's ownership and operational control. We engaged a consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems and which manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified CMC and cGMP issues and deficiencies. We believe that we have successfully closed out the April 2018 FDA inspection of the Boca Facility, however there can be no assurances as to the timing by which the FDA may make such a determination after any inspection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Healthcare Reform Law also creates new rebate obligations for our products under Medicare Part D, a partial, voluntary prescription drug benefit created by the U.S. federal government primarily for persons 65 years old and over. The Part D drug program is administered through private insurers that contract with CMS. Beginning in 2011, the Healthcare Reform Law generally requires that in order for a drug manufacturer's products to be reimbursed under Medicare Part D, the manufacturer must enter into a Medicare Coverage Gap Discount Program agreement with the Secretary of the U.S. Department of Health and Human Services, and reimburse each Medicare Part D plan sponsor an amount equal to 50% savings for the manufacturer's brand name drugs and biologics which the Part D plan sponsor has provided to its Medicare Part D beneficiaries who are in the "donut hole" (or a gap in Medicare Part D coverage for beneficiaries who have expended certain amounts for drugs). The Part D plan sponsor is responsible for calculating and providing the discount directly to its beneficiaries and for reporting these amounts paid to CMS's contractor, which notifies drug manufacturers of the rebate amounts it must pay to each Part D plan sponsor. The rebate requirement could adversely affect our future financial performance, particularly if contracts with Part D plans cannot be favorably renegotiated or the Part D plan sponsors fail to accurately calculate payments due in a manner that overstates our rebate obligation. Regarding access to our products, the Healthcare Reform Law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research ("CER"). While the stated intent of CER is to develop information to guide providers to the most efficacious therapies, outcomes of CER could influence the reimbursement or coverage for therapies that are determined to be less cost-effective than others. Should any of our products be determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our future financial prospects and results.

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

Developments in the worldwide economy may adversely impact our business.

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

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

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

Our operations have consumed substantial amounts of cash since inception. For the nine months ended September 30, 2018 and 2017, we had negative cash flows from operations of \$43.9 million and \$23.9 million, respectively, and for the years ended December 31, 2017 and 2016, we had negative cash flows from operations of approximately \$37.3 million and \$18.3 million, respectively. We expect to continue to spend substantial amounts on product development, including commercialization activities, procuring raw material plasma, manufacturing, conducting potential future clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We currently anticipate, based upon our projected revenue and expenditures, as well as the additional \$10.0 million we expect to be able to access under the Credit Agreement, that our current cash, cash equivalents and accounts receivable will be sufficient to fund our operations, as currently conducted, into the second quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing prior to the end of the second quarter of 2019. This time frame may change based upon how quickly we are able to execute on our operational initiatives and the various financing options available to us. However, if the assumptions underlying our estimated expenses prove to be incorrect, we may have to raise additional capital sooner than we currently expect. Until such time, if ever, as we can generate a sufficient amount of product revenue to achieve profitability, we expect to continue to finance our operations through additional equity or debt financings or corporate collaboration and licensing arrangements. If we are unable to raise additional capital as needed, we will have to delay, curtail or eliminate our product development activities, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, as well as future commercialization efforts.

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

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

Our cash balances could be adversely affected if the financial institutions in which we hold our cash were to fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. While we monitor the cash balances in our operating accounts on a daily basis and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit cash fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our cash balances; however, we can provide no assurance that access to our cash balances 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 (the "Sarbanes-Oxley Act") and related rules, our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we have been required to upgrade, and may need to implement further upgrades, to our financial, information and operating systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

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

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

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

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

Risks Associated with our Common Stock

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

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

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

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

An investment in our Common Stock is extremely speculative and there can be no assurance of any return on any such investment.

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

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

As of November 5, 2018 most of our 46,351,243 outstanding shares of Common Stock, as well as a substantial number of shares of our Common Stock underlying outstanding warrants, were available for sale in the public market, subject to certain restrictions with respect to sales of our Common Stock by our affiliates, either pursuant to Rule 144 under the Securities Act (“Rule 144”) or under effective registration statements. The 4,295,580 shares of Common Stock and the 8,591,160 NV Biotest Shares acquired by BPC in the Biotest Transaction were subject to a lock-up for six months after closing of the Biotest Transaction, which lock-up expired on December 6, 2017. For three years after the end of such six-month period, subject to certain limited exceptions, under the Stockholders Agreement, sales by the Biotest Trust (as the transferee of BPC’s remaining 10,109,534 shares of our Common Stock pursuant to the Biotest Transfer Agreement effective July 24, 2018) of our equity interests may not exceed 15% of the issued and outstanding Common Stock in any twelve-month period; provided, however, that if our market capitalization increases to double our market capitalization immediately following the closing of the Biotest Transaction, then the Biotest Trust may sell up to 20% of our issued and outstanding Common Stock in any twelve-month period; provided, further, that (x) if our market capitalization increases to triple our market capitalization immediately following the closing of the Biotest Transaction, or (y) upon the one-year anniversary of the Biotest Trust holding less than a 25% economic interest in us, then the Biotest Trust may sell its equity interests in us at any time (subject to applicable securities laws). On May 14, 2018, we, ADMA BioManufacturing and ADMA Bio Centers entered into the Biotest Transfer Agreement with BPC, Biotest AG, Biotest US and the Biotest Trust whereby BPC transferred to us, for no cash consideration, the 8,591,160 NV Biotest Shares, representing 100% of our then-issued and outstanding non-voting common stock. Immediately upon transfer of the NV Biotest Shares to us, the shares were retired and are no longer available for issuance. At the closing of the Biotest Transaction, we entered into the Registration Rights Agreement with BPC, pursuant to which the Biotest Trust, as BPC’s transferee, has, among other things, certain registration rights under the Securities Act with respect to its shares of our Common Stock, subject to certain transfer restrictions. Sales of a substantial number of shares of our Common Stock, or the perception that such sales may occur, may adversely impact the market price of our Common Stock.

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

Provisions of our A&R Certificate of Incorporation, our Bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. As of September 30, 2018, the Biotest Trust, our directors and executive officers and their affiliates beneficially owned in excess of 36% of the outstanding shares of our Common Stock. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings;
- the ability of our Board to institute a stockholder rights plan, also known as a poison pill, that would work to dilute our stock;

- classification of our Board and limitation on filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our Company; and
- authorization of the issuance of “blank check” preferred stock, with such designation rights and preferences as may be determined from time to time by the Board, without any need for action by stockholders.

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

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

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

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

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

Penny stock regulations may affect your ability to sell our Common Stock.

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

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

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

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

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

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

We will incur increased costs when we cease being an “emerging growth company.”

When we cease to be an “emerging growth company” and when our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 of the Sarbanes-Oxley Act (“Section 404”) will correspondingly increase. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

Our A&R Certificate of Incorporation authorizes the issuance of up to 10,000,000 shares of “blank check” preferred stock, with such designation rights and preferences as may be determined from time to time by the Board. Currently, our A&R Certificate of Incorporation authorizes the issuance of up to 75,000,000 shares of Common Stock, of which 23,842,273 shares remain available for issuance and may be issued by us without stockholder approval, and up to 8,591,160 shares of non-voting common stock, all of which were reacquired by us in May 2018 pursuant to the Biotest Transfer Agreement and were subsequently retired and are no longer available for issuance.

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: November 8, 2018

By: /s/ Adam S. Grossman
Name: Adam S. Grossman
Title: President and Chief Executive Officer

Date: November 8, 2018

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
10.1	<u>Assignment and Assumption Agreement (ADMA Loan), dated as of July 20, 2018, by and among Biotest AG, Biotest Pharmaceuticals Corporation, ADMA BioManufacturing, LLC and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 24, 2018).</u>
10.2	<u>Agreement to Transfer Land, dated as of July 20, 2018, by and among Biotest Real Estate Corp., Biotest AG, Biotest Pharmaceuticals Corporation, ADMA BioManufacturing, LLC and ADMA Biologics, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on July 24, 2018).</u>
10.3+	<u>Amendment #1 to the Plasma Supply Agreement, dated as of July 19, 2018, by and between Biotest Pharmaceuticals Corporation and ADMA BioManufacturing, LLC (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2018).</u>
10.4+	<u>Amendment to Plasma Purchase Agreement, dated as of July 19, 2018, by and between Biotest Pharmaceuticals Corporation and ADMA BioManufacturing, LLC (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2018).</u>
31.1*	<u>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.</u>
31.2*	<u>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.</u>
32.1**	<u>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.</u>
32.2**	<u>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.</u>
101*	The following materials from ADMA Biologics, Inc.'s Form 10-Q for the quarter ended September 30, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2018 (Unaudited) and December 31, 2017, (ii) Condensed Consolidated Statements of Operations (Unaudited) for the three and nine months ended September 30, 2018 and 2017, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited) for the nine months ended September 30, 2018, (iv) Condensed Consolidated Statements of Cash Flows (Unaudited) for the nine months ended September 30, 2018 and 2017, and (v) Notes to (Unaudited) Condensed Consolidated Financial Statements.

* Filed herewith.

** In accordance with SEC Release 33-8238, Exhibit 32.1 and 32.2 are being furnished and not filed.

+ Confidential treatment has been granted with respect as to certain portions of this exhibit. Such portions have been redacted and submitted separately to the SEC.

**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.;
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: November 8, 2018

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.;
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: November 8, 2018

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer (Principal
Financial and Accounting Officer)

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
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 September 30, 2018, 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: November 8, 2018

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 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 September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Brian Lenz, 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: November 8, 2018

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer (Principal
Financial and Accounting Officer)