

ADMA BIOLOGICS, INC.  
Form 10-Q  
November 03, 2017

**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, 2017

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-36728

**ADMA BIOLOGICS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  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. (Check one):

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
(Do not check if a smaller reporting company)	Emerging growth company <input checked="" type="checkbox"/>

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 1, 2017, there were 25,793,404 shares of the issuer's common stock outstanding, comprised of 17,202,244 shares of voting common stock and 8,591,160 shares of non-voting common stock.

## ADMA BIOLOGICS, INC. AND SUBSIDIARIES

## INDEX

## PART I FINANCIAL INFORMATION

Item 1.	Financial Statements	
	<u>Condensed Consolidated Balance Sheets as of September 30, 2017 (Unaudited) and December 31, 2016</u>	1
	<u>Condensed Consolidated Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2017 and 2016</u>	2
	<u>Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit) (Unaudited) for the Nine Months Ended September 30, 2017</u>	3
	<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2017 and 2016</u>	4
	<u>Notes to (Unaudited) Condensed Consolidated Financial Statements</u>	5
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	26
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk.</u>	42
Item 4.	<u>Controls and Procedures.</u>	43
PART II OTHER INFORMATION		
Item 1.	<u>Legal Proceedings.</u>	44
Item 1A.	<u>Risk Factors.</u>	44
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds.</u>	67
Item 3.	<u>Defaults Upon Senior Securities.</u>	67
Item 4.	<u>Mine Safety Disclosures.</u>	67
Item 5.	<u>Other Information.</u>	67
Item 6.	<u>Exhibits.</u>	67
	<u>SIGNATURES</u>	68

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.

Table of Contents

**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 of our recent acquisition of certain assets from Biotest Pharmaceuticals Corporation (“BPC”), 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 of Bivigam once the deficiencies in the November 2014 warning letter (the “Warning Letter”) with respect to outstanding issues at the plasma fractionation facility in Boca Raton, FL acquired from BPC in June 2017 have been resolved to the satisfaction of the U.S. Food and Drug Administration (the “FDA”), as well as a positive review of the optimized manufacturing process under a Prior Approval Supplement by the FDA;

our ability to successfully resubmit to the FDA our Biologics License Application (the “BLA”) for our lead pipeline product candidate, RI-002, once the deficiencies identified in the July 2016 Complete Response Letter (the “CRL”) have been resolved by us and/or our third party vendors to the satisfaction of the FDA, and other requests for information included therein have been provided by us;

our plans to develop, manufacture, market, launch and build our own commercial infrastructure and commercialize RI-002 and the success of such efforts;

the safety, efficacy and expected timing of and our ability to obtain and maintain regulatory approvals for our products and product candidates, including the timeframe within which we may receive approval from the FDA, if at all, of our BLA resubmission for RI-002 and the labeling or nature of any such approvals;

the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals;

our dependence upon 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 as well as RI-002 for any purpose by physicians, patients or payers;
  
  - concurrence by the FDA with our conclusions and the satisfaction by us of its guidance;
  
- the comparability of results of our immune globulin products to other comparably run intravenous immunoglobulin (“IVIG”) clinical trials;
  
- the potential of RI-002 and Bivigam to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease (“PIDD”);
  
- our ability to market and promote Nabi-HB in the competitive environment and to generate meaningful revenues;

Table of Contents

- our intellectual property position, including our expectations of the scope of patent protection with respect to RI-002, or other future pipeline product candidates;
- our manufacturing capabilities, third-party contractor capabilities and strategy;
- our plans relating to manufacturing, supply and other collaborative agreements;
- our estimates regarding expenses, capital requirements and the need for additional financing;
- possible or likely reimbursement levels for our currently marketed products and, if any, if and when RI-002 is approved for marketing;
- estimates regarding market size, projected growth and sales 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.



Table of ContentsPART I  
FINANCIAL INFORMATION

## Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2017 (Unaudited)	December 31, 2016 (Note 2)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 13,601,391	\$ 9,914,867
Short-term investments	—	5,390,184
Accounts receivable, net	1,499,809	1,018,027
Inventories	13,418,971	5,020,146
Prepaid expenses and other current assets	2,078,509	313,914
Assets held for sale	845,389	—
Total current assets	31,444,069	21,657,138
Property and equipment, net	29,755,541	2,000,784
Intangible assets, net	5,737,175	—
Goodwill	3,529,509	—
Assets to be transferred under purchase agreement	1,596,493	—
Deposits and other assets	750,693	27,163
<b>TOTAL ASSETS</b>	<b>\$ 72,813,480</b>	<b>\$ 23,685,085</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 9,156,341	\$ 2,564,681
Accrued expenses	3,860,121	2,385,356
Current portion of notes payable	—	6,111,111
Current portion of deferred revenue	145,154	145,154
Other current liabilities	177,250	16,559
Total current liabilities	13,338,866	11,222,861
Notes payable, net of discount	14,534,340	12,321,640
End of term liability, notes payable	1,790,000	1,790,000
Deferred revenue, net of current portion	2,582,908	2,690,033
Note payable - related party, net of discount	14,834,696	—
Obligation to transfer assets under purchase agreement	12,621,844	—
Other non-current liabilities	118,318	117,813
<b>TOTAL LIABILITIES</b>	<b>\$ 9,820,972</b>	<b>\$ 28,142,347</b>



COMMITMENTS AND CONTINGENCIES	—	—
STOCKHOLDERS' EQUITY (DEFICIT)		
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, 17,202,244 and 12,886,741 shares issued and outstanding	1,722	1,289
Common Stock - non-voting, \$0.0001 par value, 8,591,160 shares authorized, 8,591,160 and 0 shares issued and outstanding	859	—
Additional Paid-In Capital	150,700,918	102,476,267
Accumulated Deficit	(137,710,991)	(106,934,818)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	12,992,508	(4,457,262 )
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$72,813,480	\$23,685,085

See notes to (unaudited) condensed consolidated financial statements.

Table of Contents**ADMA BIOLOGICS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
<b>REVENUES:</b>				
Product revenue	\$ 4,693,703	\$ 2,902,155	\$ 10,650,558	\$ 7,226,368
License and other revenue	35,708	35,708	107,125	107,125
Total Revenues	4,729,411	2,937,863	10,757,683	7,333,493
<b>OPERATING EXPENSES:</b>				
Cost of product revenue (exclusive of amortization expense shown below)	11,291,116	1,735,771	17,241,422	4,346,433
Research and development	1,814,069	1,677,263	4,365,205	7,104,864
Plasma centers	1,582,694	1,482,586	4,662,340	4,057,306
Amortization of intangibles	273,828	—	346,849	—
Selling, general and administrative	4,195,464	1,779,115	12,908,498	5,211,148
<b>TOTAL OPERATING EXPENSES</b>	<b>19,157,171</b>	<b>6,674,735</b>	<b>39,524,314</b>	<b>20,719,751</b>
<b>LOSS FROM OPERATIONS</b>	<b>(14,427,760 )</b>	<b>(3,736,872 )</b>	<b>(28,766,631 )</b>	<b>(13,386,258 )</b>
<b>OTHER INCOME (EXPENSE):</b>				
Interest income	8,014	11,605	34,440	37,130
Interest expense	(782,969 )	(605,972 )	(2,043,982 )	(1,611,411 )
Other income	—	—	—	4,496
<b>OTHER EXPENSE, NET</b>	<b>(774,955 )</b>	<b>(594,367 )</b>	<b>(2,009,542 )</b>	<b>(1,569,785 )</b>
<b>NET LOSS</b>	<b>\$ (15,202,715 )</b>	<b>\$ (4,331,239 )</b>	<b>\$ (30,776,173 )</b>	<b>\$ (14,956,043 )</b>
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	<b>\$ (0.59 )</b>	<b>\$ (0.34 )</b>	<b>\$ (1.67 )</b>	<b>\$ (1.26 )</b>
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:</b>				
Basic and Diluted	25,790,805	12,886,741	18,415,468	11,906,276

See notes to (unaudited) condensed consolidated financial statements.



Table of Contents**ADMA BIOLOGICS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN  
STOCKHOLDERS' EQUITY (DEFICIT)****(Unaudited)****For the Nine Months Ended September 30, 2017**

	Common Stock		Non-Voting		Additional	Accumulated	Total
	Voting	Amount	Shares	Amount	Paid-in	Deficit	
	Shares				Capital		
Balance - January 1, 2017	12,886,741	\$1,289	—	\$—	\$102,476,267	\$(106,934,818)	\$(4,457,262 )
Stock-based compensation	—	—	—	—	1,052,970	—	1,052,970
Shares issued in connection with acquisition	4,295,580	430	8,591,160	859	47,164,180	—	47,165,469
Stock options exercised	19,923	3	—	—	7,501	—	7,504
Net loss	—	—	—	—	—	(30,776,173 )	(30,776,173)
Balance - September 30, 2017	17,202,244	\$1,722	8,591,160	\$859	\$150,700,918	\$(137,710,991)	\$12,992,508

See notes to (unaudited) condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2017	2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(30,776,173)	\$(14,956,043)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,231,265	351,702
Loss on disposal of fixed assets	4,155	—
Stock-based compensation	1,052,970	996,088
Amortization of debt discount	555,568	482,878
Amortization of license revenue	(107,125 )	(107,125 )
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable	(481,782 )	(403,063 )
Inventories	(201,472 )	(1,171,961 )
Prepaid expenses	(969,042 )	(370,631 )
Other assets	(723,530 )	—
Accounts payable	5,228,096	689,366
Accrued expenses	1,277,700	(143,586 )
Other current liabilities	(3,775 )	(22,920 )
Net cash used in operating activities	(23,913,145)	(14,655,295)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Sales of short-term investments	5,390,184	—
Purchase of short-term investments	—	(4,658,514 )
Purchase of property and equipment	(666,457 )	(63,386 )
Cash acquired in acquisition transaction	12,500,000	—
Net cash provided by (used in) investing activities	17,223,727	(4,721,900 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Principal payments on notes payable	(4,444,444 )	—
Proceeds from issuance of common stock, net of offering expenses	—	12,900,541
Proceeds from the exercise of stock options	7,504	—
Proceeds from issuance of related party note payable	15,000,000	—
Proceeds from issuance of note payable	—	4,000,000
Payment of debt issuance costs	(174,839 )	(47,104 )
Payments of leasehold improvement loan	(12,279 )	(11,226 )
Net cash provided by financing activities	10,375,942	16,842,211
Net increase (decrease) in cash and cash equivalents	3,686,524	(2,534,984 )

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-Q

Cash and cash equivalents - beginning of period	9,914,867	10,440,959
Cash and cash equivalents - end of period	\$13,601,391	\$7,905,975

See notes to (unaudited) condensed consolidated financial statements.

Table of Contents

**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 and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and prevention of certain infectious immunological 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 BioCenters”). ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of the Biotest Therapy Business Unit (“BTBU”) of Biotest Pharmaceuticals Corporation (“BPC” and, together with Biotest AG, “Biotest”) as more fully described below. ADMA BioCenters is the Company’s source plasma collection business, with facilities located in Norcross, GA and Marietta, GA. These facilities have approved licenses with the U.S. Food and Drug Administration (the “FDA”) and certifications from the German Health Authority (the “GHA”) and the Korean Ministry of Food and Drug Safety. ADMA BioCenters supplies ADMA with a portion of its raw material plasma for the manufacture of RI-002, ADMA’s lead pipeline product candidate, which the Company is currently developing for the treatment of Primary Immune Deficiency Disease (“PIDD”).

As discussed in Note 3, on June 6, 2017, ADMA completed the acquisition of certain assets (the “Biotest Assets”) of BTBU, which includes 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”). In addition to Nabi-HB and Bivigam, BTBU also provides contract manufacturing services for certain clients, including the sale of intermediate by-products. 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.

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.

Concurrent with the closing of the Biotest Transaction, the Company received a cash infusion from Biotest in the amount of \$12.5 million and a \$15.0 million loan from Biotest evidenced by a 6% subordinated note payable to BPC with a maturity of 5 years (see Note 4). In addition, BPC committed to participate in any future equity offering or private placement undertaken by the Company in an amount equal to \$12.5 million.

Prior to the closing of the Biotest Transaction, 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 Biologics License Application for RI-002 (the "BLA") for the treatment of PIDD. In July 2016, the FDA issued a Complete Response Letter (the "CRL") to the Company for the BLA. While the CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in the BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002, the 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 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. Following the completion of the Biotest Transaction, ADMA now has control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and the Company's highest priority is to remediate the outstanding compliance issues that were identified at the Boca Facility in the Warning Letter. The Company is currently working with a consulting firm consisting of quality management systems and biologics production subject matter experts in preparation for a re-inspection by the FDA in order to improve the FDA inspection classification relative to the Warning Letter compliance issues as indicated in the CRL, and the Company expects to be inspection-ready for the FDA by the end of 2017. Once the Warning Letter status is improved following the FDA inspection, the Company anticipates that it will be in a position to refile its BLA for RI-002 during the middle of 2018.



Table of Contents

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**

**NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

As of September 30, 2017, the Company had working capital of \$18.1 million, including \$13.6 million of cash and cash equivalents. Based upon the Company's current projected revenue and expenditures for 2017, including regulatory and consulting fees for the remediation of the Warning Letter and ongoing discussions with the FDA, 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 equity commitment from Biotest, are sufficient to fund ADMA's operations, as currently conducted, through the end of the first quarter of 2018. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, the Company will need to raise additional capital prior to the end of the first quarter of 2018. 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, commercial manufacturing ramp-up activities and the various financing options being explored. The Company currently has no firm commitments for additional financing other than the equity commitment from Biotest, 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, 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 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, 2017 of \$137.7 million. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities to fund its research and development, commercial programs and meet its obligations on a timely basis through the foreseeable future. As such, these factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of asset carrying amounts and the classification of liabilities that might be necessary from the outcome of this uncertainty.

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.

Table of Contents

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**

**NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**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 related notes thereto as of and for the year ended December 31, 2016 included in the Company’s Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the “SEC”) on February 24, 2017. 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, 2017 and its results of operations for the three and nine months ended September 30, 2017 and 2016 and cash flows for the nine months ended September 30, 2017 and 2016.

During the three and nine months ended September 30, 2017 and 2016, comprehensive loss was equal to the net loss amounts presented for the respective periods in the accompanying condensed consolidated interim statements of operations. In addition, certain prior year balances have been reclassified to conform to the current presentation. Specifically, the non-current portion of the Company’s deferred rent liability and leasehold improvement loan have been reclassified to other non-current liabilities and the current portion of the Company’s leasehold improvement loan has been reclassified to other current liabilities in the accompanying balance sheet as of December 31, 2016. Operating results for the nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2017.

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, valuation of inventory, assumptions used in the fair value determination of stock-based compensation, warrants, and the allowance for the valuation of future tax benefits.

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, will be 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, short-term investments 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 loan and security agreement with Oxford Finance, LLC (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, 2017 (see Notes 3 and 4), which is held by a principal stockholder of the Company and was issued concurrent with an acquisition transaction with such stockholder, the Company has concluded that an estimation of fair value for this note is not practicable.

Table of Contents**ADMA BIOLOGICS, INC. AND SUBSIDIARIES****NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**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, 2017 and December 31, 2016, a single customer accounted for 58% and 95%, respectively, of the Company's total accounts receivable.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill at September 30, 2017 and December 31, 2016 was \$3.5 million and \$0, respectively. All of the Company's goodwill is attributable to its ADMA BioManufacturing business segment. The following table presents the changes in the carrying amount of goodwill during the nine months ended September 30, 2017:

Balance as of January 1, 2017	\$—
Goodwill recorded in connection with the acquisition of the Biotest Assets	3,529,509
Balance as of September 30, 2017	\$3,529,509

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 two-step goodwill impairment process.

The first step compares a reporting unit's fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit's goodwill impairment loss, if any. Step two compares the carrying value of the reporting unit's goodwill to its implied fair value, which is the fair value of the reporting unit less the fair value of the unit's assets and liabilities, including identifiable intangible assets. If the implied fair value of goodwill is less than its carrying amount, a goodwill impairment loss is recognized. The Company performs its annual goodwill impairment test as of October 1 of each year.

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 nine months ended September 30, 2017 and 2016, the Company determined that there was no impairment of its long-lived assets.

Revenue recognition

Revenues for the nine months ended September 30, 2017 are comprised of (i) revenues from Nabi-HB, (ii) product revenues from the sale of normal source human plasma collected from the Company's 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 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.

Table of Contents

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**

**NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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 shipment. Product revenues are recognized at the time of delivery if the Company retains the risk of loss during shipment. Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement have been completed.

For the nine months ended September 30, 2017, two of the Company's customers, SK Plasma Co., Ltd. ("SK") and BPC, represented 76% of the Company's total revenues, with BPC representing approximately 68% of the Company's total revenues and SK representing approximately 8% of the Company's total revenues. For the nine months ended September 30, 2016, sales to BPC and SK represented 83% and 12%, respectively, 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. Additionally, expenses associated with remediating the issues identified in the Warning Letter for the three and nine months ended September 30, 2017 in the amount of \$2.0 million and \$2.5 million, respectively, are expensed as incurred and are reflected in cost of product revenue in the accompanying consolidated statements of operations. As the Boca Facility did not resume production until late in the third quarter of 2017, all operating expenses associated with the facility, other than the Nabi-HB production that was capitalized into inventory, have been expensed as incurred since acquisition.

Loss per common share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. For purposes of computing basic and diluted loss per share, the non-voting class of common stock (see Note 3) 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 net loss per share is calculated by dividing net loss attributable to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of shares of common stock, including the non-voting class 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 in the diluted net loss per share computation is excluded to the extent that it would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented. For the nine months ended September 30, 2017 and 2016, the following securities were excluded from the calculation of diluted loss per common share because of their anti-dilutive effects:



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

	For the nine months ended September 30,	
	2017	2016
Stock options	3,282,792	1,535,187
Warrants	188,859	300,446
	3,471,651	1,835,633

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 ended September 30, 2017, the Company granted stock options to purchase 86,000 and 1,942,595 shares of common stock, respectively, to its directors and employees. During the three and nine months ended September 30, 2016, the Company granted stock options to purchase 0 and 100,984 shares of common stock, respectively, to its directors and employees.

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. 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. The ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. The Company does not expect this new guidance to have a material impact on its condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations – Clarifying the Definition of a Business*, which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. The Company adopted this standard in the second quarter of 2017 and the adoption of this standard did not have a material impact on its condensed consolidated financial statements as of and for the nine months ended September 30, 2017.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other (Topic 350)*, which removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under the ASU, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The ASU is effective prospectively for fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company does not expect this new guidance to have a material impact on its condensed consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash*, which clarifies guidance and presentation related to restricted cash in the statement of cash flows, including stating that restricted cash should be included within cash and cash equivalents in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, with early adoption permitted, and is to be applied retrospectively. The Company will adopt this standard in the fourth quarter of 2017, and it is not expected to have a material impact on the Company's consolidated financial statements.

Table of Contents

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**

**NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. The Company adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on its condensed consolidated financial statements as of and for the nine months ended September 30, 2017.

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

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes*, which includes amendments that require deferred tax liabilities and assets be classified as non-current in a classified statement of financial position. The amendments in this ASU are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted as of the beginning of an interim or annual reporting period. The amendments may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company adopted this standard in the second quarter of 2017. As the Company carried a full valuation allowance against its deferred tax assets as of September 30, 2017 and December 31, 2016, adoption of this standard did not have a material impact on its condensed consolidated financial statements.

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805), Simplifying the Accounting for Measurement-Period Adjustments*, which includes amendments that require an acquirer to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this ASU require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the changes to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in this ASU require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied

prospectively to adjustments to provisional amounts that occur after the effective date of the ASU with earlier application permitted for financial statements that have not yet been made available for issuance. The Company adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on its condensed consolidated financial statements as of and for the nine months ended September 30, 2017.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. The standard requires entities to measure most inventory “at the lower of cost and net realizable value,” thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures, one of which is net realizable value). The Company adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on the Company’s condensed consolidated financial statements as of and for the nine months ended September 30, 2017.

Table of Contents

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**

**NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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 becomes effective in calendar year 2018 and early adoption in calendar year 2017 is permitted. 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 will be effective for the Company beginning in the first quarter of 2018. Early adoption is permitted.

ADMA will adopt the new standard and related updates effective January 1, 2018, and intends to use the modified retrospective method of adoption. The Company has undertaken an initial impact analysis, which includes reviewing the terms and conditions of ADMA’s existing customer contracts and applying the five discrete criteria required for recognizing revenue as set forth in ASU 2014-09. Based upon its preliminary analysis undertaken through September 30, 2017, the Company currently does not expect the new revenue recognition guidance to have a material impact on its consolidated financial statements, and expects to conclude such analysis by December 31, 2017. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may, in conjunction with the completion of the Company’s overall assessment of the new guidance, impact the Company’s current conclusions.

**3.**

**ACQUISITION**

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-Q

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 expands the Company's product offering with two FDA-approved products and provides 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 items 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 non-voting shares of common stock. The Company will also transfer ownership of two of its plasma centers to Biotest on January 1, 2019 as additional consideration.

The purchase price was calculated as follows:

Issuance of 12,886,740 shares of common stock (voting and non-voting) valued at \$3.66 per share	\$47,165,468
Transfer of two plasma collection centers	12,621,844
Total purchase price	\$59,787,312

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

The following table summarizes the preliminary allocation of the purchase consideration to the assets acquired and liabilities assumed based on their estimated fair values:

Cash	\$ 12,500,000
Inventory	8,197,354
Land and buildings	20,000,000
Property and equipment	8,209,800
Assets held for sale	845,389
Other current assets	795,553
Trademark and other intangible rights to Nabi-HB	4,100,046
Right to intermediates	907,421
Customer contract	1,076,557
Goodwill	3,529,509
Liabilities assumed	(374,317 )
Total purchase price	\$59,787,312

The Company engaged various third party valuation specialists to determine the fair value of the land and buildings, property and equipment, right to intermediates, customer contract and Nabi-HB intangible assets, as well as the assets held for sale. Some of the valuations and underlying analyses that were performed are preliminary and are subject to change upon finalization of more detailed analyses of the facts and circumstances that existed at the date of the transaction. Any such changes would change the allocation of the purchase price. Therefore, the foregoing purchase price allocation is preliminary and subject to change within the measurement period.

Assets held for sale reflects certain manufacturing equipment acquired in the transaction that will not be utilized in the manufacture or development of any of the Company's current products or product candidates. The Company expects that the sale of these assets will be completed within one year from the date of the acquisition transaction. Goodwill is expected to be deductible for tax purposes.

As a result of the foregoing transaction, BPC became a principal stockholder and Biotest became a related party of the Company. 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 Company incurred a total of approximately \$5.8 million in transaction closing costs, which were expensed as incurred as selling, general and administrative expenses in the consolidated statement of operations. For the three and nine months ended September

30, 2017, transaction closing costs amounted to approximately \$0.1 million and \$3.9 million, respectively.

The following unaudited pro forma summary presents consolidated information of the Company as if the business combination had occurred on January 1, 2016. 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.



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
As reported	\$ 4,729,411	\$ 2,937,863	\$ 10,757,683	\$ 7,333,493
Proforma	\$ 4,729,411	\$ 19,608,202	\$ 29,021,453	\$ 63,484,513
Net loss				
As reported	\$ (15,202,715 )	\$ (4,331,239 )	\$ (30,776,173 )	\$ (14,956,043 )
Proforma	\$ (15,202,715 )	\$ (21,484,499 )	\$ (40,029,464 )	\$ (51,967,975 )
Basic and diluted net loss per share:				
As reported	\$ (0.59 )	\$ (0.34 )	\$ (1.67 )	\$ (1.26 )
Proforma	\$ (0.59 )	\$ (0.83 )	\$ (1.55 )	\$ (2.10 )

**4.****DEBT**

A summary of outstanding senior notes payable is as follows:

	September 30, 2017	December 31, 2016
Oxford - Gross proceeds	\$ 20,000,000	\$ 20,000,000
Paydown of principal balance	(4,444,444 )	—
	15,555,556	20,000,000
Less:		
Debt discount	(1,021,216 )	(1,567,249 )
Current portion	—	(6,111,111 )
Senior notes payable	\$ 14,534,340	\$ 12,321,640

Senior Notes Payable

On June 19, 2015, the Company entered into a Loan and Security Agreement (the “LSA”) with Oxford Finance, LLC (“Oxford”), for up to \$21.0 million of debt financing in two term loan tranches. The first term loan tranche of \$16.0

million from the LSA (the “Term A Loan”) was primarily used to repay the Company’s previous debt facility with Hercules Technology Growth Capital, Inc. dated December 2012. On May 13, 2016, the Company amended the LSA with Oxford (the “Amended LSA”) which provided ADMA with an additional \$4.0 million term loan (the “Term B Loan”), which brings the total principal amount borrowed to \$20.0 million. The outstanding term loans bear interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three-month U.S. LIBOR rate (as reported in *The Wall Street Journal*) on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.54% on the outstanding principal balance. The effective interest rates for the Term A Loan and the Term B Loan, including backend fees equal to 8.95% of the total funded amount, are 11.4% and 13.04%, respectively. The Company began repaying the principal balance on February 1, 2017 in equal installments for a period of 36 months, unless accelerated as a result of certain events of default. The backend fees are due at the earlier of loan maturity or prepayment, with all term loans maturing no later than January 1, 2020. As of September 30, 2017 and December 31, 2016, the loans are secured by the Company’s assets, except for its intellectual property (which is subject to a negative pledge). The LSA contains customary representations, warranties and covenants, including limitations on incurring indebtedness, engaging in mergers or acquisitions and making investments, distributions or transfers. The Company was in compliance with all such covenants as of September 30, 2017.

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

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

Pursuant to the Amended LSA, (i) the Company paid a total facility fee of \$125,000; (ii) certain adjustments were made to the time periods for any applicable prepayment fees; and (iii) certain defined terms were adjusted, including a new February 1, 2017 amortization date. The Amended LSA further provided for customary representations, warranties and covenants for the Company. Except as otherwise amended, the Amended LSA did not alter the terms of the LSA.

On October 10, 2017, the Company entered into a Credit Agreement (the "Credit Agreement") with Marathon Healthcare Finance Fund, L.P. ("Marathon" or the "Lender") where by the Company received a \$30.0 million senior secured term loan from Marathon. A portion of the net proceeds was used to retire all outstanding amounts due under the Amended LSA (see Note 13).

Related Party Note Payable

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

	September 30, 2017	December 31, 2016
Biotest - Gross proceeds	\$ 15,000,000	\$ —
Less:		
Debt discount	(165,304 )	—

Note payable - related party \$ 14,834,696 \$ —

In connection with the acquisition of the Biotest Assets (see Note 3), ADMA BioManufacturing issued a subordinated note payable to BPC 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 the senior note payable with Oxford. 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, 2017. The Company incurred \$0.2 million of debt issuance costs in connection with the issuance of this note, which were recorded as a debt discount. The debt discount is being amortized as interest expense over the term of the note.

## 5. STOCKHOLDERS' EQUITY (DEFICIT)

In connection with the acquisition of the Biotest Assets (see Note 3), the Company issued 4,295,580 shares of its voting common stock and 8,591,160 shares of its non-voting common stock. The rights and preferences of the non-voting common stock are substantially similar to those of the common stock. BPC is prohibited, without the prior written consent of the Company's Board of Directors, from selling or otherwise "Transferring" (as defined in that certain Stockholders Agreement, dated as of June 6, 2017, by and between the Company and BPC (the "Stockholders Agreement")) such shares of voting common stock and non-voting common stock for six months following the acquisition of BTBU (the "Lock-Up Period") and is thereafter, for a period of three years from and after the expiration of the Lock-Up Period (the "Standstill Period"), prohibited from selling, or otherwise Transferring, shares of the Company in excess of 15% of the issued and outstanding shares of voting common stock in a 12-month period (calculated on an as-converted basis), subject to certain exceptions set forth in the Stockholders Agreement. The non-voting common stock will (A) automatically convert into voting common stock upon the earliest to occur of the following: (i) the expiration or earlier termination of the Standstill Period, (ii) immediately prior to the consummation of any a Liquidation Event (as defined in the Stockholders Agreement), (iii) immediately prior to a Company Insolvency Matter (as defined in the Company's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation")); (B) automatically convert upon the consummation of a Permitted Sale (as defined in the Certificate of Incorporation); and (C) be convertible, at the option of BPC, upon (i) a Market Sale (as defined in the Certificate of Incorporation), and (ii) upon certain Dilutive Issuances (as defined in the Certificate of Incorporation).

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

On May 3, 2016, the Company completed an underwritten public offering of 2,176,154 shares of its common stock, for gross proceeds of approximately \$14.1 million. Net proceeds from this offering were approximately \$12.9 million, after payment of underwriting discounts and offering expenses of approximately \$1.2 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-200638) that was declared effective by the SEC on December 23, 2014.

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. Because there has been limited data related to the Company's common stock, similar public companies and a pro rata percentage of the Company's common stock volatility were used for calculating ADMA's volatility for use in the fair value computation of stock option grants under the Black-Scholes methodology. The following assumptions were used to determine the fair value of options granted during the nine months ended September 30, 2017 and 2016:

	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Expected term	5.8 - 6.3 years	5.8 - 6.3 years
Volatility	58-64%	51-52%
Dividend yield	0.0	0.0
Risk-free interest rate	1.60-2.29%	1.54-1.79%

The weighted average remaining contractual life of stock options outstanding and expected to vest at September 30, 2017 is 8.0 years. The weighted average remaining contractual life of stock options exercisable at September 30, 2017 is 5.7 years.



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

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, 2017	
	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	1,535,187	\$ 7.90
Forfeited	(87,324 )	\$ 8.03
Expired	(13,727 )	\$ 8.60
Granted	1,942,595	\$ 3.76
Exercised	(93,939 )	\$ 2.68
Outstanding at end of period and expected to vest	3,282,792	\$ 5.59
Options exercisable	1,275,001	\$ 7.88

During the nine months ended September 30, 2017, an aggregate of 91,139 option shares were exercised in cashless exercise transactions resulting in the issuance of an aggregate of 17,123 shares of common stock, and an aggregate of 2,800 option shares were exercised for cash. Stock-based compensation expense for the three and nine months ended September 30, 2017 and 2016 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	\$ 141,405	\$ 95,076	\$ 262,822	\$ 383,909
Plasma centers	10,341	15,289	36,288	40,044
Selling, general and administrative	331,946	152,598	726,062	572,135
Cost of goods sold	22,038	—	27,798	—
Total stock-based compensation expense	\$ 505,730	\$ 262,963	\$ 1,052,970	\$ 996,088

As of September 30, 2017, the Company had \$4.5 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 2.9 years.

**6. INVENTORIES**

The following table provides the components of inventories:

	September 30, 2017	December 31, 2016
Raw materials	\$10,350,535	\$5,020,146
Work-in-progress	801,074	—
Finished goods	2,267,362	—
Total inventories	\$13,418,971	\$5,020,146

Inventories are stated at the lower of cost or market with cost being determined on the first-in, first-out method. Finished goods inventories as of September 30, 2017 is comprised of Nabi-HB, recorded at fair value as part of the purchase price allocation of the Biotest Assets acquired. Raw materials includes materials expected to be used in the production of RI-002, as there are alternative uses for these materials. All other activities and materials associated with the production of inventories used in research and development activities are expensed as incurred.



Table of Contents**ADMA BIOLOGICS, INC. AND SUBSIDIARIES****NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****7. INTANGIBLE ASSETS**

Intangible assets at September 30, 2017 and December 31, 2016 consist of the following:

	September 30, 2017			December 31, 2016		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Trademark and other intangible rights related to Nabi-HB®	\$4,100,046	\$ 185,478	\$3,914,568	\$—	—	\$ —
Right to intermediates	907,421	41,050	866,371	—	—	—
Customer contract	1,076,557	120,321	956,236	—	—	—
Total	\$6,084,024	\$ 346,849	\$5,737,175	\$—	—	\$ —

Under the previous contract manufacturing agreement between ADMA and BPC, intermediate by-products derived from the manufacture of RI-002 were property of Biotest. As a result of the transaction, ADMA now has the right to these intermediate products. The customer contract pertains to a contract manufacturing agreement with a third party that the Company assumed upon the completion of the acquisition of the Biotest Assets. Amortization expense related to these acquisition-related intangible assets 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 2017	\$273,828
2018	1,095,314
2019	1,095,314
2020	816,675
2021	715,352

**8. PROPERTY, PLANT AND EQUIPMENT**

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

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-Q

	September 30, 2017	December 31, 2016
Manufacturing and laboratory equipment	\$ 7,901,218	\$ 306,411
Office equipment and computer software	726,354	188,277
Furniture and fixtures	473,638	1,030,257
Leasehold improvements	1,473,693	2,699,104
Land	4,339,441	—
Buildings	15,660,559	—
	30,574,903	4,224,049
Less: Accumulated depreciation and amortization	(819,362 )	(2,223,265 )
	\$ 29,755,541	\$ 2,000,784

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.

Table of Contents

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**

**NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**9. RELATED PARTY TRANSACTIONS**

The Company leases an office building and equipment from Areth, LLC (“Areth”) pursuant to a shared services agreement on a month-to-month basis of which terms were amended by the Company’s Board of Directors in June 2016. Rent expense amounted to \$48,000 for the three months ended September 30, 2017 and 2016, and \$144,000 for the nine months ended September 30, 2017 and 2016. Areth is a company controlled by Dr. Jerrold B. Grossman, the Company’s Vice Chairman, and Adam S. Grossman, the Company’s President and Chief Executive Officer. The Company pays Areth monthly fees for the use of such office space and for other information technology, general warehousing and administrative services. Effective October 1, 2017, monthly rent on this facility was reduced to \$10,000. The Company also reimburses Areth for office and building related (common area) expenses, equipment and certain other operational expenses, which have not been material to the condensed consolidated financial statements for the nine months ended September 30, 2017 and 2016.

The Company maintains deposits and other accounts at Lakeland Bankcorp, Inc., formerly Pascack Bankcorp, a bank of which Dr. Grossman served as a director through January 2016, and which was approximately 5%-owned by members of the Grossman family. Pascack Bankcorp was acquired by Lakeland Bancorp, Inc. in January 2016 and Dr. Grossman is currently a member of the Corporate Advisory Council of Lakeland Bancorp Inc.

As of September 30, 2017, the Company has a \$15.0 million subordinated note payable to BPC (see Note 4), and recognized interest expense on this note for the three and nine months ended September 30, 2017 in the amount of \$0.2 million and \$0.3 million, respectively.

For the three and nine months ended September 30, 2017 and 2016, the Company recognized revenues under its out-licensing agreement with Biotest of approximately \$36,000 and \$0.1 million, respectively. Deferred revenue of \$2.7 million and \$2.8 million as of September 30, 2017 and December 31, 2016, respectively, is related to this agreement.

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, 2017 were \$2.8 million and \$7.3 million, respectively. Plasma sales to Biotest for the three and nine months ended September 30, 2016 were \$2.3 million and \$6.1 million, respectively. Accounts receivable includes \$0.9 million and \$1.0 million due from Biotest as of September 30, 2017 and December 31, 2016, respectively. Additionally, Biotest is a supplier of plasma to ADMA, with the Company purchasing approximately

\$1.7 million and \$1.2 million of plasma in the nine months ended September 30, 2017 and 2016, respectively. Included in accounts payable is \$1.4 million and \$0.1 million due to Biotest as of September 30, 2017 and December 31, 2016, respectively. The following table summarizes the related party balances with Biotest:

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Sale and purchase of plasma				
Product revenue	\$ 2,808,640	\$ 2,267,051	\$ 7,262,915	\$ 6,107,240
Purchases	1,411,500	326,820	1,735,640	1,215,075
License revenue	35,708	35,708	107,125	107,125
Interest expense	230,000	—	290,000	—

	September 30, 2017	December 31, 2016
Accounts receivable	\$876,551	\$969,675
Prepaid expenses and other current assets	91,222	—
Accounts payable	1,393,667	82,427
Accrued expenses	222,671	—
Note payable, net of discount	14,834,696	—
Accrued interest	290,000	—
Deferred revenue	2,725,741	2,832,867

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, 2017, \$0.2 million 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 sheet.

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, 2017.

10.

**COMMITMENTS AND CONTINGENCIES**

*General Legal Matters*

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

*Operating leases*

In connection with the acquisition of the Biotest Assets, the Company assumed two warehouse leases in Boca Raton, FL for additional storage space for raw materials, spare parts and other supplies related to its business. These leases expire on December 31, 2017 and July 31, 2018, respectively. The aggregate minimum lease payments for these two leases are approximately \$9,000 per month. Additionally, in September 2016, BPC entered into a lease for 36 months for certain specialized equipment related to process development. This equipment is utilized by the Company and the Company reimburses BPC in the approximate amount of \$3,500 per month.

20

Table of Contents

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**

**NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

On February 17, 2017, ADMA BioCenters entered into a lease (the “Lease”) with Home Center Properties, LLC, a Georgia limited liability company (“Landlord”), for approximately 12,167 square feet located at 166 Earnest W. Barrett Parkway, Marietta, GA (the “Premises”). ADMA BioCenters will utilize the Premises as a facility specializing in the collection of human plasma and blood, general office administration and any other related use. The Lease has an initial term of approximately eight years and nine months (the “Initial Term”), commencing July 1, 2017 (the “Lease Commencement Date”), with rent payments commencing 150 days after the Lease Commencement Date. ADMA BioCenters’ total monthly cost of the Premises (inclusive of Landlord’s “Operating Costs”, “Taxes” and “Insurance Charges” (as such terms are defined in the Lease)) will range from approximately \$20,000 to \$27,000 during the Initial Term. Provided that the Lease is in full force and effect and that there has been no event of default (as defined in the Lease) beyond the expiration of any applicable notice and cure period, ADMA BioCenters has the option to extend the term of the Lease for two additional periods of five years each (each, an “Extension Term”), each Extension Term on the same terms, covenants and conditions as the Lease, with the rent for each Extension Term to equal the mutually agreed fair market value of the Premises on the commencement of such Extension Term. The Lease also contains customary default provisions, representations, warranties and covenants.

Contract filler agreement

The Company has an agreement with a third party to fill and package RI-002. This contract filler is also the only provider approved by the FDA to fill and package Nabi-HB and Bivigam. The Company has been working this contract filler to fill Nabi-HB and Bivigam on an as-needed basis in accordance with the Company’s commercial and production requirements, and expects to continue to be able to do so. The Company has entered into a statement of work which covers the commercial filling of Nabi-HB for the foreseeable future. There can be no assurances, however, that this contract filler will be able to continue to fill and package Nabi-HB and Bivigam on terms that are acceptable to the Company.

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. The agreement terminates on December 31, 2020, with 2020 being a wind-down year. All other years contemplate minimum production requirements as well as a payment due to the counterparty to the contract of \$1.5 million per year if a minimum of 11 batches are not manufactured in that year and no other breach or default has occurred.

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.

**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 Florida, acquired on June 6, 2017 (see Note 3). The Plasma Collection Centers segment consists of two FDA-licensed source plasma collection facilities located in Georgia, with a third collection center scheduled to open in late 2017 (see Note 10). 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:



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

## 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
Gross (loss) profit	(7,672,207 )	1,074,794	35,708	(6,561,705 )
Loss from operations	(10,532,500 )	(507,900 )	(3,387,360 )	(14,427,760)
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

## Three Months Ended September 30, 2016

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	\$ —	\$ 2,902,155	\$35,708	\$2,937,863
Cost of product revenue	—	1,735,771	—	1,735,771
Gross profit	—	1,166,384	35,708	1,202,092
Loss from operations	—	(316,202 )	(3,420,670 )	(3,736,872 )
Other expense, net	—	—	(594,367 )	(594,367 )
Net loss	—	(316,202 )	(4,015,037 )	(4,331,239 )
Total assets	—	2,707,636	24,787,750	27,495,386

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-Q

Depreciation and amortization expense	—	103,493	13,815	117,308
---------------------------------------	---	---------	--------	---------

Table of Contents**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
Gross (loss) profit	(9,631,840 )	3,040,976	107,125	(6,483,739 )
Loss from operations	(13,650,801 )	(1,621,364 )	(13,494,466)	(28,766,631)
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)
Capital expenditures	360,000	291,194	15,263	666,457
Depreciation and amortization expense	881,496	309,606	40,163	1,231,265

## Nine Months Ended September 30, 2016

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	\$ —	\$ 7,226,368	\$ 107,125	\$ 7,333,493
Cost of product revenue	—	4,346,433	—	4,346,433
Gross profit	—	2,879,935	107,125	2,987,060
Loss from operations	—	(1,177,371 )	(12,208,887)	(13,386,258)
Other expense, net	—	—	(1,569,785 )	(1,569,785 )
Net loss	—	(1,177,371 )	(13,778,672)	(14,956,043)
Capital expenditures	—	46,304	17,082	63,386

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-Q

Depreciation and amortization expense	—	311,012	40,690	351,702
---------------------------------------	---	---------	--------	---------

Table of Contents**ADMA BIOLOGICS, INC. AND SUBSIDIARIES****NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****12. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION**

Supplemental cash flow information for the nine months ended September 30, 2017 and 2016 is as follows:

	2017	2016
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	\$ 1,217,524	\$ 1,104,417
Noncash Financing and Investing Activities:		
Assets acquired through the issuance of common stock and liabilities assumed	\$ 60,161,629	\$ —
Equipment acquired reflected in accounts payable and accrued liabilities	\$ 1,363,563	\$ —
End of term liability for Oxford Note Payable	\$ —	\$ 358,000
Warrants issued in connection with note payable	\$ —	\$ 86,300

**13. SUBSEQUENT EVENTS**

On October 10, 2017 (the “Marathon Closing Date”), the Company entered into the Credit Agreement with Marathon and Wilmington Trust, National Association, as the administrative agent for the Lender (the “Administrative Agent”) (see Note 4). 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, the Company used approximately \$17.0 million of the Tranche One Loan to retire and pay in full the Company’s existing credit facility with Oxford and all of the obligations thereunder in accordance with the terms of the LSA, as amended by the Amended LSA, including the end-of-term liability of \$1.8 million and prepayment penalties of \$0.2 million. The Company 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

Company intends to use the remaining approximately \$6.0 million of proceeds 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 the Company's 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 U.S. 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 U.S. of RI-002.

On the Marathon Closing Date, the Company issued a promissory note in favor of the Administrative Agent in the principal amount of \$30.0 million (the "Tranche One Note"), evidencing the Company's 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 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.

Table of Contents

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**

**NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

The Company 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, the Company is 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.

As consideration for the Credit Agreement, the Company issued warrants to purchase an aggregate of 339,301 shares of the Company's common stock to the Lender and certain of its affiliates (the "Tranche One Warrants"). The Tranche One Warrants, which the Company valued at \$0.6 million, have (i) an exercise price equal to \$3.0946, which was the trailing 10-day volume weighted-average price of the Company's common stock prior to the Marathon Closing Date, and (ii) an expiration date of October 10, 2024. The Company issued the Tranche One Warrants in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act of 1933, as amended (the "Securities Act"). The Tranche One Warrants and the shares of common stock issuable thereunder may not be offered, sold, pledged or otherwise transferred in the U.S. absent registration or an applicable exemption from the registration requirements under the Securities Act.

Based on the fair value of the Tranche One Warrants, the facility fee and the fees and expenses associated with obtaining the Credit Facility, the effective interest rate on the Tranche One Note is approximately 16.5%. The Company's obligations under the Credit Agreement are secured by a first-priority lien and security interest in substantially all of the Company's assets, including a mortgage on the Boca Facility, and those of the Company's 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 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. In addition, the Company may not permit its liquidity, 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, to be less than \$5.5 million at any time. The Credit Agreement also required the establishment of the debt service reserve account. The Company is currently required to maintain a minimum balance in this account of \$5.5 million. Upon the satisfaction of certain conditions related to some of the Company's leased properties, the minimum required balance in

the debt service reserve account will be reduced to \$4.0 million.

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.



Table of Contents

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 the consolidated financial statements and other consolidated financial information included elsewhere herein, and in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2016. The various sections of this discussion contain a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described throughout this quarterly report on Form 10-Q. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ materially.*

OVERVIEW

**Our Business**

We are a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and prevention of certain infectious immunological diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. We currently have two marketed products: Nabi-HB, indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen ("HBsAg"); and Bivigam, indicated for the treatment of primary humoral immunodeficiency. We are also developing a pipeline of plasma-derived therapeutics, including our lead pipeline product candidate, RI-002 for the treatment of Primary Immune Deficiency Disease ("PID"). Our product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases.

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 includes two United States Food and Drug Administration (the "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 German Health Authority (the "GHA"). In addition to 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 ADMA BioManufacturing, LLC ("ADMA BioManufacturing") subsidiary.

Concurrent with the closing of the acquisition of the Biotest Assets, we received \$12.5 million in cash consideration in addition to a \$15.0 million subordinated note from Biotest at 6% interest payable to BPC with a maturity of five years, and Biotest committed to participate in any future equity offering or private placement undertaken by the Company in an amount equal to up to \$12.5 million on a pro-rata basis. At the closing of the Biotest Transaction, we delivered to BPC an aggregate equity interest equal to 50%, less one share, of our issued and outstanding capital stock comprised of 25%, or 4,295,580 shares, of our voting common stock, \$0.0001 par value per share (“Common Stock”), and 8,591,160 shares in the form of our non-voting common stock, \$0.0001 par value per share (the “Non-Voting Common Stock”) (calculated as of immediately following the closing and on a post-closing issuance basis). The Non-Voting Common Stock is convertible into our Common Stock upon the occurrence of certain specified events.

As part of the purchase price to acquire the Biotest Assets, we have agreed to transfer ownership of our two plasma collection facilities to BPC on January 1, 2019. We are progressing with the construction of our third plasma collection facility and we expect to file our BLA with the FDA and initiate collections for this facility by the end of 2017.

We anticipate that our principal sources of liquidity will only be sufficient to fund our activities as currently conducted through the end of the first quarter of 2018. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing prior to the end of the first quarter of 2018. This time frame may change based upon how quickly we are able to execute on our quality management systems’ remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options we are exploring. 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 incorrect, we may have to raise additional capital sooner than the end of the first quarter of 2018.

Table of Contents

**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.

*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 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. Although we expect to resume production in the fourth quarter of 2017, Bivigam is not expected to be available for sale throughout the remainder of 2017 and FDA clearance for relaunch is expected to occur during the middle of 2018.

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

We are currently developing our lead pipeline product candidate, RI-002, for the treatment of PIDD, and have completed a pivotal Phase III clinical trial, which met the primary endpoint of no SBIs 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 called fractionation, which purifies immune globulins (“IgG”) from this blended plasma pool resulting in a final intravenous immunoglobulin (“IVIG”) product enriched with naturally occurring polyclonal anti-pathogen antibodies (e.g., streptococcus pneumonia, H. influenza type B, cytomegalovirus, measles, 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 (the “BLA”) for RI-002 for the treatment of PIDD. In July 2016, the FDA issued a Complete Response Letter (the “CRL”), which reaffirmed the issues set forth in the November 2014 warning letter that had been issued by the FDA to Biotest related to certain issues identified at the Boca Facility (the “Warning Letter”), but did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in our BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies related to Chemistry, Manufacturing and Controls (“CMC”) and Good Manufacturing Practices (“GMP”) at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of our BLA until, among other things, these deficiencies are resolved. Following the completion of the Biotest Transaction, we now have control over the regulatory, quality, general operations and drug substance manufacturing process and our highest priority is to remediate the outstanding compliance issues that were identified at the Boca Facility in the Warning Letter. We are currently working with a consulting firm consisting of quality management systems and biologics production subject matter experts in preparation for a re-inspection by the FDA in order to improve the FDA inspection classification relative to the Warning Letter compliance issues as indicated in the CRL, and we plan to be inspection-ready for the FDA by the end of 2017. Once the Warning Letter status is improved following the FDA inspection, we anticipate that we will be in a position to refile our BLA for RI-002 during the middle of 2018.

Table of Contents

**Evaluation of RI-002 in PIDD Patients**

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

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

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

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

**Rationale for the Potential Evaluation of RI-002 in RSV Infected Patients**

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

## Table of Contents

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

From April 2009 through February 2011, RI-001 was also administered to 15 compassionate use patients where physicians requested access to the product for treating their patients with documented lower respiratory tract RSV infections due to the fact that these patients had failed conventional therapeutic interventions. Serum samples were obtained from 13 patients. Samples showed that patients demonstrated a four-fold or greater rise in RSV antibody titers from baseline. Serum samples were not obtained from two patients that received Palivizumab. All 11 patients who received RI-001 within an average of 4.4 days after the onset of the diagnosis of RSV survived. The drug was well-tolerated in all 15 patients and there were no reports of serious adverse events attributable to RI-001. Data from our Phase II clinical trial, compassionate use experience and data obtained from the evaluation of RI-002 in the infected cotton rat animal model has been presented at various conferences the past several years.

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

## **Manufacturing and Supply of our Products**

In order to produce plasma-derived immunoglobulin products, raw material plasma is collected from human donors and then manufactured into specialized products. Historically, plasma for our products and product candidates has been collected from healthy donors at FDA-licensed plasma donation centers. Source plasma is collected at any one of over 400 FDA-licensed donation centers located throughout the U.S., using a process called automated plasmapheresis. This sterile, self-contained, automated process separates red blood cells and other cellular components in the blood, which are then returned to the donor. Source plasma obtained by plasmapheresis is tested and must be negative for antibodies to human immunodeficiency virus types 1 and 2 (HIV-1/2), HBsAg and HCV, using FDA-licensed serological test procedures.

After receipt of the source plasma, the frozen plasma is thawed and pooled and goes through a process called "fractionation." This process is referred to as the Cohn method or cold ethanol method of fractionation. During cold

ethanol fractionation, classes of proteins are precipitated and removed by centrifugation or filtration. The fractionation process includes the following steps; precipitation and absorption, depth filtration, centrifugation and chromatography. Because of the human origin of the raw material and the thousands of donations required in the fractionation process, the major risk associated to plasma products is the transmission of blood-borne infectious pathogens. These purification processes have the potential to reduce the viral load. The manufacturing process also utilizes a multistep viral removal/inactivation system, which further increases the safety of the products. The following manufacturing processes have been validated for their capability to eliminate or inactivate viruses: precipitation during cold ethanol fractionation, solvent/detergent treatment, and nanofiltration. Incorporation of these processes in the manufacturing process ensures that the Company's products comply with the requirements of the FDA and are safe and efficacious.

### **Sales and Commercialization of Our Products**

Historically, Nabi-HB has been sold through independent distributors, drug wholesalers acting as sales agents, specialty pharmacies and other alternate site providers. In the U.S., third-party drug wholesalers ship a significant portion of Nabi-HB through their distribution centers. These centers are generally stocked with adequate inventories to facilitate prompt customer service. Sales and distribution methods include frequent contact by sales and customer service representatives, automated communications via various electronic purchasing systems, circulation of catalogs and merchandising bulletins, direct-mail campaigns, trade publication presence and advertising.



## Table of Contents

While we are working towards remediating the Warning Letter and other CMC and GMP inspection deficiencies and eventually refiling our BLA resubmission for RI-002, we expect to continue our commercialization efforts for our approved products and plan to bolster these initiatives by hiring a small, specialty sales force to market Nabi-HB, Bivigam upon its relaunch and, upon approval by the FDA, RI-002 to hospitals, physician offices/clinics, and other specialty treatment organizations. We also anticipate staffing our company with additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, third-party reimbursement, inventory and logistics, human resources and financial and operational management. If and when we receive FDA approval, we may also use a network of national distributors to assist with order fulfillment for RI-002 for use by healthcare professionals and hospitals.

### **Pharmaceutical Pricing and Reimbursement of Our Products**

All sales of Nabi-HB and Bivigam in the U.S. depend in part upon the availability of reimbursement from third-party payers. Third-party payers include government health programs, managed care providers, private health insurers and other organizations. Nabi-HB and Bivigam are reimbursed or purchased under several government programs, including Medicaid, Medicare Parts B and D, the 340B/Public Health Service program and pursuant to an existing contract with the Department of Veterans Affairs. Medicaid is a joint state and federal government health plan that provides covered outpatient prescription drugs for low-income individuals. Under Medicaid, drug manufacturers pay rebates to the states based on utilization data provided by the states.

### **Plasma Collection Facilities**

Our wholly-owned subsidiary, ADMA Bio Centers Georgia, Inc., (“ADMA BioCenters”), operates two FDA-licensed, GHA and Korean Ministry of Food and Drug Safety-certified source plasma collection facilities located in the U.S., which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our products or product candidates is sold to third-party customers in the U.S., 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 have agreed to transfer ownership of our two existing plasma collection facilities to BPC on January 1, 2019. We are progressing with the construction of our third plasma collection facility and we expect to file our BLA with the FDA and initiate collections for this facility by the end of 2017.

RESULTS OF OPERATIONS

**Financial Operations Overview**

Revenues

Revenues for the three and nine months ended September 30, 2017 are comprised of Nabi-HB product revenues, product revenues from the sale of normal source human plasma collected from our plasma collection centers segment and license and other revenues which are initially recorded as deferred revenue and amortized into income over the terms of the respective agreements. In exchange for the out-licensing of RI-002 to market and sell in Europe and selected countries in North Africa and the Middle East, Biotest has provided us with certain services and a financial payment received in accordance with the related license agreement and is obligated to pay us certain amounts in the future if certain milestones are achieved.

A significant amount of our revenues are attributed to a single customer, BPC. For the nine months ended September 30, 2017, two of our customers, SK Plasma Co., Ltd. (“SK”) and BPC, represented approximately 76% of our total revenues, with BPC representing 68% of our total revenues and SK representing 8% of our total revenues. Although we expect this concentration to decrease over the remainder of the year and into 2018 as additional sales of Nabi-HB are reflected in our consolidated financial statements, these two customers are still expected to account for a significant portion of our revenues.

## Table of Contents

Product revenues from the sale of human plasma collected at our FDA-licensed plasma collection centers and from sales of Nabi-HB are recognized at the time of transfer of title and risk of loss to the customer, which occurs, depending on the agreement with the customer, at the time of shipment or at the time of delivery if we retain the risk of loss during shipment. Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement have been completed.

### Cost of Product Revenue

In addition to the cost of products sold during the period, cost of product revenue also includes unabsorbed manufacturing expenses associated with the Boca Facility. This includes manufacturing salaries and wages, indirect overhead charges and consulting fees associated with remediating the Warning Letter, which are expensed as incurred. As the Boca Facility only resumed production late in the third quarter of 2017, substantially all operating expenses associated with the facility have been expensed as incurred since acquisition.

For our Plasma Collections Centers segment, cost of product revenue reflects the cost of direct materials and other direct costs that had been previously capitalized into inventory.

### Plasma Center Expenses

Plasma center expenses include 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, all of which are expensed as incurred. The direct costs associated with the plasma collection process, including direct materials and testing, are capitalized into inventory.

### Research and Development Expenses

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

The process of conducting preclinical studies, clinical trials and regulatory activities necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, regulatory, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainties associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. R&D expenses decreased for the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016, due to lower validation, testing and production costs associated with RI-002 and the related BLA filing.

In connection with the approval of the BLA for Bivigam on December 19, 2012, BTBU committed to perform two additional post-marketing studies. The first is a pediatric study to evaluate the efficacy and safety of Bivigam in children and adolescents, and the second is 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 pending completion, and the costs of the studies will be expensed as incurred. We currently expect 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.

## Table of Contents

### Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses consist of costs related to the Biotest Transaction, wages, salaries, stock-based compensation and benefits for senior management and staff unrelated to R&D or manufacturing, legal fees, accounting and auditing fees, commercialization and marketing activities, information technology, investor relations fees, rent, maintenance and utilities, insurance, travel and other expenses related to the general operations of our business. For the three and nine months ended September 30, 2017, SG&A expenses increased mainly as a result of expenses incurred in connection with the Biotest Transaction, including fees paid for legal, accounting, and financial advisory fees related to the issuance of a fairness opinion and due diligence fees.

### Other Income and Expense

Interest income consists of interest earned on our cash and cash equivalents and short-term investments. Interest expense consists of interest incurred on our notes payable, as well as the amortization of debt discount resulting from end of term fees, value of warrants issued, and deferred financing fees.

### **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.

### ***Revenue Recognition***

Depending on the agreement with the customer, revenue from the sale of human plasma collected by ADMA BioCenters is recognized at the time of transfer of title and risk of loss to the customer, which usually occurs at the time of shipment. Product revenue is recorded net of wholesaler chargebacks, contractual allowances and other discounts and is recognized at the time of delivery if we retain the risk of loss during shipment. Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement with Biotest have been completed.

### **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 service period on a straight-line basis. For the purpose of valuing stock options granted to our employees, directors and officers, we used the Black-Scholes option pricing model. We granted options to purchase an aggregate of 1,942,595 and 100,984 shares of Common Stock during the nine months ended September 30, 2017 and 2016, respectively. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of our awards. The expected term of the options granted is in accordance with Staff Accounting Bulletins 107 and 110, which is based on the average between vesting terms and contractual terms. The expected dividend yield reflects our current and expected future policy for dividends on our Common Stock. The expected stock price volatility for our stock options was calculated by examining the pro rata historical volatilities for similar publicly traded industry peers and the trading history for our Common Stock. We will continue to analyze the expected stock price volatility and expected term assumptions and will adjust our Black-Scholes option pricing assumptions as appropriate.

Table of Contents

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

***Research and Development Expenses***

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

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 annual gross revenues exceed \$1 billion or we issue more than \$1 billion of non-convertible debt in any three-year period, we would cease to be an emerging growth company prior to the end of such five-year period. As an "emerging growth company," we may, under Section 7(a)(2)(B) of the Securities Act, delay adoption of new or revised accounting standards applicable to public companies until such standards would otherwise apply to private companies. We may take advantage of this extended transition period until the first to occur of the date that we (i) are no longer an "emerging growth company" or (ii) affirmatively and irrevocably opt out of this extended transition period. We have elected to take advantage of the benefits of this extended transition period. Our condensed consolidated financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Securities Act Section 7(a)(2)(B), upon issuance of a new or revised accounting standard that applies to our condensed consolidated financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard. As an emerging growth company, we are also exempt from the requirement to have our independent auditors provide an attestation report on our internal control over financial reporting.

In May 2017, the Financial Accounting Standards Board (the "FASB") issued Accounting Standard 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. 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. The ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. We do not expect this new guidance to have a material impact on our condensed consolidated financial statements.



Table of Contents

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations – Clarifying the Definition of a Business*, which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. We adopted this standard in the second quarter of 2017 and the adoption of this standard did not have a material impact on our condensed consolidated financial statements as of and for the nine months ended September 30, 2017.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other (Topic 350)*, which removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under the ASU, “an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The ASU is effective prospectively for fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We do not expect this new guidance to have a material impact on our condensed consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash*, which clarifies guidance and presentation related to restricted cash in the statement of cash flows, including stating that restricted cash should be included within cash and cash equivalents in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, with early adoption permitted, and is to be applied retrospectively. We will adopt this standard in the fourth quarter of 2017, and it is not expected to have a material impact on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. We adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on our condensed consolidated financial statements as of and for the nine months ended September 30, 2017.

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

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes*, which includes amendments that require deferred tax liabilities and assets be classified as non-current in a classified statement of financial position. The amendments in this ASU are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted as of the beginning of an interim or annual reporting period. The amendments may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. We adopted this standard in the second quarter of 2017. Because we carry a full valuation allowance against our deferred tax assets as of September 30, 2017 and December 31, 2016, adoption of this standard did not have a material impact on our condensed consolidated financial statements.

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805), Simplifying the Accounting for Measurement-Period Adjustments*, which includes amendments that require an acquirer to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this ASU require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the changes to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in this ASU require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in this ASU are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The amendments should be applied prospectively to adjustments to provisional amounts that occur after the effective date of the ASU with earlier application permitted for financial statements that have not yet been made available for issuance. We adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on our condensed consolidated financial statements as of and for the nine months ended September 30, 2017.

Table of Contents

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. The standard requires entities to measure most inventory “at the lower of cost and net realizable value,” thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures, one of which is net realizable value). We adopted this standard in the first quarter of 2017 and the adoption of this standard did not have a material impact on our condensed consolidated financial statements as of and for the nine months ended September 30, 2017.

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 becomes effective in calendar year 2018 and early adoption in calendar year 2017 is permitted. 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 will be effective for the Company beginning in the first quarter of 2018. Early adoption is permitted.

We will adopt the new standard and related updates effective January 1, 2018, and we intend to use the modified retrospective method of adoption. We have undertaken an initial impact analysis, which includes reviewing the terms and conditions of our existing customer contracts and applying the five discrete criteria required for recognizing revenue as set forth in ASU 2014-09. Based upon our preliminary analysis undertaken through September 30, 2017, we currently do not expect the new revenue recognition guidance to have a material impact on our consolidated financial statements, and we expect to conclude such analysis by December 31, 2017. We continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may, in conjunction with the completion of our overall assessment of the new guidance, impact our current conclusions.

Table of Contents

## Three Months Ended September 30, 2017 Compared to Three Months Ended September 30, 2016

The following table presents a summary of the changes in our results of operations for the three months ended September 30, 2017 compared to the three months ended September 30, 2016:

	Three Months Ended September 30,		Percentage	
	2017	2016	Increase/ (Decrease)	
Revenues	\$ 4,729,411	\$ 2,937,863	61	%
Cost of product revenue (exclusive of amortization expense shown below)	11,291,116	1,735,771	550	%
Gross (loss) profit	(6,561,705 )	1,202,092	-646	%
Research and development expenses	1,814,069	1,677,263	8	%
Plasma center expenses	1,582,694	1,482,586	7	%
Amortization of intangibles	273,878	—	NM	
Selling, general and administrative expenses	4,195,414	1,779,115	136	%
Loss from operations	(14,427,760 )	(3,736,872 )	286	%
Other expense, net	(774,955 )	(594,367 )	30	%
Net loss	\$ (15,202,715 )	\$ (4,331,239 )	251	%

***Revenues***

We recorded total revenues of \$4.7 million during the three months ended September 30, 2017 compared to \$2.9 million during the three months ended September 30, 2016. Total revenues include: (i) sales of Nabi-HB in the amount of \$1.9 million for 2017, with no comparable amount in 2016; (ii) product revenue of \$2.8 million for the three months ended September 30, 2017 attributable to our ADMA BioCenters plasma collection centers segment and derived from the sale of human source plasma, compared to product revenue of \$2.9 million for the three months ended September 30, 2016; and (iii) license and other revenue in the amount of approximately \$36,000 for the three months ended September 30, 2017 and 2016, which pertains to services and financial payments provided by Biotest in accordance with our license agreement. The increase in total revenue of \$1.8 million for the three months ended September 30, 2017 was attributable to sales of Nabi-HB. The normal source plasma and high-titer RSV plasma which we did not sell was allocated to inventory in anticipation of commercial manufacturing. We have not generated any revenue from our therapeutics research and development business.

**Cost of Product Revenue**

Cost of product revenue was \$11.3 million for the three months ended September 30, 2017, and \$1.7 million for the three months ended September 30, 2016. The increase in cost of product revenue of \$9.6 million is attributable to unabsorbed manufacturing costs related to the Boca Facility, including approximately \$2.0 million of third party consultant fees pertaining to the remediation efforts in response to the Warning Letter, and the production of Nabi-HB, both of which were acquired on June 6, 2017.

### **Research and Development Expenses**

R&D expenses were \$1.8 million for the three months ended September 30, 2017, as compared to \$1.7 million for the three months ended September 30, 2016. The three months ended September 30, 2017 reflects \$0.6 million of R&D expenses related to the Boca Facility that were not present in 2016, largely offset by lower validation, testing, BLA filing and production costs related to RI-002 in 2017.

### **Plasma Center Expenses**

Plasma center expenses were \$1.6 million for the three months ended September 30, 2017, as compared to \$1.5 million for the three months ended September 30, 2016. Plasma center operating expenses consist of: general and administrative plasma center costs; overhead comprised of rent, maintenance, utilities, wages, stock-based compensation and benefits for center staff; plasma collection supplies, plasma transportation and storage (off-site); advertising and promotion expenses; and computer software fees related to donor collections. The increase in plasma center expenses is attributable to increasing the hours of operations at our Marietta, GA location as compared to the three months ended September 30, 2016. We expect that as plasma collections increase, our operating expenses will continue to increase.

Table of Contents

**Selling, General and Administrative Expenses**

SG&A expenses were \$4.2 million for the three months ended September 30, 2017, an increase of \$2.4 million from the three months ended September 30, 2016. The increase was primarily due to \$2.0 million of SG&A expenses associated with BTBU during the three months ended September 30, 2017 and, to a lesser extent, a \$0.2 million increase in stock-based compensation.

**Loss from Operations**

Our operating loss was \$14.4 million for the three months ended September 30, 2017, as compared to \$3.7 million for the three months ended September 30, 2016. The increase in operating loss was mainly due to the \$9.6 million increase in cost of product revenue associated with the Boca Facility, including Warning Letter remediation expenses and unabsorbed manufacturing costs, the \$2.4 million increase in SG&A expenses in 2017 and \$0.3 million of amortization expense related to intangible assets recognized in the Biotest Transaction, partially offset by the \$1.8 million increase in total revenues.

**Other Income (Expense); Interest Expense**

Other expense, net was \$0.8 million for the three months ended September 30, 2017, as compared to \$0.6 million for the three months ended September 30, 2016. The increase is primarily due to increased interest expense on the note payable to Biotest of \$0.2 million.

***Net Loss***

Net loss was \$15.2 million for the three months ended September 30, 2017, an increase of \$10.9 million from the three months ended September 30, 2016, primarily as a result of the increase in operating loss and, to a lesser extent, the increase in interest expense.

Nine Months Ended September 30, 2017 Compared to Nine Months Ended September 30, 2016

Edgar Filing: ADMA BIOLOGICS, INC. - Form 10-Q

The following table presents a summary of the changes in our results of operations for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016:

	Nine Months Ended September 30,		Percentage	
	2017	2016	Increase/ (Decrease)	
Revenues	\$ 10,757,683	\$ 7,333,493	47	%
Cost of product revenue (exclusive of amortization expense shown below)	17,241,422	4,346,433	297	%
Gross (loss) profit	(6,483,739 )	2,987,060	-317	%
Research and development expenses	4,365,205	7,104,864	-39	%
Plasma center expenses	4,662,340	4,057,306	15	%
Amortization of intangibles	346,899	—	NM	
Selling, general and administrative expenses	12,908,448	5,211,148	148	%
Loss from operations	(28,766,631 )	(13,386,258 )	115	%
Other expense, net	(2,009,542 )	(1,569,785 )	28	%
Net loss	\$ (30,776,173 )	\$ (14,956,043 )	106	%

**Revenues**

We recorded total revenues of \$10.8 million for the nine months ended September 30, 2017, as compared to \$7.3 million for the nine months ended September 30, 2016. The increase in total revenue of \$3.4 million is primarily due to sales of Nabi-HB in 2017 and to an increase in plasma sales to BPC of \$1.2 million. Total revenues include: (i) sales of Nabi-HB in the amount of \$2.4 million for 2017, with no comparable amount in 2016, (ii) product revenue of \$8.2 million for the nine months ended September 30, 2017 attributable to our ADMA BioCenters plasma collection centers segment, compared to \$7.2 million for the nine months ended September 30, 2016, and (iii) license and other revenue in the amount of \$0.1 million for the nine months ended September 30, 2017 and 2016 in accordance with our license agreement with Biotest.

Table of Contents

**Cost of Product Revenue**

Cost of product revenue was \$17.2 million for the nine months ended September 30, 2017, and \$4.3 million for the nine months ended September 30, 2016, an increase of \$12.9 million. The increase is mainly attributable to unabsorbed manufacturing costs related to the Boca Facility, including approximately \$2.5 million of third party consultant fees pertaining to the remediation efforts in response to the Warning Letter, and the production of Nabi-HB, and to a sales volume-related increase at ADMA BioCenters of approximately \$0.9 million.

**Research and Development Expenses**

R&D expenses were \$4.4 million for the nine months ended September 30, 2017, a decrease of \$2.7 million as compared to the same period of a year ago. The decrease is primarily the result of lower validation, testing, BLA and production costs related to RI-002 in 2017.

**Plasma Center Expenses**

Plasma center expenses were \$4.7 million for the nine months ended September 30, 2017, an increase of \$0.6 million as compared to \$4.1 million for the nine months ended September 30, 2016. The increase in plasma center expenses is attributable to hiring additional staff and increasing the hours of operations at our Marietta, GA location during the first quarter of 2017.

**Selling, General and Administrative Expenses**

SG&A expenses were \$12.9 million for the nine months ended September 30, 2017, an increase of \$7.7 million from \$5.2 million for the nine months ended September 30, 2016. SG&A expenses increased primarily due to Biotest Transaction costs of \$3.9 million, including fees paid for legal, accounting and financial advisory services related to due diligence and other costs associated with the acquisition of the Biotest Assets and the issuance of a fairness opinion, and \$3.0 million of SG&A expenses associated with BTBU with no comparable amounts in 2016. SG&A expenses in 2017 also include \$0.3 million of one-time compensation expense associated with the Biotest Transaction, an increase in insurance expense of \$0.3 million associated with the acquisition of the Biotest Assets and an increase in stock-based compensation of approximately \$0.2 million.



***Loss from Operations***

Our operating loss was \$28.8 million for the nine months ended September 30, 2017, as compared to \$13.4 million for the nine months ended September 30, 2016. The increase was mainly due to the increase in cost of product revenue of \$12.9 million, the \$7.7 million increase in SG&A expenses, the \$0.6 million increase in plasma center expenses and amortization of intangible assets of \$0.3 million, partially offset by the \$3.4 million increase in total revenues and the \$2.7 million decrease in R&D expenses.

**Other Income (Expense); Interest Expense**

Other expense, net was \$2.0 million for the nine months ended September 30, 2017, compared to \$1.6 million for the nine months ended September 30, 2016. The increase is due to higher interest expense, including amortization of debt discount, resulting from the note payable to BPC and to the increase of \$4.0 million to our then-current debt to Oxford Finance, LLC (“Oxford”) in May of 2016.

***Net Loss***

Net loss was \$30.8 million for the nine months ended September 30, 2017, an increase of \$15.8 million from the same period of a year ago. The increase was mainly due to the increases in operating loss and, to a lesser extent, interest expense.

**LIQUIDITY AND CAPITAL RESOURCES**

As of September 30, 2017, we had working capital of \$18.1 million, consisting primarily of \$13.6 million of cash and cash equivalents, \$1.5 million of accounts receivable, \$13.4 million of inventories, \$0.8 million of assets held for sale and \$2.1 million of prepaid expenses, partially offset by \$13.0 million of accounts payable and accrued expenses and \$0.3 million of deferred revenue and other current liabilities.

Table of Contents

We have had limited revenue from operations, incurred cumulative losses of \$137.7 million since inception and for the nine months ended September 30, 2017 and 2016 we had negative cash flows from operations of \$23.9 million and \$14.7 million, respectively. We have funded our operations to date primarily from the sale of our equity securities, loans from venture debt lenders, acquisition proceeds and loans from our primary stockholders. In June 2017, we received \$27.5 million in connection with the Biotest Transaction, comprised of a cash infusion from BPC into the acquired business in the amount of \$12.5 million and an unsecured subordinated 6% note payable to BPC in the amount of \$15.0 million. In addition, BPC has provided us with a firm equity commitment to invest up to an additional \$12.5 million in future equity financings of the Company. In May 2016, we completed an underwritten public offering of our Common Stock and we received net proceeds of approximately \$12.9 million. Also in May 2016, we amended our Loan and Security Agreement (the “LSA”) with Oxford and borrowed an additional \$4.0 million. Our funds are being used and have been used: to conduct clinical trials; to manufacture drug products; to collect and procure plasma; to test plasma donors for RSV titers; to file our BLA for RI-002; to conduct pre-launch activities; for commercialization and marketing activities; for the buildout and expansion of our plasma centers; for expenses related to the Biotest Transaction; remediation of the Warning Letter and the remainder for selling, general and administrative expenses, research and development expenses and for other business activities and general corporate purposes.

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 existing credit facility with Oxford and all of the obligations thereunder in accordance with the terms of the LSA, as amended by the LSA Amendment dated May 13, 2016 (the “LSA Amendment”), 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. We intend to use the remaining approximately \$6.0 million of proceeds 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 the Company’s 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 U.S. 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 U.S. 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.

Table of Contents

The Company 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.

As consideration for the Credit Agreement, we issued warrants to purchase an aggregate of 339,301 shares of our Common Stock to the Lender and certain of the Lender's affiliates (the "Tranche One Warrants"). The Tranche One Warrants, which we valued at \$0.6 million, have (i) an exercise price equal to \$3.0946, which was the trailing 10-day volume weighted-average price of our Common Stock prior to the Marathon Closing Date, and (ii) an expiration date of October 10, 2024. The Company issued the Tranche One Warrants in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The Tranche One Warrants and the shares of Common Stock issuable thereunder may not be offered, sold, pledged or otherwise transferred in the U.S. absent registration or an applicable exemption from the registration requirements under the Securities Act.

Based on the fair value of the Tranche One Warrants, the facility fee and the fees and expenses associated with obtaining the Credit Facility, the effective interest rate on the Tranche One Note is approximately 16.5%. Our obligations under the Credit Agreement are secured by a first-priority lien and security interest in substantially all of our Company's assets, including a mortgage on the Boca Facility, and those of ADMA's 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 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, we may not permit our liquidity, 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, to be less than \$5.5 million at any time. The Credit Agreement also required the establishment of the debt service reserve account. We are currently required to maintain a minimum balance in this account of \$5.5 million. Upon the satisfaction of certain conditions related to some of our leased properties, the minimum required balance in the debt service reserve account will be reduced to \$4.0 million.

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.

#### Future Financing Needs

We expect to continue to spend substantial amounts on product development, quality and regulatory activities, procuring raw material plasma, manufacturing, conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We currently anticipate, based upon our projected revenue and expenditures, that our cash, cash equivalents, projected revenue and accounts receivable, along with the equity commitment from Biotest, will be sufficient to fund our operations, as currently conducted, through the end of the first quarter of 2018. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity prior to the end of the first quarter of 2018. This time frame may change based upon how quickly we are able to execute on our quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options we are exploring. We currently have no firm commitments for additional financing other than the equity commitment from Biotest, 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 be forced to reduce or forgo sales and marketing efforts and forgo attractive business opportunities.

Table of Contents

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 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, to fund our research and development and commercial programs 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.

## Cash Flows

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

	Nine Months Ended September 30,	
	2017	2016
Net cash used in operating activities	\$(23,913,145)	\$(14,655,295)
Net cash provided by (used in) investing activities	17,223,727	(4,721,900 )
Net cash provided by financing activities	10,375,942	16,842,211
Net change in cash and cash equivalents	3,686,524	(2,534,984 )
Cash and cash equivalents - beginning of period	9,914,867	10,440,959
Cash and cash equivalents - beginning of period	\$ 13,601,391	\$ 7,905,975

Table of Contents*Net Cash Used in Operating Activities*

The following table illustrates the primary components of our cash flows from operations:

	Nine Months Ended	
	September 30,	
	2017	2016
Net loss	\$(30,776,173)	\$(14,956,043)
Non-cash expenses, gains and losses	2,736,833	1,723,543
Changes in accounts receivable	(481,782 )	(403,063 )
Changes in inventories	(201,472 )	(1,171,961 )
Changes in prepaid expenses	(969,042 )	(370,631 )
Changes in accounts payable and accrued expenses	6,505,796	545,780
Other	(727,305 )	(22,920 )
Cash used in operations	\$(23,913,145)	\$(14,655,295)

Cash used in operations increased by \$9.2 million, mainly due to the higher net loss, partially offset by larger increases in accounts payable and accrued expenses. The increase in accounts payable and accrued expenses in 2017 is primarily the result of the Biotest Transaction and the operations associated with the Boca Facility as we prepared to resume commercial production late in the third quarter of 2017. The increase in non-cash expenses in 2017 is mainly due to increased depreciation expense on property and equipment and amortization expense for intangible assets acquired in the Biotest Transaction (see Note 3 to the consolidated financial statements).

*Net Cash Provided by (Used in) Investing Activities*

Net cash provided by investing activities was \$17.2 million for the nine months ended September 30, 2017, which reflects the \$12.5 million cash received by us in connection with the acquisition of the Biotest Assets, and the redemptions of short-term investments in the amount of \$5.4 million, partially offset by capital expenditures in the amount of \$0.7 million. Our capital expenditures were mainly the result of the continued build out of our third ADMA BioCenters plasma collection facility. We expect our total capital expenditures will be between \$1.0 million and \$2.0 million for the remainder of fiscal 2017.

Net cash used in investing activities was \$4.7 million for the nine months ended September 30, 2016, which was related to the purchase of short-term investments.

*Net Cash Provided by Financing Activities*

Net cash provided by financing activities totaled \$10.4 million for the nine months ended September 30, 2017, consisting primarily of \$15.0 million received from the issuance of the note payable to BPC, partially offset by repayments on the principal balances of our notes payable to Oxford in the amount of \$4.4 million.

Net cash provided by financing activities totaled \$16.8 million for the nine months ended September 30, 2016, which consisted primarily of \$12.9 million of net proceeds received from the issuance of Common Stock during the second quarter of 2016 and \$4.0 million received from Oxford during the second quarter of 2016.

**Effect of Inflation**

Inflation did not have a significant impact on our net sales, revenues or net loss in 2016, 2015 and 2014, or for the nine months ended September 30, 2017.

**Off-Balance Sheet Arrangements**

None.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.



Table of Contents

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. We are currently integrating the business processes and information systems in effect prior to the closing of the Biotest Transaction with those of ADMA BioManufacturing, including internal controls. In accordance with guidance issued by the SEC, companies are allowed to exclude acquisitions from their assessment of internal controls over financial reporting during the first year subsequent to the acquisition while integrating the acquired operations.

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, 2017. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures as of September 30, 2017 are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures. Our evaluation excluded the Biotest Assets, which were acquired on June 6, 2017 and were immediately contributed into ADMA BioManufacturing. At September 30, 2017, ADMA BioManufacturing had total assets (unaudited) of \$55.5 million.

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

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial

reporting.

43

Table of Contents

PART II  
OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

*There are numerous and varied risks that may prevent us from achieving our goals. We believe that the following are the material risks that we face. If any of the following risks actually occurs, our business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of our Common Stock could decline and investors in our Common Stock could lose all or part of their investment.*

**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 nearly all of our revenues from the sale of plasma by our plasma collections facilities. Following completion of the Biotest Transaction, we began generating revenues from our sale of Nabi-HB. 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 by the end of the first quarter of 2018, we will likely not have sufficient cash flow and liquidity to fund our business operations as we currently operate,

forcing us to potentially curtail our activities and significantly reduce or cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our Common Stock may decline. In addition, if we raise additional funds through license arrangements or through the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or assets or grant licenses on terms that are not favorable to us.

Based upon our projected revenue and expenditures for 2017 and 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 equity commitment from Biotest, will be sufficient to fund our operations, as currently conducted, through the end of the first quarter of 2018. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing prior to the end of the first quarter of 2018. This timeframe may change based upon how quickly we are able to execute on our quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options we are exploring. These estimates may 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 trial or 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.

Table of Contents

***Failure to timely and effectively remediate the outstanding Warning Letter and other inspection issues and deficiencies at the Boca Facility will have a material adverse effect on our business.***

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for RI-002. In response to our BLA submission in 2015, in July 2016 the FDA issued the CRL. The CRL did not specify or request the need for any additional clinical trials or data; however, the CRL reaffirmed the issues set forth in the Warning Letter issued to Biotest relating to inspection issues identified at the Boca Facility. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies related to CMC and GMP at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of our BLA until, among other things, these deficiencies are resolved. Following the completion of the Biotest Transaction, we now have control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and our highest priority is to remediate the outstanding compliance issues at the Boca Facility in the Warning Letter. We have engaged a leading consulting firm 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 Practices (“cGMP”) issues and deficiencies. We expect to be inspection-ready by the end of 2017 and subsequently expect to improve the FDA inspection classification relative to the Warning Letter after the next inspection by the FDA. However, there can be no assurances that our 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 such Warning Letter and other inspection issues and deficiencies and/or receive approval from the FDA, as well as passing an FDA inspection within this timeline, if at all, will have a material adverse effect on our business, prospects, financial condition and results of operations.

***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 nine months ended September 30, 2017 and 2016, we incurred net losses of \$30.8 million and \$15.0 million, respectively, and from our inception in 2004 through September 30, 2017, we have incurred an accumulated deficit of \$137.7 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
- integrate the Biotest Assets into our business.

Table of Contents

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 prior to the end of the first quarter of 2018 to fund our operations in order to continue as a going concern.***

CohnReznick LLP, our independent registered public accounting firm, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2016, indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern. If we are unable to improve our liquidity position we may not be able to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements. We may also be forced to make reductions in spending, including delaying or curtailing our clinical development, trials or commercialization efforts, or seek to extend payment terms with our vendors and 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. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause our security holders to suffer the loss of all or a substantial portion of their investment in our company.

We anticipate that our principal sources of liquidity, which includes the equity commitment from Biotest, will only be sufficient to fund our activities, as currently conducted, through the end of the first quarter of 2018. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing prior to the end of the first quarter of 2018. This time frame may change based upon how quickly we are able to execute on our quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options we are exploring. 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 first quarter of 2018.

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

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

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

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

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

ADMA BioCenters operates FDA-licensed, GLA and KMFDS certified source plasma collection facilities located in the U.S., which provide us with a portion of our blood plasma for the manufacture of our products and product candidates. Plasma collected from ADMA BioCenters' facilities that is not used to manufacture our products and product candidates is sold to third-party customers in the U.S., and other locations where we are approved globally under supply agreements or in the open "spot" market. Furthermore, we are progressing with the construction of our third plasma collection facility, and we expect to file our BLA with the FDA and initiate collections for this facility by the end of 2017. Nabi-HB and Bivigam are manufactured at the Boca Facility, an FDA-licensed facility certified by the GHA. A portion of our revenues are dependent upon the continued operation of these facilities. Our operations are vulnerable to interruption by fire, weather related events such as: hurricanes, wind and rain, electric power loss, telecommunications failure, and other acts of God, equipment failure and breakdown, human error, employee issues and events beyond our control. We do not have detailed disaster recovery plans for our facilities and we do not 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.



Table of Contents

***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 for our BLA for RI-002. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon our 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.

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

Table of Contents

***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 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 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 U.S. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the U.S.

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

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

Table of Contents

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

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

We depend on independent investigators and collaborators, such as universities and medical institutions, contract laboratories, clinical research organizations, 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 76% of our total revenue for the nine months ended September 30, 2017, and, therefore, the loss of such single customer could have a material adverse effect on our business, results of operations and financial condition.***

Historically, a significant amount of our total revenue is attributable to a single customer, BPC. For the nine months ended September 30, 2017, two of our customers, SK and BPC, represented 76% of our total revenue, with BPC representing 68% of our total revenue and SK representing 8% of our total revenue. Although we expect this concentration to decrease over the remainder of the year as additional sales of Nabi-HB, revenues from our contract manufacturing services and sale of intermediate by-products are reflected in our consolidated financial statements, these two customers are still expected to account for a significant portion of our total revenue.

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

- our ability to sell our products at competitive prices;

Table of Contents

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

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

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

***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 ADMA Biologics, 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 this prospectus and our other materials, including those undertaken by us or our engaged consultants, may not prove to be representative of current and future market conditions or future results.***

This prospectus and our other materials include statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and surveys and studies we commissioned regarding the market potential for 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 such report. Readers should not place undue reliance on this information.



Table of Contents

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

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

***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, and it is uncertain when production of Bivigam will resume. As a result, it was communicated to customers that Bivigam will not be available for sale or distribution at least through the end of 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 resume 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 it operates.

Furthermore, there is no assurance and no definitive timeline as to when or if the Warning Letter will be resolved by the FDA, or when the FDA will inspect our operations. 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;

Table of Contents

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 the two plasma collection facilities in the U.S. 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 are currently constructing a new plasma collection facility, we cannot guarantee 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 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, BPC's parent corporation, and Biotest US Corporation, a Delaware corporation and subsidiary of Biotest AG (together with Biotest AG, the "Biotest Guarantors"), 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 addition, we have agreed to indemnify BPC for any assumed liability, and BPC has agreed to indemnify us for any excluded asset or excluded liability. The parties' representations and warranties (other than fundamental representations and warranties) survive for 15 months following the closing of the Biotest Transaction, fundamental representations survive indefinitely, tax representations survive until the date that is 30 days following the applicable statute of limitations, covenants to be performed on or prior to the closing of the Biotest Transaction survive for 15 months following the closing of the Biotest Transaction, and post-closing covenants survive in accordance with their terms or if no term is specified, indefinitely. Each party's indemnification obligations with respect to (a) its representations and warranties (other than its fundamental representations) are subject to a \$25,000 mini-basket and \$750,000 true deductible and (b) its representations, warranties and pre-closing covenants are subject to a \$25,000,000 cap. Significant indemnification claims by BPC or its affiliates or a breach by BPC or its affiliates of any indemnity obligations owed to us under the Purchase 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.

Table of Contents

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, or if we did not receive access or the ability to diligence certain information, as well as appropriate representations and or warranties, or 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 are or could be discovered are not otherwise covered by the representations and warranties of Biotest and BPC and therefore indemnifiable. If we failed to identify any important issues, or if it were not possible to uncover all material issues or if we did not receive representations and warranties and indemnification concerning any or all material or non-material issues, it could result in a material adverse effect on our business, financial condition, results of operations and stock price.

***The Credit Agreement with 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 which provides for the \$40.0 million Credit Facility, comprised of the Loans, which Tranche Two Loan availability is subject to the satisfaction of certain conditions. We used approximately \$17.0 million of the Tranche One Loan to retire and pay in full our existing credit facility with Oxford and all of the obligations thereunder in accordance with the terms of the LSA, as amended by the LSA Amendment. The Loans each have an April 10, 2022 Maturity Date, subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default. 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. 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 the 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 U.S. and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater 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.

Table of Contents

***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 U.S. and in some other countries, when market exclusivity expires and generic versions are approved and marketed or when biosimilars are introduced (even if only for a competing product), there are usually very substantial and rapid declines in a product's revenues.

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

Patent rights covering 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.



Table of Contents

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

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

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

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

predict the continued duration and severity of the adverse conditions in the U.S. and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

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

Our success will depend on the expansion of our commercial 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, dated as of June 6, 2017, by and between the Company and BPC, which prohibits BPC and its affiliates collectively from, among other things, acquiring more than (i) 50%, less one share, of the Company's 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 Biotest acquiring additional shares of our Common Stock or taking other actions with the goal of acquiring additional shares of our Common Stock.

Table of Contents

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

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

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

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

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

We currently operate under an FDA warning letter, due to operations identified by the FDA in prior FDA inspections while under Biotest operational control. We have engaged a leading 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 expect to be inspection-ready by the end of 2017 and subsequently expect to improve the FDA inspection classification relative to the Warning Letter after the next inspection by the FDA.



Table of Contents

***If we do not receive FDA approval for additional plasma collection centers, one of which is currently under construction, before January 1, 2019, then we may be required to seek a waiver and extension from Biotest for the contractually required transfer of two of our facilities.***

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

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

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

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

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

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

Table of Contents

Failure to satisfy requirements under the Federal Food, Drug, and Cosmetic Act can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct. In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients, they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the U.S., Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities (e.g., FDA in the U.S.), nor can companies promote unapproved products. In limited circumstances, companies may disseminate to physicians information regarding unapproved uses of approved products or results of studies involving investigational products. If such activities fail to comply with applicable regulations and guidelines of the various regulatory authorities, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if such activities are prohibited, it may harm demand for our products. Promotion of unapproved drugs or devices or unapproved indications for a drug or device is a violation of the Federal Food, Drug, and Cosmetic Act and subjects us to civil and criminal sanctions. Furthermore, sanctions under the Federal False Claims Act have recently been brought against companies accused of promoting off-label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for 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 U.S., we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all, which would preclude us from commercializing products in those markets.

In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of their product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in efficacy for

our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the U.S. or the European Union, we could be adversely affected.

Also, under the U.S. Foreign Corrupt Practices Act, the U.S. has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the U.S., generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business. To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the U.S. Health and Human Services Department Office of Inspector General (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.



Table of Contents

***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 profitability.

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

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

Despite overlapping safeguards, including the screening of donors and other steps to remove or inactivate viruses and other infectious disease causing agents, the risk of transmissible disease through blood plasma products cannot be entirely eliminated. For example, since plasma-derived therapeutics involves the use and purification of human plasma, there has been concern raised about the risk of transmitting human immunodeficiency virus ("HIV"), prions, West Nile virus, H1N1 virus or "swine flu" and other blood-borne pathogens through plasma-derived products. There are also concerns about the future transmission of H5N1 virus, or "bird flu." In the 1980s, thousands of hemophiliacs

worldwide were infected with HIV through the use of contaminated Factor VIII. Other producers of Factor VIII, though not us, were defendants in numerous lawsuits resulting from these infections. New infectious diseases emerge in the human population from time to time. If a new infectious disease has a period during which time the causative agent is present in the bloodstream but symptoms are not present, it is possible that plasma donations could be contaminated by that infectious agent. Typically, early in an outbreak of a new disease, tests for the causative agent do not exist. During this early phase, we must rely on screening of donors (e.g., for behavioral risk factors or physical symptoms) to reduce the risk of plasma contamination. Screening methods are generally less sensitive and specific than a direct test as a means of identifying potentially contaminated plasma units. During the early phase of an outbreak of a new infectious disease, our ability to manufacture safe products would depend on the manufacturing process' capacity to inactivate or remove the infectious agent. To the extent that a product's manufacturing process is inadequate to inactivate or remove an infectious agent, our ability to manufacture and distribute that product would be impaired. If a new infectious disease were to emerge in the human population, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to procure plasma, manufacture our products or both. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived products. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma used in the production of our products.

Table of Contents

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

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

***Our ability to commercialize our products, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from governmental agencies, health administration authorities, private health maintenance organizations and health insurers and other healthcare payers, and also 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 reimbursement. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, as well as to the timing, language, specifications and other details pertaining to the approval of such products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such product. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced. Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products, such as plasma-derived products, are subject to price controls in several of the world's principal markets, including many countries within the European Union. In the U.S., where pricing levels for our products are substantially established by third-party 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.

Table of Contents

***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 U.S., we expect in the future to face greater competition from biosimilar products, including a possible increase in patent challenges.

***The implementation of the Healthcare Reform Law in the U.S. may adversely affect our business.***

Through the March 2010 adoption of the Healthcare Reform Law in the U.S., substantial changes are being made to the current system for paying for healthcare in the U.S., including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. The changes contemplated by the Healthcare Reform Law are subject to rule-making and implementation timelines that extend for several years, and this uncertainty limits our ability to forecast changes that may occur in the future. However, implementation has already begun with respect to certain significant cost-saving measures under the Healthcare Reform Law, for example with respect to several government healthcare programs, 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, with respect to Medicaid, in order for a manufacturer's products to be reimbursed by federal funding under Medicaid, the manufacturer must enter into a Medicaid rebate agreement with the Secretary of the U.S. Department of Health and Human Services, and pay certain rebates to the states based on utilization data provided by each state to the manufacturer and to CMS, and pricing data provided by the manufacturer to the federal government. The states share 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 the 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.

Table of Contents

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 U.S. As a result of loss of jobs, patients may lose medical insurance and be unable to purchase supply or may be unable to pay their share of deductibles or co-payments. Hospitals adversely affected by the economy may steer patients to less costly therapies, resulting in a reduction in demand, or demand may shift to public health hospitals, which may purchase at a lower government price. While to date we cannot directly trace any material reduction in demand to the recession, if economic conditions do not improve, the impact may become material.

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

***We 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, 2017 and 2016, we incurred research and development expenses of approximately \$4.4 million and \$7.1 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 that, based upon our projected revenue and expenditures, our current cash, cash equivalents and accounts receivable, along with the equity commitment from Biotest, will be sufficient to fund our operations, as currently conducted, through the first quarter of 2018. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing prior to the end of the first quarter of 2018. This time frame may change based upon how quickly we are able to execute on our operational initiatives and the various financing options we are exploring. 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 equity or debt financings or corporate collaboration and licensing arrangements. If we are unable to raise additional capital, we will have to delay, curtail or eliminate our product development activities, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, as well as future commercialization efforts.



Table of Contents

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

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

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

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation 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 fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules, our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the 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, 2016, we had Federal and state NOLs of \$87.8 million and \$75.2 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.

Table of Contents

**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.

Table of Contents

***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 October 31, 2017, approximately half of our 25,793,404 outstanding shares of common stock, as well as a substantial number of shares of our Common Stock underlying outstanding warrants, are available for sale in the public market, 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 12,886,740 shares of common stock, including 8,591,160 shares of Non-Voting Common Stock, recently acquired by BPC in the Biotest Transaction are subject to a lock-up for six months after closing of the Biotest Transaction, which lock-up expires on December 6, 2017. For three years after the end of such six-month period, subject to certain limited exceptions, under the stockholders agreement entered into between the Company and BPC upon closing the Biotest Transaction, sales by BPC of our equity interests may not exceed 15% of the issued and outstanding common stock of ADMA in any twelve-month period; provided, however, that if our market capitalization increases to double our market capitalization immediately following the closing of the Biotest Transaction, then BPC may sell up to 20% of our issued and outstanding common stock in any twelve-month period; provided, further, that (x) if our market capitalization increases to triple our market capitalization immediately following the closing of the Biotest Transaction, or (y) upon the one-year anniversary of BPC holding less than a 25% economic interest in us, then BPC may sell its equity interests in us at any time (subject to applicable securities laws). At the closing of the Biotest Transaction, we entered into a registration rights agreement with BPC, pursuant to which BPC will have, 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 certificate of incorporation, our by-laws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our Common Stock.***

Provisions of our certificate of incorporation, our by-laws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. As of October 31, 2017, BPC, our directors and executive officers and their affiliates beneficially owned in excess of 75% of the outstanding shares of common stock. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

· the inability of stockholders to call special meetings;

· the ability of our board of directors (the “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 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.

Table of Contents

***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 Nasdaq, we may be subject to delisting. As a result, our stock price may decline and our Common Stock may be delisted. If our stock were no longer listed on Nasdaq, the liquidity of our securities likely would be impaired.***

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

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

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

We could be an emerging growth company until December 31, 2018, which is the last day of the fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed \$1 billion or we issue more than \$1 billion of non-convertible debt in any three-year period, we would cease to be an emerging growth company prior to the end of such five-year period.



Table of Contents

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

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

***Our Board of Directors 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 Amended and Restated Certificate of Incorporation (the “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 57,797,756 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 are issued and outstanding.

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.

67

Table of Contents

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 3, 2017 By: /s/ Adam S. Grossman

Name: Adam S. Grossman

Title: President and Chief Executive Officer

Date: November 3, 2017 By: /s/ Brian Lenz

Name: Brian Lenz

Title: Vice President and Chief Financial Officer

Table of Contents

**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</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, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2017 (Unaudited) and December 31, 2016, (ii) Condensed Consolidated Statements of Operations (Unaudited) for the three and nine months ended September 30, 2017 and 2016, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit) (Unaudited) for the nine months ended September 30, 2017, (iv) Condensed Consolidated Statements of Cash Flows (Unaudited) for the nine months ended September 30, 2017 and 2016, 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.